THE OPIOID CRISIS AS UNJUST ENRICHMENT*

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The opioid crisis is widely considered as one of the most severe health crises in American history, with over 800,000 deaths attributed to opioid use in the past two decades. Projections estimate an additional one million deaths by 2030. The long-term impacts of the crisis are staggering, as annual costs of nearly $500 billion devastate communities and neglect and direct exposure affect the lives of children.

Despite the regulatory frameworks established by agencies like the Food and Drug Administration, Drug Enforcement Administration, and Centers for Disease Control and Prevention, the legal system has failed to prevent or effectively respond to the crisis. In fact, instead of providing adequate solutions, these agencies enabled the crisis by approving opioid drugs for widespread use. Opioid litigation has emerged as an alternative legal response and has indeed secured settlements amounting to tens of billions of dollars. Yet these awards pale in comparison to the full cost of the crisis, measured in hundreds of billions of dollars annually. The core of the problem is that much of the harm caused by the crisis is not compensable under existing doctrine. At the same time, opioid marketing remains incredibly profitable for pharmaceutical companies; this perverse dynamic assures the perpetuation of the crisis.

This Article offers a reorientation of opioid litigation, shifting the focus from harms to gains. In doing so, the Article is the first to propose the doctrine of

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unjust enrichment as a foundation for the burgeoning field of opioid litigation. In particular, we suggest that profits made by pharmaceutical companies through deceptive practices constitute unjust enrichment. By misrepresenting the risks of opioid use and engaging in fraudulent marketing strategies, these companies have obtained ill-gotten gains that should be forfeited.

More important, we argue that this reconceptualization of opioid litigation can revolutionize the response to the crisis and finally offer an effective legal path forward. Even if much of the harm caused by opioids is not compensable through litigation, effective deterrence can still be achieved if defendants are stripped of their ill-gotten gains, those obtained through the dishonest marketing of opioids. In fact, this form of remedy is a necessary element in any solution to the crisis. Otherwise, if irresponsible marketing of opioid drugs remains incredibly profitable for key market actors, the crisis is all but certain to persist.

INTRODUCTION

The opioid crisis has turned many American communities into haunted landscapes of despair and devastation. Across the country, there are "abandoned cities" and "ghost towns"[1] where addiction continues to tighten its grip on the fabric of daily life.[2] In Philadelphia's Kensington neighborhood, dubbed the "Walmart of Heroin,"[3] open-air drug markets thrive.[4] The streets echo with the cries of addicts who refuse shelter, even in freezing temperatures, to avoid the agony that comes with withdrawal.[5] At the same time, morgues are "filled to capacity," and corpses are "stored for days in rented refrigerated tractor-trailers."[6] In Portland, Oregon, overdose rates continue to soar as the city's sidewalks fill with tents housing drug users.[7] Seattle's fire department responds to about fifteen overdose calls each day,[8] with officials noting that "[overdose] statistics have gone from bad to worse."[9] These scenes of death and neglect starkly illustrate the catastrophic impact of opioid addiction, a national tragedy, the full scope of which continues to unfold.

The opioid epidemic is widely regarded as one of the most severe healthcare crises in American history.[10] Over the past two decades, over

1. Spencer Platt, *Photographing the Desperate Opioid Crisis in America's Abandoned Cities*, NEWSWEEK, https://www.newsweek.com/photographing-desperate-opioid-crisis-americas-abandoned-cities-opinion-1129027 [https://perma.cc/3XXN-T9ZR (staff-uploaded archive)] (last updated Sep. 21, 2018, at 14:05 ET) ("So many of the communities now devastated by opioids are located in former towns and cities where factories were the largest employer. Most of these places are now ghost towns with little to offer the residents who stayed.").

2. *Id.*

3. Jennifer Percy, *Trapped by the 'Walmart of Heroin*,' N.Y. TIMES MAG. (Oct. 10, 2018), https://www.nytimes.com/2018/10/10/magazine/kensington-heroin-opioid-philadelphia.html [http://perma.cc/EK5K-SZ5P (staff-uploaded, dark archive)].

4. *Id.*

5. *Id.*

6. *See, e.g.*, BARRY MEIER, PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC ix (2018).

7. Jan Hoffman, *Scenes from a City That Only Hands Out Tickets for Using Fentanyl*, N.Y. TIMES (July 31, 2023), https://www.nytimes.com/2023/07/31/health/portland-oregon-drugs.html [http://perma.cc/L83X-SJNH (staff-uploaded, dark archive)].

8. *Fentanyl Crisis in WA Needs a Turning Point, so What Is Being Done?*, SEATTLE TIMES, https://www.seattletimes.com/seattle-news/fentanyl-crisis-in-wa-needs-a-turning-point-so-what-is-being-done/ [http://perma.cc/BM2E-BJH5] (last updated Mar. 3, 2024, at 06:00 ET).

9. *Id.*

10. *See* James G. Hodge, Jr., Chelsea L. Gulinson, Leila F.S. Barraza, Walter G. Johnson, Drew Hensley & Haley R. Augur, *Exploring Legal and Policy Responses to Opioids: America's Worst Public Health Emergency*, 70 S.C. L. REV. 481, 482 (2019) (describing the public declarations in response to "the worst [public health emergency] confronting the country" since the origination of emergency classification in 2001); Daniel G. Aaron, *Opioid Accountability*, 89 TENN. L. REV. 611, 664–65 (2022) ("'The current opioid addiction crisis is, in many ways, a replay of history.' Quite possibly, this opioid crisis may be distinct for being the worst on a per capita level." (quoting Andrew Kolodny, David T. Courtwright, Catherine S. Hweang, Peter Kreiner, John L. Eadie, Thomas W. Clark & G. Caleb Alexander, *The*

800,000 Americans have died from opioid misuse,[11] with one in three Americans reporting knowing someone who died in this epidemic.[12] By the end of this decade, an additional million lives are projected to be lost.[13] The *annual* costs of the crisis, including loss of life, productivity loss due to addiction, and healthcare expenditures, are approaching $500 billion.[14] Children are among those most severely affected: parents' addiction leads to child neglect, infants are born with opioid addiction, and children die from exposure to even small amounts of the drug.[15]

The opioid crisis is also a tragic failure of our legal system. Supposedly, all legal mechanisms necessary to prevent the crisis were in place. Since opioids are Schedule II narcotics,[16] all aspects of manufacturing, distribution, marketing, and use are under the heavy regulation of agencies, including the Food and Drug Administration ("FDA"), the Drug Enforcement Agency ("DEA"), and the Centers for Disease Control and Prevention ("CDC").[17] As

Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 18 ANNUAL REV. PUB. HEALTH 559, 561 (2015))); German Lopez & Sarah Frostenson, *How the Opioid Epidemic Became America's Worst Drug Crisis Ever, in 15 Maps and Charts*, VOX, https://www.vox.com/science-and-health/2017/3/23/14987892/opioid-heroin-epidemic-charts [https://perma.cc/U5U9-QELL (staff-uploaded, dark archive)] (last updated Mar. 29, 2017, at 16:51 UT).

11. Chris McGreal, *'I Don't See How It Ends': Expert Sounds Alarm on New Wave of US Opioids Crisis*, GUARDIAN (Jan. 28, 2024, at 07:00 ET), https://www.theguardian.com/us-news/2024/jan/28/us-opioids-crisis-fentanyl-appalachia [http://perma.cc/9QUG-M3K4] [hereinafter McGreal, *How It Ends*].

12. Kerry Breen, *About 1 in 3 Americans Have Lost Someone to a Drug Overdose, New Study Finds*, CBS NEWS (May 31, 2024, at 15:29 ET), https://www.cbsnews.com/news/drug-overdose-deaths-opioid-crisis-substance-use/ [http://perma.cc/H9S5-YU5E].

13. *See, e.g.*, McGreal, *How It Ends*, *supra* note 11 ("[F]entanyl and other drugs . . . together have claimed 800,000 American lives over the past quarter of a century with predictions of another million deaths by the end of the decade. But federal regulators and prosecutors failed to seize the moment."); Sara Reardon, *Mega-Model Predicts US Opioid Deaths Will Soon Peak*, NATURE NEWS (June 1, 2022), https://www.nature.com/articles/d41586-022-01519-z [https://perma.cc/E4PE-DQG5 (staff-uploaded, dark archive)] ("Under an 'optimistic' scenario, 543,000 people would die between 2020 and 2032, whereas a 'pessimistic' scenario would see 842,000 deaths over this period.").

14. Nora Freeman Engstrom & Robert L. Rabin, *Pursuing Public Health Through Litigation*, 73 STAN. L. REV. 285, 288 (2021) ("A 2017 report from the Council of Economic Advisers estimated that the economic cost of the opioid crisis exceeds $500 billion annually, which works out to nearly 3% of U.S. gross domestic product.").

15. CORWIN N. RHYAN, ALTARUM, THE POTENTIAL SOCIETAL BENEFITS OF ELIMINATING OPIOIDS OVERDOSES, DEATHS, AND SUBSTANCE USE DISORDERS EXCEEDS $95 BILLION PER YEAR 3 (2017), https://altarum.org/sites/default/files/2024-01/Research-Brief_Opioid-Epidemic-Economic-Burden.pdf [http://perma.cc/6ERK-EADS] ("[M]any of [the] 2016 cases of child neglect are associated with parents with an opioid substance use disorder."); Elissa Philip Gentry & Benjamin J. McMichael, *Contaminated Relationships in the Opioid Crisis*, 72 HASTINGS L.J. 827, 830 (2021) ("Increased opioid use has fueled growth in . . . the occurrence of neonatal abstinence syndrome.").

16. Engstrom & Rabin, *supra* note 14, at 336.

17. Rebecca A. Delfino, *A New Prescription for the Opioid Epidemic: 360-Degree Accountability for Pharmaceutical Companies and Their Executives*, 73 HASTINGS L.J. 301, 328 (2022) ("The [Controlled Substances Act ("CSA")] provides the Attorney General, FDA, and DEA with broad authority to regulate various drugs.").

has become apparent, those regulatory frameworks failed to prevent the crisis and still seem to be struggling to offer effective solutions.[18]

In response to the crisis, opioid litigation has become a burgeoning legal field with thousands of lawsuits filed over the years, some leading to settlements of tens of billions of dollars.[19] Despite these supposed successes, opioid litigation has so far been merely a patch, far from providing a real solution to the crisis.[20] Even damages awards in the tens of billions of dollars pale in comparison to the true costs of the crisis, which amount to *hundreds of billions of dollars every year*.[21] The reason for this discrepancy is that much of the epidemic's harm is unrecoverable under existing litigatory frameworks.[22] The full magnitude of mass-addiction-related harms is elusive as its effects remain scattered across numerous communities, and the long-term impact on future generations remains unknown.[23]

Against this backdrop, this Article is the first to explore the doctrine of unjust enrichment as a potential legal response to the opioid crisis.[24] Under this common-law framework,[25] courts can strip defendants of their ill-gotten gains so that they do not profit from their own wrongful conduct.[26] We demonstrate a solid basis for arguing that the gains of opioid manufacturers resulting from unlawful practices—that is, revenues generated through the misrepresentation

18. *See infra* Section II.A.

19. For an overview of opioid litigation and settlement agreements, see Richard C. Ausness, *Opioid Lawsuits: Is There Any End in Sight?*, 33 HEALTH MATRIX 193, 237 (2023) (discussing the global settlement agreement, Professor Ausness notes: "[O]n February 25, 2022, the Committee announced that more than 90% of the local government litigants had approved new proposed settlement. This settlement would allocate funds to state and local government entities and Indian tribes based on population and the proportionate share of the opioid epidemic's impact."). For further details on the global settlement agreement and the breakdown of payments, see Christine Minhee, *OST's Global Settlement Tracker*, OPIOID SETTLEMENT TRACKER, https://www.opioidsettlementtracker.com/globalsettlementtracker [http://perma.cc/3D6K-86AT] (last updated Nov. 18, 2025).

20. *See, e.g.*, Katheryn Houghton & Aneri Pattani, *Millions in Opioid Settlement Funds Sit Untouched as Overdose Deaths Rise*, CBS NEWS (Dec. 12, 2023, at 05:00 ET), https://www.cbsnews.com/news/opioid-settlement-funds-millions-untouched-as-overdose-deaths-rise/ [http://perma.cc/3DVD-DXWP].

21. Engstrom & Rabin, *supra* note 14, at 288.

22. *See* Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C. L. REV. 565, 606 (2019) [hereinafter Ausness, *Opioid Litigation*] (discussing opioid litigation theories of liability and concluding that "[i]n addition to limitations in the liability theories identified above, government plaintiffs will also have to contend with a host of other doctrines that potentially limit liability[,] . . . suggest[ing] that there is no assurance that government plaintiffs will necessarily satisfy state law requirements in every state").

23. *See infra* Subsection IV.A.1.

24. *See infra* Section III.B.

25. For a description associating disgorgement of ill-gotten gain—now considered part of the unjust-enrichment doctrine in American law—with the equitable doctrine of waiver of tort, see text accompanying notes 241–44, *infra*.

26. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 (A.L.I. 2011) ("A person who is unjustly enriched at the expense of another is subject to liability in restitution.").

and manipulation of opioid-related risks—constitute unjust enrichment.[27] Pharmaceutical companies have systematically and intentionally misrepresented the risks associated with opioid use and addiction to maximize their profits.[28] Dishonest, manipulative, and fraudulent practices have been central to the strategies of pharmaceutical companies in marketing opioids to physicians and patients and in securing regulatory approvals,[29] whereas their systemic failure to monitor, report, and halt suspicious orders has thwarted regulatory safeguards and further contributed to the spread of the epidemic.[30] Profits flowing from such deceptive practices fall under the doctrinal category of unjust enrichment;[31] therefore, pharmaceutical companies can be compelled to forfeit these profits.[32]

We argue that this doctrinal shift can have dramatic implications for opioid litigation[33] and for the future of the crisis more broadly.[34] Existing litigation focuses on the harm that plaintiffs, mainly opioid users and public authorities, can *prove* in court.[35] And while great, these harms are miniscule in comparison to the overall harm of the crisis to society and to the public at large, which will extend into the lives of future generations and will only become more apparent over time.[36] Consequently, the detrimental effects of mass addiction are mostly unrecoverable through litigation.[37] This means that current monetary awards fail to offer full compensation and, equally important, fail to deter wrongdoers.[38] Opioid sales are incredibly profitable for pharmaceutical

27. *See infra* Section III.B.

28. *See* Joseph H. Donroe, M. Eugenia Socias & Brandon D.L. Marshall, *The Deepening Opioid Crisis in North America: Historical Context and Current Solution*, 5 CURRENT ADDICTION REPS. 454, 455 (2018) ("Marketing [of opioid-pills] emphasized low addiction potential and high efficacy of opioids used for chronic pain, both misrepresentations of the existing data.").

29. Engstrom & Rabin, *supra* note 14, at 308–09 ("In green-lighting OxyContin in 1995, the FDA relied on this [time-release] mechanism when it permitted Purdue to make an unusual, untested, and in retrospect fateful claim: that the delayed-release nature of OxyContin's formula was '"believed to reduce" its appeal to drug abusers compared with shorter-acting painkillers.'").

30. *In re* Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3917575, at *5 (N.D. Ohio Aug. 19, 2019) ("[A] distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances."); Delfino, *supra* note 17, at 329–30 (discussing the DOJ indictment of Rochester Drug Cooperative, Inc. for CSA violations and alleging that the company continued to sell opioid pills to pharmacies despite the fact that "[t]he company's compliance department repeatedly warned executives that the pharmacies in question displayed 'red flags' such as purchasing only controlled substances and accepting a high amount of cash from customers").

31. *See infra* Section III.A.

32. *See infra* Section III.B.

33. *See infra* Part IV.

34. *See infra* Section IV.B.

35. For discussion and analysis of the opioid litigation, see Ausness, *Opioid Litigation*, *supra* note 22, at 569–94.

36. *See infra* Section IV.A.

37. *See infra* Section IV.A.

38. *See infra* Section IV.B.

companies.[39] Moreover, since pharmaceutical companies do not pay the full costs of the crisis, their profits provide an incentive to perpetuate the opioid crisis.[40] In fact, having anticipated the compensation amounts they now must pay, pharmaceutical companies would have acted exactly as they did to access the high profits obtainable through opioid sales.[41]

The application of unjust-enrichment doctrine directly addresses this problem. Under this doctrine, optimal deterrence can be obtained even if not all harms are compensable.[42] Shifting the focus of litigation from *harms* to *gains* achieves this goal: if pharmaceutical companies are stripped of their ill-gotten gains, their incentive to perpetuate the crisis diminishes significantly.[43] This form of remedy is therefore an essential element in any comprehensive legal response to the crisis.[44]

In proposing this approach, the Article offers three novel contributions. The first contribution is doctrinal—explaining the applicability of the unjust-enrichment doctrine within the framework of opioid litigation. The second contribution is conceptual—restructuring opioid litigation around gains instead of harms. The third contribution is normative—highlighting the important practical advantages of approaching opioid litigation through the lens of unjust enrichment law.

The Article proceeds as follows. Part I presents the factual background for our analysis by describing the opioid crisis, its origins, and its effects. It highlights the deceptive practices pharmaceutical companies employed to secure the approval, and design the marketing, of opioids. Part II offers the legal background, detailing the response to the crisis in both regulation and

39. *E.g.*, Engstrom & Rabin, *supra* note 14, at 309 ("Within just a few years of its approval, OxyContin became the nation's most prescribed Schedule II narcotic. Sales skyrocketed from $45 million in 1996 to $1.5 billion in 2002 and to almost $3 billion in 2009.").

40. *See infra* Section IV.B.

41. U.S. SENATE HOMELAND SEC. & GOVERNMENTAL AFFS. COMM., FUELING AN EPIDEMIC, REPORT THREE: A FLOOD OF 1.6 BILLION DOSES OF OPIOIDS INTO MISSOURI AND THE NEED FOR STRONGER DEA ENFORCEMENT 20 (2018) [hereinafter FUELING AN EPIDEMIC, REPORT THREE], https://www.govinfo.gov/app/details/GOVPUB-Y4_G74_9-PURL-gpo110311 (click "Download PDF") [http://perma.cc/2PAW-CL2D] ("As Frank Younker, former diversion group supervisor of the DEA Cincinnati field office, explained[,] . . . '[d]uring my time at DEA, it seemed to me that these larger corporations in the industry were not interested in doing the right thing, at least not until their profits were hurt and their names were being tied to the opioid epidemic in the headlines.' Jonathan Novak, a former DEA enforcement attorney, agreed, noting that 'it seems like the only time that any of the distributors and manufacturers want to listen is when it is hurting their bottom line.'").

42. *See* Robert Cooter & Ariel Porat, *Disgorgement Damages for Accident*, 44 J. LEGAL STUD. 249, 249 (2015) [hereinafter Cooter & Porat, *Disgorgement Damages*] (discussing a similar remedy in the context of accident and arguing that stripping an "injurer's gain from untaken precaution divided by the probability of liability . . . is the minimum liability necessary to provide injurers with efficient incentives for care").

43. *Id.*

44. *See infra* Section IV.B.

litigation. It highlights the limitations of existing legal schemes, showing that a comprehensive legal response is still missing. Part III explores the possibility of applying the unjust-enrichment doctrine to opioid manufacturers' revenues. It includes a full doctrinal analysis, focusing on the legal implications of pharmaceutical companies' fraudulent practices. Part IV is a comparative analysis that showcases the potential advantages of basing opioid litigation on the unjust-enrichment doctrine. It explains in detail why harm-based remedies are inherently undercompensatory in the context of the opioid crisis and why a shift to gain-based remedies can offer more suitable levels of recovery and deterrence. It also details additional advantages of our proposal and explores its implementation in practice. A short conclusion follows.

I. THE OPIOID CRISIS

This Part offers a thorough review of the opioid crisis and its immense harms. Section I.A describes the short-term, long-term, and intergenerational harms of mass opioid addiction to individuals, communities, and public systems. Section I.B then traces the unfolding of the crisis, focusing on the misrepresentation of opioids' risks, aggressive marketing practices, the co-optation of patient advocacy, and the failure of manufacturers, distributors, and regulators to respond to mounting warning signs. This review is necessary to describe the unique nature of the detrimental effects of mass opioid addiction and to highlight the critical role pharmaceutical companies have played in the development of one of the most severe public health crises of our time.

A. *Opioid Harms*

For more than two decades, prescription opioids have brought ruin to American individuals and communities. From 1995 to 2022, opioids have claimed the lives of 800,000 Americans,[45] with the annual death toll continuously increasing from 50,000 in 2019 to 69,000 in 2020, 81,000 in 2021, and more than 103,000 in 2022.[46] While the estimated annual death toll decreased to 83,000 in 2023 and 55,000 in 2024,[47] the trend and its causes are

45. McGreal, *How It Ends*, *supra* note 11.

46. *See* Rajeev Darolia & Colleen Heflin, *The Social and Community Consequences of the Opioid Epidemic*, 703 ANNALS AM. ACAD. POL. & SOC. SCI. 7, 7–8 (2022) ("In 2020, the number of opioid-related deaths surged almost 40 percent from the prior year to about 69,000 and then spiked a further 20 percent to almost 81,000 deaths in 2021."); Elyse Wild, *'We Hold You Sacred': How a Mobile Drug Unit Is Fighting the Opioid Crisis in the Cherokee Nation*, GUARDIAN (Feb. 8, 2024, at 10:00 ET), https://www.theguardian.com/us-news/2024/feb/08/opioid-epidemic-cherokee-nation-mobile-health-care [http://perma.cc/N4BA-YPFQ].

47. Press Release, Nat'l Ctr. for Health Stats., US Overdose Deaths Decrease Almost 27% in 2024 (May 14, 2025) (on file with the North Carolina Law Review); Farida B. Ahmad, Jodi A.

uncertain,[48] and opioids are projected to claim the lives of an estimated one million or more Americans by the end of this decade.[49] Opioid users face multiple life-threatening risks, including fatal overdose and the contraction of HIV, tuberculosis, and hepatitis.[50] Some who attempt to overcome their opioid dependency end up taking their own lives because the withdrawal process is so excruciating.[51]

Yet even the unprecedented death toll fails to fully capture the devastating effects of opioids. An estimated two million Americans suffer from opioid use disorder,[52] a medical condition that can range from dependence on opioids to actual addiction.[53] Most people who become addicted to opioids are first exposed to the drug through "a clinical prescription that they receive in a clinical setting, and then they'll go on to develop an addiction."[54] The effects of the opioid crisis extend beyond opioid users and are associated with increases in child neglect, neonatal abstinence syndrome (children born with opioid addiction),[55] car accidents,[56] decreases in property value,[57] and diminished perceptions of personal safety and well-being.[58] At the national level, a significant rise in hospital admissions for opioid dependency and opioid-related diseases,[59] as well as increases in Medicare spending,[60] are crippling a healthcare

Cisewski, Lauren M. Rossen & Paul Sutton, *Provisional Drug Overdose Death Counts*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION: NAT'L CTR. FOR HEALTH STATS., https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/9KQ9-25EP] (last updated Jan. 14, 2026).

48. *See infra* note 288 and accompanying text (noting the possibility that this trend is not necessarily encouraging, as it most likely indicates the transition from prescription to illicit opioid use and the parallel raise in heroin and fentanyl use).

49. McGreal, *How It Ends*, *supra* note 11 (describing "predictions of another million deaths by the end of the decade").

50. RHYAN, *supra* note 15, at 2–3.

51. Chris McGreal, *US Health Agency Accused of Bowing to Drug Industry with New Opioid Guidance*, GUARDIAN (Dec. 17, 2022, at 17:00 ET), https://www.theguardian.com/us-news/2022/dec/17/cdc-accused-opioid-guidelines-drug-industry-pressure [http://perma.cc/PQ6G-8X5E] ("The notion that there are patients losing access to an effective treatment, and therefore they have no choice but to kill themselves because they're in so much pain now, that's a hoax. But the idea that someone in the context of acute withdrawal would kill themselves, that certainly could be real because it's so excruciating.").

52. Donroe et al., *supra* note 28, at 456.

53. Alexander M. Dydyk, Nitesh K. Jain & Mohit Gupta, *Opioid Use Disorder: Evaluation and Management*, NAT'L LIBR. OF MED.: NAT. CTR. FOR BIOTECHNOLOGY INFO., https://www.ncbi.nlm.nih.gov/books/NBK553166/ [http://perma.cc/RT7Z-45QL] (last updated Jan. 17, 2024).

54. Gentry & McMichael, *supra* note 15, at 831 (quoting Scott Gottlieb, Comm'r, U.S. Food & Drug Admin.).

55. *Id.* at 830 ("Increased opioid use has fueled growth in . . . the occurrence of neonatal abstinence syndrome.").

56. *Id.*

57. RHYAN, *supra* note 15, at 3.

58. *Id.*

59. Gentry & McMichael, *supra* note 15, at 830 (describing a massive uptick in "opioid-related emergency room visits, opioid-related hospital admissions, and the occurrence of neonatal abstinence syndrome (infants born addicted to opioids)" (footnotes omitted)).

60. RHYAN, *supra* note 15, at 2.

system still coping with the effects of COVID-19. Experts estimate that the *annual* cost of the opioid crisis, primarily due to productivity loss and healthcare expenditures, exceeds $95 billion,[61] with the social harm of the crisis increasing to $500 billion a year when accounting for the (economic) value of the loss of human life.[62]

These short-term harms are compounded by the opioid epidemic's long-term and intergenerational adverse effects. Studies reveal that children exposed to opioids—for example, by living with a struggling parent or encountering friends and classmates using opioids—are more likely to suffer malnutrition and food insecurity,[63] struggle at school,[64] and enter a foster care system that is underprepared to deal with the opioid epidemic's toll on children.[65] Furthermore, opioid use is more common in communities already suffering from high unemployment, poor economic conditions, and a history of exploitation.[66] In these circumstances, opioids might cause a vicious cycle where employers adopt technological solutions to address the opioid-induced labor shortage, thereby shrinking an already small job market and frustrating communities' attempts to recover.[67]

These long-term and indirect harms of the epidemic, which rob children of opportunities and transform communities into unemployment "ghost towns"

61. *Id.* at 1.

62. Engstrom & Rabin, *supra* note 14, at 288.

63. Darolia & Heflin, *supra* note 46, at 11 ("[S]tates with higher initial OxyContin misuse rates had an increase in food insecurity after OxyContin reformulation.").

64. Rajeev Darolia & John Tyler, *The Opioid Crisis and Community-Level Spillovers onto Children's Education*, BROOKINGS (Apr. 13, 2020), https://www.brookings.edu/articles/the-opioid-crisis-and-community-level-spillovers-onto-childrens-education/ [http://perma.cc/4NRV-W5QL] ("[E]xposure to the epidemic is likely to impact important education outcomes other than test scores, such as attendance, probability of school disciplinary action, graduation, or college enrollment.").

65. LAUDAN Y. ARON, SARAH BENATAR & REBECCA PETERS, URB. INST., SUPPORTING CHILDREN AND FAMILIES AFFECTED BY THE OPIOID EPIDEMIC 11 (2020), https://www.urban.org/sites/default/files/publication/103249/supporting-children-and-families-affected-by-the-opioid-epidemic_0.pdf [http://perma.cc/Y6WX-U7CL] (suggesting that the shortage of foster parents is "(1) because there are too few to meet the growing need, and (2) because many existing foster parents are unprepared to care for children who have experienced trauma or the effects of neonatal substance exposure, and child welfare agencies cannot provide the support these foster parents need").

66. *See, e.g.*, *id.* at 3 (discussing Appalachian communities); Wild, *supra* note 46 (discussing Native Americans).

67. Mohammad S. Jalali, Michael Botticelli, Rachael C. Hwang, Howard K. Koh & R. Kathryn McHugh, *The Opioid Crisis: A Contextual, Social-Ecological Framework*, 18 HEALTH RSCH. POL'Y & SYS. 87, 91–92 (2020), https://link.springer.com/article/10.1186/s12961-020-00596-8 (click "Download PDF") [https://perma.cc/9A9V-YY67 (staff-uploaded archive)] (noting the connection between unemployment, lower life satisfaction, and higher drug use among the population); Julia Paris, Caitlin Rowley & Richard G. Frank, *The Economic Impact of the Opioid Epidemic*, BROOKINGS: USC-BROOKINGS SCHAEFFER ON HEALTH POL'Y (Apr. 17, 2023), https://www.brookings.edu/articles/the-economic-impact-of-the-opioid-epidemic/ [https://perma.cc/2RYJ-AVGX] ("[R]egions with higher exposure to opioid prescriptions experienced significant declines in labor force participation.").

that only those unable to escape inhabit,[68] are central to understanding the inadequacy of current legal responses and the new approach proposed in this Article.[69]

B. *The Unfolding of the Crisis*

In 1995, Purdue Pharmaceutical gained approval for the opioid-based analgesic drug, OxyContin[70]—the "wonder drug" that promised to forever change our relationship with pain.[71] Twice as powerful as morphine, oxycodone (OxyContin's active ingredient)[72] was first synthesized in 1916.[73] Purdue's innovation was designed to provide continuous pain relief rather than immediate effects.[74] This delayed-release mechanism allowed a single OxyContin pill to contain higher levels of oxycodone, and to relieve pain for an extended period; the mechanism, and Purdue's assertions that it reduced the risks of addiction and abuse, were pivotal in the FDA's approval of the drug.[75]

OxyContin soon became Purdue's golden goose, with sales increasing from $45 million in 1996 to $3 billion in 2009, accounting for ninety percent of Purdue's prescription drug revenues.[76] Success breeds competition, and pharmaceutical companies including Actavis, Endo, Insys Therapeutics, Janssen Pharmaceutical, Johnson & Johnson, Mallinckrodt, and Teva Pharmaceutical USA all began manufacturing, marketing, and selling their own opioid-based painkillers.[77] Apparently, selling drugs more powerful and addictive than heroin

68. *E.g.*, McGreal, *How It Ends*, *supra* note 11 (describing the effect of dried-out coal mines and the opioid crisis on the Appalachian town of St. Charles and noting that "the population in St. Charles collapsed to the point where in 2022 the Virginia legislature removed the town's charter because no one ran for office for two elections").

69. *See infra* Parts III–IV.

70. *See generally* A. Ordóñez Gallego, M. González Barón & E. Espinosa Arranz, *Oxycodone: A Pharmacological and Clinical Review*, 9 CLIN. & TRANSL. ONCOL. 298 (2007) (describing the chemical properties of OxyContin).

71. Engstrom & Rabin, *supra* note 14, at 307–08.

72. *See id. See generally* Julia Riley, Elon Eisenberg, Gerhard Müller-Schwefe, Asbjørn M. Drewes & Lars Arendt-Nielsen, *Oxycodone: A Review of Its Use in the Management of Pain*, 24 CURRENT MED. RSCH. & OP. 175 (2008) (providing a comprehensive evaluation of oxycodone and its role in clinical settings to offer an evidence-based perspective on its use in practice).

73. Engstrom & Rabin, *supra* note 14, at 308.

74. *Id.*

75. *Id.*

76. *Id.* at 309.

77. *Id.* at 317 ("[S]econd-wave [opioid-litigation] plaintiffs have looked far beyond Purdue . . . . Additional manufacturers named in this second wave include Insys, . . . Endo, . . . Teva, . . . Mallinckrodt Pharmaceuticals, . . . and Johnson & Johnson."); U.S. SENATE HOMELAND SEC. & GOVERNMENTAL AFFS. COMM., FUELING AN EPIDEMIC, REPORT TWO: EXPOSING THE FINANCIAL TIES BETWEEN OPIOID MANUFACTURERS AND THIRD PARTY ADVOCACY GROUPS 2–3 (2018) [hereinafter FUELING AN EPIDEMIC, REPORT TWO], https://www.hsgac.senate.gov/media/dems/breaking-millions-in-payments-among-findings-of-mccaskill-opioid-investigation-into-ties-between-manufacturers-and-third-party-advocacy-groups/ (click "Read the Report") [https://perma.cc/B63N-RHBJ].

to the general public is good business. For example, in the three years following the 2012 approval of its fentanyl-based drug, Insys tripled its revenues, recorded a forty-five percent increase in profits, and saw a threefold increase in its share value.[78] With no shortage in demand, sales skyrocketed. From 1999 until 2010, prescription opioid sales registered a fourfold increase,[79] and by 2016, sixty-seven million Americans were filling at least one opioid prescription a year.[80] In 2015, more than twelve million Americans used a prescription opioid for nonmedical purposes,[81] also known as prescription opioid misuse.[82] Each year, the amount of prescription opioids sold in the United States equals the analgesic effect of about 640 milligrams of morphine per person, roughly four times greater than the amount sold per person in the European Union.[83]

1. Pain-Washing: Misrepresenting the Drug

Human beings strive to avoid pain,[84] and the fight against pain is undoubtedly a noble cause. Pharmaceutical companies effectively framed their

78. FUELING AN EPIDEMIC, REPORT TWO, *supra* note 77, at 5 ("Insys revenues tripled and profits rose 45% between 2013 and 2015, and the value of company stock increased 296% between 2013 and 2016.").

79. Gery P. Guy Jr., Kun Zhang, Michele K. Bohm, Jan Losby, Brian Lewis, Randall Young, Louise B. Murphy & Deborah Dowell, *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015*, 66 MORBIDITY & MORTALITY WKLY. REP. 697, 697 (2017).

80. Jason Zhang, Jennifer F. Waljee, Thuy D. Nguyen, Amy S. Bohnert, Chad M. Brummett, Mark C. Bicket & Kao-Ping Chua, *Opioid Prescribing by US Surgeons, 2016–2022*, 6 J. AM. MED. ASS'N NETWORK OPEN 1, 1 (2023).

81. Donroe et al., *supra* note 28, at 456 ("In 2015, an estimated 12,462,000 people aged 12 and older had non-medical use of prescription opioids in the past year, with over two million doing so for the first time.").

82. Prescription opioid misuse consists of practices such as using the prescription to consume "greater amounts [of pills], more often, or longer than you were told to take them . . . or use in any other way a doctor did not direct you to use them." Beth Han, Wilson M. Compton, Carlos Blanco, Elizabeth Crane, Jinhee Lee & Christopher M. Jones, *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, 167 ANNS. INTERN. MED. 293, 294 (2017).

83. Guy Jr. et al., *supra* note 79, at 699–700.

84. In Western philosophy, the human desire to avoid pain is discussed at least as early as ancient Greek thought. *E.g.*, David Konstan, *Epicurus*, STAN. ENCYCLOPEDIA PHIL.: FALL 2022 EDITION, https://plato.stanford.edu/archives/fall2022/entries/epicurus [https://perma.cc/Y5A9-C9V9] (last updated July 8, 2022) ("Epicurus does not treat *khara* [joy] as an end, or part of the end for living: rather, he tends to describe the goal by negation, as freedom from bodily pain and mental disturbance."). Similarly, Jeremy Bentham's principle of utility famously articulates the belief that people are naturally inclined to minimize pain and maximize pleasure. JEREMY BENTHAM, AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION i–vi (1789). Interestingly, the research on the avoidance of pain in humans shows that pain aversion does not only concern the physical sensation but also the emotional response it triggers. *See generally, e.g.*, Gregory Corder, Biafra Ahanonu, Benjamin F. Grewe, Dong Wang, Mark J. Schnitzer & Grégory Scherrer, *An Amygdalar Neural Ensemble that Encodes the Unpleasantness of Pain*, 363 SCIENCE 276 (2019) (finding it is possible to manipulate the physical sensation of pain independent of the subjective unpleasantness associated with that feeling).

promotion of opioid drugs around the human aversion to pain in their crusade to secure FDA approval.

Since the early 1990s, pharmaceutical companies have aggressively promoted opioids as a miracle solution to the problem of pain.[85] The 1995 approval of OxyContin was accompanied by Purdue's aggressive marketing campaign, emphasizing OxyContin's high efficacy and low risk of addiction.[86] Companies claimed that opioid use entails a very low risk of addiction and abuse,[87] often relying on a single-paragraph letter by Jane Porter and Dr. Hershel Jick in the 1980 volume of the New England Journal of Medicine ("NEJM") as their sole empirical evidence.[88]

Commonly known as the "Porter and Jick letter," the short text reports an analysis of the medical records of 11,882 patients with no history of addiction who received one (or more) doses of opioids while hospitalized.[89] Relying on the findings in these highly controlled conditions, the authors conclude that long-term prescription of opioids poses a low risk to patients.[90] A 2017 study, also published in the NEJM, notes the impact of this letter:

> [A] five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that [opioid] addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[91]

The campaign to promote opioids was immensely successful. Renowned medical institutions, including the World Health Organization, adopted the Porter and Jick letter.[92] Adding to its credence, in 1995—the year OxyContin received its approval—the American Pain Society, a patient advocacy group, launched its "pain as the fifth vital sign" campaign.[93] This initiative encouraged health providers to measure and address patients' pain no differently than they

85. Delfino, *supra* note 17, at 320.

86. *Id.* ("The Sacklers' aggressive marketing and advertising efforts for the drug arrived in a marketplace of doctors and consumers eager to deploy OxyContin to treat all forms of pain. A tsunami of opioid prescriptions followed.").

87. Gentry & McMichael, *supra* note 15, at 836.

88. Delfino, *supra* note 17, at 311–12.

89. *Id.* at 312.

90. *Id.*

91. Pamela T.M. Leung, Erin M. MacDonald, Matthew B. Stanbrook, Irfan A. Dhalla & David N. Juurlink, *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEJM 2194, 2194–95 (2017).

92. Delfino, *supra* note 17, at 312.

93. Donroe et al., *supra* note 28, at 455 ("Organizations eventually embraced the idea of 'pain as the fifth vital sign,' and the undertreatment of pain became an important marker of hospital performance. Subsequent years saw a dramatic rise in opioid prescriptions.").

do the four other vital signs: blood pressure, pulse, temperature, and respiration.[94]

"Pain as a vital sign" was quickly adopted by the U.S. Department of Veterans Affairs as well as the Joint Commission, an organization responsible for accreditation standards.[95] Soon afterward, the Joint Commission issued new standards for the treatment of pain, emphasizing "the need to perform systematic assessments of patients' pain levels regularly and frequently while hospitalized."[96] And, in 1997, two patient advocacy organizations—the American Pain Society and the American Academy of Pain Medicine—issued a joint statement endorsing the use of opioids for noncancer, chronic pain and asserting the low risk of addiction posed by prescription opioids.[97]

2. Helping the Medicine Go Down: Marketing and Patient Advocacy

Once approved and legitimized, opioids required marketing. Two characteristics of Purdue's marketing practices, later adopted by other opioid manufacturers, are of particular importance: the marketing of opioids to treat chronic pain and direct-to-consumer ("DTC") marketing.

Regarding the first practice, before the introduction of OxyContin, opioids were primarily for the treatment of short-term, acute, end-of-life (often cancer-related) pain. Purdue sought to change that to reap greater profits.[98] As a 2017 CDC report explains, the use of opioids to treat chronic pain boosts opioid sales in three interrelated ways: *first*, "[c]hronic pain is one of the most common reasons for seeking medical attention,"[99] and promoting the use of opioids for chronic pain, whether or not approved by the FDA, greatly increases the pool of potential opioid consumers;[100] *second*, using opioids for chronic pain increases the average length of active prescriptions for opioids; and *third*, since opioids' pain-relieving effects diminish over time, prolonged use of opioids increases the average prescribed dosage.[101]

The second characteristic of Purdue's marketing campaign, DTC marketing, entails the promotion of pharmaceutical products by a direct appeal to prospective consumers.[102] In theory, the intention of DTC marketing of

94. *Id.*

95. *Id.*

96. Delfino, *supra* note 17, at 314.

97. Donroe et al., *supra* note 28, at 455.

98. *See* Delfino, *supra* note 17, at 312.

99. Guy Jr. et al., *supra* note 79, at 699.

100. Delfino, *supra* note 17, at 320–21 ("The [Food and Drug Modernization Act of 1997] allows companies to engage in off-label 'detailing' to doctors, which is the practice of persuading doctors to prescribe drugs to patients for uses that the FDA has not approved. . . . 20% of all prescriptions that doctors write are for off-label uses.").

101. Guy Jr. et al., *supra* note 79, at 697.

102. *See* Delfino, *supra* note 17, at 317 n.96.

drugs was to inform consumers of the risks and benefits of new treatments and medications.[103] In reality, "the primary purpose of DTC advertising [was] not to educate consumers, but instead to encourage them to actively seek out medication that their physician would not otherwise prescribe."[104] Unlike the pill it promoted, the effectiveness of DTC marketing finds strong evidentiary support with studies finding doctors prescribe the drugs that patients request approximately seventy-five percent of the time.[105]

The lack of public funding for independent research on the efficacy of opioids helped the success of Purdue's marketing campaign.[106] As Professor Delfino writes, "Without publicly funded research and independent studies, there was nothing to countervail the industry's misrepresentation of reports such as Porter and Jick, which the industry used to promote the marketing of opioids."[107] "As a result," she concludes, "the aggressive marketing to doctors and consumers remained effective in boosting drug sales well into the 2000s."[108]

Independent research on the addictive nature of opioids appeared only in recent years. In direct contradiction to the claims of opioid manufacturers, for example, the FDA found OxyContin to be addictive "even 'at recommended doses' and 'in patients appropriately prescribed OxyContin.'"[109] And a 2017 CDC report states, "Patients are at risk for continuing opioids long-term once they have received them for 5 days, and are unlikely to discontinue opioids after they have received them for 90 days."[110] This research reveals that physicians who treat chronic pain by prescribing recommended doses of opioids for five days or more expose their patients to a meaningful risk of opioid addiction, and patients taking prescription opioids for more than ninety days are more likely to become addicted than they are to return to an opioid-free existence.

These observations raised broader concerns about whether the drug's formulation truly reduced its potential for abuse. Researchers later challenged the industry's claims that the slow-release mechanism of prescription opioids prolonged their effects while reducing abuse potential with practitioners finding that "OxyContin supplied only eight hours of pain relief, rather than the touted twelve" and patients realized "they could crush the pills and then snort the dust

103. *Id.* at 320.

104. David C. Vladeck, *The Difficult Case of Direct-to-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 286 (2007).

105. *Id.* at 270.

106. Delfino, *supra* note 17, at 314.

107. *Id.*

108. *Id.* at 322.

109. *See* Engstrom & Rabin, *supra* note 14, at 309 n.122 (citing U.S. FOOD & DRUG ADMIN., OXYCONTIN (OXYCODONE HYDROCHLORIDE) EXTENDED-RELEASE TABLETS: FULL PRESCRIBING INFORMATION § 5.1 (2016), https://www.fda.gov/media/131026/download [https://perma.cc/468T-R4ZV (staff-uploaded archive)] (last updated Sep. 2018)).

110. Guy Jr. et al., *supra* note 79, at 701.

or mix it with water and inject it, for not just the cessation of pain, but, rather, for an electric, heroin-like high."[111]

Nevertheless, Purdue and other opioid manufacturers refused to leave success to chance. Between 2006 and 2015, opioid manufacturers "spent more than $880 million nationwide on lobbying and campaign contributions[,] . . . more than 200 times what those advocating for stricter [opioid] policies spent."[112] They also used their wealth and power to enlist patient advocacy groups for their cause, encountering little resistance along the way.

Patient advocacy groups, with reputations as credible arbiters of facts and proponents of patients' well-being, hold significant power in shaping public opinion and health policies and wield "extensive influence in specific disease areas."[113] To illustrate, a 2018 U.S. Senate Homeland Security and Governmental Affairs Committee ("HSGAC") report found that a single patient advocacy group, the U.S. Pain Foundation, "participated in more than 30 state and national advocacy coalitions, alliances, and task forces . . . [and was] actively engaged in 70 legislative bills in 20 states with the support of 250 advocates engaged in outreach to policymakers."[114]

Patient groups advocating for pain management began promoting the long-term use of opioids to treat chronic pain in the mid-1990s. In 1995, the American Pain Society commenced its "pain as the fifth vital sign" campaign,[115] and, as late as 2009, the American Geriatrics Society joined the American Academy of Pain Medicine in recommending that "[a]ll patients with moderate to severe pain . . . be considered for opioid therapy."[116]

Patient advocacy groups did much more than merely promote the use of opioids to treat chronic pain. They also played an important role in providing credibility to pharmaceutical companies' claims of low opioid addiction potential. The 2009 joint statement by the American Academy of Pain Medicine and the American Pain Society, for example, provides that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[117] Similarly, according to the American Geriatrics Society's guide entitled *Finding Relief: Pain Management for Older Adults*,

111. Engstrom & Rabin, *supra* note 14, at 309.

112. FUELING AN EPIDEMIC, REPORT TWO, *supra* note 77, at 15.

113. *Id.* at 2.

114. *Id.* at 13.

115. *See* Donroe et al., *supra* note 28, at 455 ("In 1995, coinciding with the introduction of OxyContin™, the American Pain Society introduced the widely embraced 'pain as the fifth vital sign' campaign.").

116. *Id.*

117. *Id.*

"[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[118]

In addition to disseminating the message of opioid manufacturers and boosting their credibility, patient advocacy groups lobbied for opioid use.[119] In 2014, for example, as the effects of the opioid crisis were already plainly visible,[120] the Academy of Integrative Pain Management and the American Cancer Society lobbied to keep in place a 2001 Tennessee law that not only prevented the prosecution of doctors who overprescribe opioids but also obliged physicians to refer patients to an "opioid-friendly" doctor if they refused to prescribe opioids themselves.[121]

Advocacy groups have also come to the aid of physicians charged with drug trafficking. In 2005, for example, the National Pain Foundation filed an amicus brief to the U.S. Court of Appeals for the Fourth Circuit in support of a doctor "convicted of 16 counts of drug trafficking" for prescribing "excessive amounts of Oxycodone and other dangerous narcotics—in one instance more than 1,600 pills a day—to addicts and others, some of whom then sold the medication on a lucrative black market."[122]

Patient advocacy groups do not have to publicly disclose the identity of their donors and are free to pick and choose which donations to make public. A 2018 HSGAC report found that only fifty-seven percent of the patient advocacy groups disclose donation amounts, and a mere twelve percent "have published policies in place for managing institutional conflicts of interest."[123] Disclosed or not, patient advocacy organizations' unmitigated advocacy for opioid use for managing chronic pain was expensive. As the HSGAC report further states, from 2012 until 2017, "five opioid manufacturers . . . contributed nearly $9 million to leading patient advocacy organizations and professional societies operating in the opioids policy area."[124] Of the 104 patient advocacy

118. Third Amended Complaint at 91, City of Chicago v. Purdue Pharma L.P., 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (No. 14 CV 4361).

119. *See* FUELING AN EPIDEMIC, REPORT TWO, *supra* note 77, at 1 ("These [patient advocacy] groups have . . . lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding.").

120. Rose A. Rudd, Puja Seth, Felicita David & Lawrence Scholl, *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1445 (2016) ("[D]rug overdose deaths nearly tripled during 1999–2014. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid."); Kai H. Young, Melissa Ehman, Randall Reves, Brandy L. Peterson Maddox, Awal Khan, Terence L. Chorba & John Jereb, *Tuberculosis Contact Investigations—United States, 2003–2012*, 64 MORBIDITY & MORTALITY WKLY. REP. 1369, 1378 (2016) ("The United States is experiencing an epidemic of drug overdose (poisoning) deaths. Since 2000, the rate of deaths from drug overdoses has increased 137%, including a 200% increase in the rate of overdose deaths involving opioids (opioid pain relievers and heroin).").

121. FUELING AN EPIDEMIC, REPORT TWO, *supra* note 77, at 13.

122. *Id.* at 14.

123. *Id.* at 2.

124. *Id.* at 3.

groups reviewed in the report, eighty-three percent received funding from the pharmaceutical industry, and "at least 39% ha[d] a current or former industry executive on the governing board."[125]

Opioid manufacturers have also made significant payments to individual members of patient advocacy organizations. Between 2013 and 2016, for example, opioid manufacturers paid Dr. Steven Stanos, then-president of the American Academy of Pain Medicine, and Dr. Charles Argoff, president of the American Academy of Pain Medicine Foundation, over $90,000 and $600,000, respectively.[126]

The timing of industry payments to advocacy organizations leaves little doubt about their underlying purpose. Payments from Insys to advocacy groups, for example, "rose significantly [after] 2012—when the company received U.S. Food and Drug Administration approval for its fentanyl drug Subsys."[127] Similarly, Janssen's annual payments to advocacy organizations, which ranged from $99,250 to $239,902 in the years 2012 to 2014, ceased entirely after Janssen sold the rights to its opioid product line to Depomed.[128]

3. Keeping the Gravy Train Rolling: Turning a Blind Eye

Opioid manufacturers are not the only contributors to the pharmaceutical industry's perpetuation of the opioid crisis. Opioids are a Schedule II narcotic, meaning that manufacturers, distributors, and retailers must keep records on the distribution and sale of even a single pill.[129] It would require a herculean effort to ignore the mounting evidence of the scope and effect of the opioid crisis. The pharmaceutical industry, however, proved more than up to the task.

Three companies—McKesson, AmerisourceBergen, and Cardinal Health—control ninety percent of the U.S. drug distribution market.[130] In 2017, all three companies ranked in the top fifteen of the Fortune 500 list, with the annual revenues of each exceeding $125 billion.[131] The three big distributors played a central role in the spread of opioids.[132] Between 2012 and 2017, for

125. *Id.* at 2.

126. *Id.* at 10.

127. *Id.* at 5.

128. *Id.*

129. Engstrom & Rabin, *supra* note 14, at 336.

130. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 5 ("Three companies—McKesson, AmerisourceBergen, and Cardinal Health—account for approximately 90% of drug distribution revenue in the United States.").

131. *Id.*

132. *See id.* ("According to the Washington Post, however, at least 13 distributors, including McKesson, AmerisourceBergen, and Cardinal Health, 'knew or should have known that hundreds of millions of pills were ending up on the black market.' In some cases, distributors continued to send pills '[e]ven when they were alerted to suspicious pain clinics or pharmacies by the DEA and their own employees.'" (quoting Lenny Bernstein, David S. Fallis & Scott Higham, *How Drugs Intended for*

example, they cumulatively "shipped 780 million hydrocodone and oxycodone pills to West Virginia—enough to provide 433 pain pills for every man, woman and child'" in the state.[133] During the same years, McKesson, AmerisourceBergen, and Cardinal Health "shipped around 1.6 billion dosage units of opioid products to Missouri alone," the equivalent of "more than 260 dosage units for every Missourian during the five-year period."[134]

Distributors similarly did not have concerns when shipping nine million hydrocodone pills to a single pharmacy in Kermit, West Virginia, and its 392 residents, "even as the surrounding Mingo County population suffered the fourth-highest rate of prescription opioid overdose in the United States."[135] Indeed, McKesson alone distributed more hydrocodone pills to Mingo County in one year than it did in "five other consecutive years combined."[136]

Retailers and pharmacies were often more than willing participants in this practice. The St. Louis County drug monitoring program, for example, found that "county physicians prescribe enough painkillers per month to provide every resident with three pills" and discovered that a single pharmacy in Webb City was unable to "account for more than 35,000 hydrocodone dosage units and almost 20,000 oxycodone dosage units between May 2014 and March 2015."[137]

This stage of the evolution of the crisis also implicated opioid manufacturers. The generic manufacturer, Mallinckrodt, for example, paid thirty-five million dollars to settle a DEA allegation that it "ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state."[138] Another example is the settlement agreement Endo reached with the attorney general of New York in 2016:

> Although Endo had issued a written policy requiring [sales representatives] to report signs of abuse, diversion and inappropriate prescribing, certain Endo sales representatives who detailed New York [healthcare providers] testified that they did not know about any policy

Patients Ended Up in the Hands of Illegal Users, WASH. POST (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html [https://perma.cc/P2KS-ETHE (staff-uploaded archive)])).

133. Eric Eyre, *Drug Firms Poured 780M Painkillers into WV Amid Rise of Overdoses*, CHARLESTON GAZETTE-MAIL, https://wvgazettemail.com/news/legal_affairs/drug-firms-poured-780m-painkillers-into-wv-amid-rise-of-overdoses/article_99026dad-8ed5-5075-90fa-adb906a36214.html [https://perma.cc/RN2B-XBCE (staff-uploaded archive)] (last updated Mar. 17, 2026).

134. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 1.

135. Letter from Claire McCaskill, Ranking Member, U.S. Senate Homeland Sec. & Governmental Affs. Comm., to Mark Trudeau, President & CEO, Mallinckrodt Pharms. (July 26, 2017) [hereinafter McCaskill, Letter to Trudeau].

136. *Id.*

137. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 4.

138. *Id.* at 6.

> or duty to report problematic conduct observed in [providers'] offices, and did not report anyone, even when they saw suspicious behavior.[139]

These examples demonstrate how the pharmaceutical supply chain continued to distribute extraordinary quantities of opioids in the face of repeated and clear indicators of diversion, misuse, and overprescription, helping to entrench the epidemic despite mounting warning signs.

II. THE STATE OF THE LAW

Opioids, as Schedule II narcotics,[140] are under strict regulatory scrutiny. The manufacturing, distribution, and sale of opioids are subject to specific legislation, primarily the Controlled Substances Act ("CSA");[141] the Federal Food, Drug, and Cosmetic Act ("FDCA");[142] and the False Claims Act ("FCA").[143] They are also subject to the Racketeer Influenced and Corrupt Organizations Act ("RICO").[144] The FDA, DEA, and CDC all directly take part in regulating opioid-based drugs and in tracking their effect on public health.[145] Moreover, both the Department of Justice ("DOJ") and the Department of Health and Human Services ("DHHS"), which includes the CDC, exercise powers over the manufacturing, distribution, and use of opioids. The DOJ prosecutes drug offenders, while the DHHS informs and educates the public and issues guidelines on opioid use and the treatment of adverse effects.[146]

This thick regulatory network exists to prevent the type of opioid crisis that has unfolded and its horrific consequences. However, the responses of legislators and regulators were slow, with both branches of government struggling to address the causes and effects of the opioid crisis. We address the legislative and regulatory failure to prevent the crisis and mitigate its scope and consequences in Section II.A. Section II.B then moves from public to private law, discussing claims brought by individuals, communities, cities, and states against the pharmaceutical industry; their initial failure; and their later partial, though much-delayed, success. Together, these sections portray a gloomy

139. *Id.*

140. Engstrom & Rabin, *supra* note 14, at 336.

141. Pub. L. 91-513, tit. II, 84 Stat. 1242 (1970) (codified as amended in scattered sections of 21 U.S.C.).

142. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i).

143. Act of June 25, 1948, ch. 645, § 287, 62 Stat. 683, 698 (codified as amended at 18 U.S.C. § 287); False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729–33).

144. Pub. L. No. 91-452, § 901(a), 84 Stat. 941 (1970) (codified as amended at 18 U.S.C. §§ 1961–68).

145. *See* Delfino, *supra* note 17, at 328 ("The CSA provides the Attorney General, FDA, and DEA with broad authority to regulate various drugs.").

146. *See id.*; Engstrom & Rabin, *supra* note 14, at 350–51.

picture of how regulatory, criminal, and private-law tools have proved to be insufficient to prevent the crisis ex ante or to fully address its consequences ex post.

A. *Gatekeeper Failure and the Opioid Crisis*

The CSA lists opioids as a Schedule II narcotic, classifying them as having "an accepted medical use but pos[ing] a high potential for abuse, and such abuse may lead to severe psychological or physical dependence."[147] To legally produce and sell opioids, pharmaceutical manufacturers and distributors must register with the U.S. Attorney General and comply with the CSA's requirements pertaining to the drug's "distribution, labeling, and warning."[148]

Alongside the CSA, the FDCA further obliges pharmaceutical companies to "test, produce, and market their drug[]" without it being "adulterated or misbranded," thereby prohibiting "false or misleading representation . . . about some aspect[s] of the drug's nature."[149] Like the FDCA, the FCA also imposes criminal and civil liability for false presentations and claims; unlike the FDCA, however, the FCA specifically prohibits making false assertions to governmental agents.[150]

The legislative focus on testing, labeling, and warning reflects the deep information asymmetries in the pharmaceutical market.[151] Typically, neither patients nor prescribers have access to independent information on a drug's content, efficacy, or side effects and instead must rely on the information provided by the drug's manufacturer and distributor. The FDA, the primary regulator of pharmaceutical drugs in the U.S. market, alleviates information asymmetries through the mandatory approval process of new drugs.[152]

To legally introduce a new drug into the U.S. market, pharmaceutical companies must provide the FDA with evidence-based information pertaining to, inter alia, the drug's content, efficacy, intended uses, and side effects.[153] Even when the FDA grants approval, it limits that approval to specific medical conditions. Pharmaceutical companies thus may not market the drug for non-

147. Delfino, *supra* note 17, at 328.

148. *Id.* at 328–29.

149. *Id.* at 324 (citing United States v. Torigian Labs, Inc., 577 F. Supp. 1514, 1525 (E.D.N.Y. 1984), *aff'd sub nom.*, United States v. Torigian Labs., 751 F.2d 373 (2d Cir. 1984)).

150. *Id.* at 326–27.

151. Anna Rivers, *FDA Effectiveness Standards: Helpful or Harmful?*, *in* KNOWLEDGE AND INCENTIVES IN POLICY 79, 79–80 (Stefanie Haeffele ed., 2018) (accounting for the expansion of the FDA's regulatory powers as the result of the thalidomide tragedy and the need to reduce information asymmetries, as "people were being misled by pharmaceutical manufacturers about their products" and criticizing these regulatory efforts as being overly focused on drug effectiveness rather than drug safety).

152. Delfino, *supra* note 17, at 356–57.

153. *Id.* at 328–29.

FDA-approved purposes.[154] Nevertheless, physicians may prescribe drugs for non-FDA-approved purposes, known as "off-label" uses, and the Food and Drug Modernization Act of 1997 allows pharmaceutical companies' sales representatives to "detail" prescribers—that is, to convince doctors to prescribe drugs for off-label purposes.[155] Detailing has proved to be a successful sales strategy with an estimated twenty percent of all prescriptions being for off-label uses.[156]

In addition to the FDA, the DEA supervises pharmaceutical companies and enforces the CSA.[157] Though the DEA has various tools in its arsenal, the most effective one vis-à-vis the pharmaceutical industry is the issuance of Immediate Suspension Orders ("ISOs") instructing actors in violation of the CSA to cease the manufacturing, distribution, and sale of opioids.[158] Former DEA supervisor Frank Younker has highlighted the significance of ISOs, compared to other enforcement tools, such as orders to show cause and letters of admonition, remarking:

> [I]n essence, [ISOs are] the only way to get a distributor or manufacturer or large pharmacy chain to listen and comply with its obligations under the CSA. During my time at DEA, it seemed to me that these larger corporations in the industry were not interested in doing the right thing, at least not until their profits were hurt and their names were being tied to the opioid epidemic in the headlines.[159]

Others in the DEA share this sentiment, with enforcement attorney Jonathan Novak remarking that "it seems like the only time that any of the distributors and manufacturers want to listen is when it is hurting their bottom line."[160]

The CDC, a "major operating component[] of the Department of Health and Human Services,"[161] is a third governmental organization directly related to opioids, operating alongside the FDA and the DEA. The CDC issues guidelines for the use of prescription drugs and keeps track and disseminates information on the scope and implications of drug use through, inter alia, its

154. *Id.* at 326.

155. *Id.* at 320–21.

156. *Id.*

157. *Id.* at 328.

158. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 27 ("[W]ithout at least the credible threat of an ISO at its disposal, DEA will struggle to achieve sufficient compliance among companies with well-documented histories of lax anti-diversion approaches.").

159. *Id.* at 20.

160. *Id.*

161. *CDC Organization and Leadership*, CTRS. FOR DISEASE CONTROL & PREVENTION: ABOUT CDC (Jan. 26, 2024), https://www.cdc.gov/about/organization/index.html [https://perma.cc/TF8C-NXHJ].

Morbidity and Mortality Weekly Report.[162] At least in theory, the CDC is an independent source of information pertaining to both the potential adverse effects of opioid use and its actual implications in the United States, placing it in an ideal position to sound the alarm before an impending crisis unfolds.

Supposedly, the multilayered regulatory framework in which the pharmaceutical industry operates should have been sufficient to prevent crises such as the opioid epidemic. At the very least, it appears well-equipped to identify imminent threats and nip them in the bud. Time and again, however, the facts have proven otherwise.

The gatekeepers' failure in addressing the opioid crisis traces back to its very beginning. As commentators have shown, when approving OxyContin in the early 1990s, the FDA not only failed to require Purdue to offer sufficient empirical evidence of the drug's efficacy and alleged low potential for abuse and addiction but also permitted Purdue to use so-called enriched-enrollment protocols in the drug's clinical trial.[163] These protocols allow drug manufacturers to remove patients from the trial who did not respond to the drug.[164] Thus, "if the drug was failing the clinical trial, the researchers would remove the subjects who showed that it was failing and continue the trial without them."[165]

Eventually, as Professor Delfino notes, "the FDA approved Purdue's extended-release OxyContin in 1995 based on only one study, a two-week clinical trial,"[166] with Purdue conducting "no clinical studies on its addictive potential" on which to substantiate its claim that the drug is "safer than rival painkillers."[167] The FDA did not fare better when conducting its oversight duties, allowing Purdue to "mislabel its opioids" and imply "they were indicated for a broader range of conditions than supported by medical evidence."[168]

Even as the crisis was reaching its highwater mark, the FDA continued its close relations with opioid manufacturers. In 2012, for example, the FDA approved a Risk Evaluation Mitigation Strategies ("REMS") program to train physicians on the proper use of opioids for the treatment of chronic pain. Though the FDA mandated the REMS training programs, the pharmaceutical industry, which is also responsible for developing their content, funds them. Naturally, the profound involvement of the pharmaceutical industry in creating an FDA-mandated training program on the use of opioids introduced deep

162. *See Morbidity and Mortality Weekly Report (MMWR)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 30, 2025), https://www.cdc.gov/mmwr/index.html [https://perma.cc/DWJ8-6FP6].

163. Delfino, *supra* note 17, at 317.

164. *Id.*

165. *Id.*

166. *Id.* at 317–18.

167. *Id.* at 318.

168. *Id.* at 317.

concerns about the program's educational benefits and its ultimate effect on the prescribing practices of physicians and the well-being of patients.[169]

A similar story is true of the DEA. Like the FDA, the DEA can stop the circulation of drugs by issuing ISOs to drug manufacturers, distributors, and retailers. Yet, between 2012 and 2017, with the adverse effects of the opioid crisis on American individuals, families, and communities clear for all to see, the DEA did not issue a single ISO against a manufacturer or distributor of opioids, and the total number of ISOs issued against individual pharmacies and practitioners, whether opioid-related or not, fell from fifty-eight in 2011 to fewer than ten in each year from 2014 to 2017.[170] Indeed, former DEA employees conceded that though there was no formal change in policy, the DEA has "unofficially raised the bar for proceeding with enforcement actions,"[171] from a "preponderance of evidence" to "beyond a reasonable doubt."[172] As HSGAC's ranking member Claire McCaskill stated:

> The ISO statute was a deterrent to some of the largest companies in America, that there were serious and significant consequences if they did not do it by the book. When you remove that deterrent, then things get even sloppier, and when things get sloppy in the area of opioids, people die.[173]

Scholars often describe the revolving door between the regulator and the regulated as reflecting the intimate relations between the pharmaceutical industry and the agencies that regulate it.[174] The FDA agent overseeing the

169. Donroe et al., *supra* note 28, at 458.

170. There was no comparable drop in less severe sanctions. *See* FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 21–22.

171. *Id.* at 25.

172. *Id.*

173. *Id.* at 21. Though the DEA offers a voluntary license surrender, "only 22 distributors have voluntarily surrendered registrations between 2011 and 2017, and this list does not include McKesson, AmerisourceBergen, or Cardinal Health." *Id.* at 2.

174. For a general discussion of regulatory capture, see George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971) ("[R]egulation is acquired by the industry and is designed and operated primarily for its benefit."); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1684–87 (1975); Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1343 (2013) (describing the triangle in which interest groups, congressional committees, and agencies maintain stable, mutually beneficial alliances as "the most vivid metaphor for government collusion"); Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039, 1060–67 (1997). For a discussion of capture in the context of the pharmaceutical industry in general and the opioid crisis in particular, see Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-Fault Fix*, 35 N.Y.U. REV. L. & SOC. CHANGE 793, 808–12 (2011) (discussing capture in the FDA); Liza Vertinsky, *Pharmaceutical (Re)Capture*, 20 YALE J. HEALTH POL'Y L. & ETHICS 146, 151–52 (2021) ("The pharmaceutical industry is one of the most highly regulated industries . . . . It is also, not surprisingly, an industry in which the largest companies exercise significant influence over the regulatory process."); Laura Karas, *FDA's Revolving Door: Reckoning and Reform*, 34 STAN. L. & POL'Y

approval of OxyContin, for example, became a Purdue employee two years after the drug's approval.[175] According to 2020 figures, nearly two thirds of the registered lobbyists for the pharmaceutical industry are former federal officials.[176]

At the DEA, former employees claim that "the revolving door between the agency and the distribution industry" was behind the informal hardening of the agency's ISO policy.[177] Indeed, all three "major distributors" boast of the number of former DEA officials in their ranks.[178] At AmerisourceBergen, the former assistant special agent in charge of the Atlanta field office now leads the company's diversion control team, with the company also hiring the services of "a consulting group comprised of former DEA employees" to conduct inspections and investigations.[179] McKesson's Controlled Substances Monitoring Program "includes individuals with more than 240 years of cumulative DEA enforcement experience,"[180] and Cardinal Health employs the former associate chief counsel at the DEA as its chief regulatory counsel and senior vice president.[181]

Finally, it was not until March 2016 that the CDC issued "the first national standards for prescription opioids," which many hailed as a significant

REV. 1, 52 (2023) ("[I]n 2007, a House hearing convened a panel of four FDA commissioners . . . to address, among other things, 'scientific integrity' at the agency, specifically the concern that 'key decisions at FDA have been made under the cloud of real or perceived political interference.' Former Commissioner [Frank] Young spoke of a 'revolving door syndrome' at the FDA that leads to relatively short stints of employment among top agency personnel and that may compromise stable leadership."); Jonathan P. Caulkins & Peter Reuter, *Ending the War on Drugs Need Not, and Should Not, Involve Legalizing Supply by a For-Profit Industry*, 21 AM. J. BIOETHICS 31, 33 (2021) ("The prescription opioid disaster is yet another reminder of the fragility of regulation in this country. The industry was able to persuade the FDA to let it market OxyContin, despite a weak evidence base on its dependency creating properties. There have been credible allegations of corruption related to the licensing, with the senior FDA official taking an industry job soon after he had made the critical decisions."); *see also* Sydney Lupkin, *Big Pharma Greets Hundreds of Ex-Federal Workers at the 'Revolving Door*,' KFF HEALTH NEWS, https://khn.org/news/big-pharma-greets-hundreds-of-ex-federal-workers-at-the-revolving-door/ [https://perma.cc/49V2-VYW8] (last updated Jan. 28, 2018) ("Nearly 340 former congressional staffers now work for pharmaceutical companies or their lobbying firms."); *A Bitter Pill: How Big Pharma Lobbies to Keep Prescription Drug Prices High*, CITIZENS FOR RESP. & ETHICS IN WASH. (June 18, 2018), https://www.citizensforethics.org/reports-investigations/crew-reports/a-bitter-pill-how-big-pharma-lobbies-to-keep-prescription-drug-prices-high/ [https://perma.cc/XM9L-AQWG] ("We also examined how Big Pharma utilizes the 'revolving door' between government agencies and lobbying firms to push back against new regulations. These cases revealed that because of the industry's lobbying power, it is incredibly difficult for the government to implement meaningful reform.").

175. Caulkins & Reuter, *supra* note 174, at 33.

176. Delfino, *supra* note 17, at 318 ("In 2020, more than sixty-three percent (955 of 1,502) of registered pharmaceutical industry lobbyists disclosed that they were once federal officials.").

177. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 20.

178. *Id.*

179. *Id.* at 15.

180. *Id.*

181. *Id.*

step in addressing the crisis and restricting the use of opioids to manage chronic pain.[182] Accounting for the delayed publication, Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing, said that "[t]he opioid lobby has very actively blocked interventions that might result in more cautious prescribing or reduced prescribing. They've very clearly defended their financial stake in the status quo."[183]

Nevertheless, the CDC issued new guidelines in 2022 that dialed back on warnings about the dangers of prescribing opioids.[184] Indeed, comparing the CDC's milder 2022 description of opioids as carrying "considerable potential risk" with its more dire 2016 warning that opioids pose "serious risks, including overdose and opioid use disorder" sufficiently alarmed Florida's deputy health secretary, Dr. Kenneth Scheppke.[185] He added: "'Potential' risk? . . . While opioids can be necessary for severe conditions and end-of-life care, the general public shouldn't be told they are 'essential' for pain management."[186]

Regulators are not the only ones who seemed unwilling to confront and address the opioid crisis. In 2016, the U.S. Senate unanimously passed the Ensuring Patient Access and Effective Drug Enforcement Act of 2016,[187] which set new standards for the issuance of ISOs. According to a DEA administrator at the time, the new standards "make it more difficult to issue an [ISO] to non-compliant manufacturers and distributors,"[188] stripping the agency of the most effective tool in its arsenal.

Although the DEA refrained from issuing ISOs, it did impose fines on opioid manufacturers and distributors, primarily for failing to report suspicious orders. In 2017, for instance, the DEA and Mallinckrodt reached a settlement in which the company agreed to pay a $35 million fine for not reporting suspicious orders related to the 500 million opioid pills it shipped to Florida between 2008 and 2012.[189] From 2011 to 2017, two of the "big three" distributors agreed to pay seemingly hefty fines for their failure to detect and report suspicious orders, with McKesson paying $150 million and Cardinal Health paying $44 million.[190] Yet neither fine exceeded 0.08% of the respective

182. FUELING AN EPIDEMIC, REPORT TWO, *supra* note 77, at 1.

183. *Id.* at 14.

184. *See* Kenneth Scheppke, *Florida Rejects the CDC's New Opioid Guidelines*, WALL ST. J. (Nov. 21, 2022, at 18:51 ET), https://www.wsj.com/articles/florida-rejects-the-cdcs-new-opioid-guidelines-crisis-medication-overdose-pain-morphine-dosage-healthcare-drug-death-11669071808?=&url_trace_7f2r5y6=https://www.floridahealth.gov/newsroom/2022/11/20221122-cdc-relax-opioid-guidelines.pr.html [https://perma.cc/T8VN-5ZAV (staff-uploaded, dark archive)].

185. *Id.*

186. *Id.*

187. Pub. L. No. 114-145, 130 Stat. 354 (2016) (codified as amended in scattered sections of 21 U.S.C.).

188. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 26–27.

189. *Id.* at 6.

190. *Id.* at 7.

company's annual revenues, and, during the same period, each company paid more in compensation to a single employee—its CEO—than it did in fines.[191]

In 2007, Purdue pleaded guilty to FDCA felony misbranding violations that federal prosecutors charged them with in Virginia, conceding that the company had "marketed OxyContin with the intent to defraud or mislead."[192] Purdue agreed to pay more than $600 million in fines, with several company executives pleading guilty to misdemeanors.[193] Yet the subsequent guilty plea by Purdue Pharma in 2020 to almost identical allegations that pertained to the company's actions between their 2007 conviction and 2017 clearly indicates the limited effectiveness of the criminal approach.[194] The DOJ has also tried to hold pharmaceutical companies and executives accountable for drug violations and has brought RICO charges against them. Notably, in 2019, Rochester Drug Cooperative ("RDC") became the first pharmaceutical company to face a charge of drug trafficking under the CSA.[195] The basis of this charge was RDC's distribution of opioids to pharmacies despite repeated warnings from the company's compliance department about the legitimacy of the orders.[196] Here, too, RDC resolved the charges by agreeing to a forfeiture of $20 million.[197]

B. *Opioid Litigation*

Overall, existing regulatory frameworks have failed to provide an appropriate response to the opioid crisis. The regulators' original mistake was to approve these drugs, and their ongoing failure to contend with the crisis is evident. These continuous failures are intimately connected to the revolving door dynamic and to the problems of regulatory capture.[198]

The turn to litigation is a natural response to this regulatory deadlock. Litigation offers individuals and communities victimized by the opioid crisis an additional avenue to seek legal redress when problems of regulatory capture and underenforcement, as discussed above, hinder effective regulatory action. Indeed, since the early 2000s, thousands of individuals, municipalities, and

191. *See id.* at 15, 24.
192. Delfino, *supra* note 17, at 325.
193. *Id.* at 325–26.
194. *Id.* at 326.
195. *Id.* at 329.
196. *Id.* at 329–30.
197. *Id.* at 330.
198. *See, e.g.*, Marie Doole, Theo Stephens & Geoff Bertram, *Navigating Murky Waters: Characterizing Capture in Environmental Regulatory Systems*, 20 POL'Y Q. 44, 44 (2024); *see also supra* Section II.A.

states have brought civil claims against manufacturers, distributors, and retailers that took part in the spread of opioids in American communities.[199]

Courts largely dismissed the initial wave of opioid litigation claims, the plaintiffs of which included individuals suffering from opioid addiction and the families of opioid-overdose victims.[200] Later claims, filed by public authorities, were more successful, culminating in a $50 billion global settlement agreement.[201] This Section offers a review of this new and growing litigatory

199. *E.g.*, E. Me. Med. Ctr. v. Teva Pharms. USA Inc., 581 F. Supp. 3d 281, 283 (D. Me. 2022) ("[D]efendants . . . are alleged to have unlawfully marketed, distributed, and dispensed prescription opioids. Plaintiffs assert six state-law causes of action and primarily seek to recover what they have paid and will pay to provide opioid-related care."); Rosen v. CVS Health Corp., No. 4:21-CV-02734, 2021 WL 5826782, at *1 (S.D. Tex. Dec. 8, 2021) ("The Rosens allege that . . . [d]efendants 'knowingly agreed, contrived, combined, confederated, and conspired among themselves and with other entities' to create 'national conditions allowing for and promoting opioid addiction.'"); Enriquez v. Johnson & Johnson, No. A-1174-19, 2021 WL 5272370, at *1 (N.J. Super. Ct. App. Div. Nov. 12, 2021) (alleging that the defendants fueled New Jersey's opioid crisis through deceptive marketing that minimized addiction risks and overstated benefits, leading insurers to bear inflated costs and consumers to face higher premiums and copays); City of Galax v. Purdue Pharma, L.P., No. 7:18-CV-00617, 2019 WL 653010, at *1 (W.D. Va. Feb. 14, 2019) ("Each plaintiff alleges that some or all defendants misrepresented the safety and the addictive properties of prescription opioids and engaged in conduct that resulted in prescription opioids being over-distributed and over-prescribed, such as failing to report or halt suspicious orders and encouraging doctors to over-prescribe."); City of Chicago v. Purdue Pharma L.P., 211 F. Supp. 3d 1058, 1062 (N.D. Ill. 2016) ("Plaintiff . . . alleges as follows. The defendant pharmaceutical companies, through a deceptive and unfair marketing campaign, reversed the medical understanding of opioids so that prescribing opioids to treat chronic pain long-term would be commonplace."); Engstrom & Rabin, *supra* note 14, at 311 ("Between April 2001 and January 2007, over 1,400 such suits [by individual plaintiffs] were initiated. But these suits confronted—and were frequently confounded by—a number of obstacles, and they rarely survived motions for summary judgment."); *id.* at 319 (asserting that suits by public plaintiffs, "including some 2,700 suits initiated by cities, municipalities, counties, Indian tribes, and hospitals," are "proceeding along two separate, though sometimes overlapping, tracks: (1) a federal [multidistrict litigation] (where scores of federal cases are consolidated), and (2) numerous state courts, scattered across the country"); City of Boston v. Purdue Pharma, L.P., No. 1884CV02860, 2020 WL 416406, at *1 (Mass. Super. Ct. Jan. 3, 2020) (alleging that defendants "opioid manufacturers . . . , opioid distributors, retail pharmacies, and certain individuals . . . played a role in causing the overprescription and diversion of prescription opiates in the Cities"); Mecklenburg County v. Purdue Pharma, L.P., No. 3:19-CV-463, 2019 WL 3207795, at *1 (E.D. Va. July 16, 2019) ("Mecklenburg County groups the defendants into the following categories: (1) the 'Manufacturer Defendants,' who are alleged to have directly caused a public health crisis by failing to adhere to FDA regulations and by failing to implement measures to prevent the filing of suspicious orders; (2) the 'Distributor Defendants,' who purchased opioids from the Manufacturer Defendants and allegedly failed to effectively monitor and report suspicious orders of prescription opioids or to implement measures to prevent the filing of invalid prescriptions; (3) the 'Pharmacy Benefit Manager Defendants' (a.k.a. the 'PBM Defendants'), who established formularies to reimburse pharmaceutical companies thereby perpetuating the opioid epidemic; and (4) the 'Doe Defendants,' who were sued under a fictitious name for participating in the activities that caused the opioid epidemic and for helping the other defendants.").

200. Engstrom & Rabin, *supra* note 14, at 310–14.

201. *See, e.g.*, *Global Opioid Settlement*, TEX. ATT'Y GEN., https://www.texasattorneygeneral.gov/globalopioidsettlement [https://perma.cc/3MMW-V27D]; *Executive Summary of National Opioid Settlements*, NAT'L OPIOID SETTLEMENT (June 5, 2024), https://nationalopioidsettlement.com/executive-summary/ [https://perma.cc/LL5G-MBPZ].

field and provides an assessment of its significance as a response to the opioid crisis. The review shows that, despite some important victories, opioid litigation in its current form does not offer a real answer to the deep challenges the crisis presents.

On May 29, 2001, Joe Hale became the first lawyer to file a suit against Purdue for the company's role in an opioid-related overdose death.[202] Jackie Burton, a twenty-eight-year-old mother of two from McDermott, Ohio, had overdosed on opioids two years earlier.[203] Though initially hopeful, Hale withdrew the claim on the eve of trial "after a few court hearings with him at one table and six or eight well-dressed Purdue attorneys on the other."[204]

About two weeks after Hale filed the suit on Jackie Burton's behalf, on June 11, 2001, the attorney general of West Virginia became the first public actor to advance a private-law claim against Purdue for its marketing and distribution of OxyContin in the state.[205] The West Virginia suit ended in a $10 million settlement, prompting other states to file similar claims.[206] In 2007, soon after the West Virginia settlement, twenty-six other states and the District of Columbia reached a $19.5 million settlement with Purdue.[207]

Purdue has not been the only opioid manufacturer facing private-law claims. In 2019, for example, the Cleveland County District Court in Oklahoma ordered Johnson & Johnson to pay $465 million in damages to the state.[208] The Oklahoma Supreme Court, however, overturned the decision on grounds that the public-nuisance doctrine should only address "discrete, localized problems" rather than "policy problems," such as the opioid crisis.[209] More recently, Judge Dan A. Polster in the U.S. District Court for the Northern District of Ohio consolidated in a multidistrict litigation thousands of claims by counties, municipalities, and native tribes after adjudication in federal courts.[210] It was this collective procedure that ended in the $50 billion global settlement agreement.[211]

202. Engstrom & Rabin, *supra* note 14, at 310.

203. *See id.*

204. *Id.* at 349 n.320 (quoting SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC 201 (2015)).

205. *Id.* at 314.

206. *Id.*

207. *Id.* at 314–15.

208. State *ex rel.* Hunter v. Purdue Pharma L.P., 2019 OK Dist. Ct. 816U, ¶ 63; State *ex rel.* Hunter v. Johnson & Johnson, 2021 OK 54, ¶ 6, 499 P.3d 719, 722; Engstrom & Rabin, *supra* note 14, at 320 n.191.

209. *Hunter*, 499 P.3d at 731.

210. Engstrom & Rabin, *supra* note 14, at 319.

211. Defendants include "Insys . . . , Endo . . . , Teva . . . , Mallinckrodt Pharmaceuticals . . . , and Johnson & Johnson . . . , AmerisourceBergen, Cardinal Health, and McKesson . . . , [as well as] Walmart, Walgreens, and CVS." *Id.* at 317–18.

In their claims against the pharmaceutical industry, plaintiffs typically mention the industry's aggressive marketing of opioids,[212] its unlawful misrepresentation of the risks of using opioids for chronic pain,[213] and its failure to monitor opioid distribution and report suspicious orders.[214] They argue that these failures indicate a lack of due care in opioid manufacturing, marketing, and distribution with the intent to "deceive[] potential users . . . by relaying positive information while downplaying the known adverse and serious health effects."[215] Plaintiffs argue pharmaceutical companies provided inadequate warnings to consumers and designed a defective pill whose delayed release mechanism is not difficult to manipulate and is subject to "foreseeable misuse."[216] Private-law claims against pharmaceutical companies, whether by private or public plaintiffs, share similar theories of liability with primary bases in public nuisance, negligence, restitution, and consumer law.[217]

When basing their claims on the theory of public nuisance, plaintiffs must generally prove that (i) an unreasonable activity (ii) within the defendant's control (iii) is the proximate cause (iv) of a substantial interference with a right the public holds in common.[218] Like other claims plaintiffs currently use, this is a *harm-based* claim: the element of "substantial interference" reflects some conceptualization of harm to the plaintiff.

Another theory of liability opioid plaintiffs advance has its basis in the doctrine of negligence.[219] To establish a successful claim in negligence, the

212. *See*, *e.g.*, *supra* text accompanying note 199; *In re* Nat'l Prescription Opiate Litig., 82 F.4th 455, 458 (6th Cir. 2023), *certifying question to*, 179 Ohio St. 3d 74, 2024-Ohio-5744, 265 N.E.3d 1 ("Defendants assert that plaintiffs' claims sound in product liability because they accuse them of 'marketing, distributing, dispensing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Plaintiff's community.'"); City and County of San Francisco v. Purdue Pharma L.P., No. 18-CV-07591, 2022 U.S. Dist. LEXIS 65149, at *9–10 (N.D. Cal. Apr. 7, 2022) ("Plaintiff's claims are based on two theories of liability: (1) that Endo made false and misleading statements about the safety and risks of opioids . . . and (2) that Endo failed to design and operate effective systems to identify suspicious orders of opioids and to prevent diversion of opioids."); *see also* Gentry & McMichael, *supra* note 15, at 839 ("The heart of the [opioid-litigation] complaints center[s] on two general patterns of behavior. Pharmaceutical manufacturers and distributors either (1) engaged in misleading or fraudulent advertising or (2) failed to monitor supply chains of controlled substances.").

213. Gentry & McMichael, *supra* note 15, at 839.

214. *See, e.g.*, City and County of San Francisco v. Purdue Pharma L.P., 2022 U.S. Dist. LEXIS 65149, at *10; Culpeper County v. Purdue Pharma, L.P., No. 3:19-CV-00037, 2019 WL 3855310, at *1 (W.D. Va. Aug. 16, 2019) ("The plaintiffs allege that some or all defendants misrepresented the safety and the addictive properties of prescription opioids and engaged in conduct that resulted in prescription opioids being over-distributed and over-prescribed, such as failing to report or halt suspicious orders and encouraging doctors to over-prescribe.").

215. Engstrom & Rabin, *supra* note 14, at 310–11 (quoting Complaint ¶ 21, Burton v. Purdue Pharma L.P., No. 01CIB005 (Ohio Ct. C.P. Apr. 25, 2001), 2001 OH C.P. Ct. Pleadings LEXIS 16).

216. *Id.* at 346–47.

217. *Id.* at 303, 316.

218. Ausness, *Opioid Litigation*, *supra* note 22, at 567–68.

219. *See, e.g.*, *id.* at 574–76.

plaintiffs must preponderantly prove that the defendants (i) owed them a duty of care and (ii) breached their duty (iii) and that the breach was the cause-in-fact and proximate cause of (iv) the plaintiffs' harm.[220] Under this framework, plaintiffs argue that the DTC promotion of opioids was "designed to appeal to unsuitable consumers"[221] and "vulnerable members of the public,"[222] that the ease with which users can manipulate and abuse the pills' slow release mechanism for nonmedical purposes was foreseeable,[223] and that the industry failed to "supervise illegal or tortious conduct by distributors and retail sellers."[224]

Plaintiffs in opioid litigation have also based their claims on consumer-protection laws and practices of fraudulent misrepresentation.[225] In such cases, plaintiffs point to drug companies' marketing of opioids to argue that they constitute material and false representations of facts in violation of federal and state consumer-protection laws, false claims acts, and the common-law tort of fraudulent misrepresentation.[226]

Public plaintiffs have also advanced restitution claims against opioid manufacturers and distributors, though, as Professor Ausness notes, "many of them have provided little detail or analysis."[227] In these claims, plaintiffs typically seek compensation for increases in public expenditure on healthcare, law enforcement, and child and family services attributed to the harm caused by the sale of dangerous products.[228] These claims are reminiscent of classic tobacco litigation where plaintiffs famously sought to hold tobacco companies accountable for the massive health expenditures smoking caused.[229] To win such

220. *Id.* at 574.

221. *Id.* at 575.

222. *Id.*

223. Engstrom & Rabin, *supra* note 14, at 346–47.

224. Ausness, *Opioid Litigation*, *supra* note 22, at 575.

225. *Id.* at 577–82.

226. *Id.* at 579, 582.

227. *Id.* at 590.

228. *See*, *e.g.*, Complaint & Jury Trial Demanded at 6–7, County of Lackawanna v. Purdue Pharma L.P., No. 17-CV5156 (Pa. Ct. Com. Pl. Sep. 25, 2017) ("The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States, including Pennsylvania and Lackawanna County. Consequently, public health and safety throughout the United States, including Lackawanna County, has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.").

229. As Professors Engstrom and Rabin note,

> the state-initiated tobacco litigation culminated with a master settlement agreement . . . agreed to by the four major tobacco companies and forty-six states plus five U.S. territories and the District of Columbia. . . . [T]he MSA extinguished states' current and future claims against the industry. In return, the industry agreed to provide to the states roughly $206 billion over

claims, plaintiffs must prove that the deceptive practices of pharmaceutical companies have increased public spending on healthcare, thus creating social loss.[230]

In all these types of claims, plaintiffs typically seek compensation for their *harm*. Within this existing framework, however, litigation can only offer a partial patch and never a full-blown legal response to the opioid crisis. This is because, as Section IV.A discusses, the full harms of the crisis are difficult to capture within the constraints of harm-based litigation.

To illustrate the problem, consider the global settlement agreement covering the vast majority of opioid-related claims.[231] However impressive the almost $50 billion settlement may be, it pales in comparison to the harm the crisis has caused, an estimated $500 billion *annually*.[232] Without downplaying the importance of the global settlement agreement, this low and partial level of recovery illustrates the assertion that existing litigatory tools, however important, do not provide a comprehensive legal response to the opioid crisis. A *global* settlement of $50 billion cannot possibly provide appropriate levels of deterrence and compensation when it is worth only ten percent of the *annual* harm.

This insight motivates our discussion below, exploring *gain*-based recovery as an alternative basis for opioid litigation. In the following parts of the Article, we demonstrate that loss-based liability is inherently undercompensatory in the context of opioid litigation and explain why gain-based liability can offer a way out of this deadlock.

> a twenty-five year period; restrict its advertising; abolish the Tobacco Institute, the Council for Tobacco Research, and the Center for Indoor Air Research; curtail its lobbying activity; furnish some $1.5 billion to create a foundation to conduct a national public-education campaign to reduce tobacco use; and expand public access to internal documents.

Engstrom & Rabin, *supra* note 14, at 342. For a detailed analysis comparing tobacco and the opioid litigation, see generally *id.*

230. *See* Complaint & Jury Trial Demanded, *supra* note 228, at 95 (seeking compensation for increased public expenditure flowing from pharmaceutical companies' wrongdoing, namely their deceptive marketing campaigns and assertions).

231. WEN W. SHEN, CONG. RSCH. SERV., LSB11270, NATIONAL OPIOID LITIGATION: SETTLEMENT AGREEMENTS AS OF FEBRUARY 19, 2025, at 1 (2025) ("The national opioid settlement agreements each resolved the majority, if not all, of claims asserted by state and local governments from across the country."); CARDINAL HEALTH, INC., QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 (FORM 10-Q) 32 (Feb. 22, 2024) ("In February 2022, we . . . approved a settlement agreement (the 'National Opioid Settlement Agreement') to settle the vast majority of opioid lawsuits and claims brought by states and political subdivisions."); *see also* Engstrom & Rabin, *supra* note 14, at 321.

232. Engstrom & Rabin, *supra* note 14, at 288.

III. UNJUST ENRICHMENT

Regulation proved insufficient to prevent the opioid crisis. In fact, regulators catalyzed the crisis by approving the drugs and then further exacerbated it by creating the false impression that agencies appropriately monitor pharmaceutical companies and distribution chains. While litigation offers some remedy, it fails to provide appropriate levels of deterrence and offers compensation that seems almost ridiculously small in comparison to the magnitude of the crisis.

We suggest that a focus on gains rather than harms, based on the law of unjust enrichment, can reorient opioid litigation and that this paradigm shift can produce a meaningful legal response to the opioid crisis. In this Part, we first explain the basic principles of the law of unjust enrichment and then explore its application to opioid litigation.

A. *The Law of Unjust Enrichment: Doctrine and Principles*

A cause of action in unjust enrichment consists of three basic elements: (i) the defendant's benefit (ii) was unjustly obtained (iii) at the expense of the plaintiff.[233] Subject to some defenses,[234] plaintiffs meeting these requirements are entitled to defendants' profits.[235] A cause of action in unjust enrichment thus focuses on defendants' unjust benefits rather than on plaintiffs' wrongful losses.

The American view of unjust enrichment encompasses a wide array of claims whose common objective is "to prevent [a] person from profiting

233. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 (A.L.I. 2011) ("[A] person who is unjustly enriched at the expense of another is subject to liability in restitution.").

234. An example is the doctrine of change of position, which limits restitution when the recipient of a mistaken payment relied on the mistaken payment in good faith so that returning the payment to the payor would be detrimental to the recipient. *Id.* § 65 cmts. a, d. Another example is the doctrine of discharge for value, which exempts a recipient of a mistaken payment from restitution, even if there is no proof of detrimental reliance, under the following two conditions: first, the transfer of payment was for payment of an existing debt, and second, the recipient had no notice of the mistake. *See, e.g.*, Citibank, N.A. v. Brigade Cap. Mgmt., LP, 49 F.4th 42, 59–60 (2d Cir. 2022) (delineating the doctrine's boundaries in the case where the plaintiffs did not rely on the sum transferred by mistake); *see also* Banque Worms v. BankAmerica Int'l, 570 N.E.2d 189, 190 (N.Y. 1991); RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 67 (A.L.I. 2011). For further review of the doctrine, see generally Andrew Kull, *Defenses to Restitution: The Bona Fide Creditor*, 81 B.U. L. REV. 919 (2001); Maytal Gilboa & Yotam Kaplan, *The Costs of Mistakes*, 122 COLUM. L. REV. F. 61, 73–77 (2022).

235. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 (A.L.I. 2011); *see also* Douglas Laycock, *The Scope and Significance of Restitution*, 67 TEX. L. REV. 1277, 1279 (1989). For an analysis of the major categories of restitutionary claims, see generally Francesco Giglio, *Gain-Related Recovery*, 28 OXFORD J. LEGAL STUD. 501 (2008) (distinguishing two types of gain-related recovery—the first describes restitution as a legal response of giving back, and the second describes it as a mechanism of taking away the defendant's benefit without a reference to the purpose of the award—and maintaining that the court-applied right to restitution transfers the claimant's wealth up to the level of the defendant's benefit).

unjustly at another's expense."[236] Possible claims based on unjust enrichment range from cases where defendants actively profited from their wrongful behavior to cases where the defendant experienced enrichment without actively committing any wrongdoing.[237] A core example of the latter includes the duty of a recipient of a mistaken payment to return the money to the mistaken payor.[238] Another familiar paradigm of unjust enrichment is restitution of unrequested investments of a person who secured the defendant's life.[239] In these cases, courts grant unjust enrichment remedies even when the plaintiff did not seek the conferred benefit.[240]

Cases where defendants actively commit a tort or a crime and benefit as a result more easily meet the normative "unjust" requirement,[241] as the unjustness of malfeasances is easier to recognize than the unjustness of nonfeasance.[242]

236. Emily Sherwin, *A Short History of the Restatement of Restitution and Unjust Enrichment*, *in* THE AMERICAN LAW INSTITUTE: A CENTENNIAL HISTORY 255, 256 (Andrew S. Gold & Robert W. Gordon eds., 2023).

237. *See, e.g.*, HANOCH DAGAN, UNJUST ENRICHMENT: A STUDY OF PRIVATE LAW AND PUBLIC VALUES 3–4 (1997) (distinguishing cases where "the defendant is passive and the plaintiff herself confers the benefit upon him" from cases where the enriched party is an invader, who "appropriates, i.e., takes or acquires in order to use or exploit [the plaintiff's] interest without consent").

238. Mistaken money payments can result, for example, from clerical errors, *see, e.g.*, *Citibank, N.A. v. Brigade Cap. Mgmt., LP*, 49 F.4th 42, 53–55 (2d Cir. 2022); misinterpretation of pay orders, *see, e.g.*, *Banque Worms v. BankAmerica Int'l*, 570 N.E.2d 189, 190–91 (N.Y. 1991); or incorrect assessments of the legal validity of existing debts, *see, e.g.*, *Est. of Hatch ex rel. Ruzow v. NYCO Minerals, Inc.*, 270 A.D.2d 590, 591 (N.Y. App. Div. 2000).

239. The paradigmatic case that demonstrates restitution following a life rescue is *Cotnam v. Wisdom*, 104 S.W. 164 (Ark. 1907), where two physicians administered medical-surgical assistance to an unconscious individual after his ejectment from a streetcar and did not receive payment for their services. The Arkansas Supreme Court granted restitution in a ruling, now the widely accepted standard, that permits physicians to sue for the cost of the services they provide in such cases of emergency care for unconscious patients. *Id.* at 165–66.

240. DAGAN, *supra* note 237, at 3–4 (noting that conference of benefit may result "due to altruistic motives, in order to serve her self-interest, or simply by mistake").

241. Daniel Friedmann, *Restitution of Benefits Obtained Through the Appropriation of Property or the Commission of a Wrong*, 80 COLUM. L. REV. 504, 505 (1980) ("[W]hen one person has benefited at the expense of another as the result of a tortious act, it is almost axiomatic that his enrichment was 'unjust.'").

242. *See* Stephen A. Smith, *Justifying the Law of Unjust Enrichment*, 79 TEX. L. REV. 2177, 2182 (2001) (noting the normative difficulty in imposing liability on a defendant to return a mistaken payment transferred to her without regard to her knowledge or fault: "[L]eaving aside cases in which a defendant has undertaken an obligation (i.e., contract cases), we generally hold that people are not and should not be subject to a court order unless they have done something wrong (i.e., are at fault)."). The normative difficulty Professor Smith articulated is the focus of a rich literature dedicated to justifying restitution when the source of liability is not the defendant's wrongdoing. *See* Emily Sherwin, *Restitution and Equity: An Analysis of the Principle of Unjust Enrichment*, 79 TEX. L. REV. 2083, 2106–12 (2001) (arguing that unjust enrichment is merely a title lumping together various doctrines, with no direct role in guiding adjudication); Lionel Smith, *Restitution: A New Start?*, *in* THE IMPACT OF EQUITY AND RESTITUTION IN COMMERCE 91, 95–97, 101–02 (Peter Devonshire & Rohan Havelock eds., 2018) (arguing that there is no general concept tying the different categories of liability in unjust

Scholars often describe the enrichment-based recovery in such cases as disgorgement of wrongful gain.[243] The remedy of disgorgement has been developed from the "waiver-of-tort" doctrine, which enabled tort victims to elect to waive the tort and be entitled to disgorgement of the wrongdoer's profits instead of compensation for their harm; in such cases, recovery can exceed compensatory damages.[244]

As Section III.B describes, scholars have recognized the deceitful, manipulative, and fraudulent representation of information regarding the effectiveness and addiction risks of opioids, and the continuous and systematic failure to monitor, document, and halt suspicious orders as not only tortious but at times also criminal behavior.[245] The increases in revenues that pharmaceutical manufacturers, distributors, and retailers received as a result of selling opioid pills while engaging in such deceptive actions constitutes unjust benefits, and patients who bought them should therefore receive disgorgement damages. This remedial function of restitution can strip the ill-gotten gains from the pharmaceutical industry actors. At the same time, this remedy represents a reversal of the patients' payments for opioid pills they purchased and consumed based on inaccurate, manipulated, and fraudulent information about their efficacy and risks.[246] As we explain below, courts should order restitution of payments traceable to the tortious conduct of pharmaceutical companies and their distributors to prevent them from retaining immense profits their wrongful practices tainted. This in turn can deter them from pursuing such gain-seeking strategies in the future.

enrichment together). *See generally* Ernest J. Weinrib, *Correctively Unjust Enrichment*, *in* PHILOSOPHICAL FOUNDATIONS OF THE LAW OF UNJUST ENRICHMENT 31 (Robert Chambers, Charles Mitchell & James Penner eds., 2009) (justifying restitution in cases such as mistaken payments based on an idea of performance and acceptance); Maytal Gilboa & Yotam Kaplan, *The Other Hand Formula*, 26 LEWIS & CLARK L. REV. 883 (2022) (arguing that the source of liability in such cases is not sufficiently clear and proposing a simple mathematic formula describing liability in unjust enrichment).

243. *See, e.g.*, RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 51(4) (A.L.I. 2011) (defining disgorgement in terms of eliminating the profit attributable to the defendant's misconduct). For an overview of the evolution of this claim, see generally William A. Keener, *Waiver of Tort*, 6 HARV. L. REV. 223 (1892); Arthur L. Corbin, *Waiver of Tort and Suit in Assumpsit*, 4 YALE L.J. 221 (1910).

244. When the wrongdoer's gain is smaller than the plaintiff's compensable loss, it is unlikely that the plaintiff would choose to waive loss-based damages and seek disgorgement instead. *See, e.g.*, Laycock, *supra* note 235, at 1285.

245. *See infra* Subsection III.B.1.

246. While the concepts of "restitution" and "unjust enrichment" aim to capture the obligation to reverse an unjustified transfer of wealth between the parties, the term "disgorgement" usually indicates a form of recovery designed to strip from the defendant all benefits obtained through their wrongdoing, rather than reversing an unjustified transfer of benefit. *See supra* text accompanying notes 243–44.

B. *Doctrine in Action: A Gain-Based Remedy for Opioid Victims*

The following subsections delineate the doctrinal framework necessary for opioid victims to make a claim of unjust enrichment. The analysis focuses on the three basic elements that together establish a cause of action in unjust enrichment, namely, that the defendant (i) unjustly (ii) benefited (iii) at the expense of the plaintiff.[247]

1. Unjust

Two patterns of facts support the classification of pharmaceutical companies' behavior as unjust: the dishonest, manipulative, and fraudulent representation of facts pertaining to the high efficacy and low addiction risk of opioid pills and the persistent and systemic failure to monitor, report, and halt suspicious orders.[248] As this Subsection now turns to explain, whether or not such behavior meets the criminal threshold,[249] it is sufficient to meet the law's "unjust" requirement.

As noted, the marketing and advertising of drugs in general, and of Schedule II narcotics in particular, must be "accurate, balanced, evidence-based, and consistent with FDA-approved prescription information."[250] One reason for these requirements is that consumers of prescription drugs and the physicians who prescribe them rarely have access to independent information about their efficacy and risks.[251] Instead, both rely on the information drug companies provide when deciding whether to prescribe the drug for patient consumption.[252] Accordingly, a significant reason to find drug companies' behavior unjust is their abuse of this reliance. Pharmaceutical companies conveyed highly misleading information and denied consumers and prescribers the agency and freedom to make informed decisions, all in order to sell more products and increase profits. Indeed, Purdue pled guilty to "overstating the benefit and understating the addictive potential of OxyContin with intent to

247. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 (A.L.I. 2011).

248. *See supra* Section I.B.

249. On multiple occasions, the behavior of pharmaceutical companies was a sufficient basis for criminal charges against them. In a 2016 settlement agreement with the attorney general of New York, Endo conceded that its "sales representatives . . . did not know about any policy or duty to report problematic conduct . . . and did not report anyone, even when they saw suspicious behavior." FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 6. In 2017, the opioid manufacturer Mallinckrodt paid a $35 million fine for "ignor[ing] its responsibility to report suspicious orders as 500 million of its pills ended up in Florida between 2008 and 2012—66 percent of all oxycodone sold in the state." *Id.* McKesson and Cardinal Health, two of the "big three" distributors, similarly conceded that they "failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances." *Id.*

250. Engstrom & Rabin, *supra* note 14, at 336.

251. *See* Rivers, *supra* note 151, at 79–80.

252. *Id.*

defraud or mislead,"[253] effectively admitting that the company's actions reflected a calculated and conscious decision to maximize profits by disseminating misinformation and misleading those who relied on it.

Pharmaceutical companies have misled not only patients and prescribers but also other stakeholders through their dissemination of inaccurate, manipulated, and fraudulent information about the efficacy and risks of opioid pills. They similarly misled the government and its agencies,[254] which relied on such information as part of the drug approval process.[255] Healthcare coverage providers, including Medicaid and Medicare, also relied on pharmaceutical companies' information in their decisions to cover the cost of the drug for insured patients.[256]

The second pattern of behavior rendering companies' enrichment "unjust"—their failure to monitor, report, and halt suspicious orders[257]—constitutes a breach of their legal duty to report "every sale, delivery or other disposal" of opioid pills and account for the origins and final destination of every single opioid pill.[258] Monitoring and reporting, if duly performed, can reduce the flow of prescription drugs into the illegal drug market. These actions also protect individuals and communities from the adverse effects of opioid overprescription and consequently ensure that insurance companies do not pay for prescriptions that are medically unjustifiable. As described above, pharmaceutical companies failed spectacularly in fulfilling these duties. This

253. Donroe et al., *supra* note 28, at 455; *see also* FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 6 (citing a "complaint from the City of Chicago alleg[ing] that Cephalon sought to 'expand the market for its branded opioids[]' in part through 'misleading claims about functional improvement, addiction risk, pseudoaddiction, and the safety of alternatives to opioids'" and a similar complaint by the State of Ohio, according to which Allergan "created and disseminated 'advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain,' as well as materials 'that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain'").

254. Engstrom & Rabin, *supra* note 14, at 308–09 ("In green-lighting OxyContin in 1995, the FDA relied on this mechanism when it permitted Purdue to make an unusual, untested, and in retrospect fateful claim: that the delayed-release nature of OxyContin's formula was 'believed to reduce' its appeal to drug abusers compared with shorter-acting painkillers.").

255. *Id.*

256. *See* Enriquez v. Johnson & Johnson, No. A-1174-19, 2021 WL 5272370, at *1 (N.J. Super. Ct. App. Div. Nov. 12, 2021) ("The complaint alleged defendants fueled the opioid crisis in New Jersey, causing insurance companies to pay the costs of opioid medication and addiction treatment for their insureds."); McCaskill, Letter to Trudeau, *supra* note 135, at 1 ("Medicare Part D spending on commonly abused opioids increased 165% between 2006 and 2015, and one out of three Part D recipients received at least one prescription opioid in 2016 at a cost of $4.1 billion.").

257. *In re* Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3917575, at *5 (N.D. Ohio Aug. 19, 2019) ("[A] distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances."); Gentry & McMichael, *supra* note 15, at 841 (explaining that the prescribers' use of expert judgment when prescribing drugs does not mitigate this duty).

258. Engstrom & Rabin, *supra* note 14, at 336.

failure was apparent, for instance, when a single pharmacy in Webb City could not account for more than 55,000 opioid pills in less than a year[259] or when physicians in the County of St. Louis prescribed "enough painkillers per month to provide every resident with three pills."[260] Though anecdotal, these facts indicate a wider practice, illustrating the pharmaceutical industry's systematic and comprehensive refusal to meet its legal obligations.[261] Pharmaceutical companies failed to issue and apply policies necessary to monitor orders for opioid pills, turned a blind eye to suspicious orders of hundreds of millions of opioid pills, and continued to manufacture and distribute opioids for the sake of filling their coffers while ignoring clear warning signs.

2. Enrichment

The doctrinal element of enrichment is the defining characteristic and primary focus of the law of unjust enrichment.[262] In our context, enrichment can be measured by the growth in revenues resulting from pills that patients would not have purchased—or which physicians would not have prescribed—were it not for the pharmaceutical industry's deceitful behavior, manipulating patients into addictive patterns of consumption.[263] Identifying the growth in the defendant's revenues due to their tortious behavior requires investigation into concepts of causality.[264] Only profits tainted by fraud or misconduct above and beyond the legitimate level of profit constitute unjust enrichment and should be subject to restitution.

Tracking the growth in revenues over the years in which the pharmaceutical companies engaged in the described illegal actions can help distinguish between legitimate and wrongful sales.[265] As mentioned above, the

259. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 4.

260. *Id.*

261. *See supra* Section I.B.

262. Laycock, *supra* note 235, at 1278.

263. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 49(2) (A.L.I. 2011) (noting the basic rule for measuring a defendant's enrichment, according to which "[e]nrichment from a money payment is measured by the amount of the payment or the resulting increase in the defendant's net assets, whichever is less").

264. Such a distinction requires both causal and normative analysis. For studies dedicated to such analysis, see generally Maytal Gilboa, *Linking Gains to Wrongs*, 35 CAN. J.L. & JURIS. 365 (2022) [hereinafter Gilboa, *Linking Gains to Wrongs*] (explaining how but-for causation applies in such cases); Maytal Gilboa & Yotam Kaplan, *Loser Takes All: Multiple Claimants and Probabilistic Restitution*, 10 U.C. IRVINE L. REV. 907 (2020) (focusing on the question of causation and uncertainty in cases of wrongful enrichment); Maytal Gilboa, *Substitute Victims*, 66 B.C. L. REV. 797, 838–40 (2025) (demonstrating the implementation of causal examination in gain-based-damages-oriented cases, particularly focusing on applying the doctrine of unjust enrichment in cases where injurers harness the structure of tort law remedies to benefit at the expense of the poor).

265. *See* Complaint at 122, 124, City of Lansing v. Purdue Pharma L.P., No. 1:17-cv-01114 (W.D. Mich. Dec. 19, 2017) (distinguishing between defendants' illicit (inflated) and nonillicit profits by

aggressive and misleading marketing of opioids boosted annual sales fourfold or more.[266] Before the intentionally misleading campaign that paved the way for the approval of OxyContin,[267] the opioid market was significantly smaller, as opioid use was largely for short-term, acute, or end-of-life pain management. The fraudulent effort to broaden and normalize opioid use for chronic pain expanded the market to roughly four times its original size. At their peak, opioid sales in the United States, per person, reached four times those in the European Union,[268] where the promotion of additional opioid uses was not through fraudulent practices. The profits generated by the artificially and unlawfully expanded market constitute unjust enrichment, distinguishable from the legitimate profits associated with appropriate opioid sales.[269]

3. At the Victim's Expense

The third element of the doctrine of unjust enrichment requires plaintiffs to prove that the defendant's unjust enrichment came at their expense.[270] The paradigmatic case for establishing this requirement is "one in which the benefit on one side of the transaction corresponds to an observable loss on the other."[271] The pharmaceutical manufacturers, distributors, and retailers who tried to conceal the addictive potential of opioids, sometimes even manipulating the data, induced patients to increase their purchase rates.[272] The payments that patients made in reliance on pharmaceutical companies' misrepresentations constitute unjust enrichment at the expense of those patients. Such payments

alleging defendants committed a RICO violation by "engag[ing] in a conspiracy to *expand the market* for opioid drugs—thus *inflating their own profits* . . . "to maximize the members' profits at all costs" and "to manufacture, encourage *excessive prescriptions*, distribute, and sell as many highly addictive—and often deadly—pills as legally possible" (emphases added)).

266. FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 7.

267. Donroe et al., *supra* note 28, at 455; *see also* FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 6.

268. *See* Guy Jr. et al., *supra* note 79, at 699–700.

269. *See supra* Subsection I.B.2.

270. *See supra* Section III.A.

271. RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 1 cmt. a (A.L.I. 2011).

272. *See* Donroe et al., *supra* note 28, at 455 ("Marketing emphasized low addiction potential and high efficacy of opioids used for chronic pain, both misrepresentations of the existing data, and sponsored over 20,000 educational events on managing pain with opioids in the US."); *Probe Reveals Flood of 780M Painkillers in 6 Deadly Years in West Virginia*, CBS NEWS (Dec. 20, 2016, at 11:36 ET), https://www.cbsnews.com/news/probe-780-million-painkillers-in-6-years-west-virginia/ [https://perma.cc/G3KJ-FEFQ] ("Drug wholesalers shipped 780 million hydrocodone and oxycodone pills to West Virginia in just six years, a period when 1,728 people fatally overdosed on these two painkillers . . . . That amounts to 433 of the frequently abused opioid pills for every man, woman and child in the state of 1.84 million people."); FUELING AN EPIDEMIC, REPORT THREE, *supra* note 41, at 7 ("Between 2012 and 2017, according to information provided to the Committee, the three major drug distributors shipped approximately 1.6 billion opioid dosage units to Missouri—or around 260 doses per resident.").

thus meet the most basic intuition of the "at-the-expense" element, envisaging the pharmaceutical industry's benefit on one side of the transaction that corresponds to a loss "on the other side."[273] The "other side" refers to patients' payments for the excessive use of opioid prescriptions because of the pharmaceutical industry's wrongdoing as well as the insurance companies that covered the cost of such prescriptions.[274]

Having delineated the basic doctrinal framework of a claim of unjust enrichment for opioid victims, we will now highlight the advantages of this approach compared to existing legal solutions.

IV. COMPARATIVE ANALYSIS

As we have sketched throughout this Article, in the thirty years since Purdue's introduction of OxyContin, drug manufacturers, distributors, and retailers have found opioid profiteering irresistible, fueling the pill's scourge of destruction.

With opioid-related harms estimated at around $500 billion a year,[275] the fact that companies choose to continuously engage in the opioid trade can only mean they are not receiving full accountability for the costs of the crisis. Thus, it is clear that litigation currently fails to induce injurers to fully internalize the harms they cause. Accordingly, this Article proposes shifting the focus from harms to gains and provides a preliminary sketch of the necessary conditions to implement a profit-oriented approach to opioid litigation based on unjust enrichment.

In this Part of the Article, we complete our analysis by highlighting three primary advantages of our proposal for gain-based opioid litigation compared to the current harm-based one. We start by fleshing out the advantages of shifting the focus from harm to gain in the context of opioid litigation, explaining how a gain-based approach can overcome the doctrinal limitations of harm-based litigation. Next, we compare the deterrence qualities of gain-based and harm-based remedies in opioid litigation and then discuss the advantages of a gain-based approach in terms of the identity and the diversity of prospective plaintiffs.

273. *See supra* Section III.A.

274. *Id.*

275. Engstrom & Rabin, *supra* note 14, at 288.

A. *Harms v. Gains*

A major obstacle to current opioid litigation is showing that the harm suffered by plaintiffs is legally compensable.[276] We divide the harms caused by the crisis into three primary types: (1) harms to individuals (that is, opioid users and family members); (2) dispersed public harms (that is, harms suffered by communities and the public at large as well as public expenditures to address and mitigate these harms); and (3) long-term and intergenerational harms (that is, future harms to individuals and communities experiencing the adverse effects of opioids). We use this typology to show the limitations of harm-based liability in compensating opioid victims and deterring similar crises in the future due to the divergence between *actual* harm and *compensable* harm. We then demonstrate how a focus on gains can offer a solution to the problem.

1. Harm to Individuals

Although numbers alone can hardly capture the extent of human suffering, they reveal something about the scope of the crisis. Between 1991 and 2013, opioid prescriptions soared from 76 million to "a peak of 219 million prescriptions a year,"[277] the defined daily dose of opioids nearly doubled,[278] and opioid sales recorded a fourfold increase.[279]

Over the course of twenty-three years, from 1999 to 2022, opioids claimed more than 800,000 lives nationwide with over 103,000 reported deaths in 2022 alone.[280] Opioid overdoses became "the number one cause of unintentional injury-related death in the US,"[281] far exceeding the "carnage caused by either car crashes or gun violence."[282] Prescription opioids are directly responsible for approximately half of all opioid-related deaths and, as the primary gateway to illicit opioid use, are indirectly responsible for many more.[283]

A 2023 estimate reported that close to nine million Americans used opioids for nonmedical reasons.[284] Moreover, though opioid users might consume both prescription and illicit opioids, prescription opioids are often "the

276. While not all opioid claims are formally in tort, plaintiffs generally seek compensation for their incurred harms, whether in the form of bodily injury or out-of-pocket expenses. *See, e.g.*, Ausness, *Opioid Litigation*, *supra* note 22, at 602–05 (discussing the economic-loss and municipal-cost-recovery doctrines as limiting the types of legally compensable harms).

277. Delfino, *supra* note 17, at 312.

278. *See* Donroe et al., *supra* note 28, at 454.

279. *See* Guy Jr. et al., *supra* note 79, at 697.

280. Wild, *supra* note 46.

281. Donroe et al., *supra* note 28, at 454.

282. Engstrom & Rabin, *supra* note 14, at 287.

283. *See* Guy Jr. et al., *supra* note 79, at 697.

284. *See Opioid Use Disorder*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/patients-families/opioid-use-disorder [https://perma.cc/KCB7-3FLK]; *see also supra* note 82 and accompanying text.

first opioid encountered in a trajectory toward illicit consumption."[285] As Scott Gottlieb, former FDA Commissioner, explained, "Most people who become addicted to opioids become medically addicted. Their first exposure is going to be a clinical prescription that they receive in a clinical setting, and then they'll go on to develop an addiction."[286]

Recently, opioid prescription rates have been on the decline, but this trend is not necessarily encouraging, as it most likely indicates the transition from prescription to illicit opioid use. The American Society of Addiction Medicine, for example, estimates that eighty percent of all heroin users in the United States started with prescription pills,[287] suggesting that policymakers must consider any decrease in prescription rates alongside the parallel increases in heroin and fentanyl use.

Individuals filing opioid-related claims against pharmaceutical companies typically seek compensation for harms caused by "opioid dependency."[288] Usually, such dependency is a result of receiving a prescription for opioid pills aimed to mitigate chronic pain or physical trauma.[289] More powerful and addictive than heroin,[290] opioids encourage a pattern whereby the intake of individuals who develop dependency on a drug soon exceeds the amount physicians prescribe to them.[291] In *Foister v. Purdue Pharma*,[292] for example, one plaintiff received a prescription for two opioid pills a day; after becoming addicted, the plaintiff continuously increased his opioid consumption,

285. Scott E. Hadland, Magdalena Cerdá, Yu Li, Maxwell S. Krieger & Brandon D.L. Marshall, *Association of Pharmaceutical Industry Marketing of Opioids Products to Physicians with Subsequent Opioid Prescribing*, 178 J. AM. MED. ASS'N INTERNAL MED. 861, 861 (2018) (citing Theodore J. Cicero, Matthew S. Ellis & Zachary A. Kasper, *Increased Use of Heroin as an Initiating Opioid of Abuse*, 74 ADDICTIVE BEHAVS. 63, 63–64 (2017)).

286. *See supra* note 54 and accompanying text.

287. *See Opioid Addiction: 2016 Facts and Figures*, AM. SOC'Y OF ADDICTION MED. (2016), https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf [https://perma.cc/TML5-XLU9].

288. *See id.* ("Addiction is a primary, chronic and relapsing brain disease characterized by an individual pathologically pursuing reward and/or relief by substance use and other behaviors.").

289. *See id.* ("Four in five new heroin users started out misusing prescription painkillers.").

290. *See* DRUG ENF'T ADMIN., DRUG FACT SHEET: FENTANYL 1 (2020), https://www.dea.gov/sites/default/files/2020-06/Fentanyl-2020_0.pdf [https://perma.cc/AWE7-KALY (staff-uploaded archive)] ("Fentanyl is a potent synthetic opioid drug approved by the Food and Drug Administration for use as an analgesic (pain relief) and anesthetic. It is approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic."); WORLD HEALTH ORG., WHO GUIDELINES FOR THE PHARMACOLOGICAL AND RADIOTHERAPEUTIC MANAGEMENT OF CANCER PAIN IN ADULTS AND ADOLESCENTS 133 tbl. A6.2 (2018), https://www.ncbi.nlm.nih.gov/books/NBK537492/pdf/Bookshelf_NBK537492.pdf [https://perma.cc/XJJ9-J5QQ] (comparing the "[a]pproximate potency of opioids relative to morphine").

291. *See* Guy Jr. et al., *supra* note 79, at 697 ("[A]verage dosages of opioid prescriptions tend to be higher for patients who are prescribed opioids for long periods of time.").

292. 295 F. Supp. 2d 693 (E.D. Ky. 2003).

eventually taking seven or more pills each day.[293] Individuals who develop an opioid dependency after receiving a medical prescription for opioids often turn to the illicit drug market to avoid the excruciating, sometimes deadly, opioid withdrawal syndrome.[294]

Considering the scale of these harms and the tragedies they reflect, one would assume that courts would readily make compensation for personal harms available and routinely grant it in opioid litigation. Not so. The vast majority of individuals' claims for personal harms do not survive summary judgment.[295] In fact, by the end of 2003, Purdue issued a press statement boasting its sixty-five-to-zero win-loss record against individuals addicted to its product and family members of those who died from it.[296] Four years later, in May 2007, the *New York Times* reported on the hundreds of individual claimants Purdue's legal team defeated,[297] most of them unable to survive summary judgment.[298]

Besides well-known disparities in wealth, experience, and legal sophistication,[299] pharmaceutical companies' "[b]lame the patient" strategy thwarted individual plaintiffs.[300] The companies employ this tactic as the basic foundation of their defense,[301] grounded on the "wrongful-conduct rule."[302] Under this rule, a plaintiff "cannot maintain a tort action for injuries that are sustained as the direct result of his or her knowing and intentional participation

293. *Id.* at 698.

294. *See* Mansi Shah & Martin R. Huecker, *Opioid Withdrawal*, NAT'L LIBR. OF MED.: NAT. CTR. FOR BIOTECHNOLOGY INFO., https://www.ncbi.nlm.nih.gov/books/NBK526012/ [https://perma.cc/E37W-NAEL] (last updated July 21, 2023) ("Opioid withdrawal syndrome is a life-threatening condition resulting from opioid dependence.").

295. *See* Engstrom & Rabin, *supra* note 14, at 311 ("Between April 2001 and January 2007, over 1,400 such suits were initiated. But these suits confronted—and were frequently confounded by—a number of obstacles, and they rarely survived motions for summary judgment.").

296. *Id.* at 313.

297. *Id.* at 313–14. A notable exception is the $75 million settlement between Purdue and approximately 5,000 individuals, the details of which remain strictly confidential. *See* Esmé E. Deprez & Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry*, BLOOMBERG BUSINESSWEEK (Oct. 5, 2017, at 04:00 ET), https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry [https://perma.cc/FVM5-Q5H5].

298. Engstrom & Rabin, *supra* note 14, at 311. The same is true of class action claims, with the Supreme Court's decision in *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), all but barring opioid-related class actions. *See* Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 598 (S.D. Ohio 2003) (denying a motion for class certification, noting "[t]he class is riddled with individual issues").

299. *See* Yotam Kaplan & Ittai Paldor, *Social Justice and the Structure of the Litigation System*, 101 N.C. L. REV. 469, 477–86 (2023).

300. *See* Engstrom & Rabin, *supra* note 14, at 312.

301. *Id.*

302. *Id.* ("[P]laintiffs—who admittedly abused narcotics—were thwarted by the wrongful-conduct rule."). For a discussion on the origins and more recent adoption of the rule, see generally Samuel Fresher, *Opioid Addiction Litigation and the Wrongful Conduct Rule*, 89 U. COLO. L. REV. 1311 (2018).

in a criminal act."[303] Though the *Restatement (Second) of Torts* rejects the wrongful conduct rule,[304] courts and legislators have increasingly referred to it,[305] often citing public policy concerns.[306] As the Supreme Court of Appeals of West Virginia explained, the wrongful conduct rule reflects tort law's refusal to condone illegal acts and to allow plaintiffs to profit from their own wrongful acts or shift responsibility for such acts to others.[307] Many consider the rule to be necessary to "avoid damage to the public's perception of the legal system."[308]

In *Foister*, for example, the Kentucky district court considered several claims from individuals suffering from opioid addiction.[309] Many of the plaintiffs shared a similar story to the one just discussed. One plaintiff, James Craig, a fifty-six-year-old man, received an OxyContin prescription to alleviate his arthritis.[310] Two months after receiving his initial prescription, Craig "was taking between three and seven pills a day," eventually resorting to "buying OxyContin illegally."[311] Rodney Howard, a thirty-year-old miner and logger, received an OxyContin prescription to mitigate the pain of his Crohn's disease in January 2000.[312] "By March of that year, he was taking OxyContin orally every 60 to 90 minutes,"[313] often crushing the pills and injecting their substance.[314] Neither Craig's nor Howard's claims survived summary judgment.[315] As the district court in Kentucky put it, "These parties . . . are left with the dilemma which *they created*. Because they must inevitably rely on their illegal actions to establish their claims, their claims should be denied in the first instance."[316]

303. *See, e.g.*, Greenwald v. Van Handel, 88 A.3d 467, 472 (Conn. 2014); *see also* Orzel v. Scott Drug Co., 537 N.W.2d 208, 212 (Mich. 1995) ("A person cannot maintain an action if, in order to establish his cause of action, he must rely, in whole or in part, on an illegal or immoral act or transaction to which he is a party.").

304. RESTATEMENT (SECOND) OF TORTS § 889 (A.L.I. 1977) ("One is not barred from recovery for an interference with his legally protected interests merely because at the time of the interference he was committing a tort or a crime.").

305. *See*, *e.g.*, Tug Valley Pharm., LLC v. All Plaintiffs Below in Mingo Cnty., 773 S.E.2d 627, 630 n.6 (W. Va. 2015) ("Many states have adopted statutory iterations of the rule, including Alaska, California, Florida, Louisiana, Ohio, Oregon, and Texas.").

306. *See* Fresher, *supra* note 302, at 1320–24.

307. *See Tug Valley*, 773 S.E.2d at 629 ("[R]espondents invoked the 'wrongful conduct rule' as adopted in other jurisdictions, which stands for the proposition that a plaintiff may not recover when his or her unlawful conduct or immoral act caused or contributed to the injuries." (citing *Orzel*, 537 N.W.2d at 212)).

308. *See id.* at 631 (citing *Orzel*, 537 N.W.2d at 213).

309. Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 696–702 (E.D. Ky. 2003).

310. *Id.* at 698.

311. *Id.*

312. *Id.*

313. *Id.*

314. *Id.*

315. *See id.* at 709.

316. *Id.* at 705 (emphasis added).

While some courts criticize this use of the wrongful conduct rule,[317] they often end up rejecting plaintiffs' claims on similar grounds, based on rules of comparative or contributory negligence.[318] Whatever the doctrinal basis, the outcome is the same: courts consider the personal harm of opioid use to be self-inflicted and thus deny partial or full recovery.[319] In the context of opioid litigation, where defendants' information allowed them to anticipate, if not purposely cause, plaintiffs' medical opioid addiction, tort law's exclusion of so-called "self-inflicted" harm entails severe underdeterrence.[320]

Our proposal to base remedies on gains rather than harms avoids this problem. In particular, a claim in unjust enrichment bases the recovery amount on the defendants' unjust revenues instead of the plaintiffs' harms. Accordingly, such a claim focuses on the link between the defendants' wrongdoing and the enrichment causally attributed to this wrongdoing,[321] rather than on the causal link between the defendants' wrongful behavior that inflicted harm on the plaintiffs.[322] Therefore, neither the plaintiffs' harm nor its causes or contributing factors are necessary to establish a cause of action in unjust enrichment.[323]

Under the framework of an unjust enrichment claim, defendants should not be able to use opioid victims' addiction against them. Thus, even if some of

317. *See, e.g.*, Tug Valley Pharm., LLC v. All Plaintiffs Below in Mingo Cnty., 773 S.E.2d 627, 634–35 (W. Va. 2015) ("[P]rohibit[ing] recovery to the plaintiff if he is at fault in the slightest degree is manifestly unfair, and in effect *rewards the substantially negligent defendant by permitting him to escape any responsibility for his negligence*." (quoting Bradley v. Appalachian Power Co., 256 S.E.2d 879, 885 (W. Va. 1979))).

318. *See, e.g.*, *id.* at 633 ("The countervailing view to adoption of the wrongful conduct rule, as advocated by respondents, posits that a plaintiff's wrongful conduct is simply a matter to be evaluated by the jury under our system of comparative negligence.").

319. *See id.* at 634 ("Since Texas's shift to the proportionate responsibility scheme, . . . most Texas courts have used a plaintiff's unlawful act to measure proportionate responsibility and reduce recovery, rather than completely bar the plaintiff from recovering damages." (quoting Dugger v. Arredondo, 408 S.W.3d 825, 830 (Tex. 2013))).

320. *See id.* at 636 ("[T]he key question is which approach would better deter criminal activity: (a) barring plaintiff's recovery, thereby encouraging plaintiff to obey the law, or (b) allowing plaintiff's recovery, thereby encouraging defendant to obey the law?" (quoting Robert A. Prentice, *Of Tort Reform and Millionaire Muggers: Should an Obscure Equitable Doctrine Be Revived to Dent the Litigation Crisis?*, 32 S.D. L. REV. 53, 112 (1995))); Robert Cooter & Ariel Porat, *Does Risk to Oneself Increase the Care Owed to Others? Law and Economics in Conflict*, 29 J. LEGAL STUD. 19, 19 (2000) ("As applied by courts, the Hand Rule balances the injurer's burden of precaution and the victims' reduction in risk. In this application, risk to oneself does not increase the duty owed to others.").

321. Per this inquiry, we believe that the pharmaceutical industry's aggressive marketing campaign; its use of inaccurate, partial, and misleading information on the benefits and addictive nature of opioid pills; and its failure to monitor, report, and halt suspicious orders are all indicative of the link between pharmaceutical companies' unjust acts and their opioid-trade profits.

322. *See* Gilboa, *Linking Gains to Wrongs*, *supra* note 264, at 367.

323. *See generally* Maytal Gilboa, Yotam Kaplan & Roee Sarel, *Climate Change as Unjust Enrichment*, 112 GEO. L.J. 1039 (2024) (exploring unjust enrichment as a route for recovery in climate litigation, where individualized harm is often difficult to show).

the harm to plaintiffs may be attributable to their patterns of opioid use, the defendants' profits flow from the defendants' wrongful conduct. Simply put, profits attributable to pharmaceutical companies' misrepresentation of opioids constitute unjust enrichment, regardless of the precise causes of subsequent harms from opioid use. This renders victim-blaming strategies largely irrelevant. Of course, tracing gains that are attributable to pharmaceutical companies' fraudulent practices can be challenging, especially concerning the need to distinguish the gain that originated from the companies' wrongful actions from gain that resulted from legitimate activity.[324] Yet such challenges are no different than those arising in any case involving enrichment-based remedies,[325] and courts must further develop doctrinal tools to contend with these issues when litigating these cases.[326] More importantly, arguments regarding contributory fault are largely irrelevant when the basis of the claim is in fraud or intentional misrepresentation. Defenses in unjust enrichment law that theoretically could have assisted opioid defendants usually require a showing of good faith by the defendant.[327] Considering pharmaceutical companies' systematic and intentional use of deceptive practices, such defenses seem futile.

2. Dispersed (Public) Harms

The opioid epidemic first inflicted harm on individuals. Yet the scope of the crisis means that communities and the public at large bear much of its impact. Our healthcare system, in particular, now must cope with a seventy-percent increase in opioid-abuse admissions, with increases in "injection-related infections such as endocarditis, osteomyelitis, septic arthritis, and epidural abscess rising significantly as well."[328] Between 2010 and 2015, for example, North Carolina's hospital system recorded a twelvefold increase in the number of opioid-related endocarditis cases.[329] Nationwide, the *annual* healthcare costs of the opioid crisis—the cost of treating overdose victims and opioid-related

324. For a discussion of this issue, see Subsection III.B.2, *supra*.

325. *See, e.g.*, Gilboa et al., *supra* note 323, at 1083–85.

326. *Cf. id.* at 1047.

327. For example, in cases of restitution for mistaken payments, the change-of-position defense limits restitution when the recipient of a mistaken payment relied on the payment in good faith, so that returning it to the payor would cause them loss. *See* RESTATEMENT (THIRD) OF RESTITUTION & UNJUST ENRICHMENT § 65 cmts. a, d (A.L.I. 2011). The "discharge-for-value" defense similarly includes a good faith requirement. Citibank, N.A. v. Brigade Cap. Mgmt., LP, 49 F.4th 42, 85–87 (2d Cir. 2022) (Park, J., concurring) (delineating the doctrine's requirements). For a review of the discharge-for-value doctrine, see Kull, *supra* note 233, at 927–29; Gilboa & Kaplan, *supra* note 263, at 77–78.

328. Donroe et al., *supra* note 28, at 458.

329. *Id.*

medical conditions, as well as Medicare costs—exceed an estimated $20 billion.[330]

Alongside the healthcare system, the criminal justice system—including law enforcement, the judiciary, and the corrections framework—confronts an increase in opioid-related crimes and offenses, as well as in costs associated with opioid-related threats, making routine tasks, such as executing search warrants, more dangerous and difficult.[331]

The opioid epidemic is also responsible for increases in opioid-related car accidents and neonatal abstinence syndrome, as well as "decreased quality of life; emotional burdens of use and . . . the loss of loved ones; and other disparate community impacts, such as decreased property values, loss of perceived community well-being and safety, and downstream impacts on the children of parents with a substance use disorder."[332] Opioid dependency is a leading cause of child neglect, as many "cases of child neglect are associated with parents with an opioid substance use disorder."[333] Beyond the human toll, opioid-related expenditures on child and family assistance and education are estimated to exceed $10 billion a year.[334]

Finally, from the perspective of the U.S. economy, the opioid crisis causes an estimated annual loss of $55 billion in productivity and wages.[335] Opioids are a leading cause of the reduction in the U.S. labor force, with one study suggesting that opioids account for nearly half of the decline in labor force participation among men and twenty-five percent of the decline among women.[336] Within the workforce, twelve percent of employees are estimated to receive at least one opioid prescription per year, and three quarters of employers report experiencing adverse effects from the crisis.[337] Employees coping with opioid use and addiction "take 50% more days of unscheduled leave than other workers, have an average turnover rate 44% higher than that for the workforce as a whole, and are more likely to experience occupational injuries that result in time away from work,"[338] further reducing the available workforce.

Unfortunately, dispersed harms are not fully compensable through tort litigation and similar types of lawsuits. Public plaintiffs have filed multiple claims, primarily based on negligence and public nuisance grounds, seeking to recover out-of-pocket healthcare, childcare, and family care expenses incurred

330. RHYAN, *supra* note 15, at 2 tbl. 2.

331. *Id.*

332. *Id.*

333. *Id.*

334. *See id.*

335. *See id.* at 2.

336. *See* Paris et al., *supra* note 67, at 2 ("[T]he opioid epidemic accounts for 43% of the decline in men's labor force participation rate between 1999 and 2015, and 25% of the decline for women.").

337. *Id.*

338. *Id.*

as a result of the opioid crisis.[339] Courts, however, are often reluctant to allow recovery for such dispersed public harms, perceiving them as "public policy matters that should be dealt with by the legislative and executive branches."[340]

In other contexts, courts have used various means to exclude dispersed harms. Some courts hold that such harms do not violate a public right, which is a prerequisite for a successful public nuisance claim. The Illinois Supreme Court, for example, rejected Cook County and the City of Chicago's claim that Beretta, a gun manufacturer, violated the public's right to protection from "a threat to its health, welfare and safety" on grounds that the violated rights were an aggregation of individuals' rights, rather than a right the public held in common.[341] As the Supreme Court of Connecticut ruled in *Ganim v. Smith & Wesson*,[342] the "test" for what constitutes a public right, "is not the number of persons annoyed, but the possibility of annoyance to the public by the invasion of its rights."[343] In the context of opioid litigation, the Oklahoma Supreme Court held Johnson & Johnson owes no duty toward the public in the "manufacturing, marketing, and selling of prescription opioids,"[344] relying on the rationale that public nuisance was "never before . . . applied to products, however harmful."[345]

To recover dispersed harms, plaintiffs must further show that the defendants' wrongful conduct caused the expenditures they seek to recover. A causal relationship, however, may be difficult to prove.[346] Pharmaceutical companies are often able to point to multiple intervening factors standing between their wrongful acts and increases in public expenditure, including the prescribing physician, the dispensing pharmacy, and various criminal elements involved in the sale of prescription and illegal opioids.[347] Moreover, with opioid addiction often preying on disadvantaged communities, it may be particularly difficult to show the extent to which the opioid crisis—as opposed to, for example, other social policy initiatives, such as those aimed at correcting historical wrongs—caused increases in public spending.

Finally, courts may bar attempts to recover public expenses on grounds of the municipal-cost-recovery doctrine,[348] also known as the free-public-services

339. *See supra* Section I.A.

340. State *ex rel.* Hunter v. Johnson & Johnson, 499 P.3d 719, 731 (Okla. 2021).

341. Ausness, *Opioid Litigation*, *supra* note 22, at 568; *see also Hunter*, 499 P.3d at 727 (finding the *Beretta* decision to be "instructive on this issue").

342. 780 A.2d 98 (Conn. 2001).

343. *Id.* at 132.

344. *Hunter*, 499 P.3d at 730.

345. State v. Lead Indus. Ass'n, 951 A.2d 428, 456 (R.I. 2008).

346. Ausness, *Opioid Litigation*, *supra* note 22, at 597.

347. *See, e.g.*, *Hunter*, 499 P.3d at 731.

348. *See, e.g.*, City of Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1144 (Ill. 2004).

doctrine.[349] According to this doctrine, "public expenditures made in the performance of governmental functions are not recoverable in tort."[350] This rule generally applies even where municipalities dispensed public services because of the defendant's wrongful acts.[351]

Some courts do not explicitly adopt the municipal-cost-recovery doctrine but still reach similar conclusions on other grounds. For instance, in *State ex rel. Hunter v. Johnson & Johnson*,[352] the Oklahoma Supreme Court stated, "Our Court, over the past 100 years in deciding nuisance cases, has never allowed the State to collect a cash payment from a defendant . . . apportioned to address social, health, and criminal issues arising from conduct alleged to be a nuisance."[353] Given the extent of public expenditures to address and to mitigate the adverse effects of the opioid crisis, excluding such harms as noncompensable further contributes to the underdeterrence of harm-oriented liability.

Here, too, the shift from harm-based to gain-based liability allows courts to better contend with the problem. While the harms of the opioid crisis are dispersed, the opioid industry's gains are discrete and specific to the particular pharmaceutical companies that misrepresented the risks and benefits associated with opioid use. The gains attributable to the increase in the market of these products are detectible by using proxies such as the rise in the companies' revenues following the aggressive marketing of opioids.[354]

Recouping the profits that the pharmaceutical industry has accrued from opioid sales can assist in alleviating some of the financial burden public institutions and states have borne and discourage similar harmful actions in the future.

3. Long-Term and Intergenerational Harms

So far, we have focused on the harms the opioid crisis has already inflicted, whether those of particular individuals or those dispersed throughout communities. With more than 800,000 deaths, 12 million opioid users, the tearing-up of families, the overburdening of the healthcare system, the reduction of the labor force, and a $95 billion annual burden on the U.S. economy, it already ranks as one of the worst public health crises in U.S. history.[355]

349. *Id.*

350. *Id.*

351. *Id.* at 1143–44. As the *City of Chicago* court further explained, the doctrine has its basis in the "identity of the claimant and the nature of the cost," rather than on questions of causation or underlying tort theory and is independent of whether the harm was caused by a "single, discrete disaster, such as fires and explosions" or "frequent incidents of handgun violence." *See id.* at 1144, 1146.

352. 499 P.3d 719 (Okla. 2021).

353. *Id.* at 729.

354. *See* Gilboa et al., *supra* note 323, at 1082–85.

355. McGreal, *How It Ends*, *supra* note 11.

Just as significant, however, are opioid-related harms whose adverse effects will continue long into the future. In this Section, we discuss two such harms that will have profound implications for both individuals' lives and for society at large in the years to come: (1) the reduced prospects of upward socioeconomic mobility for children in hard-hit communities (*intergenerational despair*) and (2) the collapse of communities due to changes in employment patterns, incarceration, and stigma (*persistent unemployment*).

About 8.7 million children live "with at least one parent with a substance use disorder, and an estimated 623,000 parents with opioid use disorder live with children."[356] People with an opioid-struggling family member are ten times more vulnerable to misuse opioids themselves, and seventy percent of people who report using opioids say they obtained them from a family member or close friend.[357] Opioid misuse by parents and high rates of opioid misuse in the community overall also correlate with food insecurity,[358] and "children born to parents using opioids struggle more to develop and thrive."[359]

Opioids also place children at greater risk of being removed from their home—for example, because of a "parent's negligence, arrest, or death."[360] Displaced children are commonly placed with foster families that lack the tools to handle the challenges of trauma or prenatal substance exposure, and child welfare agencies often cannot provide these foster families the support they need.[361]

Researchers have long been studying multigenerational drug use but have only recently begun to study the effects of opioid-struggling parents or communities on children's education. The findings seem to confirm common-sense suspicions. For example, according to one study:

> [C]ounties that experienced higher drug overdose rates from 1995 to 2014 have lower average third- and eighth-grade test scores than counties with lower overdose rates. Further, the relationship between higher overdose rates and lower test scores is particularly strong in rural counties. Finally, the places with the highest overdose rates and lowest test scores tend to be economically disadvantaged.[362]

356. ARON ET AL., *supra* note 65, at v.

357. Jalali et al., *supra* note 67, at 89–90.

358. Darolia & Heflin, *supra* note 46, at 11 ("[S]tates with higher initial OxyContin misuse rates had an increase in food insecurity after OxyContin reformulation.").

359. Martina Whelshula, Margo Hill, S.E. Galaitsi, Benjamin Trump, Emerson Mahoney, Avi Merky, Kelsey Poinsatte-Jones & Igor Linkov, *Native Population and the Opioid Crisis: Forging a Path to Recovery*, 41 ENV'T SYS. & DECISIONS 334, 336 (2021).

360. *Id.*

361. *Id.*

362. Darolia & Heflin, *supra* note 46, at 11.

Other studies similarly suggest that children in opioid-struggling communities have slower learning rates than children in other communities even after controlling for community and school differences.[363]

For many children in opioid-struggling communities—often already suffering from high unemployment and degraded socioeconomic conditions—education is the primary pathway to social and economic upward mobility. The opioid crisis undermines children's abilities to gain an education, enroll in college, and attend and pay attention in class, thereby crippling children's prospects, "exacerbating already existing educational achievement gaps," and undermining children's "future economic opportunity,"[364] thus fostering intergenerational despair.

Alongside effects on children's education, opioid-struggling communities also experience a reduction in the labor force. As noted earlier, studies suggest that the opioid crisis accounts for nearly half of the recorded decline in men's participation in the labor force and twenty-five percent of the decline among women; three quarters of surveyed employers say the crisis has adversely affected them.[365]

High unemployment and turnover are harmful to employees and employers, with the latter having to repeatedly invest in searching, hiring, and training new employees.[366] Rather than increasing wages, however, employers respond to the shrinking labor force by investing in technology. As the authors of one study find, "establishments in high-opioid growth counties employ fewer people and spend comparatively more on information technology."[367]

Once employers invest in technological solutions to address the labor shortage, reverting back to a labor-rich regime seems unlikely. Accordingly, even if an opioid-struggling community miraculously recovers, its members may face the risk of long-term and persistent unemployment in a local economy that can no longer accommodate a workforce of pre-epidemic size. In particular, reduced employment opportunities may motivate community members to seek employment elsewhere. Assuming individuals able to find employment elsewhere are often those with marketable skills as well as the drive and ambition to bear the social and economic costs of leaving their communities, the result would be to rob opioid-struggling communities of their more productive members.

363. *Id.*

364. Darolia & Tyler, *supra* note 64.

365. Paris et al., *supra* note 67, at 2 (noting that more than twelve percent of employees "receive[] an opioid prescription each year" and that workers who suffer from opioid abuse disorder "take nearly [fifty percent] more days of unscheduled leave," have a forty-four percent higher turnover rate, and are more susceptible to "occupational injuries that result in time away from work").

366. *Id.* at 8.

367. *Id.* at 7.

Lastly, because widespread opioid use and dependency tend to result in high unemployment rates, recovered individuals and communities could face the prospect of a vicious circle: despair leads to opioid use, which reduces the available workforce, which in turn leads employers to adopt technological solutions, and technological unemployment breeds further despair and opioid use. Much of this harm is yet to materialize and is therefore unlikely to be compensable in the framework of tort-style litigation. First, defendants may claim that such harms far exceed the scope of their duty to consumers of their products.[368] Pharmaceutical companies may argue they have no duty of care regarding harms linked to employment and education prospects, especially when such harms pertain to long-term and indirect effects.[369]

More fundamentally, such harms are economic and speculative in nature; that is, they pertain to *prospective* harms and lost earnings *opportunities*, rather than to already-suffered physical harms or out-of-pocket expenses. Pure economic and speculative harms are generally noncompensable on grounds of the economic-loss doctrine.[370] Though the origins, rationales, and scope of the doctrine are subject to dispute,[371] most understand the doctrine as "a judicially created doctrine . . . to preclude tort liability in certain situations where a victim has suffered purely financial losses (that is, no physical injury or damage to property),"[372] often on grounds of the "disastrous effects of imposing 'liability in an indeterminate amount for an indeterminate time to an indeterminate class.'"[373]

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

369. *See, e.g.*, Benjamin C. Zipursky, *Rights, Wrongs, and Recourse in the Law of Torts*, 51 VAND. L. REV. 1, 11 (1998) (discussing the classic ruling in the matter of *Palsgraf v. Long Island Railroad*, 162 N.E. 99 (N.Y. 1928), and addressing the elementary principle that "[a] defendant is liable only for the injuries that he could reasonably have foreseen").

370. *See, e.g.*, Dan B. Dobbs, *An Introduction to Non-Statutory Economic Loss Claims*, 48 ARIZ. L. REV. 713, 715 (2006) ("The first of the economic loss rules (the stranger rule), . . . is that, subject to some qualifications, a defendant owes no duty to exercise reasonable care for the pure stand-alone economic interests of strangers—that is to persons with whom the defendant has no relationship by contract, undertaking, or specific legal obligation.").

371. *See, e.g.*, Moransais v. Heathman, 744 So. 2d 973, 979 (Fla. 1999) ("The exact origin of the economic loss rule is subject to some debate and its application and parameters are somewhat ill-defined."); *see also* Catherine M. Sharkey, *In Search of the Cheapest Cost Avoider: Another View of the Economic Loss Rule*, 85 U. CIN. L. REV. 1017, 1018 (2018) ("[T]he origins of the economic loss rule are disputed, as are its parameters and scope.").

372. Sharkey, *supra* note 371, at 1017.

373. *Id.* at 1029 (citing Judge Benjamin Cardozo's decision in *Ultramares Corp. v. Touche, Niven & Co.*, 174 N.E. 441, 444 (N.Y. 1931)); *see also In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 840 (N.D. Ill. 2002) ("Lost profits are frequently speculative because we cannot predict potential customers' behavior to a sufficient degree of certainty. . . . Given the unbounded group of potential plaintiffs, damages would be limitless. So, although the original policy bases for the economic loss doctrine are not present, because of the type of injury, these cases seem to fit, at least linguistically, within the economic loss doctrine."); City of Chicago v. Beretta U.S.A. Corp., 821 N.E.2d 1099, 1106,

Since the economic-loss doctrine bars the recovery of economic and speculative damages,[374] it is particularly relevant to the long-term harms the opioid crisis has caused, such as intergenerational despair and perpetual unemployment. Because reduced employment and educational opportunities pertain to one's lost *prospective* earnings, courts would likely consider them both speculative and purely financial, thereby further reducing the portion of opioid harm for which the pharmaceutical companies that instigated the crisis may be legally liable.[375]

For all these reasons, and with the effects of the crisis still unfolding, harm-based claims are highly limited in their ability to reflect the true cost of the crisis. In particular, compensation for the long-term adverse effects of opioids on family ties, community resilience, children's education, employment, earning potential, and upward social mobility is largely unattainable.[376]

Shifting from harm-based to gain-based recovery can bypass these difficulties. First, the emphasis on defendants' revenues attributable to their wrongful behavior allows courts to focus on *existing* profits instead of facing the hurdles of seeking to hold defendants liable for future and speculative harms. If courts consider present profits to be unjust enrichment, then the pharmaceutical companies' existing marketing practices will no longer be profitable in the short term, resulting in effective deterrence.

Second, gain-based liability has no limitation regarding purely economic losses or gains. In fact, recovery in unjust enrichment often has its basis in pure economic gains,[377] and this has never been problematic. Thus, the fact that the profits of pharmaceutical companies are monetary in nature should not bar recovery under this doctrinal framework. Measuring recovery based on unjust gains also avoids the complex issue of converting abstract values into monetary amounts. The gains of pharmaceutical companies are monetary by nature. Unjust enrichment remedies based on these monetary gains are easier to measure compared to loss-based remedies that aim to reflect abstract future harms, such as persistent and widespread unemployment.[378]

1143 (Ill. 2004) (relying on *StarLink* to reject the City and County's claim to recover "the costs of emergency medical services, law enforcement efforts, the prosecution of violations of gun control ordinances, and other related expenses," finding such costs to be purely economic "in the sense that they represent costs incurred in the absence of harm to a plaintiff's person or property" (citing *StarLink*, 212 F. Supp. 2d at 841)).

374. *StarLink*, 212 F. Supp. 2d at 840.

375. *Id.*

376. *See id.*

377. *See supra* Section III.A.

378. *See, e.g.*, Gilboa, *Linking Gains to Wrongs*, *supra* note 264, at 367 ("[W]hereas in [tort] cases focusing on the plaintiff's harm, the but-for result must ultimately be translated into monetary terms to determine the recovery amount, in gain-based damages cases, the but-for result reflects both the difference that the defendant's wrongfulness has made and the sum of recovery.").

Third, future harms are difficult to attribute to specific actors: it is difficult to determine which company caused which part of the harm. Things are much simpler with gains: the unjust enrichment of each company is a share of its own profits. This mode of remedy is based on a comparison between the company's revenues with and without the misleading and manipulative actions that engendered the opioid crisis.

More generally, the causal chain necessary for establishing a gain-based claim in opioids litigation is simpler compared to that required for a harm-based claim. Both claims are based on the same assertion, described in detail above: that fraudulent practices led to an increase in opioids sales. Assume a court accepts this claim. This, in itself, is insufficient to establish harm-based liability. The plaintiffs will need to additionally prove that the increase in sales resulted in harm, and successfully counter claims that intervening factors severed this causal link. This daunting additional step is unnecessary for establishing gain-based liability. If fraud led to a fourfold increase in sales, the increase in profits constitutes unjust enrichment. The causal link between the wrong *and the gain* is already implied in this holding, regardless of the subsequent harm caused by the sales. Conceptually, profits are an immediate outcome of product sales, while harms are a more remote outcome, therefore more difficult to prove in court.

B. *Profits and Deterrence*

Through the lens of harm-based compensation, effective deterrence of injurers requires that they fully internalize the consequences of their actions.[379] Throughout this Article, we have highlighted the devastation and destruction the opioid crisis has brought to American individuals and society.[380] Indeed, the immeasurable opioid-related harms seem to far exceed the pharmaceutical companies' opioid profits. Thus, one may argue that harm-based liability should assure appropriate levels of deterrence. That is, once companies internalize the harms caused by the irresponsible marketing of opioids, then this activity will become unprofitable, which will deter them from engaging in it. As the analysis in the previous sections reveals, however, compensation for the harms the crisis has caused is far from full; in fact, there is a substantial disparity between the *actual* harms the pharmaceutical industry has caused and the harms for which it is currently accountable. This implies that the opioid crisis entails a problem of underdeterrence.

379. *See* Omer Pelled, *The Proportional Internalization Principle in Private Law*, 11 J. LEGAL ANAL. 160, 161 (2019) ("Complete internalization provides incentives to act whenever it is socially desirable to do so.").

380. *See supra* Section I.A.

A good indication of the limited deterrent effect of harm-based claims is the aforementioned 2021 global opioid settlement agreement, which settled the vast majority of harm-based opioid claims for approximately $50 billion,[381] an amount equal to *one tenth* of the estimated social cost of the crisis *in a single year*.[382]

Though the global settlement provides much-needed funds for public authorities dealing with the detrimental effects of opioids, its ability to deter future injurers is doubtful. Opioid revenues for the fiscal year 2024 alone totaled $24 billion,[383] with the United States and Canada accounting for over sixty percent of the global opioid market.[384] Given the size of the opioid market, an industry-wide payment of $50 billion, spread over multiple years, seems unlikely to deter market actors from actively engaging in the dishonest marketing of opioids and is more likely to lead them to treat it merely as the "cost of doing business."

The divergence between *actual* and *compensable* harms means that harm-based claims fail to achieve the goal of deterrence. Unjust-enrichment-based claims, measuring remedies by the defendant's gains, can fill this gap. Firms are highly unlikely to engage in dishonest marketing practices if any resulting gains are subject to a remedy in unjust enrichment.

Gain-based claims also allow courts to fine-tune the scope of liability to prevent underdeterrence.[385] Similarly, and to the extent gain-based remedies may overdeter firms, courts can rely on the strict reporting duties of pharmaceutical companies to exclude any revenues that are not "unjust," even if they resulted during the period in which the particular firm was involved in marketing opioids.[386]

381. *See supra* note 201 and accompanying text.

382. Engstrom & Rabin, *supra* note 14, at 288.

383. *Opioid Market—By Drug Type, by Application, by Route of Administration, by Distribution Channel, Global Forecast 2025–2034*, GLOB. MKT. INSIGHT (Feb. 2025), https://www.gminsights.com/industry-analysis/opioid-market [https://perma.cc/94D9-3P69] ("The global opioid market size was valued at USD 25 billion in 2024."); *Global Opioids Market Size, Share, and COVID-19 Impact Analysis, by Product Type (Methadone, Codeine, Fentanyl, Oxycodone, Morphine, Hydrocodone, and Others), by Application (Pain Management, Cough Treatment, and Diarrhea Treatment), and by Region (North America, Europe, Asia-Pacific, Latin America, Middle East, and Africa), Analysis and Forecast 2025–2035*, SPHERICAL INSIGHTS (July 2025), https://www.sphericalinsights.com/reports/opioids-market [https://perma.cc/LF3K-VPDW] ("The global opioids market size was worth around USD 23.96 billion in 2024 and is predicted to grow to around USD 28.02 billion by 2035.").

384. *Opioid Use Disorder Market Summary*, GRAND VIEW RSCH. https://www.grandviewresearch.com/industry-analysis/opioid-use-disorder-market [https://perma.cc/4BXE-46K5].

385. Gilboa et al., *supra* note 323, at 1047.

386. For example, before the introduction of OxyContin, the primary use of opioid pills was to manage end-of-life (mostly cancer-related) pain. In these circumstances, the risk of addiction is far less problematic. *See* Guy Jr. et al., *supra* note 79, at 697.

Gain-based remedies can efficiently deter pharmaceutical companies by threatening to deny them their unjustly gotten gains. Even though stripping opioid companies of their unjust revenues may still fall short of requiring them to pay for the entire harm they caused, it may still achieve optimal deterrence by curbing the profit that incentivizes corporate actors to generate the crisis.[387]

C. *The Identity of Plaintiffs*

We conclude this Part of the Article by addressing the identity of potential plaintiffs in opioid litigation. As explained above, public plaintiffs have achieved greater success compared to individuals in opioid litigation. Indeed, thousands of states, municipalities, Indian tribes, and local authorities have filed claims against pharmaceutical companies[388] and were parties to the global settlement agreement.[389]

In the context of opioid litigation, public authorities may enjoy several advantages compared to individual plaintiffs. For example, public authorities usually have greater resources in terms of time, money, and manpower than individuals.[390] This allows them to proceed with their claims even when they confront the pharmaceutical companies' well-financed legal teams.[391] Public authorities can also utilize the awards they receive to support and rebuild the communities the opioid crisis has harmed.

The availability of gain-based liability further adds to the advantages of public plaintiffs. Under harm-based litigation, public authorities must still overcome such problems as identifying the *public* right that was violated,[392] the dispersed nature of the harm,[393] and the fact that some harms will only emerge in years to come.[394] A focus on gains helps public plaintiffs avoid all these difficulties.

387. *See* Cooter & Porat, *Disgorgement Damages*, *supra* note 42, at 249; Pelled, *supra* note 379, at 161.

388. *See* Engstrom & Rabin, *supra* note 144, at 319.

389. *See* Clayton J. Masterman, *Opioid Settlements and Profitable Public Nuisances*, 40 TOURO L. REV. 393, 395 (2025).

390. Rebecca L. Haffajee, Beau Kilmer & Eric Helland, *Government Opioid Litigation: The Extent of Liability*, 70 DEPAUL L. REV. 275, 279–80 (2021) ("Compared to individuals, governments can compete on a more level playing field with opioid companies, by bringing to bear their significant resources and hiring highly trained outside counsel on a contingency fee basis.").

391. *See id.*

392. State *ex rel.* Hunter v. Johnson & Johnson, 499 P.3d 719, 726–27 (2021) ("A public nuisance involves a violation of a public right; a public right is more than an aggregate of private rights by a large number of injured people. . . . [A]s the manufacture and distribution of products rarely cause a violation of a public right, we refuse to expand public nuisance to claims against a product manufacturer."); Ausness, *Opioid Litigation*, *supra* note 22, at 568 ("Interference with a public right is essential to any public nuisance claim.").

393. *See supra* Subsection IV.A.2.

394. *See supra* Subsection IV.A.3.

More importantly, a focus on gain-based liability ties the opioid crisis to public institutions and naturally justifies their role as plaintiffs. Thus, a key element in the wrongdoing that cultivated the crisis is not only the misleading of individual patients but also the use of inaccurate and misleading claims to deceive public authorities and regulators. Similarly, to receive FDA approval for their products, pharmaceutical companies have misled not only the government agencies tasked with governing Schedule II narcotics, but also the insurers paying for their products. For insured individuals, health insurance, Medicare Part D, or Medicaid often fully or partially cover the costs of opioid pills.[395] Accordingly, with respect to insured individuals, the pharmaceutical companies have enriched themselves not only at the expense of those individuals but also at the expense of insurers who eventually paid for the pills. Public authorities and insurers, therefore, should have a valid claim in unjust enrichment to recover these payments, which amount to billions of dollars every year.[396] Gain-based recovery should be available to public healthcare providers and insurers for the multiple years during which they made payments to the pharmaceutical industry based on misrepresentation and false reporting.[397]

CONCLUSION

With hundreds of thousands of deaths in the past two decades and projections of many more fatalities and devastating harms by the end of this decade, the opioid crisis represents a pressing public health emergency. The crisis also exposes the limitations of our regulatory systems. In response to regulatory failures stemming from problems of capture and the revolving-door dynamic, individuals and public authorities are increasingly turning to litigation to seek effective remedies for the devastating crisis. Yet traditional causes of actions, based on compensation for harm, have proven unsatisfactory.

The gist of the problem is that the harms of mass addiction are inherently difficult to prove and are not fully compensable under existing frameworks of harm-based liability. Courts often consider harm to individual patients as self-inflicted, while the broader social effects of mass addiction are too widely dispersed, and the enduring impact on subsequent generations is too indeterminate. This results in the outright rejection of claims or in unsatisfactory settlement amounts that are dwarfed by the actual costs of the crisis. Thus, while litigation seems a promising legal channel to fill the gaps left by regulatory failure, its focus on harm-based doctrines renders it ineffective.

395. Whelshula et al., *supra* note 360, at 336 (claiming that health insurance is more likely to cover prescription opioids rather than more expensive medical procedures such as corrective surgery); *see also supra* note 256 and accompanying text.

396. McCaskill, Letter to Trudeau, *supra* note 135, at 1.

397. *See supra* Section III.B.

To address this issue, we propose an approach that can transform opioid litigation: a doctrinal paradigm shift from harm-based to gain-based recovery. The doctrinal framework of unjust enrichment can provide appropriate remedies to opioid victims and deter the pharmaceutical companies that are responsible for the spread of the opioid epidemic. Without this form of liability, pharmaceutical companies remain motivated to perpetuate the crisis and to further promote the extensive use of opioids to boost their profits.

After providing a detailed account of the basic elements necessary for a valid claim of unjust enrichment in opioid litigation, the Article demonstrates that the systematic deceptive practices of pharmaceutical companies fit the doctrinal requirements that render their profits "unjust." The practical implication of this analysis is that pharmaceutical companies should not be able to retain the profits that result from their wrongful behavior.

The Article illustrates the advantages of this mode of liability over existing harm-based theories of recovery. Thus, while harm-based recovery is inherently undercompensatory, and therefore leads to underdeterrence, gain-based recovery can offer effective levels of deterrence. The shift from harm-based to gain-based liability can negate the financial incentive that pharmaceutical companies have in perpetuating the crisis and hold accountable those who profit from public harm.