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GOVERNMENT OPIOID LITIGATION: THE EXTENT OF LIABILITY

Rebecca L. Haffajee,* Beau Kilmer,** Eric Helland***

Government opioid litigation, which seeks to hold suppliers of opioid analgesic medications accountable for the devastating harms of the opioid crisis that has now claimed over half a million lives, dates back to the early 2000s. The arc of the litigation has largely mimicked that of tobacco, in which individual private tort claims have mostly been replaced by aggregate litigation. However, opioid litigation is unique in many regards, including in the number of cases, diversity of parties and causes of action alleged, and broad scope of liability asserted by plaintiffs. Over 3,300 civil opioid cases have been filed to date, predominantly by state, local and tribal governments. Following a landmark \$465 million judgment against Johnson & Johnson in Oklahoma and recent progress in settlement negotiations in the federal multi-district litigation, excitement is building about the prospects of settlements and verdicts worth tens of billions of dollars. Yet the sprawling and all-encompassing nature of the litigation—deriving from not just nonmedical uses of prescription opioids but also from illegally produced opioids (including heroin and synthetic opioids like fentanyl) not supplied by opioid companies—raises new questions.

In this article, we trace the evolution of the current opioid crisis across products and leverage this evidence to analyze the extent of defendant liability under commonly alleged causes of action by governments: negligence, RICO, public nuisance and unjust enrichment. We conclude that extending liability to population harms attributable to illegally manufactured and distributed opioids faces challenges under dominant theories and existing evidence. Nevertheless, the scale of harms related to prescription opioid misuse that can potentially be established under prevalent claims remains substantial. The

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extent of liability ultimately established will be important not only to case outcomes and potential relief afforded in the ongoing opioid litigation, but also in establishing precedent for future litigation relating to products dangerous to the public's health.

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Introduction

Government opioid litigation, which we define as civil actions seeking to hold suppliers of opioid analgesic medications liable for the devastating harms of the opioid crisis that has now claimed over half a million lives, dates back to the early 2000s.¹ The litigation is novel in many regards. It is of unusually large scope for public health litigation, with well over 3,000 cases pending in state and federal courts.² The number of government entities filing cases by 2020—totaling over 1,300 of the 3,142 counties in the U.S., 47 states, and dozens more cities and tribes—is unrivaled, even compared to the tobacco litigation.³ Also unique for public health litigation is the variety of defendants being sued up and down the supply chain, including

^{1.} Opioid Overdose: Understanding the Epidemic, CDC, https://www.cdc.gov/drugoverdose/epidemic/index.html (last reviewed June 2, 2021); see generally Farida B. Ahmad et al., Provisional Drug Overdose Death Counts, CDC, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (last updated May 12, 2021).

^{2.} See U.S. Jud. Panel on Multidistrict Litig., Statistical Analysis of Multidistrict Litigation Under 28 U.S.C. § 1407 Fiscal Year 2019 33 (2019); see generally Transfer Order, In re Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (J.P.M.L. Dec. 12, 2017).

^{3.} Case counts derived from author's analysis of cases filed in the federal multi-district opioid litigation, as further described *infra*. The Tobacco Master Settlement Agreement involved 46 states and 6 other government jurisdictions as plaintiffs. *See generally* Nat'l Ass'n of Att'ys Gen., Master Settlement Agreement (1998), *available at* https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/; The Master Settlement Agree-

manufacturers, distributors, pharmacy benefit managers, pharmacies, and even some prescribers. The diversity of claims is substantial: ranging from common law torts like negligence and fraud, to statutory claims under Racketeer Influenced and Corrupt Organizations Act (RICO) and controlled substances acts, to equitable liability theories like public nuisance and unjust enrichment. The litigation also seeks to hold opioid suppliers liable, in large part, for misuse (or nonprescribed use) of their product, rather than use as intended, as was the case with asbestos, lead paint, and tobacco.⁴ Finally, the litigation attempts to extend liability beyond harms incurred by products actually produced and distributed by defendants—namely prescription opioids—to harms directly related to illegally manufactured and distributed opioids like heroin and fentanyl. Plaintiff governments justify these extensions of liability beyond the bounds of typical products liability cases by relying on their unique characteristics of opioids (e.g., their addictive nature) allegedly known to the suppliers, and on evidence of zealous marketing and supply. Together these elements, they claim, contributed to a robust and ever-evolving market for the drug. In other words, the influx in prescription opioids started a chain reaction that facilitated a staggering host of follow-on harms.⁵

To what extent can prescription opioid suppliers can be held legally responsible for widespread, downstream, opioid-related harms, many of which were not directly caused by their products? This Article endeavors to tackle this question; first, by unpacking what is known about the evolution of the opioid crisis and the connection between different opioid products and harms, and second by examining the prevalent theories of liability asserted in the litigation and elements that must be demonstrated for them to succeed. In Part I, we briefly review the evolution of opioid litigation, from individual personal injury suits to mass tort agendas and cases waged by governments. Governments, as primary plaintiffs in the current opioid litigation, drive the types of theories asserted and, in turn, the evidence required to establish liability. In Part II, we trace the evolution of the opioid crisis

ment: An Overview, Tobacco Control Legal Consortium, https://www.publichealthlaw center.org/sites/default/files/resources/tclc-fs-msa-overview-2015.pdf (last updated Aug. 2015).

^{4.} Conversely, the opioid litigation bears certain similarities to firearm litigation, in that firearms were used in ways the manufacturers presumably did not intend (e.g., an accidental shooting by a child), but that the companies arguably could have foreseen. See, e.g., Jon S. Vernick et al., Availability of Litigation as a Public Health Tool for Firearm Injury Prevention: Comparison of Guns, Vaccines, and Motor Vehicles, 97 Am. J. Pub. Health 1991, 1993 (2007) (discussing the foreseeability and intended uses of firearms, and under what conditions the federal immunity statute will bar suits).

^{5.} Complaint at 1, Island Cty. v. Purdue Pharma, L.P., No. 2:18-cv-01127 (W.D. Wash. Aug. 1, 2018) (transferred to N.D. Ohio as case 1:18-op-45982 on Aug. 17, 2018).

and the connections between medical and nonmedical uses of pharmaceutical opioids. This section probes the evidence base for establishing that the products supplied by defendants caused or facilitated a host of downstream harms related to illegally-produced opioids. In Part III, we unpack four dominant claims asserted by government plaintiffs in the present-day litigation, as identified by analyzing a random sample of cases from federal multi-district litigation (MDL) consolidations involving theories of negligence, RICO, public nuisance, and unjust enrichment.⁶ For each of the claims, we outline the elements typically required to demonstrate liability and assess whether these elements are plausibly met for misuse of prescription opioids and, separately, use of illegally produced opioids. Finally, we conclude in Part IV that while dominant theories may establish liability for misuse of prescription opioids if adequate evidence is brought to bear by government plaintiffs, extending liability to harms deriving from use of illegally produced opioids will pose challenges given our current understanding of the crisis's etiology. Our conclusions have important implications not just for opioid litigation case outcomes, but also for the theories pursued in future public health litigation enterprises.

I. EVOLUTION OF OPIOID LITIGATION

Much like the tobacco litigation, the opioid litigation has evolved over time, from individual tort suits to aggregate forms of litigation brought by governments.⁷ In the first iteration of opioid litigation which commenced in the early 2000s, individuals injured by misuse of prescription opioids sued manufacturers, most frequently Purdue Pharma, the maker of OxyContin.⁸ These lawsuits often alleged fraudulent misrepresentation for downplaying the addictive properties of opioids in drug advertising and detailing, failure to adequately warn about opioid harms and addictiveness, and failure to include tamper-

^{6.} We selected this random sample out of all cases in the MDL as of January 2020, and these four claims emerged as among the most prominent out of all claims alleged in this sample.

^{7.} W.E. Parmet & R.A. Daynard, *The New Public Health Litigation*, 21 Ann. Rev. Pub. Health 437, 437 (2000); *see generally* Donald G. Gifford, Suing the Tobacco and Lead Pigment Industries: Government Litigation as Public Health Prescription (2010); Michael L. Rustad & Thomas H. Koenig, *Reforming Public Interest Tort Law to Redress Public Health Epidemics*, 14 J. Health Care L. & Pol'y 331, 331 (2011).

^{8.} Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 New Eng. J. Med. 2301, 2301–03 (2017); Rebecca L. Haffajee, *The Public Health Value of Opioid Litigation*, 48 J.L. Med. & Ethics 279, 283–84 (2020) (outlining the three distinct but overlapping iterations of opioid litigation, including the type of suit, public perception of opioid analgesics, claims, and usual winner in each).

resistant mechanisms.⁹ Overwhelmingly, defendants succeeded in having these suits dismissed due to lack of causation, wrongful conduct on the part of individuals, and product misuse, among other defenses.¹⁰ Some individual plaintiffs were under-resourced compared to opioid companies to pursue these suits vigorously over time. The second iteration of opioid cases that followed on the heels of individual suits were class actions. Although plaintiffs were better resourced in these aggregations, the cases typically failed to move forward as class litigation for lack of commonality among class members.¹¹

In the current iteration of litigation that began around 2005 and ballooned in 2015, government plaintiffs allege population-level harms caused by the opioid industry. So far, over 2,900 government cases have been consolidated in the federal MDL in the Northern District of Ohio¹² and over 400 more suits reside in state courts.¹³ These suits assert both *parens patriae* claims, for injuries sustained by the populations that governments serve, and also direct injuries for harms suffered by the government (e.g., for costs of providing services to those suffering from opioid addiction).¹⁴ Compared to individuals, governments can compete on a more level playing field with opioid companies, by bringing to bear their significant resources and hiring

^{9.} See supra note 8; see, e.g., Defendants' Motions for Summary Judgment, McCauley v. Purdue Pharma, L.P., No. 2:01-cv-00080 (W.D. Va. May 14, 2004); Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 696 (E.D. Ky. 2003); Timmons v. Purdue Pharma Co., No. 8:04-cv-1479-T-26MAP, 2006 WL 263602, at *1 (M.D. Fla. Feb. 2, 2006).

^{10.} McCauley v. Purdue Pharma, L.P., 331 F. Supp. 2d 449, 452 (W.D. Va. 2004); but see Andrew Joseph, A veteran New York litigator is taking on opioid makers. They have a history, STAT News (Oct. 10, 2017), https://www.statnews.com/2017/10/10/opioid-lawsuits-paul-hanly/ (describing litigator Paul Hanly's success in persuading Purdue Pharma and Abbott Laboratories to settle with 5,000 individual plaintiffs for damages suffered related to the prescription opioid OxyContin. Although the settlement agreement is not a public document, evidence discovered in these individual suits has been used in subsequent government opioid litigation).

^{11.} These class actions often were not certified because plaintiffs experienced different trajectories of opioid use (e.g., different products, different ways opioids were used/misused) that resulted in injury. *See, e.g.*, Gevedon v. Purdue Pharma, 212 F.R.D. 333, 336–37 (E.D. Ky. 2002); Campbell v. Purdue Pharma, L.P., No. 1:02cv00163, 2004 WL 5840206, at *4 (E.D. Mo. June 25, 2004).

^{12.} See United States Judicial Panel on Multidistrict Litigation, supra note 2, at 33; MDL 2804, U.S. Dist. Ct. N.D. Ohio, https://www.ohnd.uscourts.gov/mdl-2804 (last updated Apr. 9, 2021) (showing transfer orders for many cases pertaining to National Prescription Opiate Litigation).

^{13.} See Complaint for Injunctive Relief, Exs. A–C, In re Purdue Pharms. L.P., No. 19-23649-rdd (Bankr. S.D.N.Y. Sept. 18, 2019); Complaint for Injunctive Relief, Appendix A, In re Insys Therapeutics, Inc., No. 19-50261-KG (Bankr. D. Del. June 10, 2019). The public health litigation concerning asbestos involved a larger number of cases, over 700,000, with the difference being that these were predominantly filed by individual plaintiffs rather than governments. Michelle J. White, Asbestos and the Future of Mass Torts, 18 J. Econ. Persps. 183, 183 (2004).

^{14.} Edgar Aliferov, The Role of Direct-Injury Government-Entity Lawsuits in the Opioid Litigation, 87 FORDHAM L. REV. 1141, 1156–60 (2018).

highly trained outside counsel on a contingency fee basis.¹⁵ Research demonstrating the patterns of misconduct among opioid suppliers that resulted in population-level injuries and tremendous company profits is germane and fundamental to some of the theories of recovery asserted, like public nuisance and unjust enrichment.¹⁶ Harnessing large-scale data on opioid prescribing, use disorder, addiction, and overdoses and linking this temporally and spatially to prescription opioid marketing and distribution can help provide evidence of a causal connection; the lack of such evidence was one reason why individual cases alleging addiction attributable to multiple causes (e.g., product misuse, illicit purchase, diversion, polypharmacy) were susceptible to failure.¹⁷

Dozens of government opioid cases have settled for millions of dollars, with increasing frequency in recent years. Cases that have not settled typically remain in pre-trial stages, with some decisions that have ruled on dispositive motions; they therefore provide limited authority to predict how the claims alleged will ultimately resolve. In the one trial verdict so far in this line of litigation, a state court judge ruled against Johnson & Johnson in a case alleging public nuisance, awarding \$465 million to the State of Oklahoma. The nation's three largest opioid distributors (McKesson, Cardinal Health, and AmerisourceBergen) have proposed to pay more than \$19 billion over 8 years to settle federal litigation against them, although no agreement

^{15.} See Andrew Harris et al., Justice for Opioid Communities Means Massive Payday for Their Lawyers, Bloomberg (July 25, 2018), https://www.bloomberg.com/graphics/2018-opioid-law-suits/.

^{16.} See generally Christopher Ogolla, What are the Policy Implications of Use of Epidemiological Evidence in Mass Torts and Public Health Litigation?, 23 St. Thomas L. Rev. 157 (2010). Tobacco, lead paint, and asbestos cases also gravitated toward aggregated and government cases, relying on evidence that linked exposure to products at issue to disease incidence and prevalence over time. Haffajee, *supra* note 8, at 283–84.

^{17.} An example showing this distinction is as follows: an individual obtains prescription opioids by purchasing them on the illegal market, later overdosing. If the individual brings suit against a drug manufacturer or distributor, she will have a hard time defeating defenses that she engaged in illegal activity and used the product not as medically prescribed. However, at the population level, epidemiological evidence can demonstrate that overprescribing attributable to aggressive marketing and surplus distribution resulted in excess medications in intended users' possession; these medications could then be diverted to the illegal market and obtained by unintended users, a foreseeable consequence of flooding a market with prescription opioids.

^{18.} See Haffajee, supra note 8, at 288–90; Rebecca L. Haffajee & Michael R. Abrams, Settling the Score: Maximizing the Public Health Impact of Opioid Litigation, 80 Ohio State L.J. 701, 713–14 (2019).

^{19.} Judgment After Non-Jury Trial at 26, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019); Stephanie Becker & Emily Smith, *Oklahoma judge miscalculated how much Johnson & Johnson would pay for the state's opioid crisis*, CNN (Oct. 16, 2019, 7:55 AM), https://www.cnn.com/2019/10/15/health/oklahoma-opioid-judgment-miscalculation/index.html.

has been reached.²⁰ And recently, Purdue Pharma arrived at a bank-ruptcy settlement with the Department of Justice that would settle it's civil and criminal federal cases for approximately \$8 billion.²¹ These examples demonstrate the potential for government litigation to achieve certain tort litigation goals, namely the recovery of damages, injunctive relief, and accountability in the form of admitted or implied wrongdoing. Nevertheless, the sums extracted, awarded, or proposed so far do not approach the potential magnitude of far-ranging harms alleged in these suits: some estimates suggest public and private costs up to hundreds of billions of dollars per year nationally, with governments bearing about half of these costs.²²

II. Public Health Evidence for Opioid-Related Liability

The opioid crisis has evolved over the past two decades in terms of its magnitude and the types of products used. The per capita rate of opioid-involved overdose deaths has more than tripled in the U.S. since 2000, with preliminary data indicating there were more than 50,000 opioid-involved overdose deaths in 2019.²³ While the harms from the crisis extend beyond mortality, the change in the composition of these opioid-involved deaths is striking. Illegally produced synthetic opioids like fentanyl now account for the largest share of opioid-involved deaths, but we cannot simply focus on these synthetics. Many of the deaths involving synthetic opioids also involve other substances²⁴ and, as documented later in this Article, many of the in-

^{20.} Jan Hoffman, *Opioid Settlement Offer Provokes Clash Between States and Cities*, N.Y. Times (Mar. 13, 2020), https://www.nytimes.com/2020/03/13/health/opioids-settlement.html.

^{21.} Press Release, U.S. Department of Justice, Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid.

^{22.} Haffajee & Abrams, *supra* note 18, at 721–23; *Economic Toll of Opioid Crisis in U.S. Exceeded \$1 Trillion Since 2001*, Altarum (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001#:~:text=February%2013%2C%202018,health%20 research%20and%20consulting%20institute.; *see generally* The Underestimated Cost of the Opioid Crisis, Council Econ. Advisers (2017); Corey Rhyan, *The potential societal benefit of eliminating the opioid crisis exceeds \$95 billion per year*, Altarum (Nov. 16, 2017), https://altarum.org/publications/potential-societal-benefit-eliminating-opioid-crisis-exceeds-95-billion-year.

^{23.} Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths* — *United States*, 2000–2014, 64 Morbidity & Mortality Wkly. Rep. 1378, 1378 (2016); Nana Wilson et al., *Drug and Opioid-Involved Overdose Deaths* — *United States*, 2017–2018, 69 Morbidity & Mortality Wkly. Rep. 290, 290 (2020). Provisional estimates suggest that after leveling somewhat in 2018, opioid-involved overdose deaths increased further in 2019 to reach 50,042. Ahmad et al., *supra* note 1.

^{24. &}quot;The worsening and expanding drug overdose epidemic in the United States now involves potent synthetic drugs, often in combination with other substances, and requires urgent action."

dividuals using illegally produced opioids today initiated their opioid use with prescription opioids. The remainder of this Section outlines the progression and relationships between prescription opioids, heroin, and illegally-produced synthetic opioids to provide context for the potential responsibility defendants to the opioid litigation bear for each.

A. Prescription Opioids

The rise in prescription opioid overdose deaths began its precipitous climb in the late 1990s, following increased prescribing of opioids in the previous decade. The undertreatment of chronic pain, a serious public health concern of its own, garnered increased scrutiny in the 1980s.²⁵ Widespread concern about adequately treating pain along with several other factors paved the way for increased prescribing of opioids. Prominent contributors to increased prescribing include:

- the publication of multiple non-rigorous medical journal articles in the mid-1980s, suggesting that opioids may be effective in treating chronic pain and not habit forming;
- the 1995 release of OxyContin by Purdue Pharma, followed by other extended-release and highly potent forms of opioid painkillers;
- Food and Drug Administration (FDA) approval of multiple, highly potent prescription opioids, including OxyContin labeling that stated iatrogenic addiction to be "very rare";
- the aggressive marketing of opioid drugs as non-addictive and appropriate for the treatment of non-cancer, chronic pain by manufacturers through various channels;
- release by the Joint Commission, which accredits health care organizations, of pain management standards for organizations to enhance their treatment of pain in patients that embraced "Pain: The Fifth Vital Sign" messaging also promoted by The American Pain Society and the U.S. Veterans Health Administration; and

Christine L. Mattson et al., *Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019*, 70 Morbidity & Mortality Wkly. Rep. 202, 207 (2021).

^{25.} Inst. of Med., Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research (2011). The Institute of Medicine is now known as the National Academy of Sciences.

 health care factors, such as favorable reimbursement and patient satisfaction incentives, that favored prescription opioids to treat pain.²⁶

These multiple factors drove marked increases in opioid prescribing, which rose steadily from 72.4 prescriptions per 100 persons in 2006 to a peak of 81.3 prescriptions per 100 persons in 2012.²⁷ The national rate of opioid prescribing declined by 2018 to 51.4 prescriptions per 100 persons.²⁸ The amount of opioids prescribed in the U.S., as measured in the standardized unit of morphine milligram equivalents (MMEs), peaked at 782 MME per capita in 2010 and decreased to 640 MME in 2015—at which time it still remained about three times as high as it was in 1999.²⁹

Over the past 20 years, the amount and doses of opioids prescribed have varied tremendously by geography, with areas in Appalachia raising high concerns, but also pockets across the country exhibiting high prescription levels.³⁰ Overwhelmingly, the source of these opioid prescriptions has been from a prescription written by a physician—either directly to the person consuming the opioid or one step-removed (e.g., the prescription was written for a family member or friend).³¹ In other words, the volume of opioid analgesics prescribed by health care providers, who apparently received a substantial

^{26.} Rebecca L. Haffajee, Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws, 67 HASTINGS L.J. 1621, 1627–29 (2016); Art Van Zee, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, 99 Am. J. Pub. Health 221, 223, 225 (2009) (detailing the history of marketing and public representations by manufacturers and their connection to the opioid overdose epidemic); Daniel Ciccarone, The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis, 71 Int'l. J. Drug Pol'y 183, 184 (2019) (describing how the introduction of extended release long-acting opioid formulations, once the delayed release mechanisms were bypassed by crushing and injecting or snorting the drug, facilitated misuse when the entire potent dose was discharged at once); David W. Baker, The Joint Commission's Pain Standards: Origins and Evolution 2–5 (2017).

^{27.} U.S. Opioid Prescribing Rate Maps, CDC, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html (last updated Dec. 7, 2020). In 2012, over 255 million opioid prescriptions were written, enough for every American adult to have a bottle of opioid pills. *Id.*

^{28.} *Id.* Even though the opioid prescribing rate in 2018 is the lowest is has been in 13 years, the rate is still relatively high. *Id.* In 11% of counties, enough prescriptions were still written for every person to have one in 2018. *Id.*

^{29.} Gery P. Guy et al., Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015, 66 Morbidity & Mortality Wkly. Rep. 697, 697–704 (2017).

^{30.} Anne Schuchat & Debbie Dowell, *Opioid Prescribing is Still High and Varies from County to County*, CDC, https://www.cdc.gov/media/dpk/prescription-drug-overdose/opioid-prescribing/index.html (last updated Jan. 28, 2020) (displaying geographic variation in 2015 in terms of morphine milligram equivalents dispensed in counties across the country); Guy et al., *supra* note 28.

^{31.} U.S. Dep't of Health & Human Servs., Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings 3 (2014); Elinore F. McCance-Katz, 2018 National Survey of Drug Use and Health (NSDUH) Releases, Substance Abuse &

amount of their information about opioid prescribing from drug companies,³² facilitated substantial supply that could then be misused and lead to addiction among patients and/or persons accessing diverted pills.

Studies demonstrate the risks inherent in increased opioid prescription and usage. Increases in prescriptions are correlated over time with rising adverse health consequences, such as treatment admissions for opioid use disorder and opioid overdose deaths.³³ Measures of potentially inappropriate prescribing—including high morphine dosages, overlapping opioid and benzodiazepine prescriptions, obtaining opioids from multiple pharmacies or prescribers in a short time period, and cash purchases of opioids—are positively associated with all-cause mortality, opioid overdoses (both fatal and nonfatal), and rates of hospitalizations.³⁴

Because of this connection between higher risk opioid prescribing and negative health outcomes, many government- and provider-level responses to the opioid crisis have focused on controlling the supply of prescriptions opioids. These policies include enforcing requirements for reporting among suppliers, educating providers and giving them tools (like prescription drug monitoring programs) to improve prescribing decisions, or rolling out drug take-back programs to retrieve excess opioids in people's homes.³⁵ However, many of these initiatives were instituted only in recent years, after the peak of opioid prescribing around 2012 and have been criticized for limiting opioid prescribing too substantially for certain patients in therapeutic need of analgesic relief.³⁶ Many governments also turned to litigation to fill

MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/data/release/2018-national-survey-drug-use-and-health-nsduh-releases.

^{32.} See Haffajee, supra note 28; Van Zee supra, note 28.

^{33.} Leonard J. Paulozzi et al., Vital Signs: Overdoses of Prescription Opioid Pain Relievers — United States, 1999—2008, 60 MORBIDITY & MORTALITY WKLY. REP. 1487, 1487–92 (2011).

^{34.} See, e.g., Adam J. Rose et al., Potentially Inappropriate Opioid Prescribing, Overdose, and Mortality in Massachusetts, 2011–2015, 33 J. GEN. INTERNAL MED. 1512 (2018); Jane A. Gwira Baumblatt et al., High-Risk Use by Patients Prescribed Opioids for Pain and Its Role in Overdose Deaths, 174 JAMA INTERNAL MED. 796 (2014); Amy S. B. Bohnert et al., A Detailed Exploration Into the Association of Prescribed Opioid Dosage and Overdose Deaths Among Patients With Chronic Pain, 54 Med. Care 435 (2016); Amy S. B. Bohnert et al., Association Between Opioid Prescribing Patterns and Opioid Overdose-Related Deaths, 305 JAMA INTERNAL MED. 1315 (2011).

^{35.} See, e.g., State Successes, CDC, https://www.cdc.gov/drugoverdose/policy/successes.html (last updated July 29, 2019); Rebecca L. Haffajee, Prescription Drug Monitoring Programs — Friend or Folly in Addressing the Opioid-Overdose Crisis?, 381 New Eng. J. Med. 699, 699 (2019).

^{36.} Haffajee, supra note 8, at 283–85. See, e.g., George Comerci et al., Controlling the Swing of the Opioid Pendulum, 378 New Eng. J. Med. 691, 691–93 (2018).

this regulatory void and obtain retroactive relief for the host of harms and costs they have incurred related to the prescription opioid scourge.

B. Heroin

Heroin has been used in the U.S. for more than a century, first as a pharmaceutical grade medicine and eventually an illegally produced powder or tar.³⁷ Illegal heroin use increased in the 1960s and 1970s, primarily in big cities, but it eventually became less prevalent. Of course, heroin use did not disappear, and people who use heroin today are no longer just living in large urban areas.³⁸

Although there existed a robust market for heroin prior to the prescription opioid increases, the heroin market expanded substantially after massive expansion of the prescription opioid market. While there is tremendous uncertainty surrounding these figures, those who used heroin four or more times in the past month—what the White House Office of National Drug Control Policy (ONDCP) defines as a chronic heroin user—increased over 40 percent from 2006 to 2016, from about 1.6 million in 2006 to 2.3 million in 2016.³⁹ As well, heroin consumption, measured in pure metric tons, increased from 27 in 2006 and 2010 to 47 by 2016 (Unfortunately, 2016 is the last year for which these figures are available).⁴⁰

Since these ONDCP "chronic user" and consumption estimates are based on models that use information about overdose deaths, we should not be surprised that they both show increases over the same period. The solid line in Figure 1 displays per capita overdose deaths involving heroin in the U.S. from 2000–2019. The rate is fairly stable from 2000–2010, but then roughly quintupled between 2010 and 2016, marking what has been called the second wave of the opioid overdose crisis.⁴¹ After 2016, the rate slowly declined. Of course, one should be careful about making inferences about consumption from overdose data since there could be measurement issues and other factors driving these overdose deaths.⁴² This is especially true for heroin which

^{37.} See generally David F. Musto et al., One Hundred Years of Heroin (2002).

^{38.} Theodore J. Cicero et al., The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years, 71 JAMA PSYCHIATRY 821, 823 (2014).

^{39.} Gregory Midgette et al., What America's Users Spend on Illegal Drugs, 2006-2016 13 (2019).

^{40.} Id. at 37.

^{41.} Center for Disease Control, *supra* note 1. Since 2016, deaths related to heroin have largely plateaued. *Id.*

^{42.} See Christopher J. Ruhm, Corrected US opioid-involved drug poisoning deaths and mortality rates, 1999–2015, 113 Addiction 1339 (2018).

was increasingly mixed with potent synthetic opioids in some parts of the country in the latter part of the series.⁴³ The dotted line in Figure 1 displays overdose deaths involving heroin that did not also mention synthetic opioids. While the heroin overdose death rates with and without synthetic opioids are similar for 2000–2014, heroin deaths excluding synthetic opioids start to flatten in 2014 and decline more sharply than heroin deaths involving synthetic opioids. Some have termed the relationship between the rise in heroin use in the 2000s and overdose deaths starting in 2010 as "intertwined."⁴⁴

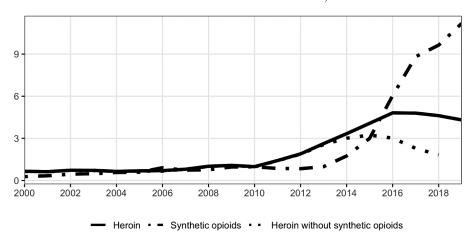


Figure 1. Drug Overdose Deaths, 2000–2019

SOURCE: Data from CDC Multiple Cause of Death files NOTE: Death rates are not age adjusted Deaths for 2019 are provisional Synthetic opioids exclude methadone

Other adverse heroin-related health outcomes also increased during this period. For example, between 2010 and 2015, the rate of Hepatitis C infections tripled, and there is evidence suggesting the increase may be partially explained by the increase in heroin injection linked to the OxyContin reformulation in 2010 to make the product more tamper resistant to crushing and misuse.⁴⁵

^{43.} See generally Bryce Pardo et al., The Future of Fentanyl and Other Synthetic Opioids (2019).

^{44.} See generally George J. Unick et al., Intertwined Epidemics: National Demographic Trends in Hospitalizations for Heroin- and Opioid-Related Overdoses, 1993–2009, PLOS ONE, Feb. 2013.

^{45.} See David Powell et al., A Transitioning Epidemic: How The Opioid Crisis Is Driving The Rise In Hepatitis C, 38 Health Aff. 287, 287 (2019).

Some estimates suggest that less than 5% of persons who misuse prescriptions transition to heroin.⁴⁶ However, according to various surveys, most people who use heroin first misused prescription opioids.⁴⁷ Whereas in the 1960s, the vast majority of people dependent on heroin initiated opioids with heroin, by the 2000s, that majority had shifted to prescription opioid initiation.⁴⁸ Those diagnosed with an OUD related to their prescription opioid use or who use multiple drugs are more prone to make this transition from prescription opioids to heroin.⁴⁹ As well, about half of patients who experienced a heroin overdose in a commercially-insured population had an opioid prescription in the past year, and about 11% had an active prescription.⁵⁰

So, even though relatively few people who misuse prescription opioids go on to use heroin, those who misuse prescriptions are more likely to do so; further a large proportion of those using heroin in recent decades do initiate with prescription opioids. Young and newer heroin users have reported transitioning from prescription opioids to heroin as their growing dependence necessitated larger and more consistent supplies than they could obtain of prescription pills.⁵¹ In some places, heroin is more readily available and the price per morphine equivalent dose is lower than prescription opioids.⁵² Research also shows that high rates of misuse of OxyContin prior to its abuse-deter-

^{46.} Prescription Opioids and Heroin Research Report, NAT'L INST. ON DRUG ABUSE, Jan. 2018, at 5; see generally Pradip K. Muhuri et al., Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States, CBHSQ DATA REV., Aug. 2013. See also Robert G. Carson et al., Predictors of transition to heroin use among initially non-opioid dependent illicit pharmaceutical opioid users: A natural history study, 160 DRUG & ALCOHOL DEPENDENCE 127, 131 (2016) (finding that 2.8% of previously non-opioid dependent prescription opioids users transitioned to heroin per year in a Midwest U.S. metropolitan population).

^{47.} Christopher M. Jones, Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers – United States, 2002–2004 and 2008–2010, 132 DRUG & ALCOHOL DEPENDENCE 95, 95 (2013). One study found that heroin initiation was nineteen times higher among those who reported prior nonmedical opioid pain reliever use than among those that didn't (0.39% vs. 0.02%). Muhuri et al., supra note 46. Another found that the vast majority (about 86%) of young, urban adults who injected drugs had used opioid painkillers nonmedically before using heroin, and that they obtained their opioid prescription pills primarily from family, friends, and personal prescriptions. Stephen E. Lankenau et al., Initiation into prescription opioid misuse amongst young injection drug users, 23 INT'L J. DRUG POL'Y 37, 39 (2012). It is important to remember that this proportion is dynamic and may vary from locale to locale.

^{48.} Cicero et al., supra note 38, at 823.

^{49.} NATIONAL INSTITUTE ON DRUG ABUSE, supra note 45.

^{50.} Pooja Lagisetty et al., *Opioid prescribing history prior to heroin overdose among commercially insured adults*, DRUG & ALCOHOL DEPENDENCE, July 1, 2020, at 3.

^{51.} Ciccarone, supra note 26, at 184.

^{52.} Sarah G. Mars et al., "Every 'Never' I Ever Said Came True": Transitions from opioid pills to heroin injecting, 25 Int'l J. Drug Pol'y 257, 261–64 (2014).

rent reformulation in 2010 are associated with elevated heroin overdose rates afterwards.⁵³

However, as Ciccarone notes, there are some interesting distinctions between the first and second opioid crisis waves. First, there are age discrepancies between the populations using each class of drugs, with those being hospitalized for heroin overdoses typically being younger (peaks at 20-34 years in 2012-14) and overdoses involving prescription opioids peaking among slightly older populations (50-64 years).⁵⁴ This can perhaps can be explained by substitution of heroin for prescription opioids in older populations, combined with new heroin initiation⁵⁵—potentially facilitated by a more robust heroin market thanks to demand from the first wave. Second, there is some geographic heterogeneity in the populations overdosing from heroin (more prevalent in Northeast and Midwest regions) and prescription opioids (prevalent across the country).⁵⁶ This variation in harms can perhaps be explained by supply-side heroin forces, with the infusion of more potent "Mexican white" heroin into Northeast and Midwest outlets, rather than more traditional "black tar" heroin in Western states.⁵⁷ All of this suggests that the heroin markets and user initiation and harms are complex and multifaceted, partly traceable to prescription opioids but hardly exclusively so. Critically, there is much we are still learning about the relationship between prescription opioids and heroin, and some facets of the heroin market may never be confidently traced to root causes or risk factors.

C. Illegally Produced Synthetic Opioids

Deaths involving synthetic opioids other than methadone (e.g., fentanyl, fentanyl analogs, and tramadol) remained relatively flat from 1999–2013, but exhibited an exponential increase from 2013 (1.0

^{53.} See generally Abby Alpert et al., Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids, Am. Econ. J. Econ. Pol'y, Nov. 2018 (finding that each percentage point reduction of OxyContin misuse associated with the reformulation increases heroin mortality by 3.2 deaths per 100,000 population). See also Theodore J. Cicero et al., Effect of Abuse-Deterrent Formulation of OxyContin, 367 New Eng. J. Med. 187, 188–89 (2012) (suggesting the reformulation reduced OxyContin misuse by up to 40%); Marc R. Larochelle et al., Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene, 175 JAMA Internal Med. 978, 985 (2015).

^{54.} Ciccarone, supra note 26, at 184.

^{55.} Id.

^{56.} Id. at 184-85.

^{57.} Id. at 185.

per 100,000 population) to 2018 (9.9 per 100,000).⁵⁸ Fentanyl is a prescription analgesic that is 50 to 100 times more potent than morphine, but the illegally manufactured versions are accounting for the lionsshare of opioid-related deaths.⁵⁹ Synthetic opioids other than methadone provisionally were involved in 37,133 out of the 50,793 opioid-involved drug overdose deaths in 2019, or over 73%.⁶⁰ The comparable figures for 2017 and 2010 were 56% and 14%, respectively.⁶¹

The geographic reach of illegally manufactured synthetic opioids is expanding. Whereas drug seizure data initially indicated these drugs were concentrated in Northeast and mid-Atlantic regions, largely replacing some heroin markets, they have more recently expanded to the West.⁶² Fentanyl and its analogs have been predominantly detected in heroin sources, in part because it is much cheaper for dealers to substitute fentanyl for an MME amount of heroin.⁶³ However, an increasing share of overdose deaths involving stimulants, including cocaine and methamphetamine, also mention synthetic opioids other than methadone. For example, Figure 2 displays cocaine overdose deaths in the US by whether heroin and/or synthetic opioids were also present. By 2018, more than half of all cocaine deaths also mentioned synthetic opioids other than methadone.⁶⁴

Over half of cocaine overdoses in 2018 also mentioned synthetic opioids. Pardo et al., *supra* note 62. See also Sarah Wakeman et al., Rise in Presence of Methamphetamine in Oral Fluid Toxicology Tests Among Outpatients in a Large Healthcare Setting in the Northeast, 15 J. Addiction Med. 85, 86 (2021) (finding common polysubstance use, with 25% of samples with methamphetamine also showing fentanyl).

^{58.} Holly Hedegaard et al., *Drug Overdose Deaths in the United States*, 1999–2018, NCHS DATA BRIEF No. 356, at 3 (2020).

^{59.} What is fentanyl?, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/drugfacts/fentanyl#ref (last updated June 1, 2021); Ciccarone, supra note 26, at 185.

^{60.} Ahmad et al., supra note 1.

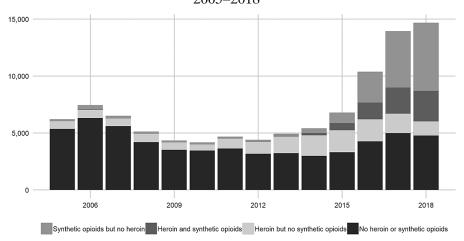
^{61.} NATIONAL INSTITUTE ON DRUG ABUSE, supra note 59.

^{62.} Ciccarone, supra note 26, at 185; Bryce Pardo et al., The dawn of new synthetic opioid era: the need for innovative interventions, 6 ADDICTION 1304, 1305 (2020).

^{63.} R. Matt Gladden et al., Changes in Opioid-Involved Overdose Deaths by Opioid Type and Presence of Benzodiazepines, Cocaine, and Methamphetamine — 25 States, July–December 2017 to January–June 2018, 68 Morbit & Mortality Wkly Rep. 737, 737 (2019) (stating that 90% increases in opioid-involved overdose deaths from 2013–2017 were primarily driven by substantial increases in deaths involving fentanyl and its analogs mixed with heroin, sold as heroin, or pressed into counterfeit pills); Pardo et al., supra note 62, at 1307 (stating that heroin costs one hundred times more than fentanyl per morphine equivalent dose).

^{64.} Overdose Death Rates, NAT'L INST. ON DRUG ABUSE (Jan. 29, 2021) https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates (demonstrating the increases in psychostimulant and, separately, cocaine overdose deaths that involved an opioid, mainly driven by the involvement of fentanyl or fentanyl analogs). See also Gladden et al., supra note 63, at 741 (finding that 24% of all opioid-involved overdose deaths involved cocaine and 12% involved methamphetamines).

Figure 2. U.S. cocaine overdose deaths involving heroin and/or synthetic opioids other than methadone, $2005{-}2018^{65}$



It remains unclear to what extent drug dealers are intentionally mixing fentanyl into other drug sources, and to what extent drug users are seeking out fentanyl versus unknowingly consuming it.⁶⁶ Many experts believe that the spread of fentanyl into markets in the U.S. is supply-side driven, when dealers decide to distribute it over heroin or diverted prescription opioids. According to very limited data, those using fentanyl seem to be people who were already using opioids previously, as opposed to new entrants to the opioid markets.⁶⁷ However, emerging evidence suggests that in certain locales inundated with fentanyl, some individuals are now seeking out the substance.⁶⁸

Some recent evidence suggests there are some connections between prescription opioid markets and heroin/fentanyl markets. Evaluating the consequences of OxyContin reformulation, Alpert and colleagues found that states with higher rates of OxyContin use for nonmedical purposes before reformulation observed a disproportionate rise in heroin overdoses and "suggestive evidence that consumers substituted

^{65.} Pardo et al., supra note 62, at 1305.

^{66.} See id.; Where is fentanyl added to cocaine? Mostly in Ohio. Result: 3,000 dead, Harm Reduction Ohio (Jan. 13, 2019), https://www.harmreductionohio.org/where-is-fentanyl-added-to-cocaine-mostly-in-ohio/; Erica Spies et al., Undetermined risk factors for fentanyl-related overdose deaths — Ohio, 2015 38 (2016).

^{67.} Pardo et al., supra note 62, at 1310.

^{68.} Jennifer J. Carroll et al., Exposure to fentanyl-contaminated heroin and overdose risk among illicit opioid users in Rhode Island: A mixed methods study, 46 Int'l J. Drug Pol'y 136, 143 (2017); Andrea Meier et al., Understanding the increase in opioid overdoses in New Hampshire: A rapid epidemiologic assessment, Drug & Alcohol Dependence, Apr. 1, 2020, at 4.

to synthetic opioids such as fentanyl" after the reformulation.⁶⁹ A more recent paper using a similar methodology and additional years of data found stronger evidence of a relationship. Powell and Pacula found that areas more exposed to OxyContin reformulation "experienced disproportionate increases in fatal overdoses involving synthetic opioids (fentanyl) and nonopioid substances. . . Instead of just short-term substitution from prescription opioid to heroin overdoses, the transition to illicit markets spurred by reformulation led to growth in the overall overdose rate to unprecedented levels."⁷⁰

A recent working paper finds strong evidence that introduction and marketing of OxyContin explains a substantial share of all opioid-related deaths from 1996 to 2017. Leveraging the fact that some states had triplicate prescription programs and Purdue Pharma did not market OxyContin as much in those states, the paper find that states with these triplicate programs had 50% lower OxyContin distribution.⁷¹ It also finds that initial non-triplicate status increased states' opioid-related death rates by over 72% for the period covering 2011–2017.⁷² This suggests that a large proportion of opioid-related deaths in recent years, the majority of which are related to heroin and illegally produced synthetic opioids since approximately 2014, can be traced back to the introduction and marketing of OxyContin.

It seems likely that the synthetic opioid markets would not have developed so quickly were there not a large pool of existing opioid users. However, the geographic variation in synthetic-related deaths and seizures remains puzzling.⁷³ Other supply-side factors related to the illegal synthetic market—such as internet distribution, lack of regulatory scrutiny for suppliers and precursor chemicals, and reduced costs to production—also played substantial roles in the spread of these products across the country, rather than the supply being driven by demand.

III. THE EXTENT OF OPIOID LIABILITY

A. Claims Alleged

Government plaintiffs participating in the opioid litigation assert two overarching "direct-injury" claims in the litigation: that opioid

^{69.} Alpert et al., supra note 53, at 31.

^{70.} David Powell and Rosalie Liccardo Pacula, *The Evolving Consequences of OxyContin Re-* formulation on Drug Overdoses, 7 American Journal of Health Economics 1 (2021).

^{71.} See generally Abby E. Alpert et al., Origins of the Opioid Crisis and Its Enduring Impacts (Nat'l Bureau of Econ. Res., Working Paper No. 26500, 2019).

^{72.} *Id*.

^{73.} Pardo et al., *supra* note 62, at 1310.

suppliers engaged in marketing schemes and supply chain schemes.⁷⁴ According to the marketing scheme theory, opioid manufacturers falsely and deceptively represented their prescription opioids to prescribers and consumers as less addictive and as more effective in treating pain-related conditions than scientific evidence established. Governments assert this was designed to dramatically increase prescribing of, demand for, and sale of prescription opioids. The supply chain theory alleges that manufacturers, distributors, pharmacy benefit managers and retail pharmacies—all of whom had or should have had oversight over volumes of opioids prescribed and sold to locales—failed to monitor, control, and report suspicious activity. This allegedly resulted in the circulation of more prescription opioids than could plausibly have been medically necessary to these locales. In essence, the companies failed to take reasonable, required steps to prevent opioid prescriptions from being diverted to nonmedical uses.

Government plaintiffs tend to frame the harms (or direct injuries) they have suffered very broadly. Types of harms and costs incurred range from those associated with healthcare (including opioid analgesic prescriptions, substance use disorder treatment and overdose), public safety and law enforcement, deaths, and children who lose their caregivers to productivity and labor costs. Government complaints typically assert that defendants are responsible for harms arising from both misused prescription opioids and "illegal opioids," or illegally manufactured and distributed opioids (including heroin and fentanyl). For example, the Complaint by Island County, Washington states the following about harms and responsibility:

The opioid abuse prevalent throughout County has affected Plaintiff in numerous ways, not only through the need for increased emergency medical services, but also through increased drug-related offenses affecting law enforcement, corrections, and courts, and through additional resources spent on community and social programs, including for the next generation of Island County residents, who are growing up in the shadow of the opioid epidemic . . . Nearly half of all opioid overdose deaths involve a prescription opioid like those manufactured by Defendants, and the increase in overdoses from non-prescription opioids is directly attributable to Defendants' success in expanding the market for opioids of any kind.⁷⁵

The County of Eaton, Michigan Complaint states the following:

Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having be-

^{74.} Aliferov, supra note 14, at 1159-60.

^{75.} Complaint at 1, 3, Island Cty. v. Purdue Pharma, L.P., No. 2:18-cv-01127 (W.D. Wash. Aug. 1, 2018) (transferred to N.D. Ohio as case 1:18-op-45982 on Aug. 17, 2018).

come addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease Control and Prevention ("CDC") identified addiction to prescription opioids as the strongest risk factor for heroin addiction . . . The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire – or simply could not afford - prescription opioids . . . Defendants' conduct in promoting opioid use has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction, overdose, and death from illicit drugs such as heroin. The costs are borne by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarcerations, treating opioid-addicted newborns in neonatal intensive care units, and burying the dead, among others.76

Finally, Stephens County, Texas alleges the following:

Due to the increase in opioid overdoses, first responders such as police officers, have been and will continue to be in the position to assist people experiencing opioid-related overdoses. In 2016, "over 1,200 law enforcement departments nationwide carried naloxone in an effort to prevent opioid-related deaths."... Defendants' deceptive marketing scheme has also detrimentally impacted children in Stephens County. Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household . . . Defendants' conduct has adversely affected Stephens County's child protection agencies in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for counties like Stephens County . . . [O]pioid addiction is a significant reason that Stephens County residents seek treatment for substance dependence. A significant number of admissions or drug addiction were

^{76.} Complaint at 3, 6–7, Cty. of Eaton v. Purdue Pharma, L.P., No. 1:18-cv-00823 (W.D. Mich. July 25, 2018) (transferred to N.D. Ohio as case 1:18-op-45971 on Aug. 15, 2018). See also Complaint at 36, Stephens Cty. v. Purdue Pharma, L.P., No. 1:18-cv-00078-C (N.D. Tex. May 29, 2018) (transferred to N.D. Ohio as case 1:18-op-45804 on July 11, 2018); Complaint at 4, Island Cty. v. Purdue Pharma, L.P., No. 2:18-cv-01127 (W.D. Wash. Aug. 1, 2018) (transferred to N.D. Ohio as case 1:18-op-45982 on Aug. 17, 2018).

associated with a primary diagnosis of opiate addiction or dependence . . . Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for [non-medical and] criminal use and fueled a new wave of addiction and injury . . . It has been estimated that 60% of the opioids to which people are addicted come, directly or indirectly, through doctors' prescriptions . . . Law enforcement agencies have increasingly associated prescription drug addiction with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace . . . The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the past decade among adults aged 18 to 25 years. Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010 . . . The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid addiction and dependence was estimated at \$25 billion, the cost of criminal justice was estimated at \$5.1 billion, and the cost of lost workplace productivity was estimated at \$25.6 billion . . . [S]ome of the repercussions for residents of Stephens County include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration, which result in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers, and law enforcement . . . Defendants' wrongful conduct caused injuries to Stephens County in the past, continues to cause injuries to Stephens County, and will continue to cause injuries to Stephens County in the future. Future damages include, but are not limited to, additional resources for counseling and medication assisted treatment of addicts, medical treatment for overdoses, life skills training for adolescents, increased law enforcement, and additional resources to treat the psychological effects of opioids and the underlying conditions that make people susceptible to opioid addiction ... While using opioids has taken a toll on Stephens County and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated \$11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.⁷⁷

^{77.} Complaint at 36–39, 41, Stephens Cty. v. Purdue Pharma, L.P., No. 1:18-cv-00078 (N.D. Tex. May 29, 2018) (transferred to N.D. Ohio as case 1:18-op-45804 on July 11, 2018).

Government plaintiffs to the opioid litigation typically adopt tortbased and equitable theories in their direct-injury claims.⁷⁸ Tort-based theories try to establish that the defendant companies breached some duty of care to the government plaintiffs, by engaging in wrongful conduct, and that this breach caused injury for which damages are owed.⁷⁹ Equitable relief theories, rather than hinging on fault, focus more on who should bear the costs when the public is damaged by the conduct of a legal business.80 Government opioid complaints endeavor to establish tort-based duties of care in causes of action like negligence and violation of the RICO Act and seek equitable relief under common-law concepts like public nuisance and unjust enrichment.81 In making these allegations, direct-injury government cases are inherently representative actions that allow for aggregation of interests at the population level and avoid conduct-based defenses, given that the governments were largely "blameless" in the opioid epidemic.82

To more deeply analyze the nature of government plaintiffs to the opioid litigation and the allegations, we analyzed all federal MDL case dockets and a random sample of initial complaints.⁸³ First, we collected all 2,847 cases filed in the MDL as of January 2020, using the transfer orders available on PACER. The website Law360 compiles a list of all cases in and MDL and provides a link to the complaints in the individual cases if available. Law360 also provides a list of individual plaintiffs and defendants in each underlying case. From this list, we were able to categorize the plaintiffs to the litigation into categories. We found that a large proportion of plaintiffs were municipal (county and city) and tribal governments. Specifically, of the 3,418 unique plaintiffs, 42% were county governments, 27% were city gov-

^{78.} Aliferov, supra note 14, at 1160.

^{79.} *Id*.

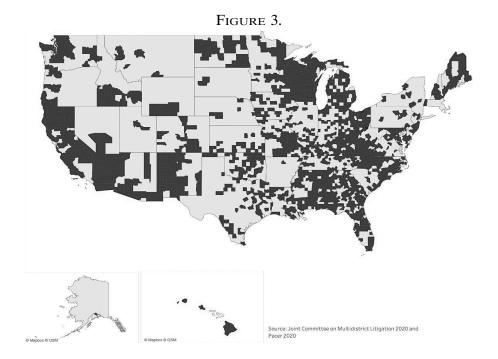
^{80.} Id.

^{81.} *Id.* It is important to bear in mind that the definitions and common law interpretations of claims alleged will differ by state (except with respect to federal statutory claims, like RICO). This variation could make a global settlement in the MDL challenging and affect the applicability of trial or dispositive motion resolutions in the overall MDL proceedings.

^{82.} Id. at 1173.

^{83.} While also of interest, government opioid cases filed in state courts—of which we believe there to be over four hundred based on bankruptcy filings that list such cases—are more difficult to systematically track and access associated complaints. We thus focused on the federal MDL cases, with the intent to probe state cases more deeply in the future. Causes of action could differ somewhat in these state cases, wherein more state governments are plaintiffs and could allege state-based claims with greater frequency. See generally Zachary D. Clopton & D. Theodore Rave, Opioid Cases and State MDLs, 70 DEPAUL L. REV. (forthcoming 2021).

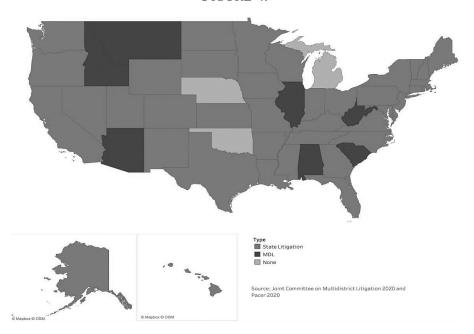
ernments, and 5% were tribal governments.⁸⁴ Governments, in particular states but also some municipalities, also are leading plaintiffs in cases filed in state courts.⁸⁵ Figure 3 depicts all county governments to the federal MDL as of January 2020, demonstrating high prevalence nation-wide, but also geographic variation. Figure 4 shows the 47 states that had joined the opioid litigation as of January 2020—40 in state court and seven in the federal MDL.



^{84.} Other plaintiffs included: public hospitals (7%), coroners (6%), labor unions (2%), police departments (1%) and state governments (<1%). The total sum exceeds 100% because many cases include multiple plaintiffs.

^{85.} Clopton & Rave, supra note 83.

Figure 4.



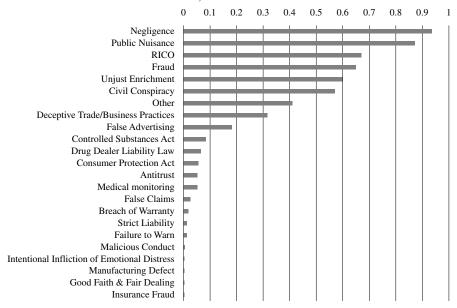
Next, to identify common causes of action in federal opioid MDL cases, we analyzed a random sample of 500 complaints (or 500 complaints). We randomly selected these cases from a list of all case dockets, and then divided the sample among 10 individuals who were trained to identify and code different allegations. Each individual coder located the initial complaint in his/her assigned cases. ReA subsample of 100 cases was randomly selected to test intercoder validity, which ranged from 78–90% depending on the cause of action.

Our results revealed dominant causes of action in this consolidated MDL (Figure 5). Out of 22 categories of causes of action alleged by plaintiffs, the top five were: negligence (alleged in 94% of complaints), public nuisance (87%), RICO (67%), fraud (64%) and unjust enrichment (60%). In the discussion that follows we focus on the most common causes of action except fraud. We chose to exclude fraud because this cause of action took many forms that were specific to the

^{86.} Cases on file with authors. For about 20% of cases, the initial complaint could not be located either on Law360 or directly from PACER. In most cases an amended complaint seems to have replaced the original complaint but in about 10% of the cases, no complaint appears to exist. These missing initial complaints do not appear to be related to the filing date or the court in which the case was originally filed, and we are unclear as to why complaints would be missing from PACER.

facts in the case and the jurisdiction in which it originated.⁸⁷ For each of these four theories, we first outline the elements required to demonstrate liability and then analyze whether these elements can be plausibly met for misuse of prescription opioids and, separately, harms arising from use of illegal opioids.

Figure 5: Frequency of Causes of Action in Opioid MDL Cases, January 2020



B. Negligence

Negligence is frequently alleged in government suits against companies supplying opioid analysics. Negligence requires that plaintiffs demonstrate: (1) that the defendants had a duty to take reasonable care to prevent harm to the plaintiff, (2) that defendants breached that duty by failing to take reasonable precautions, (3) that the de-

^{87.} For example, fraud allegations took the following forms: statutory fraud—deceptive practices (statute cited varies by locale), statutory fraud—unfair practices (statute cited varies by locale), common law fraud, and common law fraudulent concealment. To demonstrate common law fraud, plaintiffs are generally required to demonstrate the following elements: (1) false statement of material fact, (2) defendant's knowledge that the statement is untrue, (3) defendant's intent to deceive the plaintiff, (4) plaintiff's reliance on the statement, and (5) injury. Required elements could vary for statutory fraud allegations, such as violations of consumer fraud and deceptive business practices acts (e.g., may not require a showing of actual awareness of falsity). See, e.g., Second Amended Complaint at 9–11, City of Chi. v. Purdue Pharma, L.P., No. 1:14-cv-04361 (N.D. Ill. Aug. 26, 2015) (transferred to N.D. Ohio as case 1:17-OP-45169-DAP on Dec. 20, 2017)).

fendants' conduct was an actual *and* proximate cause of the plaintiff's injury, and (4) that the plaintiff subsequently suffered damages.⁸⁸ Government plaintiffs to the opioid litigation have alleged various forms of negligence, including negligent monitoring and reporting, negligent marketing, gross negligence, and negligence *per se.*⁸⁹ These claims present some opportunity for plaintiffs to demonstrate liability and possibly encourage settlements, though they also face certain challenges in establishing the duty and causation elements.

Governments claim that opioid manufacturers had various duties they failed to meet. These include a duty of drug companies to ensure their drugs were not misused; a duty of the pharmaceutical industry (up and down the supply chain) to monitor, prevent, and report suspicious orders and activities; a duty of manufacturers to market opioids in a manner that did not increase inherent risk; and a more general duty to avoid the over-prescription of opioids. More specific duties owed are discussed below for two specific negligence theories commonly raised in opioid litigation: negligent monitoring, reporting, and marketing.

Causation, another key negligence element, may be present obstacles in opioid cases. Actual causation, or cause-in-fact, requires that the plaintiff show that breach of duty is an actual cause of the harm alleged. For opioid litigation, where multiple factors contributed to opioid-related injuries, actual causation would often be established using the "substantial factor test," which asks if the defendant's act is a substantial factor in causing the injury. Given how many factors contributed to the opioid crisis and how many companies participated in manufacturing and supplying prescription opioids, determining whether a given defendant's activities constitute a "substantial factor" may be a subjective determination based on facts presented. Proximate causation requires that the harm alleged is a foreseeable result of the defendant's breach of duty and asks: is the injury of a type that a reasonable person would see as a likely result of defendant's con-

^{88.} See W. Page Keeton et al., Prosser and Keeton on Torts § 30 164–65 (5th ed. 1984); Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. Rev. 565, 574 (2019).

^{89.} Ausness, supra note 88, at 574.

^{90.} Nino C. Monea, Cities v. Big Pharma: Municipal Affirmative Litigation and the Opioid Crisis, 50 Urb. Law. 87, 138–40 (2019).

^{91.} Actual causation traditionally is established using the but-for test which asks: would the injury have occurred in the absence of the defendant's conduct? But when multiple causes contribute to an injury, the but-for test is not directly applicable, and some courts allow the substantial factor test to establish actual causation. This tests instead asks: was the defendant's action a substantial factor in causing the injury? Ausness, *supra* note 88, at 574.

duct?⁹² But when superseding causes, such as criminal acts, occur that break the chain of causation for the proximate cause analysis, liability is typically severed.⁹³

1. Negligent Marketing

In negligent marketing cases, government plaintiffs claim that product manufacturers have a duty to market their products in ways that do not increase the product's inherent risks. For instance, manufacturers are expected not to market products in a way that substantially increases the risk that purchasers who are prone to injuring themselves or others who purchase the products. If aware of a possibly dangerous situation involving the use of its product, such as misuse or diversion of addictive opioids, then manufacturers have the duty to market its product in a way that mitigates the danger. Negligent marketing claims can take different forms and be based on product design, advertising and promotional activities, and negligent distribution—some of which could conceivably apply to the actions of prescription opioid manufacturers and distributors.

^{92.} Id. at 599.

^{93.} Id.

^{94.} Richard C. Ausness, *Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing*, 53 S.C. L. Rev. 907, 912 (2002). Courts initially did not deem negligent marketing claims actionable in the early years of firearm litigation, because state laws were not considered to impose a duty on manufacturers to protect third parties absent a special relationship. *Id.* at 910. However, "[a] number of courts have now recognized a theory of liability based on the existence of a duty (often imposed on an industry as a whole) to market or distribute products only in certain ways or only to certain parties" and some courts have "determined that there are circumstances in which the distribution of a dangerous product can give rise to particularized duties with respect to the marketing of that product." 1 L. of Toxic Toxis § 6:38 (2021).

^{95.} Ausness, *supra* note 94; *See* Plaintiff's Complaint for Damages, Restitution, and Civil Penalties, New Mexico ex. rel. Balderas v. Purdue Pharma, No. D-101-CV-2017-02541 (1st Jud. Dist. Ct. Sept. 7, 2017).

^{96.} Ga. Code Ann. § 51-1-11(c) (2009).

^{97.} Ausness, supra note 94, at 912. Negligent design claims argue:

[[]S]ome non-essential design feature enhances the product's attractiveness to unsuitable users, thereby increasing the chance that these users will cause injury to themselves or others . . . Negligent marketing claims based on advertising and promotional activities would impose liability on manufacturers and other sellers whose advertising and promotional efforts induce certain types of consumers to purchase their products. Specifically, product sellers would be subject to liability for such marketing practices when they are specifically directed at vulnerable or dangerous consumers.

Id. at 912-13. Negligent distribution would:

[[]I]mpose liability upon manufacturers for engaging in negligent distribution practices. For example, liability might be imposed when manufacturers distribute the product in such a way that unauthorized users are more easily able to obtain access to it at the retail level. Courts might also hold manufacturers responsible for failing to supervise the actions of unscrupulous retail sellers . . . Another form of negligent marketing

governments allege that opioid manufacturers have targeted vulnerable groups, like veterans, and have produced high-dose formulations with easily tampered-with time release mechanisms that make them ripe candidates for misuse. There is some evidence that government plaintiff negligent marketing claims have survived motions to dismiss, although this does not demonstrate that they will ultimately succeed on their merits.⁹⁸

If a duty is established and the claims are found actionable by the courts, government plaintiffs will also need to establish a reasonable standard of care that was breached, as well as show that defendants' actions played a substantial role in causing opioid harms. In certain firearm litigation, courts found that manufacturers were not in the best position to prevent risk and that these companies' manufacturers also did nothing to enhance risk.99 In other words, gun manufacturers were not found to violate a reasonable standard of care or play a substantial role in firearm-related injuries. However, opioid litigation could be distinguishable, at least for prescription drugs. Plaintiffs allege that opioid manufacturers did in fact enhance risk by deceptively marketing products (and by failing to report and monitor their products, as discussed below), even when they had reason to know the products were being misused and diverted. While the firearm litigation targeted the inherently dangerous aspect of the products, opioid litigation is focusing on detailed allegations and evidence that defend-

would impose liability on manufacturers who fail to warn retail sellers about the dangers of selling their products to persons likely to misuse them.

Id. at 915–16. The claims can be based on products designed or marketed to appeal to unsuitable customers, targeting of advertising at unsuitable or vulnerable members of public, failure to supervise or tortious conduct by distributors and retail sellers. *Id.* at 575.

98. One court rejected the defendant's arguments that there is "no duty to protect against the misconduct of third parties, that New York does not impose a legal duty on manufacturers to control the distribution of potentially dangerous products, and that the alleged foreseeability of injuries is not a reason to find that a duty exists." Jason B. Binimow, Opioid Marketing, Promoting, and Distributing Claims Against Manufacturers and Distributors, 39 A.L.R. 7th Art. 4 (2018); In re Opioid Litig., 2018 WL 3115102 (N.Y. Sup. 2018). City of Bos. v. Purdue Pharma, LP, No. 1884-CV-02860, 2020 WL 416406, at *9 (Mass. Super. Jan. 3, 2020). But see Transfer Order, In re Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (J.P.M.L. Dec. 12, 2017). In re Nat'l Prescription Opiate Litig., 452 F. Supp. 3d 745, 788 (N.D. Ohio 2020) (In West Boca Medical Center, Inc. v. AmerisourceBergen Drug Corporation, West Boca specifically alleged that defendants engaged in negligent marketing "by overstating the benefits of chronic opioid therapy and opioids' superiority compared with other treatments . . . mischaracterize[ing] the serious risks and adverse outcomes of opioid use, . . . [and] market[ing] for indications and benefits that were outside of the opioids' labels and not supported by substantial evidence." The Court granted the motion to dismiss for the claim on the basis that Florida had not yet deemed negligent marketing a separate cause of action). Ausness, *supra* note 88, at 597.

99. *Id.* at 568; *but see* City of Bos. v. Smith & Wesson Corp., No. 199902590, 2000 WL 1473568, at *15 (Mass. Super. Ct. July 13, 2000) (allowing negligence claim to proceed based on an allegation that manufacturers engaged in affirmative acts resulting in an illegal market).

ants partook in affirmative acts. For marketing, this could potentially establish breach of a reasonable duty of care, the result of which substantially caused prescription opioid-related harms—that harms are substantial in and of themselves. This argument could be particularly compelling in locales where a given defendant supplies a product that was prevalently distributed and misused. However, establishing that defendants proximately and actually caused illegal synthetic opioid, and, to a lesser degree, heroin harms seems more of a stretch. 100 The extent of time passing between the height of the marketing of prescription opioids and particularly the increase in consumption of illegally-produced synthetic opioids, the many intervening independently contributing factors to heroin and synthetic opioid proliferation (e.g., illegal dealers, the Internet, production costs), as well as illegal activity on the part of populations using illegally-obtained opioids all weigh against triers of fact finding defendants negligently responsible for these later opioid harms.

2. Negligent Monitoring and Reporting

When governments allege negligent monitoring and reporting, typically against opioid distributors and pharmacy retailers but also sometimes manufacturers, they claim that defendants failed to exercise sufficient control over prescription opioid distribution, which facilitated an influx of opioids into the illegal market. Plaintiffs argue that they have independent rights of action derived from opioid company duties under federal and state law, most notably the Controlled Substances Act (CSA). For example, in *City of Boston v. Purdue Pharma*, Plaintiffs alleged the following:

^{100.} Particularly for Purdue Pharma, the fact that reformulation induced a shift to heroin could establish a proximate connection between prescription opioid supply and heroin-related harms. However, Purdue could argue that they were trying to make the products safer by reformulating them to be "safer." Plaintiffs, however, have argued that these higher dosages made the products more addictive, and were still easily manipulated with to achieve a more intense "high." *See infra* Part II.B.

^{101.} Complaint at 140, City of Bos. v. Purdue Pharma, L.P., No. 1:18-cv-12174 (Mass. Super. Sept. 13, 2018). *See* Plaintiff's Complaint for Damages, Restitution, and Civil Penalties at 5, New Mexico ex. rel. Balderas v. Purdue Pharma, No. D-101-CV-2017-02541 (1st Jud. Dist. Ct. Sept. 7, 2017).

^{102.} Abbe R. Gluck et al., Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis, 46 J.L. MED. & ETHICS 351, 354 (2018). The CSA requires companies supplying controlled substances like opioids to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids. *Id.* The cases rely on "DEA regulations issued under the CSA that require any entity involved in the distribution of controlled substances to 'design and operate' a system that enables them to detect suspicious orders and in turn report those orders to the DEA[,]" as well as similar state level drug enforcement laws. *Id.* at 356. For pharmacy retailers, the plaintiffs again assert a duty arising under the CSA which provides that prac-

Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report, and filling highly suspicious orders time and again. Because the purpose of these duties was to prevent the resulting harm – misuse and/or diversion of highly addictive drugs for non-medical purposes – the causal connection between Defendants' breach of duties and the ensuing harm was entirely foreseeable. 103

Defendants typically defend negligence claims by arguing that they owe no legal duty to prevent harm from the illegal drug trade and that there is not a clear causal connection between prescription opioid supply and illegal opioid markets. ¹⁰⁴ In *City of Boston*, at least with respect to negligence claims against manufacturers, that argument was rejected at the motion to dismiss stage because the Court found it plausible that there was causal connection between the defendant's activity and illegal prescription drug use. ¹⁰⁵ Whether the plausibility of a causal connection would hold not just for prescription opioid-related harms caused by the products allegedly negligently monitored, but also for illegal opioids, raises questions. Presumably it is more challenging for plaintiffs to establish that defendants could have foreseen harms from illegal fentanyl, which was not as prevalent in the market-place when prescription opioids were most heavily distributed; ¹⁰⁶ her-

titioners have a "responsibility for the proper prescribing and dispensing of controlled substances," and includes pharmacists as a practitioner with a "corresponding responsibility." *Id.* Here, the claim is that "prescriptions that raised 'red flags' were consistently filled when a 'reasonably prudent pharmacy' would have recognized these high-risk prescriptions and refused to fill such orders." *Id.*

103. Complaint at 135, City of Bos. v. Purdue Pharma, L.P., No. 1:18-cv-12174 (Mass. Super. Sept. 13, 2018).

104. See, e.g., City of Bos. v. Purdue Pharma, LP, No. 1884CV02860, 2020 WL 416406, at n.9 (Mass. Super. Jan. 3, 2020).

105. *Id.* at *9 ("[T]he Cities correctly observe that courts do not hesitate to impose a duty of care upon entities who participate in creating known or knowable risks and who are well situated to mitigate them. The Manufacturer Defendants argue, however, that the Cities are attempting to impose a duty upon them to remedy harm caused by and to third parties through the illegal drug market and drug addiction. In essence, the Manufacturer Defendants recast the argument that they made with regard to causation in asserting that they cannot be held responsible for harms caused by others over whom they have no control. As already discussed above, the Complaints contain sufficient allegations of harm to patients who suffered addiction, overdose, and other consequences as a result of the Manufacturer Defendants' [actions]. Because the foreseeability of that harm is a question of fact that in turn defines the scope of the duty owed, the Manufacturer Defendants' argument that they have no duty cannot be decided at this early stage of the litigation."). However, it is unclear whether this plausible connection extends to negligent failure to report by distributors.

106. Of note, however, there have been illegal fentanyl outbreaks over time, including one that killed about 1,000 people in the U.S. from 2005–2007. See generally Nonpharmaceutical Fentanyl-Related Deaths — Multiple States, April 2005—March 2007, 57 MORBIDITY & MORTALITY WKLY, REP. 793 (2008). See also PARDO ET AL., supra note 43.

oin could convey some level of uncertainty, given that this market at substantially existed at that time. Showing that a defendant's conduct was a "substantial factor" in this complicated array of reasons for illegal opioid use and harms is a question of fact that requires additional epidemiological evidence. Finally, defendants argue that violation of the regulatory duties to monitor and report suspicious activity does not constitute a common law duty and there is no private right of action for failing to satisfy the regulatory requirements. This argument has been rejected in some jurisdictions but could prevail in others. 108

C. Racketeer Influenced and Corrupt Organizations (RICO)

The U.S. Congress passed the RICO Act to combat organized crime and its infiltration of legitimate business.¹⁰⁹ Although the legislative history suggests that the impetus for passing the statute was to focus on criminal syndicates, nothing in the statute itself limits its applicability to organized crime.¹¹⁰ States and other jurisdictions have deployed a wide net as an alternative civil claim against opioid suppliers up and down the chain.¹¹¹ Plaintiffs stating a RICO claim must establish the following elements: the (1) conduct of (2) an enterprise (3) through a pattern (4) of racketeering activity; (5) that actually and directly injured the plaintiffs; and (6) proximately caused injury to the plain-

^{107.} See City of Bos. v. Purdue Pharma, LP, No. 1884CV02860, 2020 WL 416406, at *9 (Mass. Super. Jan. 3, 2020).

^{108.} See e.g., Binimow, supra note 98, § 24 ("In re Opioid Litigation, 2018 WL 3115102 (N.Y. Sup 2018) . . . [t]he court noted it is well settled that a violation of a regulation or ordinance constitutes some evidence of negligence.") In denying defendant's motion to dismiss, the Court in West Boca Medical Center, Inc. v. AmerisourceBergen Drug Corporation, accepted West Boca's claim that the defendant's conduct lacked reasonable care to prevent diversion of opioids, leading foreseeable injuries. In re Nat'l Prescription Opiate Litig., 452 F. Supp. 3d 745, 785–87 (N.D. Ohio 2020).

^{109.} See Gerard E. Lynch, RICO: The Crime of Being a Criminal, Parts I & II, 87 COLUM. L. REV. 661, 681 (1987).

^{110.} See id.

^{111.} See, e.g., In re Nat'l Prescription Opiate Litig., 452 F. Supp. 3d at 757, 791; see also State ex rel. Jennings v. Purdue Pharma L.P., No. N18C-01-223 MMJ CCLD, 2019 WL 446382, at *13 (Del. Super. Ct. Feb. 4, 2019) (a state civil conspiracy claim).

Civil conspiracy based in state laws has also been a popular claim alleged (57% of complaints in our sample). *See, e.g.*, City of Bos. v. Purdue Pharma, LP, No. 1884CV02860, 2020 WL 416406, at *11 (Mass. Super. Ct. Jan. 3, 2020) (discussing the Springfield Complaint joined to the Boston suit); State ex rel. Jennings v. Purdue Pharma L.P., No. N18C-01-223 MMJ CCLD, 2019 WL 446382, at *13 (Del. Super. Ct. Feb. 4, 2019). These claims rely on underlying tortious conduct, and a conspiracy alone does not establish liability. Biggs v. Eaglewood Mortg. LLC, 582 F. Supp. 2d 707, 717 (D. Md. 2008). Many of the elements otherwise required for these claims are echoed in the RICO discussion that follows, such as a common design (among two or more people) to commit an unlawful act, typically causing damage to the plaintiffs. *See In re* Am. Int'l Grp., Inc., 965 A.2d 763, 805 (Del. Ch. 2009); Eicher v. Mid Am. Fin. Inv. Corp., 748 N.W.2d 1, 15 (Neb. 2008); City of Warsaw v. Orban, 884 N.E.2d 262, 269 (Ind. Ct. App. 2007).

tiffs. 112 Generally, courts have liberally construed RICO to cover both legitimate and illegitimate activities so long as the purpose of the law is satisfied: to prohibit businesses or entities that injure others through racketeering activities.

As to the first two elements of the claim, an enterprise—broadly defined as an entity associated for the common purpose of engaging in a course of conduct as a continuing unit—must have acted. 113 This activity must be repeated (i.e., more than once) so as to establish a pattern of racketeering, defined broadly to include state and federal offenses like mail and wire fraud, bankruptcy and securities fraud, or drug-related activities.114 Finally, and similar to a negligence claim, the activity must have actually and proximately caused the plaintiff's injuries. The defendant's actions must be both a "but-for" cause, and also have led directly to the plaintiff's injury. 115 To decide whether the injury is too remote, three "policy factors" are relevant: (1) whether it is too difficult to ascertain the damages attributable to the RICO violation; (2) whether injuries force courts to "adopt complicated rules apportioning damages" in order to "obviate the risk of multiple recoveries[,]" and (3) whether there exist more "directly injured victims [who] can generally be counted on to vindicate the law as private attorneys general[.]"116 These policy factors, if present, militate against a finding of proximate cause for "derivative injuries" when RICO actions injure a primary party, and that primary injury then harms a secondary party.117

^{112. &}quot;[T]hat is, that the injuries caused by the defendants were not so remote so as to be barred by the principles governing legal liability." *See* City of Milwaukee v. Universal Mortg. Corp., 692 F. Supp. 992, 998 (E.D. Wis. 1988).

^{113.} United States v. Turkette, 452 U.S. 576, 580–81 (1981). An enterprise can exist when the defendants form an "association in fact" with an enterprise or where defendants manage or control a separate enterprise conducting racketeering activity. See, e.g., City of N.Y. v. FedEx Ground Package Sys., Inc., 175 F. Supp. 3d 351, 372 (S.D.N.Y. 2016) (holding that FedEx formed an enterprise with illegal cigarette sellers because it delivered the cigarettes to them).

^{114.} Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 482 n.3 (1985). See City of N.Y. v. LaserShip, Inc., 33 F. Supp. 3d 303, 310 (S.D.N.Y. 2014) (citing H.J., Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 241 (1989)). In the opioid litigation, racketeering relates to wire fraud, mail fraud, and drug-related offenses.

^{115.} But-for cause asks the plaintiff to prove that the defendant's violation of § 1962 "was the but-for (or transactional) cause of his injury, meaning that but for the RICO violation, he would not have been injured." UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 132 (2d Cir. 2010). Proximate cause asks if the defendant's acts "stand at too remote a distance [for plaintiffs] to recover." Holmes v. Sec. Inv'r Prot. Corp., 503 U.S. 258, 268 (1992); Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 461 (2006).

 $^{116.\} Holmes,\,503$ U.S. at 269–70; see also Ass'n of Wash. Pub. Hosp. Dists. v. Philip Morris Inc., 241 F.3d 696, 701 (9th Cir. 2001).

^{117.} For example, the Supreme Court has rejected defendant liability under 1962(c) when the cause of the plaintiff's alleged harms is too attenuated. *Anza*, 547 U.S. at 458. In *Anza v. Ideal*

In the opioid litigation, demonstrating the first five elements to state RICO claims may be feasible with respect to prescription opioid-related harms. Opioid suppliers up and down the supply chain formed enterprises that engaged in the conduct of producing, distributing, and selling prescription opioid products. Even though defendant companies were not overtly acting together, their industry-wide tacit cooperation over years-and even decades-allegedly enabled the failure to monitor and report outlier shipments and sales and deceptive marketing schemes. Plaintiffs claim that defendants engaged in this industry-wide cooperation via wire fraud, mail fraud, and Controlled Substance Act violations. But for these opioid company activities, plaintiffs argue, governments would not have suffered a host of injuries (outlined above). 119

RICO causes of action perhaps face the greatest obstacles in establishing the sixth element, or proximate causation, and in defining the government's injury. Lessons from tobacco lawsuits, where RICO was also alleged by some plaintiffs for companies' suppression and misrepresentation of the dangers of tobacco use, demonstrate the difficulty in establishing a direct link between company wrongdoing and government sustained injuries, particularly those which are derivative in nature. ¹²⁰ In the case of opioids, government injuries are arguably de-

Steel Supply Corp., plaintiffs alleged that the defendant, Ideal Steel Supply, offered lower prices because it committed tax fraud (the racketeering activity) against the state. Id. But the plaintiffs failed to satisfy proximate cause because the alleged harm resulted from "set of actions (offering lower prices) entirely distinct from the alleged RICO violation (defrauding the State)." Id. at 460. Referencing one of the Holmes "policy factors," the Supreme Court stressed that because "the State can be expected to pursue appropriate remedies" and said "adjudication of the State's claims, moreover, would be relatively straightforward" compared to the more complicated factual question "such as the number of sales Ideal lost due to National's tax practices," it follows, then, that "[t]here is no need to broaden the universe of actionable harms to permit RICO suits by parties who have been injured only indirectly." Id.

118. See generally Complaint, Cty. of Eaton v. Purdue Pharma, L.P., No. 1:18-cv-00823 (W.D. Mich. July 25, 2018) (transferred to N.D. Ohio as case 1:18-op-45971 on Aug. 15, 2018).

119. *Id*.

120. See Ass'n of Wash. Pub. Hosp. Dists., 241 F.3d at 700 (9th Cir. 2001). "There was no 'direct link' between the defendants' alleged wrongdoing and the trusts' damages" because the hospitals injuries were "entirely derivative in nature," meaning "without any injury to smokers, plaintiffs would not have incurred the additional expenses in paying for the medical expenses of those smokers." Id. at 702. As of 2001, "seven circuit courts of appeal have rejected claims" like this one, that tobacco companies RICO violations caused injuries for loss of revenue by investment funds or increased costs to hospitals. Serv. Emps. Int'l Union Health & Welfare Fund v. Philip Morris Inc., 249 F.3d 1068, 1071 (D.C. Cir. 2001).

In a different context, a county sued private companies for hiring illegal immigrants, claiming that the hiring practices amounted to a RICO violation and led to increased costs for municipal services. Canyon Cty. v. Syngenta Seeds, Inc., 519 F.3d 969, 973 (9th Cir. 2008). Though the district court dismissed for want of actual injury, the Ninth Circuit also held that had plaintiffs stated an injury, the defendants' activity still did not proximately cause the injury. *Id.* The Ninth

rivative in nature, meaning that without any injury to individuals addicted to opioids (or even their family member caregivers), governments would not have incurred any additional expenses or losses. The derivative nature of the injury seems particularly problematic for harms related to illegal opioids, where RICO activities harmed people using prescription opioids, but the harms to governments from synthetic opioids and heroin were several steps removed from that original conspiracy. Indeed, the District Court in the Northern District of California, hearing a bellwether trial for the federal MDL, recently ruled favorably on defendant motions to dismiss related to RICO charges.¹²¹ Specifically, the court relied on ninth circuit precedent to find that additional government expenditures (e.g., in providing additional public services) made under its sovereign duty to citizens do not constitute injuries for the purposes of RICO suits.¹²² This court only recognized injuries to the City of San Francisco's real property and businesses (e.g., library cleanup expenses associated with disposed of needles used to inject opioids) to be cognizable for the purposes of a RICO claim. The court went on to find that defendant opioid companies' activities were too remote to these types of city injuries to establish proximate causation.¹²³

Nonetheless, there are at least some examples where issues related to RICO's proximate cause requirement have not yet impeded opioid-related suits. For instance, the Northern District of Ohio held that a hospital had "sufficiently alleged at least one plausibly direct and fore-seeable chain of causation from injurious conduct to alleged injury to survive a motion to dismiss for lack of proximate cause." The Northern District of Ohio magistrate judge, in his report and recommendations, also found that government plaintiffs may be able to

Circuit held that "[i]ncreased demand for public health care and law enforcement may result from such varied factors as: demographic changes; alterations in criminal laws or policy; changes in public health practices; shifts in economic variables such as wages, insurance coverage, and unemployment; and improved community education and outreach by government." *Id.* at 983. This outcome should be avoided by particularized pleadings, demonstrating the link between increased municipal costs and the opioid epidemic.

^{121.} See generally City & Cty. of S.F., v. Purdue Pharma L.P., 491 F. Supp. 3d 610 (N.D. Cal. 2020).

^{122.} Id. at 648-53.

^{123.} *Id.* at 656–57 ("The City's causal chain . . . involves too many links and depends on independent and intervening acts—including criminal conduct—by third and fourth parties. For example, third—and potentially fourth and fifth—parties allegedly diverted or sold illicit opioids, administered opioids intravenously, and improperly discarded the used needles, which harmed city-owned property and businesses. While it is plausible that Defendants' conduct enabled this third-party behavior, it is impossible to conclude that Defendants' conduct directly caused the City's harm . . .").

^{124.} In re Nat'l Prescription Opiate Litig., 452 F. Supp. 3d 745, 767 (N.D. Ohio 2020).

demonstrate a direct connection between deceptive marketing and failure to monitor/report sales on the one hand, and direct injuries to the government on the other to sustain proximate causation required for a RICO claim.¹²⁵ This opinion does not establish that RICO will be a successful avenue for asserted harms, including those related to illegal opioids, particularly given that this cause of action was dismissed with prejudice by the Northern District of California. As to whether the injury is too remote, policy factors may also weigh in favor of a court not finding RICO violations with respect to illegal opioid-related harms; given that, as discussed in Section II, quantifying the magnitude of these damages is highly questionable based on the state of the evidence and our understanding of the exact nature of the relationships between prescription opioid markets and the use of illegally-produced opioids.

D. Public Nuisance

Public nuisance, an equitable theory commonly asserted against opioid companies, constitutes "an unreasonable interference with a right common to the general public." Although public nuisance law varies by jurisdiction, a government plaintiff¹²⁷ typically must demon-

^{125.} Opinion and Order, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Dec. 19, 2018) (in which the magistrate judge, in his report and recommendations, found plaintiff allegations sufficient to establish a direct chain of causation, forcing plaintiff governments to spend resources "beyond what they had budgeted to attempt to stop the flow of the excess opioids into local communities and to bear the costs associated with cleaning them up. Under this potential chain of causation, the relationship between Plaintiffs' injury and Defendants' alleged conduct is less remote than prior Sixth Circuit precedent finding proximate cause, and is not too remote to support a finding of proximate cause here.").

^{126.} RESTATEMENT (SECOND) OF TORTS § 821B(1) (Am. L. INST. 1979). Public nuisance presents a distinct action in tort from private nuisance, despite some overlapping elements. Many jurisdictions take the view that fault is not necessarily element to establishing a public nuisance claim, as distinct from private nuisance. See Commonwealth v. Barnes & Tucker Co., 319 A.2d 871, 883 (Pa. 1974) ("The absence of facts supporting concepts of negligence, foreseeability or unlawful conduct is not in the least fatal to a finding of the existence of a common law public nuisance."). Some scholars argue that searching for fault "makes even less sense" for public nuisance liability and suggest that "leading cases indicate that liability is always strict." Robert Abrams & Val Washington, The Misunderstood Law of Public Nuisance: A Comparison With Private Nuisance Twenty Years After Boomer, 54 Alb. L. Rev. 359, 370 (1990). To restrict liability to negligent or intentional interferences makes the public suffer and threatens the reach of the "state's police power to protect the health and safety of [its] citizens." Id. However, at least one jurisdiction has cabined that argument to public nuisances arising from "abnormally dangerous or ultrahazardous activity." NAACP v. AcuSport, Inc., 271 F. Supp. 2d 435, 487 (E.D.N.Y. 2003). Abnormally dangerous or hazardous activities is a form of strict liability. New York, v. Shore Realty Corp., 759 F.2d 1032, 1051-52 (2d Cir. 1985) (release of toxic chemicals was abnormally dangerous activity causing public nuisance).

^{127.} Public nuisance commonly relies on states and municipalities to seek liability and abatement of interference with said public rights. Lindsay F. Wiley, *Rethinking the New Public Health*,

strate the following elements to form the basis for this type of claim: (1) that there exists a public right; (2) that the defendant's conduct unreasonably interferes with the right; (3) that the defendant "controls" the instrumentality causing the nuisance; and (4) that the defendant's conduct is the but-for and proximate cause of the nuisance. The thrust of these claims in the opioid litigation is that opioid companies caused a public nuisance by facilitating the opioid crisis and its host of costs and harms, including increased health care costs, reduced labor productivity, flourishing black markets and illegal activity, and overdose. 129

Identifying a public right—or "public good" like air, water or public rights of way—is an essential element for a public nuisance claim. Common rights include shared resources, rather than safety or habitability rights particular to individuals. In a handful of jurisdictions, the requirement of a public right removes liability for nuisances arising from products, like lead paint or guns, and may similarly limit lia-

69 WASH. & LEE L. REV. 207, 238 (2012). When a state brings an action for public nuisance, the nuisance is "subject to abatement." Copart Indus. v. Consol. Edison Co., 362 N.E.2d 968, 971 (N.Y. 1977). The state has a sovereign interest in nuisance abatement, which is greater than that of a private plaintiff seeking to enjoin a nuisance, and therefore worthy of remedy even when the defendant's conduct generates utility. Georgia v. Tenn. Copper Co., 206 U.S. 230, 237 (1907).

128. See, e.g., State v. Lead Indus. Ass'n, Inc., 951 A.2d 428, 446–47 (R.I. 2008); NAACP, 271 F. Supp. 2d at 482.

129. Complaint, Cty. of Eaton v. Purdue Pharma, L.P., No. 1:18-cv-00823 (W.D. Mich. July 25, 2018) (transferred to N.D. Ohio as case 1:18-op-45971 on Aug. 15, 2018); Monea, *supra* note 90, at 131–32; *West Virginia's Drug Deal*, Wall St. J. (Sept. 9, 2020, 7:32 PM), https://www.wsj.com/articles/west-virginias-drug-deal-11599694366 (detailing West Virginia Attorney General actions against pharmacies, including Walgreens and CVS, using public nuisance theory).

130. Lead Indus. Ass'n, Inc., 951 A.2d at 447–48; Copart Indus., 362 N.E.2d at 971 ("[A public nuisance] consists of conduct or omissions which offend, interfere with or cause damage to the public in the exercise of rights common to all . . ."). Although public nuisance claims were traditionally asserted with respect to property rights, some courts have shown receptivity in recent years to extending these rights to products. See Judgment After Non-Jury Trial at 22, 24, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019) (finding that the "plain text of the statute does not limit public nuisances to those that affect property. Unlike other states' statutes that limit nuisances to the 'habitual use or the threatened or contemplated habitual use of any place,' Oklahoma's statute simply says 'unlawfully doing an act, or omitting to perform a duty.' There is nothing in this text that suggests an actionable nuisance requires the use of or connection to real or personal property . . . However, and in the alternative, in the event Oklahoma's nuisance law does require the use of property, the State has sufficiently shown that Defendants pervasively, systemically and substantially used real and personal property, private and public, as well as the public roads, buildings and land of the State of Oklahoma, to create this nuisance.").

131. Lead Indus. Ass'n, Inc., 951 A.2d at 448; City of Chi. v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1114 (Ill. 2004). To hold otherwise risks exploding the common law and jeopardizes the judicial (not legislative) role of the courts. Lead Indus. Ass'n, Inc., 951 A.2d at 454; Beretta U.S.A. Corp., 821 N.E.2d at 1121.

bility related to opioids. 132 Moreover, interferences must be unreasonable, defined as an interference "with the public health, the public safety, the public peace, the public comfort or the public convenience," an interference that violates a "statute, ordinance or administrative regulation," or an interference that produces a "permanent or long-lasting effect" on the public right about which the "actor knows or has reason to know[.]"133 Specific to opioids, governments allege that mass opioid distribution and marketing facilitated use, diversion, and addiction that unreasonably interfered with public health, public safety, public comfort as well as violated a number of laws in ways that have produced long-lasting effects—all of which was potentially knowable to suppliers.¹³⁴ In a landmark state court decision, Cleveland County Judge Thad Balkman agreed that Oklahoma's public nuisance law was appropriate to hold Johnson & Johnson liable for its "false, misleading, and deceptive marketing campaign[s]" related to its own products and opioids more generally, which "caused exponentially increasing rates of addiction, overdose deaths, and Neonatal Abstinence Syndrome[.]"135

^{132.} See Lead Indus. Ass'n, Inc., 951 A.2d at 455; cf. Judgment After Non-Jury Trial, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019).

^{133.} See, e.g., Armory Park Neighborhood Ass'n v. Episcopal Cmty. Servs. in Ariz., 712 P.2d 914, 922 (Ariz. 1985); Am. Elec. Power Co. v. Connecticut, 564 U.S. 410, 423 (2011); RESTATEMENT (SECOND) OF TORTS § 821B (Am. L. Inst. 1977). Notwithstanding these three categorical examples, when the public nuisance causes more harm than utility, it is likely unreasonable. See generally Lakey v. Puget Sound Energy, Inc., 296 P.3d 860, 867 (Wash. 2013). Notably, some jurisdictions require "substantial" interference, which amounts to a similar requirement. NAACP, 271 F. Supp. 2d at 486.

^{134.} Lawful activity, like certain supplying of opioids, can be a public nuisance if the circumstances demonstrate an interference with a public right. *Armory Park Neighborhood Ass'n*, 712 P.2d at 921. Lawful authorization for an activity which causes a nuisance, like a permit or license, is not a defense to a public nuisance claim, unless the law authorizes the specific nuisance. *See, e.g.*, Kitsap Cty. v. Kitsap Rifle & Revolver Club, 337 P.3d 328, 341 (Wash. Ct. App. 2014). For example, an 1890 Minnesota court enjoined the damming of a river creating swamplands that caused "disease and other public disturbances" despite legislative authorization for the dam. The court found liability because the legislature authorized constructing the dam, but not the "manner of construction or operation" causing the nuisance. Vill. of Pine City v. Munch, 44 N.W. 197, 197 (Minn. 1890). Similarly, an Arizona court enjoined a homeless shelter in a residential homeowners' association neighborhood despite compliance with criminal and zoning provisions. *Armory Park Neighborhood Ass'n*, 712 P.2d at 921.

^{135.} Judgment After Non-Jury Trial at 24–26, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019). For instance, the Judge found that the Defendants' sales representatives were trained in their Oklahoma homes regarding spreading marketing messages, conducted deceptive marketing and sale efforts in doctors' offices, hospitals, restaurants, and other venues, used company cars traveling on State and county roads to disseminate misleading messages, and sent messages into the homes of thousands of Oklahomans via computer, smart phones and other devices—all of which involve the use of property, real and personal, to create and exacerbate the public nuisance.

To state a public nuisance claim, defendants must have *control* over the instrumentality alleged to have created the nuisance when damage occurred. This element of control cabins the reach of public nuisance claims and can make them more challenging to allege when the source of the nuisance is a legally sold product like prescription opioids, lead paint or legitimately sold firearms. However, opioids may be distinguishable from other products such as lead paint or firearms, due to their addictive properties and the nature of marketing and distribution of prescription drugs. In essence, opioid companies arguably have further downstream control over use and misuse of their addictive products when they facilitate initial, widespread exposure and put into motion a host of harms. This argument could possibly be used to justify liability for heroin-related harms, given historic relationships across prescription opioid and heroin markets.

As with other tort-based theory claims discussed above, public nuisance generally requires a showing of actual and proximate causation at the population level. Actual causation demands evidence that a defendant alone or in combination, created, contributed to, or maintained the public right interference. Actual causation can present a barrier for certain product-based public nuisance claims, as it has for lead paint manufacturers, if it cannot be shown that the product being litigated caused the actual harm. This requirement could be particu-

^{136.} Lead Indus. Ass'n, Inc., 951 A.2d at 446–47; City of Manchester v. Nat'l Gypsum Co., 637 F. Supp. 646, 656 (D.R.I. 1986) ("The defendants, after the time of manufacture and sale, no longer had the power to abate the nuisance. Therefore, a basic element of the tort of nuisance is absent, and the plaintiff cannot succeed on this theory of relief."); In re Lead Paint Litig., 924 A.2d 484, 499 (N.J. 2007). Failure to allege control over the source of the public nuisance amounts to a "fatal defect." Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp., 273 F.3d 536, 541 (3d Cir. 2001).

^{137.} See, e.g., State v. Purdue Pharma L.P., No. N18C-01-223 MMJ CCLD, 2019 WL 446382, at *13 (Del. Super. Ct. Feb. 4, 2019). If the product is alleged to cause the nuisance, then the manufacturers "cannot be said to control it after it is sold to consumers." Wiley, *supra* note 127, at 245. This line of reasoning held sway in public nuisance suits against lead paint manufacturers, see, e.g., *In re Lead Paint Litig.*, 924 A.2d at 501, and gun manufacturers. *Camden Cty. Bd. of Chosen Freeholders*, 273 F.3d at 541.

^{138.} Plaintiffs alleging a public nuisance must show that the defendants caused their injury, like any other action in tort. Wiley, *supra* note 127, at 237; *Lead Indus. Ass'n, Inc.*, 951 A.2d at 450–51. *See also NAACP*, 271 F. Supp. 2d at 482 ("The actions or failures to act of multiple defendants creating in the aggregate a public nuisance can justify liability . . .").

^{139.} NAACP, 271 F. Supp. 2d at 492; City of N.Y. v. A-1 Jewelry & Pawn, Inc., 247 F.R.D. 296, 346 (E.D.N.Y. 2007). Third party or intervening actors may break the causal chain, except where "a defendant could reasonably have expected their nature and effect." *Id.* at 347.

^{140.} At least one jurisdiction has required specific evidence that the cause of the injury was the product itself to make a product-based public nuisance claim. City of St. Louis v. Benjamin Moore & Co., 226 S.W.3d 110, 115–16 (Mo. 2007). In this case, lead paint manufacturers escaped liability because neither market share evidence nor statistical probabilities revealed that lead paint in the plaintiffs' homes proved "actual causation." *Id*.

larly fatal for illegal opioid harm-related claims, given that these products are not the subjects of the litigation. Proximate cause functions as a "policy requirement" in public nuisance claims, requiring that the defendant to be "causally sufficiently close to the harm suffered that it is just or fair to hold the defendant liable for the consequences of its actions."141 In firearm litigation, the causal chain linking gun manufacturer activities to municipal costs, like fighting crime, have been considered too attenuated and remote.¹⁴² However, government plaintiffs in opioid litigation may be able to demonstrate both actual and proximate causation elements, at least for prescription opioids, if they can use data to establish a concrete relationship between harms and, separately, marketing practices employed and prescription opioids distributed. Evidence of marketing practices from internal drug company documents and drug supply data could potentially make these connections geographically and over time, as happened in the Johnson & Johnson trial in Oklahoma (which involved predominantly prescription opioid harms).143 It should be noted, however, that this Oklahoma decision is being appealed.¹⁴⁴ Public nuisance causation elements will be more challenging to establish for illegally produced opioids, given that these harms could very well be considered unforeseeable, and too attenuated and remote from company practices. 145

^{141.} A-1 Jewelry & Pawn, Inc., 247 F.R.D. at 347. See also City of N.Y. v. Milhelm Attea & Bros., Inc., 550 F. Supp. 2d 332, 351 (E.D.N.Y. 2008) (requiring "a reasonable connection between defendants' alleged actions and the harm that followed" to show proximate cause). This analysis lacks a bright line rule, but limits liability for public nuisance because "at some point, a party is simply too far removed from the nuisance to be held responsible for it." People v. Sturm, Ruger & Co., Inc., 761 N.Y.S.2d 192, 202 (N.Y. 2003); see also NAACP, 271 F. Supp. 2d at 497 (calling public nuisance proximate cause a "flexible boundary"). In its most concrete form, proximate cause asks if the defendant causing the nuisance may have foreseen the alleged injury. A-1 Jewelry & Pawn, Inc., 247 F.R.D. at 347. Foreseeability may even adapt to the nature of the public nuisance. NAACP, 271 F. Supp. 2d at 497 ("Proximate cause where the injury foreseen is slight moral distress is quite different from proximate cause where the destruction of the World Trade Towers may result in the killing of thousands.").

^{142.} Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp., 273 F.3d 536, 541 (3d Cir. 2001). *See also Sturm, Ruger & Co., Inc.*, 761 N.Y.S.2d at 203 (fearing that allowing a public nuisance suit against gun manufacturers would open the floodgates of tort litigation against "countless other types of commercial enterprises, in order to address a myriad of societal problems" which would "engulf the courts beyond their means in issues which the [political] branches are vastly better designed . . . to address").

^{143.} Judgment After Non-Jury Trial at 24–26, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019).

^{144.} Johnson & Johnson To Appeal Flawed Opioid Judgement in Oklahoma, Johnson & Johnson (Aug. 26, 2019), https://www.jnj.com/johnson-johnson-to-appeal-flawed-opioid-judgment-in-oklahoma.

^{145.} Monea, *supra* note 90, at 133 (citing City of Spokane v. Monsanto Co., No. 2:15-CV-00201-SMJ, 2016 WL 6275164, at *7–8 (E.D. Wash. Oct. 26, 2016)).

E. Unjust Enrichment

Unjust enrichment is another common claim against opioid suppliers, most commonly manufacturers, alleging that they should not be able to retain profits derived from improper and deceptive practices. 146 Unjust enrichment is an equitable doctrine, premised on the idea that a person should not be permitted to profit from her own wrongdoing.¹⁴⁷ These claims require demonstration of three elements: (1) the plaintiff conferred a benefit on the defendant, (2) the defendant knew or appreciated the benefit, and (3) the circumstances make it unfair for the defendant to retain the benefit.148 To establish the first element, a plaintiff typically must have conferred the benefit on the defendant directly, such as through a transaction between the parties. However, some states also allow indirect benefits to defendants, such as plaintiffs paying for externalities, to satisfy the requirement. 149 The remedy for unjust enrichment is restitution, or requiring the defendant to disgorge improperly retained benefits, rather than compensation for harms. 150 Unjust enrichment is sometimes called a gap filler, available when no other legal doctrine permits recovery. 151

Common unjust enrichment theories in opioid cases are that defendants failed to prevent diversion of opioids and thus profited off of the illegal opioid market (namely persons who accessed prescription opioids from the intended user), that defendants utilized deceptive

^{146.} These claims have also been attempted against accreditation bodies such as the Joint Commission, though this is a less common strategy and less likely to succeed. *See e.g.*, City of Charleston v. Joint Comm'n, 473 F. Supp. 3d 596, 608 (S.D. W. Va. 2020). Additionally, there are some actions, such as one brought by the Navajo Nation, which claim unjust enrichment against distributors and pharmacies rather than manufacturers, which may be less likely to succeed. Ausness, *supra* note 88, at 580 n.98, 590–91, 606 ("The problem with this reasoning, is that it assumes that the defendants could have been legally compelled to pay for the costs that the Navajo Nation incurred in responding to the opioid epidemic. Otherwise, these costs would not be externalities that could be characterized as a cost of business that the defendants shifted to the plaintiff.").

^{147.} RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT § 3 (Am. L. INT. 2011). Unjust enrichment allows for recovery when a party received a benefit and it would be unjust if the benefit is retained. *Id.* § 3 cmt. a, b.

^{148.} SAMUEL WILLISTON & RICHARD A. LORD, WILLISTON ON CONTRACTS § 68:5 (4th ed. 1990). Ausness, *supra* note 88, at 588 (noting that while there are slight variations from state to state, the basic structure is the same).

^{149.} See, e.g., White v. Smith & Wesson, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000); City of L.A. v. Wells Fargo & Co., 22 F. Supp. 3d 1047, 1061 (C.D. Cal. 2014).

^{150.} Restatement (Third) Restitution and Unjust Enrichment \S 1 cmt. a (Am. L. Inst. 2011); Ausness, supra note 88, at 588–89.

^{151.} See 66 Am. Jur. 2d Restitution and Implied Contracts § 28 (2020); but see RESTATEMENT (THIRD) OF RESTITUTION AND UNJUST ENRICHMENT § 4(2) (Am. L. INST. 2011). Whether a claim for unjust enrichment requires that no other adequate remedy exists varies across jurisdictions.

marketing to increase profits and thus profited off of the deception, and that defendants knowingly profited off of unnecessary use of opioids. While some complaints seek disgorgement of profits related to the sales of opioids, others seek restitution for externalities such as government spending on public health and law enforcement. Plaintiffs allege it would be unjust and inequitable for opioid suppliers to retain these benefits at the expense of governments, given these companies' failures to take requisite care in their business practices. While the complaints generally do not contain detailed unjust enrichment allegations to provide insights into how these claims might play out in trial, motion to dismiss proceedings in several opioid cases provide a window into the viability of the claims.

Defendants have argued in motions to dismiss unjust enrichment claims that they did not receive any benefit from plaintiffs, that plaintiffs failed to prove any benefits they did receive were unjust, that plaintiffs did not suffer any cognizable loss, and that plaintiffs cannot show any retention would be unjust.¹⁵⁶ Governments may first be challenged to demonstrate that they conferred a benefit on defendants in unjust enrichment claims.¹⁵⁷ Government plaintiffs who have insurance plans (e.g., Medicaid) or that run community hospitals will likely be able to prove this element by showing that they purchased opioids as a payor or safety-net provider.¹⁵⁸ In other cases, government plaintiffs argue their residents' purchases of opioids should be considered a benefit provided by their populations, or that indirect benefits were conferred on the defendants when governments paid for harm caused by suppliers' dangerous products. 159 These externality claims have had mixed success in past products-liability litigation involving asbestos, tobacco, guns, and lead paint, which may mean the success of indirect benefits conferred arguments is case- and jurisdiction-specific. 160 If a

^{152.} Ausness, *supra* note 88, at 578 n.92, 580 n.98, 590–91; Complaint at 149, City of Sterling Heights v. The Pain Ctr. USA, PLLC, No. 19-1563-CZ (Mich. Cir. Ct. Apr. 24, 2019); Opinion and Order at 38, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Dec. 19, 2018).

^{153.} Ausness, supra note 88, at 591.

^{154.} Id. at 590-91.

^{155.} Id. at 590.

^{156.} See, e.g., In re Opioid Litig., No. 400000/2017, 2018 WL 3115102, at *36 (N.Y. Sup. Ct. June 18, 2018).

^{157.} Monea, supra note 90, at 142.

^{158.} Haffajee & Mello, supra note 8, at 2302-03.

^{159.} See, e.g., In re Opioid Litig., No. 400000/2017, 2018 WL 3115102, at *24 (N.Y. Sup. Ct. June 18, 2018); Report and Recommendation at 95, In re Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Oct. 5, 2018).

^{160.} Ausness, *supra* note 88, at 589–90. Courts in some states have precedent that paying for externalities resulting from manufactures' products is considered a benefit conferred for the un-

court finds that a benefit has been conferred, it seems likely that they would find the defendant knew or appreciated the benefit, given how widespread and publicized opioid harms and costs were; while the question of fairness to allow the defendant to keep the benefit may be a value judgment.¹⁶¹

In at least four cases, unjust enrichment claims have withstood motions to dismiss, all of which predominantly argued a lack of benefit conferred. In two of these cases, plaintiffs pled that the opioid suppliers were enriched by purchases made by the plaintiffs as payors. ¹⁶² In other cases that survived these motions, courts have allowed allegations that opioid suppliers were enriched when plaintiffs paid for the negative externalities (i.e., harms) caused by the manufacturers' improper distribution practices to proceed. ¹⁶³ One court accepted this

just enrichment analysis. *See, e.g.*, City of N.Y. v. Lead Indus. Ass'n, Inc., 597 N.Y.S.2d 698, 699–01 (N.Y. App. Div. 1993) (allowing restitution claim for "reasonable costs of [lead] abatement" to survive motion to dismiss); White v. Smith & Wesson, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (allowing "the costs of the harm caused by Defendants' failure to incorporate safety devices into their handguns and negligent marketing practices" as benefit conferred); City of Bos. v. Smith & Wesson Corp., No. 199902590, 2000 WL 1473568, at *18 (Mass. Super. Ct. July 13, 2000) (permitting unjust enrichment claim based on externalities associated with gun usage); City of L.A. v. Wells Fargo & Co., 22 F. Supp. 3d 1047, 1061 (C.D. Cal. 2014) (allowing "the costs of harm caused by Defendants' discriminatory lending that the City has had to shoulder" as benefit conferred); City of L.A. v. Bank of Am. Corp., No. CV-13-9046 PA (AGRx), 2014 WL 2770083, at *12–13 (C.D. Cal. June 12, 2014) (permitting unjust enrichment claim based on externalities).

But Florida has explicitly rejected the argument stating that, "the benefit must be conferred directly from the plaintiff to the defendant. Peoples Nat'l Bank of Commerce v. First Union Nat'l Bank of Fla., N.A., 667 So. 2d 876, 879 (Fla. Dist. Ct. App. 1996) (as interpreted by City of Miami v. Bank of Am. Corp., 800 F.3d 1262, 1287–89 (11th Cir. 2015), *vacated*, Bank of Am. Corp. v. City of Miami, 137 S. Ct. 1296 (2017)).

161. Monea, supra note 90, at 143.

162. *In re* Opioid Litig., No. 400000/2017, 2018 WL 3115102 at *32–33 (N.Y. Sup. Ct. June 18, 2018); *In re* Actiq Sales & Mktg. Pracs. Litig., 790 F. Supp. 2d 313 (E.D. Pa. 2011). The New York Supreme Court rejected the argument that the relationship between the parties was too attenuated to support an unjust enrichment claim, and the Court in *In re Actiq* rejected defendant's arguments that unjust enrichment cannot occur where the plaintiff receives value in the exchange and that unjust enrichment requires a direct relationship, finding the third-party payor relationship sufficient. *Id.* at 330–31. In addition to arguments that the benefit conferred was to the patients and not the plaintiffs as payors, defendants in these types of unjust enrichment claims also contend that the plaintiffs failed to show which opioid payments were overpayments and which were proper. *See, e.g.*, Manufacturer Defendants' Joint Motion to Dismiss at 30, 32, 37–38, Salt Lake Cty. v. Purdue Pharma, L.P., No. 180902421 (Utah Dist. Ct. Sept. 5, 2019).

163. Report and Recommendation at 91, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Oct. 5, 2018); *see also* Opinion and Order at 14, 16, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio June 13, 2019) (allowing a negative externalities theory of unjust enrichment to proceed). *See also* City of Boston v. Purdue Pharma, L.P., No. 1884CV02860, 2020 WL 416406, at *10 (Mass. Super. Jan. 3, 2020) (allowing an unjust enrichment claim to proceed when defendants "benefited from opioid-related profits while the Cities expended enormous sums to abate the damage caused by those same opioid sales").

argument as a basis for the unjust enrichment claim, rejecting the defendant's argument that Ohio precedent provided that "unjust enrichment claims may only be sustained if they arise from an economic transaction between the parties." ¹⁶⁴ That court also noted, as fairness, that Ohio law specifically states that "one is unjustly enriched if the retention of a benefit would be unjust, and one should not be allowed to profit or enrich himself or herself inequitably at another's expense." ¹⁶⁵ While the plaintiffs in these cases pled sufficient claims to survive a motion to dismiss, the defendants' arguments may prove more successful at trial.

In terms of illegally produced opioid harms, it is possible that a court would accept unjust enrichment claims related to these harms if they accept that this theory of liability can arise from externalities—or indirect benefits conferred. However, some courts have also required a showing of proximate causation, even with respect to unjust enrichment claims for prescription opioid harms, ¹⁶⁶ so this could be particularly difficult to establish for illegal opioid harms (as discussed for other claims above). In addition, a court may find it difficult to accept that a defendant appreciated the benefit of municipalities and states paying for illegal opioid-related harms, or that it would be unjust to allow them to retain the benefits if these harms were not foreseeable and there was a lack of underlying duty to pay for them. ¹⁶⁷

^{164.} Report and Recommendation at 91, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Oct. 5, 2018); Opinion and Order at 37, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Dec. 19, 2018) ("'The rule of law is that an *indirect purchaser* cannot assert a common-law claim for restitution and unjust enrichment against a defendant without establishing that a benefit had been conferred upon that defendant by the purchaser.'" (quoting Johnson v. Microsoft Corp. 834 N.E.2d 791, 799 (Ohio 2005))).

^{165. 18} Ohio Jur. 3d *Contracts* § 279 (2020); Opinion and Order at 38, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP, (N.D. Ohio Dec. 19, 2018).

^{166.} In City of Charleston v. Joint Commission, defendants successfully argued that the unjust enrichment claim should be dismissed due to lack of proximate causation. 473 F. Supp. 3d 596, 626 (S.D. W. Va. 2020). The plaintiff's theory was that the defendants were unjustly enriched "when they accepted funding from pharmaceutical companies to promote the [paint management] [s]tandards that 'failed to recognize the dangerous and addictive nature of opioids.' "Id. at 609. The Court rejected this argument, stating that the plaintiffs failed to plead proximate causation between the defendants conduct and the harm alleged because there were too many intervening factors and the defendants did not have any role in manufacture or distribution of opioids. Id. at 630. In dismissing an unjust enrichment claim, the Court in City of Chicago v. Purdue Pharma stated "it is impossible for the Court or the defendants to decipher whether the prescribers who heard defendants' deceptive messages are the same individuals who prescribed defendants' drugs that were subsequently paid for by the City and therefore that defendants' misrepresentations resulted in defendants' enrichment." 211 F. Supp. 3d 1058, 1084 (N.D. Ill. 2016).

^{167.} In other public health contexts, unjust enrichment claims were challenged on the basis that there could be no enrichment when defendants lacked any obligation to pay for the claimed externalities. In *City of St. Louis v. American Tobacco Co. Inc.*, the Court found that the plain-

IV. Conclusions

The opioid litigation is novel in its diversity of parties and claims, volume of cases, and extent of injuries alleged. In many ways, it is the most ambitious public health litigation pursued to date and has the potential to set important precedent for the use of litigation as a tool to address public health crises going forward. The advent of government suits in the litigation, following failures of individual personal injury and class action suits, could be seen as a "promising step" for communities and has perhaps improved prospects for settlement and even judgments in plaintiffs favor, largely due to population-level data that can be leveraged as evidence. At the same time, and beyond the scope of this article, questions about whether litigation is an efficient solution to the prescription opioid crisis have been raised. With so many governmental entities suing at the same time, the prospects for a global settlement—and one that is fair to all parties involved—are complex. Defendant companies serve useful and important purposes in society, namely providing medications (often beyond opioids) and

tiffs had a valid claim for restitution of health care costs incurred from smoking-related illness. 70 F. Supp. 2d 1008, 1014-15 (E.D. Mo. 1999). Defendants argued that the claim should be dismissed because they did not have "a duty to provide health care to Medicaid and medically indigent patients for tobacco-related illnesses" and that plaintiffs did not intend "to charge the Distributor Defendants for their provision of the health care benefits supplied for tobacco-related illnesses." Id. at 1015. The Court found that plaintiffs alleging that the defendants "have a duty" to "bear the cost of tobacco related diseases" and that the City had to provide public benefits due to Tobacco's wrongful conduct as sufficient. Id. at 1017. The Court stated that it "could determine that the defendants in this matter . . . may have been under a duty to pay for the consequences of advertising, promoting, and eventually selling tobacco products. The defendants, including the distributor defendants, were apparently unwilling to discontinue such practices notwithstanding the fact that they were placing tobacco related products in the marketplace, which eventually required the expenditure of funds by the various plaintiffs to treat tobacco related illnesses." Id. at 1018-19; see also Order Regarding "Certain Defendants' Motion for Partial Summary Judgment On Plaintiffs' Restitution Claims," City of St. Louis v. Am. Tobacco Co., No. 22982-09652-01, (Mo. Cir. Oct. 20, 2010). This precedent is obviously helpful for government plaintiffs, as it allows them the opportunity to prove that the opioid manufacturers did have a duty to pay for the consequences of their wrongful acts, at least with respect to prescription opioids.

However, in other cases, unjust enrichment claims failed because the courts found that the defendants could not be unjustly enriched absent an original duty to pay for the externalities. In Allegheny Gen. Hosp. v. Philip Morris, Inc., the Court rejected an unjust enrichment claim "based on the theory that by paying for the medical services required by nonpaying patients, the Hospitals discharged the Tobacco Companies' legal duties and saved them from bearing costs caused by their fraudulent and wrongful conduct." 228 F.3d 429, 447 (3d Cir. 2000). The Court reasoned that the hospital had an independent duty to care for its patients, and the tobacco companies "had no legal obligation to pay the medical expenses of smokers, and thus the Hospitals' provision of medical services did not 'benefit' the Tobacco Companies by removing their obligation." Id. Though this reasoning is potentially an obstacle in opioid litigation, government plaintiffs may be able to avoid similar fates with respect to prescription opioids, though not illegal opioids, by differentiating their role from that of a hospital.

other medical supplies to patients. Many already have been driven by the opioid litigation to file for bankruptcy—in which court setting, assets available for plaintiff governments will be limited. Even if a large global settlement is reached, as happened with tobacco, prior precedent calls into question whether these funds will be used optimally to abate the opioid crisis.¹⁶⁸

Detailed information has started to establish the scope of prescription opioid marketing and distribution, and could show company knowledge of product addictiveness. Together, this evidence could help to demonstrate necessary elements for key claims relating to prescription opioid harms, like actual and proximate causation and failure to exercise reasonable care. The addictive properties of opioids suggest that once initially and sufficiently exposed, some consumers may seek these drugs in regular and growing volumes. Indeed, some evidence suggests that this was something certain opioid suppliers knew and took advantage of, to boost their sales. Plausibly, opioid companies could have foreseen the progression from medical use of prescription opioids to diversion and nonmedical use, when such vast quantities were supplied. This addiction and the costs to governments and their populations attributable to prescription opioid harms alone are substantial, particularly through 2012 but also to this day.

Nevertheless, some allegations in the opioid litigation may go too far in scope. To make the leap from marketing and supply chain schemes related to prescription opioids to foresight of a massive increase in heroin consumption and, to a greater degree, illegally produced synthetic opioid markets is substantial, when considering the elements required to establish common claims. It is particularly problematic to demonstrate proximate causation with respect to illegal opioid harms for tort-based theories of liability (e.g., negligence and RICO claims). Questions about whether opioid companies could have foreseen and should compensate for illegal opioid downstream harms may also weigh against equitable theories of liability, like public nuisance and unjust enrichment. Unless additional peer-reviewed empirical evidence emerges to more tightly link these latter waves of the

^{168.} See Haffajee & Abrams, supra note 18, at 709–13 for a more complete discussion of the tobacco settlement and its apparent public health failures.

^{169.} See, e.g., Judgment After Non-Jury Trial at 24, State ex rel. Hunter v. Purdue Pharma, L.P., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019).

^{170.} Press Release, U.S. Department of Justice, Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy (May 2, 2019), https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy;

WVURxMan, Subsys Rap Video Created by Insys Pharmaceuticals (More info in description), YouTube (Feb. 18, 2019), https://www.youtube.com/watch?v=MTwFZwjCSTE.

opioid crisis to the first wave, or demonstrate that defendants were aware of their potential, plaintiffs face an uphill battle in stating claims with respect to heroin and illegally produced synthetic opioids.

The extent of liability that can be established in the sprawling opioid litigation may have implications for future public health mass tort litigation. For example, suppliers of food products with addictive or habit-forming ingredients, like sugar and salt, are already the subjects of lawsuits related to their role in contributing to the obesity epidemic.¹⁷¹ As quantitative evidence grows to establish addictiveness of certain foods, and the relationship between threshold exposure to these foods and long-term eating habits that contribute to obesity and a host of health harms, governments may be tempted to augment their obesity litigation agendas. But can a fast-food restaurant be held liable for populations eating related foods that that satisfy similar cravings but are supplied by others, and are later shown to be even more hazardous to health? Or should legal liability be cabined to the products actually supplied by defendants? The outcomes of opioid litigation, and specific liability theories it tests, may help to answer such questions.

^{171.} Analysis of sugar industry documents may impact litigation, Thompson Coburn LLP (Nov. 11, 2016) https://www.thompsoncoburn.com/insights/blogs/food-fight/post/2016-11-11/analysis-of-sugar-industry-documents-may-impact-litigation. See also CSPI's litigators win better food labeling and more honest marketing, and encourage reforms that benefit consumers, CTR. FOR SCI. IN THE Pub. Int., https://cspinet.org/protecting-our-health/courts.