



ARTICLE

Pursuing Public Health Through Litigation

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Abstract. Over the past half-century, product-related public health crises have claimed millions of American lives. Two of these crises have been especially prominent: tobacco and opioids. In this Article, we zero in on both controversies. Like many before us, we trace how these two addictive and deadly products became widely used by the American public and analyze the myriad ways in which the products—cigarettes and prescription painkillers—are similar. From there, however, we part ways with previous analyses, as we look beyond these surface similarities to the many ways tobacco and opioids are markedly different from one another. This analysis of differences—focusing on the products’ substitutability, social utility, and price sensitivity—ultimately underscores the crushing, and easily underestimated, challenges policymakers face, to the extent they try to curb the opioid epidemic using tried-and-true supply-side mechanisms. We then turn from the crises themselves to the litigation each has generated. From a distance of two decades, we tally the successes and failures of tobacco litigation—which began in the 1950s and crested in the late 1990s—and analyze how that mixed scorecard has informed, and, going forward, ought to inform, the sprawling opioid litigation: the most complex civil action ever tackled by any American court. Finally, moving beyond this comparative analysis, we address both the future and the utility of public health litigation. Many have asked: What is the role of litigation when it comes to promoting public welfare? Harnessing lessons from both tobacco and opioids, our answer to that question offers new insights for how tort litigation complements—and, under certain conditions, can catalyze—broader regulatory strategies.

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Table of Contents

Introduction287

I. Tobacco: A Retrospective.....292

 A. The Early Days: Health Risks Rising, Then Unmasked292

 B. Individual Lawsuits: The First Two Waves.....295

 C. Aggregating Claims299

 D. Individual Claims Revived.....305

II. Opioid Litigation.....307

 A. The Early Days: “OxyContin Is Our Ticket to the Moon”307

 B. The First Wave: 2001 Through 2013.....310

 1. Individual claims.....310

 2. Public litigation314

 C. The Second Wave: 2014 to the Present.....316

III. A Tale of Two Products and Two Litigations321

 A. Product Attributes.....322

 1. Product substitution323

 2. Social utility.....329

 3. Price sensitivity329

 B. Regulatory Environments.....334

 C. Litigants and Litigation.....338

IV. Larger Lessons341

 A. What the MSA Got Wrong and Right.....342

 B. Aggregation’s Impact345

 1. Whether in tobacco or opioids, individual claims have
 mostly faltered345

 2. Aggregation and the implications of proceeding with
 surrogates and en masse.....349

 C. Value of Public-Health Litigation350

Conclusion.....362

Introduction

As a public health concern, tobacco-related disease has surrendered the limelight to the opioid crisis. And one can well understand the sense of urgency associated with the catastrophic death and disease toll attributable to the abuse of prescription painkillers. Since 1999, opioids have claimed nearly 450,000 American lives, including nearly 50,000 in 2019 alone, dwarfing the carnage caused by either car crashes or gun violence.¹ If the problem is not promptly and adequately addressed, death tolls will rise: Opioids are on track to claim the lives of another half-million Americans within the next decade. That's like wiping out all the men, women, and children in Atlanta in one fell swoop.²

And fatalities, of course, only tell a sliver of the story. Beyond the hundreds of thousands of lives lost, the lives of millions more are diminished and upended. Roughly 2.1 million Americans suffer from an opioid-use

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1. *Opioid Basics: Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/547F-UYZX> (archived Oct. 21, 2020) (reporting that, from 1999 through 2018, nearly 450,000 Americans “died from an overdose involving any opioid”); *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE, <https://perma.cc/UA6H-DH99> (archived Feb. 12, 2021) (noting 49,860 opioid-overdose deaths in 2019). For the comparison to car crashes and gun violence, see Nora Freeman Engstrom & Michelle M. Mello, *Litigation Is Critical to Opioid Crisis Response*, DAILY J. (Mar. 13, 2019), <https://perma.cc/8MCQ-T492> (to locate, click “View the live page”); and *All Injuries*, NAT'L CTR. FOR HEALTH STAT., <https://perma.cc/LP7X-Y4SV> (archived Jan. 28, 2021). Recent evidence suggests that opioid deaths may have increased sharply in 2020, in the shadow of COVID-19. See Zoe Rohrich, *Opioid Deaths Are Surging in the Pandemic. Here's How Treatment Is Adapting*, PBS NEWSHOUR (Aug. 7, 2020, 4:13 PM EDT), <https://perma.cc/9CSQ-WN2>; Hilary Swift & Abby Goodnough, “*The Drug Became His Friend*”: *Pandemic Drives Hike in Opioid Deaths*, N.Y. TIMES (updated Sept. 30, 2020), <https://perma.cc/A5MR-HURL>. Although a significant—and increasing—proportion of fatal overdoses involve heroin and illicitly manufactured fentanyl, the bulk of those who are addicted to opioids started with physician-prescribed painkillers. See *infra* Part III.A.1.
 2. Chillingly, because opioids' relationship to a victim's death is sometimes omitted from death certificates and ER records, the official numbers almost certainly understate the true death toll, likely by 20% to 35%. See Mariano-Florentino Cuéllar & Keith Humphreys, *The Political Economy of the Opioid Epidemic*, 38 YALE L. & POL'Y REV. 1, 17-18 (2019). For the population of Atlanta, see *Atlanta, Georgia Population 2020*, WORLD POPULATION REV., <https://perma.cc/GH4K-T3ZJ> (archived Oct. 21, 2020). For predictions of future fatalities, see Qishui Chen, Marc R. Larochelle, Davis T. Weaver, Anna P. Lietz, Peter P. Mueller, Sarah Mercaldo, Sarah E. Wakeman, Kenneth A. Freedberg, Tiana J. Raphael, Amy B. Knudsen, Pari V. Pandharipande & Jagpreet Chhatwal, *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, 2 JAMA NETWORK OPEN 1, 5 (2019) (predicting over 700,000 opioid-overdose deaths in the period from 2016 to 2025); and Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in the Next Decade*, STAT (June 27, 2017), <https://perma.cc/R4LD-QQAY> (to locate, click “View the live page”) (noting that researchers forecast on average nearly 500,000 opioid fatalities between 2017 and 2027).

disorder,³ over 4 million Americans misuse opioids each *month*,⁴ and an opiate-dependent American child is born every fifteen minutes.⁵ The resulting economic costs are astronomical. 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.⁶

At the same time, the ravages of smoking-related disease remain at a historic level. Over the past half-century, Americans have consumed nearly 25 trillion cigarettes, which have, in turn, killed more than 20 million Americans—that’s more than ten times the number of U.S. citizens who have died in all wars fought by the United States, combined.⁷ Further, though smoking rates are down sharply from their mid-twentieth-century peak, the habit continues to devastate the American population.⁸ Based on the most recently published Centers for Disease Control and Prevention (CDC) figures, cigarette smoking in the United States accounts for more than 480,000 premature deaths per year.⁹ That is roughly *ten times* the number of opioid-overdose deaths and accounts for about one in every five U.S. fatalities—including the deaths of an estimated 41,000 nonsmokers from exposure to

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3. *Module 5: Assessing and Addressing Opioid Use Disorder (OUD)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/75AH-JANT> (archived Oct. 21, 2020) (offering figures from 2016).
 4. Ameet Sarpatwari, Michael S. Sinha & Aaron S. Kesselheim, *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L & POL’Y REV. 463, 464 (2017).
 5. Jennifer Egan, *Children of the Opioid Epidemic*, N.Y. TIMES MAG. (May 9, 2018), <https://perma.cc/3SXX-HYZ5>.
 6. See COUNCIL OF ECON. ADVISERS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 1 (2017).
 7. OFF. OF THE SURGEON GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL; EXECUTIVE SUMMARY 1, 11, 12 & fig.2 (2014) [hereinafter HHS RETROSPECTIVE, EXECUTIVE SUMMARY], <https://perma.cc/N6M9-CBT7>.
 8. Today, 14% of U.S. adults are smokers. See *infra* note 11 and accompanying text. In the early 1960s, when smoking rates were at their peak, the comparable figure was roughly 42.4%. See Robert L. Rabin, *Tobacco Control Strategies: Past Efficacy and Future Promise*, 41 LOYOLA L.A. L. REV. 1721, 1722-23, 1723 n.6 (2008).
 9. *Smoking & Tobacco Use: Tobacco-Related Mortality*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/N3UP-RFAB> (archived Oct. 21, 2020). Cigarettes cause latent diseases, such that a smoker might smoke only when she is young, and then she might succumb to a cigarette-related disease, such as emphysema or lung cancer, years, or even decades, later. Owing to this time lag, cigarette deaths recorded now reflect the higher smoking rates of prior eras. As time goes on, we expect deaths to drop, as deaths “catch up” with sharply reduced rates of smoking. For smoking rates, both at their 1960s peak and today, see note 8 above.

secondhand smoke.¹⁰ An estimated 14% of adults—one in seven—are current cigarette smokers, with usage concentrated among those of lower educational attainment and socioeconomic status.¹¹ Economic costs associated with tobacco-related disease were recently estimated to be more than \$300 billion, including nearly \$170 billion in direct medical costs and another \$156 billion in lost productivity.¹² If the value of lives lost is factored in, the economic toll rises dramatically—to more than \$4.5 trillion per year.¹³

As might be expected, the massive human and economic toll of these two health-based crises has struck a chord in the tort system. Further, the tobacco-litigation experience—which dates back to 1954 and, in 1998, culminated in the largest settlement in the history of American civil litigation—offers an array of insights into how one might expect the opioid litigation to unfold, including tactics that might be employed, obstacles that might be confronted, and cautionary notes all actors would be wise to heed.¹⁴

10. *Smoking & Tobacco Use: Fast Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/HP36-AZLB> (archived Dec. 16, 2020) [hereinafter *CDC Tobacco Use Fact Sheet*]; see *supra* note 1 and accompanying text.

11. For contemporary smoking rates, see *CDC Tobacco Use Fact Sheet*, *supra* note 10. For demographics, see OFF. OF THE SURGEON GEN., U.S. DEP'T OF HEALTH & HUM. SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 7 (2014) [hereinafter HHS RETROSPECTIVE], <https://perma.cc/37JW-WJHL> (reporting that “very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country”). See also Arnold H. Levinson, *Where the U.S. Tobacco Epidemic Still Rages: Most Remaining Smokers Have Lower Socioeconomic Status*, 28 J. HEALTH CARE FOR POOR & UNDERSERVED 100, 102, 103 tbl.1 (2017) (finding that smoking is highly concentrated among the least economically advantaged Americans).

12. *CDC Tobacco Use Fact Sheet*, *supra* note 10.

13. To arrive at this figure, we exclude the “lost wages” component of the CDC’s measure and replace it with the cost of lost lives using the value of a statistical life (VSL) measure, as the Council of Economic Advisers did when tabulating the cost of the opioid crisis. See COUNCIL OF ECON. ADVISERS, *supra* note 6, at 3-7. Regularly used by government agencies, the VSL measure is computed by comparing tradeoffs between wealth and reduced mortality risks—reflected in, for example, wages among differentially hazardous occupations. See *id.* In particular, to arrive at the “more than \$4.5 trillion” figure, we use a crude non-age-adjusted midrange estimate of \$9.6 million per life lost, see *id.* at 7, and we multiply that by 480,000 (the annual number of lives lost, according to the CDC, see *supra* note 9 and accompanying text). More conservative and more generous estimates of VSL would produce total cost estimates from \$2.6 to \$6.4 trillion, respectively. See COUNCIL OF ECON. ADVISERS, *supra* note 6, at 7.

14. See Elysa M. Dishman, *Enforcement Piggybacking and Multistate Actions*, 2019 BYU L. REV. 421, 449 (explaining that the master settlement agreement (MSA) constituted “the largest settlement in American history”). For the 1954 date, see note 37 and the accompanying text below. For more on the massive tobacco settlement, see note 97 and the accompanying text below.

Many have remarked on the myriad similarities between tobacco and opioids.¹⁵ Both are highly addictive products that were sold in stunningly high volumes to a mostly unwitting public. Both were marketed by well-resourced manufacturers who resolutely exaggerated the products' benefits and downplayed their risks. And of course, both products were utilized (by some measure, ingested) by millions of Americans, to devastating effect.

Many, too, have remarked on the obvious similarities between the *litigation* that both episodes spawned.¹⁶ These include that the litigation came to be aggregated, rather than individualized; that it's being quarterbacked by public, rather than private, actors (though, in both, the public actors are assisted by highly specialized private litigators); and that, like the tobacco litigation before it, the opioid litigation seems destined to involve the payment of eye-popping sums.

Here, we reassess these surface-level similarities. But our analysis proceeds to deeper depths and canvasses a wider terrain. From this broader perspective, we also identify critical *differences* between the two products, and the respective litigation responses. In our view, these crucial differences—chiefly, the products' differential susceptibility to substitution (particularly via black-market alternatives); their divergent social utility; the fact that, for opioids (unlike cigarettes), price is not a potent policy lever; and the opioid litigation's crowded roster of players on both the plaintiff and defendant sides—stand to complicate the resolution of the opioid litigation, as well as effective policy responses to this public-health catastrophe.

15. As one group of researchers has aptly put it: "Invariably, when scholars have examined the opioid crisis and how to effectively address it, they have compared it with the tobacco epidemic and the remedies applied in that context." Brief of Amici Curiae in Support of Settlement with Favorable Public Health Outcomes at 5, *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio May 3, 2019), ECF No. 1626 [hereinafter *Public Health Amici*]; see also, e.g., Brief of Amici Curiae in Support of a Settlement Agreement Including Broad Transparency Provisions in the Interest of Future Research at 8, *Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804 (Sept. 12, 2019), ECF No. 2604 [hereinafter *Transparency Amici*]; Michelle L. Richards, *Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation*, 54 U. RICH. L. REV. 405, 407-08 (2020); Paul L. Keenan, Note, *Death by 1000 Lawsuits: The Public Litigation in Response to the Opioid Crisis Will Mirror the Global Tobacco Settlement of the 1990s*, 52 NEW ENG. L. REV. 69, 70, 85-88 (2017); Micah L. Berman, *Using Opioid Settlement Proceeds for Public Health: Lessons from the Tobacco Experience*, 67 U. KAN. L. REV. 1029, 1029-30, 1033 (2019); Nicolas P. Terry, *The Opioid Litigation Unicorn*, 70 S.C. L. REV. 637, 645-49 (2019); Derek Carr, Corey S. Davis & Lainie Rutkow, *Reducing Harm Through Litigation Against Opioid Manufacturers? Lessons from the Tobacco Wars*, 133 PUB. HEALTH REPS. 207, 207-08 (2018); James E. Tierney, *It's Time to Take On Big Opioid Like We Did with Big Tobacco*, BUZZFEED NEWS (Jan. 10, 2018, 3:49 PM ET), <https://perma.cc/ZEH2-CZTT>.

16. See *supra* note 15 (collecting citations).

The Article unfolds as follows. Drawing on a broad mix of primary-source material, including interviews, contemporaneous news reports, and trial court documents, Parts I and II set the stage. In particular, Part I provides a retrospective look at tobacco use in the United States alongside a short history of tobacco tort litigation. This Part shows that, starting in 1954 and continuing for four decades, *hundreds* of personal injury suits were filed against the cigarette industry, but the industry's dominance was so complete that no individual plaintiff prevailed. But then, in the early 1990s, something unexpected happened: Tactics changed, and the tide turned. The tide turned so completely, in fact, that in 1998 plaintiffs forced the tobacco industry to the negotiating table and entered into a \$206 billion “master settlement agreement” (MSA)—the largest tort payment, by far, in American history, which was heralded as a bonanza for the anti-tobacco movement.¹⁷

Part II pivots to opioids. Starting with OxyContin's 1995 approval, this Part charts the rapid rise of opioid use. It offers a detailed review of the early (and unsuccessful) first wave of opioid litigation, which involved at least 5,000 plaintiffs and 1,400 private suits—far more than previously recognized. And it canvasses the second wave of litigation, initiated by over 2,700 states, counties, cities, municipalities, and tribes, which dates back to 2014 and continues to this day.

Part III then compares and contrasts the two products, as well as the litigation each has generated. In particular, Part III surveys the many ways in which cigarettes and opioids are and are not alike. It maps the widely divergent regulatory environments the products inhabit. And it considers the different ways in which the two litigations have unfolded, and seem destined to unfold, going forward.

A final Part IV steps back to offer larger lessons, mining insights that ought to inform not just litigants', judges', and policymakers' responses to the opioid crisis or the tobacco problem, but also to future (as-yet-unidentified) public-health calamities. In particular, with more than two decades of distance, Part IV evaluates what the MSA—which (mostly) closed the book on tobacco litigation—got right and wrong. It analyzes the power of aggregation in addressing individual injuries, in part by exploring the financial and cultural challenges that continue to confront individual plaintiffs, especially when those plaintiffs bear some responsibility (however tenuous) for their current plight. Lastly, it confronts the following hotly contested question: What is the role of tort litigation in protecting the public health? Addressing that question

17. See Sylvia Nasar, *Smokescreen: The Ifs and Buts of the Tobacco Settlement*, N.Y. TIMES (Nov. 29, 1998), <https://perma.cc/GM3W-R7F3> (recognizing that, at the time it was inked, the MSA was “hailed as a triumph of the public interest over special interests”); Dishman, *supra* note 14, at 449. For more on the MSA, see notes 96-97, 282-88 and the accompanying text below.

head on, this Part amasses new support for what we dub a “catalyst” theory of litigation. Drawing on both the tobacco and opioid episodes, we show that litigation can, at least some of the time: (1) draw attention to the problem’s existence; (2) unearth otherwise concealed information that clarifies the problem’s origin, scope, and character; and, in so doing, (3) affect public opinion in such a way as to spur private actors to address the problem and also make political action against a powerful industry more palatable. In this way litigation can, at least some of the time, serve not as a *substitute* to governmental action, but as a *spark* to generate broader governmental and private reform.

I. Tobacco: A Retrospective

A. The Early Days: Health Risks Rising, Then Unmasked

Tobacco use in the United States predates Christopher Columbus’s arrival.¹⁸ But cigarette smoking didn’t really take off until the middle years of the last century.¹⁹ When smoking did grab hold, however, its grasp was firm: In 1900, Americans over the age of eighteen smoked an average of only 49 cigarettes per year.²⁰ By 1920, that figure ticked upward to roughly 600.²¹ By 1940, it was up to 2,558.²² Then, by 1955—by which time nearly half of Americans (68% of men and 32% of women) had acquired the habit²³—per capita consumption skyrocketed to over 3,500 cigarettes per person, per year—approximately half a pack a day for every adult American.²⁴

18. RICHARD KLUGER, *ASHES TO ASHES: AMERICA’S HUNDRED-YEAR CIGARETTE WAR, THE PUBLIC HEALTH, AND THE UNABASHED TRIUMPH OF PHILIP MORRIS* 8-9 (1996).

19. At the turn of the last century, cigarettes played second fiddle to other tobacco-delivery devices, chiefly: chewing tobacco, pipes, snuff, and cigars. HHS RETROSPECTIVE, *supra* note 11, at 705 & fig.13.1.

20. *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 35 (D.D.C. 2006), *aff’d in part and vacated in part per curiam*, 566 F.3d 1095 (D.C. Cir. 2009). All per capita figures are for those age eighteen and over. See HHS RETROSPECTIVE, *supra* note 11, at 18 fig.2.1. At the time, less than 5% of Americans smoked. ALLAN M. BRANDT, *THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA* 309 chart 5 (2007).

21. HHS RETROSPECTIVE, *supra* note 11, at 18 fig.2.1. Interestingly, as of 1920, smoking prevalence was highly gendered: Roughly 40% of men were smokers, as compared to only 5% or so of women. BRANDT, *supra* note 20, at 309 chart 5.

22. KLUGER, *supra* note 18, at 110.

23. PUB. HEALTH SERV., U.S. DEP’T OF HEALTH, EDUC. & WELFARE, *SMOKING AND HEALTH: REPORT OF THE ADVISORY COMMITTEE TO THE SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE* 26 (1964) [hereinafter 1964 SURGEON GENERAL REPORT], <https://perma.cc/5SNT-PEDM>.

24. See HHS RETROSPECTIVE, *supra* note 11, at 18 fig.2.1. Fueling these trends, during World War I, organizations like the Red Cross supplied cigarettes to men on the battlefield. KLUGER, *supra* note 18, at 63-64; BRANDT, *supra* note 20, at 52. And, during World
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But numbers only tell the half of it. By the middle years of the last century, cigarettes were an omnipresent fixture in American life. Smokers walked down every street, and they populated every room, from airport lounges and doctors' offices, to news studios and nurseries.²⁵ Indeed, smoking was so ingrained that, in 1964, the Surgeon General's Advisory Committee had ashtrays on the table when it convened to debate whether smoking causes cancer.²⁶

The cigarette's place in the popular imagination was, if anything, more prominent.²⁷ As one writer recalled, back then, "smoking was like a haircut or a new pair of shoes—it showed the world who you were, or wanted to be."²⁸ Smoking-related images, like Lauren Bacall famously asking Humphrey Bogart for a smoke in *To Have and Have Not*, personified glamour and seduction on the silver screen.²⁹ Cigarette ads on billboards were staked out along America's highways and open roads.³⁰ And Philip Morris made the Marlboro Man a shorthand for the freedom, adventure, and rugged individualism of the American West.³¹

Yet, starting in the early 1950s, bad news—in the form of reports of a relationship between smoking and lung cancer—started to break.³² As it did,

War II, President Roosevelt declared tobacco a protected crop, gave deferments to tobacco growers, and sent cigarettes to soldiers as part of their daily rations. PETER PRINGLE, *CORNERED: BIG TOBACCO AT THE BAR OF JUSTICE* 123 (1998). Ultimately, U.S. soldiers fighting in World War II came to smoke an average of thirty cigarettes per day, and many, not surprisingly, got hooked. KLUGER, *supra* note 18, at 112-13.

25. As historian Allan Brandt explained: "From coffee breaks to the college seminar room, from bars and restaurants to boardrooms and bedrooms, the cigarette was a constant presence." BRANDT, *supra* note 20, at 279.
26. HHS RETROSPECTIVE, *supra* note 11, at 774 & fig.14.1.
27. For a discussion of the cigarette's singular place in American culture during the mid-twentieth century, see Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 855-57 (1992).
28. Henry Allen, *Ah, Those Smoky Yesterdays*, WASH. POST (June 16, 1988), <https://perma.cc/4AH9-Y9B7>.
29. Rabin, *supra* note 27, at 855; KLUGER, *supra* note 18, at 114-15. See generally Aljean Harmetz, *History Is Written in Smoke*, N.Y. TIMES (Nov. 8, 1992), <https://perma.cc/8QUA-NKGY>.
30. CARRICK MOLLENKAMP, ADAM LEVY, JOSEPH MENN & JEFFREY ROTHFEDER, *THE PEOPLE VS. BIG TOBACCO: HOW THE STATES TOOK ON THE CIGARETTE GIANTS* 16 (1998) ("To drive in America in this century was to experience the sights and images of cigarettes, conveyed by the billboards lining the roadside.").
31. *Id.* (discussing the "Marlboro Country"); Robert L. Rabin, *Smoke Gets in Your Eyes*, 95 AM. SCIENTIST 444, 445 (2007) (same).
32. In fact, the very first studies uncovering a link between smoking and cancer date back quite a bit further. E.g., Herbert L. Lombard & Carl R. Doering, *Cancer Studies in Massachusetts: Habits, Characteristics and Environment of Individuals with and Without Cancer*, 198 NEW ENG. J. MED. 481, 486 (1928) ("The difference between our control
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America's love affair with the cigarette started, very gradually, to cool. Reports initially cropped up in arcane medical journals, read mostly by doctors and scientists.³³ But eventually, the reports found their way into magazines and news reports widely read by the American people.³⁴ In fairly short order, the public responded.³⁵ Per capita cigarette consumption in the United States, which had spiraled upward during the first half of the twentieth century, lost its momentum. Then, around 1960, it crested and started to recede.³⁶

group and the cancer group in respect to heavy smoking is twenty-seven per cent. This is highly significant which suggests that heavy smoking has some relation to cancer in general.”). For discussion of the earliest reports, see *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 149-53 (D.D.C. 2006), *aff'd in part and vacated in part per curiam*, 566 F.3d 1095 (D.C. Cir. 2009).

33. For a broad discussion of the accumulating scientific evidence, see *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 153-64; BRANDT, *supra* note 20, at 131-60; and Rabin, *supra* note 27, at 856.
34. BRANDT, *supra* note 20, at 160-61; Rabin, *supra* note 27, at 856-57.
35. The tobacco companies responded as well. In an effort to counter the bad news burbling out, the companies joined forces and, under the guidance of PR firm Hill & Knowlton, hatched a unified strategy. The cornerstone of that strategy was a full-page ad, titled “A Frank Statement to Cigarette Smokers,” which was published in 448 newspapers on January 4, 1954. See BRANDT, *supra* note 20, at 170-71. In that “Frank Statement,” the tobacco companies pledged to form a “joint industry group” to conduct research “into all phases of tobacco use and health,” and continued:

We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business.

We believe the products we make are not injurious to health.

We always have and always will cooperate closely with those whose task it is to safeguard the public health.

Id. at 170-71; *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 40. As a PR matter, this counter worked. At the time of the Frank Statement's publication, the companies were congratulated for their responsibility and candor. BRANDT, *supra* note 20, at 171 (collecting sources). And, more broadly, the companies' pledge “allayed the public's concerns about smoking.” *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 40. Yet, in the ensuing decades, *genuine* cooperation with those actually “safeguard[ing] the public health” was scant, and the research conducted by the “joint industry group” (initially dubbed the Tobacco Industry Research Committee and then later the Council for Tobacco Research) was skewed. See *id.* at 36-62 (discussing the “Frank Statement” and its aftermath); HHS RETROSPECTIVE, *supra* note 11, at 20 (same).

36. Before that, U.S. consumption slumped in 1953 and 1954, as news about the risk of cigarettes started to break. HHS RETROSPECTIVE, *supra* note 11, at 18 fig.2.1 (charting adult per capita cigarette consumption from 1900 to 2012). After those temporary setbacks, however, consumption rebounded until it reached a peak in 1964, just as the Surgeon General published its blockbuster report on smoking and health. *Id.* For more on the 1964 Report, which, for the first time, drew an express causal connection between smoking and lung cancer, see *id.* at 23-25; BRANDT, *supra* note 20, at 211-40; KLUGER, *supra* note 18, at 253-62; and PRINGLE, *supra* note 24, at 135-36.

B. Individual Lawsuits: The First Two Waves

Tobacco litigation dates back to precisely this period when, on March 10, 1954, Ira Charles Lowe, a factory worker suffering from lung cancer, filed a personal injury suit against cigarette behemoth R.J. Reynolds Tobacco Co. in St. Louis, Missouri.³⁷ But it's putting it mildly to say that Lowe's suit—and the scores of plaintiffs who followed in Lowe's footsteps—realized no success. From the 1950s through the early 1990s, plaintiffs filed hundreds of personal injury and wrongful death claims against the tobacco industry.³⁸ Yet no plaintiff—not one—prevailed.

The reasons for this lopsided record are varied and numerous. But part of the answer is clearly attributable to the industry's defense-side strategy.

By the mid-1950s, the tobacco companies could read the tea leaves: Already, more than 25,000 Americans were dying annually from lung cancer—a kind of cancer that just fifty years before had been “virtually unknown as a cause of death in the United States.”³⁹ Rather than holding steady, lung-cancer deaths were on the rise.⁴⁰ And studies indicated that, at least among males, well over half of those deaths were caused by cigarettes.⁴¹ Add those facts together, and it was clear enough that if plaintiffs came to believe that suits on behalf of

37. Rabin, *supra* note 27, at 857 & n.26 (discussing the fact that the first wave of cigarette litigation was launched in 1954, with the filing of *Lowe v. R.J. Reynolds Tobacco Co.* in St. Louis); *Lowe—The First Case*, TOBACCO ON TRIAL, <https://perma.cc/5BY6-UFBX> (archived Oct. 22, 2020). The case was subsequently dropped. Rabin, *supra* note 27, at 857 & n.26.

38. There is disagreement on the precise number of claims that were filed during this roughly forty-year period. One of the authors has put the figure at 275 to 350 claims, based on interviews with attorneys who were extensively involved in the litigation. See Robert L. Rabin, *Institutional and Historical Perspectives on Tobacco Tort Liability*, in *SMOKING POLICY: LAW, POLITICS, AND CULTURE* 110, 112, 128 n.31 (Robert L. Rabin & Stephen D. Sugarman eds., 1993). Peter Pringle's estimate is higher—at 813 claims, with “[n]ot a penny paid in damages.” PRINGLE, *supra* note 24, at 7. Lynn Mather provides that “[b]etween the 1950s and 1995, smokers and the families of deceased smokers filed more than 700 product liability lawsuits against the tobacco industry.” Lynn Mather, *Theorizing About Trial Courts: Lawyers, Policymaking, and Tobacco Litigation*, 23 *LAW & SOC. INQUIRY* 897, 904-05 (1998). A formerly confidential tobacco industry memo indicates that, by their count, 127 cases were initiated between 1954 and June 1980. R.J. Reynolds, *Smoking Issues—Briefing Book 7* (1980), <https://perma.cc/C6GT-ZBQV> [hereinafter *RJR Memo*].

39. *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 35; see also *id.* at 149. For the 25,000 figure, see Rabin, *supra* note 27, at 858.

40. Rabin, *supra* note 27, at 858; see also 1964 SURGEON GENERAL REPORT, *supra* note 23, at 25 (reporting that lung-cancer deaths rose from less than 27,000 in 1955 to 41,000 in 1962). Lung-cancer diagnoses were also spiraling upward, particularly among men. See BRANDT, *supra* note 20, at 106, 126.

41. Rabin, *supra* note 27, at 858.

dead or stricken smokers had even an *outside shot* at success, the companies' liability exposure would be massive and potentially crippling.⁴²

The answer the companies came to: convincingly demonstrate that tobacco litigation was, and would be, a losing proposition.⁴³ Toward that end, the tobacco manufacturers vowed to fight every claim, no matter the cost or collateral damage, through trial and any possible appeal. As one memo from industry leaders put it, lawyers' marching orders were to "[v]igorously defend any case; look upon each as being capable of establishing dangerous precedent and refuse to settle any case for any amount."⁴⁴ In pursuit of that strategy, the companies and their loyal litigators showed no mercy and spared no expense.⁴⁵

Early cigarette cases, which typically included claims of negligent failure to warn and breach of the implied warranty of merchantability, gave defendants a golden opportunity to put this cynical strategy to the test.⁴⁶ By their nature, the claims were scientifically complex—and therefore pricey. In order to prevail, a plaintiff had to assemble evidence from a veritable army of experts from a wide array of professional domains, including (often) his or her treating physician (in order to establish the plaintiff's current diagnosis and prognosis); pathology, oncology, and epidemiology (in order to establish causation); and marketing and advertising (in order to bolster claims of failure to warn).⁴⁷

42. As a confidential R.J. Reynolds memorandum put it in 1980: "The industry felt then [in the early days], and still does, that if any case were lost or settled, there would be thousands of potential claimants to whom payment—no matter how small—would be prohibitive." RJR Memo, *supra* note 38, at 7.

43. *See id.* (chalking up the industry's success to its decision "to fight the lawsuits all out"). The industry took a similarly aggressive strategy when it came to the court of public opinion. For discussion, see note 35 above.

44. J.F. Hind, Key Issue #5: External Relationships, Constraints and Regulatory 12 (1977), <https://perma.cc/R6MA-6R8G>.

45. A tobacco lawyer perhaps said it best in a confidential memorandum:

[T]he aggressive posture we have taken regarding depositions and discovery in general continues to make these cases extremely burdensome and expensive for plaintiffs' lawyers, particularly sole practitioners. To paraphrase General Patton, the way we won those cases was not by spending all of [R.J.] Reynolds' money, but by making that other son-of-a-bitch spend all of his.

William E. Townsley & Dale K. Hanks, *The Trial Court's Responsibility to Make Cigarette Disease Litigation Affordable and Fair*, 25 CAL. W. L. REV. 275, 278 (1989) (alteration in original) (quoting a tobacco industry lawyer's confidential memorandum); *see also* Patricia Bellew Gray, *Tobacco Firms Defend Smoker Liability Suits with Heavy Artillery*, WALL ST. J., Apr. 29, 1987, at 1 (explaining that tobacco companies' "secret is a lavishly financed and brutally aggressive defense that scares off or exhausts many plaintiffs long before their cases get to trial").

46. Rabin, *supra* note 27, at 859-63.

47. *See id.* at 858.

Meanwhile, the cases also raised issues of assumption of risk, contributory (and then later, comparative) negligence, general and specific causation, and damages—all of which gave defendants license to put plaintiffs on trial.⁴⁸ Exploiting that opening, industry lawyers gathered, as two plaintiffs' lawyers put it, "every scrap of paper ever generated about a plaintiff, from cradle to grave."⁴⁹ They also subjected plaintiffs—as well as a battery of the plaintiffs' friends, neighbors, associates, and far-flung acquaintances—to lengthy and invasive pretrial depositions.⁵⁰ There, the plaintiffs' education, employment, health history, personal hygiene, eating habits, personality traits, risk tolerance, and religious practices, as well as the strength (or weakness) of their familial bonds and relationships, were subjected to unsparing scrutiny.⁵¹

Further skewing this imbalance was the fact that even as they tendered broad and invasive discovery on plaintiffs (deposing, as one lawyer put it, "anyone and everyone remotely connected" to the case), defendants refused to reciprocate.⁵² They stonewalled rather than answer even simple and straightforward questions,⁵³ hid behind exaggerated (or wholly manufactured)

48. *See id.* at 858-59 (describing how tobacco companies put plaintiffs on trial).

49. Townsley & Hanks, *supra* note 45, at 277.

50. *Id.* app. A at 297 ("Defendants deposed anyone and everyone remotely connected with Plaintiff, including childhood friends, former spouses, former spouses of family members, neighbors and store owners in the neighborhood where Plaintiff lived." (quoting statement of Paul M. Monzione)); Sara D. Guardino & Richard A. Daynard, *Punishing Tobacco Industry Misconduct: The Case for Exceeding a Single Digit Ratio Between Punitive and Compensatory Damages*, 67 U. PITT. L. REV. 1, 53 (2005) (quoting a Jones Day memorandum that advised lawyers to take "extensive depositions of plaintiffs and their family members, friends, neighbors and business associates," among others); Gray, *supra* note 45 (describing the "grill[ing]" of "present and former neighbors, co-workers, supervisors, school chums, family physicians and others").

51. *See, e.g.*, Gray, *supra* note 45 (profiling one plaintiff who dropped the lawsuits she had initiated because "she could no longer stand grueling interrogations by the tobacco-company lawyers, who spent days grilling her on such topics as her infertility and her adopted son's suicide"); David Margolick, *Antismoking Climate Inspires Suits by the Dying*, N.Y. TIMES, Mar. 15, 1985, at B4 (describing the deposition of Rose Cipollone, which lasted "for four days, on issues ranging from whether she bit her fingernails to the date her father-in-law died"); Brief for Appellant at 21 & n.10, *Haines v. Liggett Grp., Inc.*, No. 93-5060 (3d Cir. Mar. 25, 1993) (recounting that, in *Cipollone v. Liggett Group, Inc.*, the plaintiff's expert, Dr. Harris, was subjected to a deposition that lasted for twelve days); *see also* Gray, *supra* note 45 ("Marriages, job histories, personal hygiene, eating habits and even churchgoing practices come under scrutiny."); Townsley & Hanks, *supra* note 45, at 287 (describing exhaustive investigations into the plaintiffs' lives and lifestyles).

52. Townsley & Hanks, *supra* note 45, app. A at 297 (quoting statement of Paul M. Monzione).

53. *See Thayer v. Liggett & Myers Tobacco Co.*, No. 5314, 1970 U.S. Dist. LEXIS 12796, at *6 (W.D. Mich. Feb. 19, 1970) (noting the defendant's "attempt to impede otherwise proper discovery"); Townsley & Hanks, *supra* note 45, app. A at 303 ("[N]o tobacco company will answer even simple questions such as its structure, corporate history, or insurance coverage." (quoting statement of George W. Kilbourne)).

claims of attorney-client privilege,⁵⁴ and made it “extremely difficult to take any depositions of corporate personnel.”⁵⁵ When discovery *was* obtained, it was subject to broad, court-imposed protective orders, which prevented plaintiffs’ counsel (who were typically cash-strapped solo practitioners) from sharing the fruits of discovery with one another.⁵⁶ By requiring each plaintiff to start from scratch and “reinvent the wheel,” these protective orders “increase[d] the cost enormously.”⁵⁷

The roughly two-dozen claims that managed to run this gauntlet and make it to the courthouse fared no better.⁵⁸ When cases were tried, defendants—who disputed the plaintiffs’ scientific evidence and drew on deeply ingrained cultural norms of individual responsibility—very often prevailed.⁵⁹ And when the rare plaintiff managed to defy the odds and actually win, the victories were fleeting.

On this score, the well-known wrongful death action *Cipollone v. Liggett Group, Inc.* is illustrative.⁶⁰ Filed in 1983, *Cipollone* ping-ponged around the

54. Michael V. Ciresi, Roberta B. Walburn & Tara D. Sutton, *Decades of Deceit: Document Discovery in the Minnesota Tobacco Litigation*, 25 WM. MITCHELL L. REV. 477, 499-500 (1999).

55. Townsley & Hanks, *supra* note 45, app. A at 294 (quoting statement of Daniel G. Childs).

56. Marc Z. Edell, *Cigarette Litigation: The Second Wave*, 22 TORT & INS. L.J. 90, 91 (1986) (“[P]rotective orders, obtained by the defendants in almost every instance, prohibited the dissemination of discovery to either the public or to other lawyers who were involved in similar litigation.”). For more on the plaintiffs’ lawyers’ limited resources, see note 73 and the accompanying text below.

57. Townsley & Hanks, *supra* note 45, at 277, app. A at 303 (quoting statement of George W. Kilbourne); see also, e.g., *Thayer*, 1970 U.S. Dist. LEXIS 12796, at *13 (finding that the expansive protective order “effectively throttled” what might have otherwise been “[f]ruitful consultation between plaintiff’s attorneys with similar cases”); *id.* at *16 (observing that “the court was witness to a spectacle wherein defendant, rich in resources, maintained complete freedom of association and consultation, . . . while plaintiff’s counsel, already disadvantaged by the limited resources available . . . were prohibited from doing likewise by a blanket protective order obtained by defendant early in the case on grounds which later proved largely illusory”).

58. See Myron Levin, *Smoking’s Big Guns*, L.A. TIMES (Dec. 15, 1996), <https://perma.cc/MEL3-NRBU> (reporting that, as of December 1996, the industry had “flicked away hundreds of damage lawsuits while going to trial but 21 times”); RJR Memo, *supra* note 38, at 7-8 (reporting that, between 1954 and 1980, “only 8 cases went to trial; the vast majority were dismissed for one reason or another before trial”). Of these, some cases were dropped prior to a final verdict. Rabin, *supra* note 27, at 860.

59. At trial, the tobacco companies leaned heavily on an assumed-risk defense (essentially, “you knew that smoking could cause cancer”), even though that defense, logically, fit uncomfortably with the industry’s concurrent denial of general causation. For a discussion, see Gary T. Schwartz, *Tobacco Liability in the Courts*, in SMOKING POLICY, *supra* note 38, at 131, 131-60; and DONALD G. GIFFORD, *SUING THE TOBACCO AND LEAD PIGMENT INDUSTRIES: GOVERNMENT LITIGATION AS PUBLIC HEALTH PRESCRIPTION* 40-41 (2010).

60. 505 U.S. 504 (1992).

court system for nearly a decade.⁶¹ But, after a four-month trial (where damages of \$400,000 were awarded), various appeals, a mostly successful trip to the Supreme Court (involving preemption and discussed in more detail below), and just months before a scheduled retrial in Newark, New Jersey, the plaintiff voluntarily dropped the case.⁶² Why? According to her lawyer, the litigation—which had already outlived the initial plaintiff and involved the out-of-pocket expenditure of more than \$500,000, to say nothing of attorney time—“had become a financial drag.”⁶³

The upshot: By the early 1990s, it appeared that forty years of hard-fought litigation had effectively come to naught, foundering on a massive imbalance in litigation resources and the hostile cultural norms of the public.⁶⁴

C. Aggregating Claims

But then, the ground shifted. Beginning in 1993, whistleblowers released internal industry documents that revealed the tobacco companies’ longstanding efforts to manipulate nicotine, suppress information about the

61. See KLUGER, *supra* note 18, at 655-77 (describing *Cipollone’s* circuitous path through the court system); Brief for Appellant, *supra* note 51, at 6-7 (same).

62. See KLUGER, *supra* note 18, at 674-77.

63. According to the *Cipollone’s* lawyer, Marc Edell, his firm ultimately decided “enough is enough.” *Suit Against Cigarette Maker Dropped; Family Requests Dismissal After Lawyers Back Out*, BALT. SUN (Nov. 6, 1992), <https://perma.cc/UG54-4W4Q>. Lest the broader lesson be lost, as news of the decision broke, counsel for Philip Morris boasted: “I think this sends a message that these cases are very difficult and very expensive to try.” *Cipollone Family Drops Landmark Cigarette Suit*, WASH. POST (Nov. 5, 1992), <https://perma.cc/QPL3-WRY2> (quoting Charles Wall, corporate counsel at Philip Morris).

Pritchard v. Liggett & Myers Tobacco Co., initially filed on October 30, 1954, met a similar fate. See 295 F.2d 292 (3d Cir. 1961); see also *Pritchard v. Liggett & Myers Tobacco Co.*, 134 F. Supp. 829, 830 (W.D. Pa. 1955) (providing filing date). There, the plaintiff, Otto Pritchard, battled Liggett for more than a decade, over the course of two trials and two trips to appellate courts. But, as his case was scheduled for trial for a third time, the plaintiff opted to surrender. KLUGER, *supra* note 18, at 281-82; Rabin, *supra* note 27, at 862; see also, e.g., *Haines v. Liggett Grp., Inc.*, 814 F. Supp. 414, 418 (D.N.J. 1993) (considering the law firm’s motion to withdraw as plaintiff’s counsel because litigation costs—which exceeded \$5 million—had become unmanageable); Edell, *supra* note 56, at 91 (describing “many voluntary dismissals” sought because plaintiffs’ counsel could not withstand the “extraordinary financial burden[]” of endless trials, appeals, and retrials).

64. See Michael McCann, William Haltom & Shauna Fisher, *Criminalizing Big Tobacco: Legal Mobilization and the Politics of Responsibility for Health Risks in the United States*, 38 LAW & SOC. INQUIRY 288, 292 (2013) (explaining that “[e]very one” of hundreds of first-wave lawsuits “failed due to corporate defense strategies disputing scientific evidence and trumpeting individual responsibility for assumed risk”).

health risks of smoking, and target their ads to children and adolescents.⁶⁵ The following year, plaintiffs' lawyers mounted two litigation attacks that seized—and built—on those developments.

The opening volley came in March 1994 in *Castano v. American Tobacco*.⁶⁶ Filed in the Eastern District of Louisiana on behalf of some 90 million claimants, the action staked a claim as “the largest class action ever attempted in federal court.”⁶⁷

Castano represented a sharp break with prior tobacco litigation. This difference was most obviously evident in *Castano's* massive size, ambitious scope, and *aggregate*—rather than *individualized*—orientation. But two other differences were just as important.

First, *Castano's* basic conception broke sharply with prior cases. Whereas prior cases had sought compensatory and sometimes punitive damages for smokers' personal injuries or wrongful deaths, *Castano* focused, instead, on *addiction*.⁶⁸ The named plaintiffs were smokers (plus the widow of one) who had unsuccessfully tried to quit smoking.⁶⁹ They sought the certification of a class comprised of similarly addicted persons.⁷⁰ And for that class, they sought funds to cover the costs of smoking cessation, alongside medical monitoring (to identify health problems early, before they progressed), and the creation of a fund to research efforts to treat and cure nicotine addiction.⁷¹ At bottom, plaintiffs alleged that the cigarette companies collectively “concealed their knowledge that nicotine is addictive” and “manipulated the levels of nicotine in cigarettes to keep customers hooked.”⁷² Among other virtues, this focus on

65. PRINGLE, *supra* note 24, at 75, 194-206; Bruce Schreiner, *Merrell Williams Jr., Kentucky Paralegal Who Became Tobacco Whistleblower, Dies at 72*, WASH. POST (Nov. 27, 2013), <https://perma.cc/4WP3-A2NL>.

66. *Castano v. Am. Tobacco Co.*, 160 F.R.D. 544 (E.D. La. 1995), *rev'd*, 84 F.3d 734 (5th Cir. 1996). For the filing date, see Glenn Collins, *Huge Tobacco Lawsuit Is Thrown Out on Appeal*, N.Y. TIMES (May 24, 1996), <https://perma.cc/TF4Z-Z538>.

67. See *Castano*, 84 F.3d at 737. For the 90 million claimants figure, see Glenn Collins, *A Tobacco Case's Legal Buccaneers*, N.Y. TIMES (Mar. 6, 1995), <https://perma.cc/C3GJ-DSL5>. More colloquially, the case was dubbed the “Mother of All Lawsuits.” PRINGLE, *supra* note 24, at 6. For a detailed discussion of *Castano*, including its many twists and turns, see Robert L. Rabin, *The Tobacco Litigation: A Tentative Assessment*, 51 DEPAUL L. REV. 331, 333-34 (2001).

68. *Castano*, 84 F.3d at 737 (“The plaintiffs filed this class complaint . . . seeking compensation solely for the injury of nicotine addiction.” (footnote omitted)).

69. Elizabeth J. Cabraser, *The Road Not Taken: Thoughts on the Fifth Circuit's Decertification of the Castano Class*, SB24 A.L.I.-A.B.A. 433, 439 (1996).

70. *Castano*, 84 F.3d at 737 (offering the class definition).

71. Cabraser, *supra* note 69, at 439.

72. Collins, *supra* note 67; see also *Castano v. Am. Tobacco Co.*, 160 F.R.D. 544, 548 (E.D. La. 1995) (summarizing the plaintiffs' allegations).

addiction—not injury—expanded the size of the class and permitted the plaintiffs to dodge tricky questions concerning general and specific causation.

Second, the sophistication and resources of plaintiff-side counsel were also night-and-day, as compared to prior efforts. Whereas prior cases had mostly been filed by inexperienced solo practitioners who were easily overwhelmed, *Castano* was a joint undertaking of roughly sixty of the nation’s leading plaintiffs’ firms, many of which had developed relevant know-how (and also amassed massive war chests) in the asbestos litigation of the 1980s.⁷³ To get *Castano* off the ground, the firms each chipped in \$100,000, and this unprecedented cooperation and financial coordination meant that, for the first time, plaintiffs could go toe-to-toe with their historically far-better-heeled adversaries.⁷⁴

The gambit worked in the district court, as, after months of intense discovery and several rounds of pretrial briefing, the trial court certified the class, concluding that the prerequisites of Federal Rule of Civil Procedure 23(b)(3) were satisfied.⁷⁵ But the victory was short-lived. In 1996, a unanimous panel of the Fifth Circuit reversed, holding that variations in state law—and the vexing choice-of-law problems those variations would invariably generate—eclipsed the “predominance” that Rule 23(b)(3) requires.⁷⁶ The day after the Fifth Circuit’s opinion came down, tobacco stocks soared, and R.J. Reynolds declared that the decision sent “a strong message that class actions created by entrepreneurial plaintiffs’ lawyers will not be accepted by the courts.”⁷⁷

Such celebrations and prognostications, though, were premature, for just as *Castano* was winding down, another case—which was, in retrospect, far more consequential—was gearing up.⁷⁸

73. See Rabin, *supra* note 27, at 858, 860 (describing the early plaintiffs’ lawyers as “lone wolves” who were “outmanned and outgunned”); Howard M. Erichson, *The End of the Defendant Advantage in Tobacco Litigation*, 26 WM. & MARY ENV’T L. & POL’Y REV. 123, 126, 129-31 (2001) (explaining that, “[i]n the early years of tobacco litigation,” plaintiffs’ lawyers were consistently “outgunned”).

74. See Erichson, *supra* note 73, at 129-31. For more on the *Castano* plaintiffs’ lawyers, see PRINGLE, *supra* note 24, at 13-15; Collins, *supra* note 67; and Glenn Collins, *Legal Titans Square Off in Big Tobacco Lawsuit*, N.Y. TIMES (Dec. 15, 1994), <https://perma.cc/L2XR-GM6B>.

75. *Castano*, 160 F.R.D. at 552-58.

76. *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 734, 740 (5th Cir. 1996). The Fifth Circuit also concluded that the trial court’s “predominance inquiry did not include consideration of how a trial on the merits would be conducted.” *Id.* at 740.

77. Collins, *supra* note 66 (reporting that “[t]he long-awaited appeals court decision . . . sent the stocks of tobacco companies soaring”); PRINGLE, *supra* note 24, at 262 (offering the R.J. Reynolds quotation).

78. In the aftermath of that ruling, plaintiffs fanned out to file “son of *Castano*” class actions in state and federal courts throughout the country. See PRINGLE, *supra* note 24, at 249; *footnote continued on next page*

Two months after *Castano's* initiation, on May 23, 1994, a groundbreaking venture was filed in the Chancery Court of Jackson County, Mississippi: a state health care reimbursement claim initiated by the state's attorney general, Mike Moore, seeking to recoup the millions the state had spent treating sick smokers.⁷⁹ Like *Castano*, Mississippi's suit was innovative, was seeking an eye-popping sum, and was spearheaded by plaintiffs' lawyers with adequate funds

Cabraser, *supra* note 69, at 451-52, 451 n.18. But these “son of *Castano*” suits saw little success. See Erichson, *supra* note 73, at 138-39.

Engle v. Liggett Group, Inc., a personal injury class action that was filed contemporaneously with *Castano*, merits a separate discussion. See 945 So. 2d 1246, 1256 (Fla. 2006) (per curiam). Filed in Florida state court, *Engle* sought the certification of a nationwide class comprised of those “who have suffered, presently suffer, or who have died from diseases and medical conditions caused by smoking cigarettes that contain nicotine.” Richard A. Daynard & Mark Gottlieb, *Tobacco Class Actions Fire Up*, TRIAL, Nov. 2001, at 18, 19 (quoting the First Amended Complaint in *Engle*). Plaintiffs prevailed on their ambitious certification motion, although the class was eventually narrowed to include not all Americans but, rather, only citizens and residents of the Sunshine State. *Id.*

After certification, *Engle* was tried and resulted in a verdict of \$12.7 million in compensatory damages and \$144.8 billion in punitive damages. Rabin, *supra* note 8, at 1735 n.51. But, after a circuitous route on appeal, the blockbuster verdict was vacated by the Florida Supreme Court. *Engle*, 945 So. 2d at 1254. While vacating the judgment, however, the court simultaneously held that future plaintiffs within the class could proceed individually, and that key findings from the prior trial—that smoking causes certain diseases, that nicotine is addictive, and that the defendants tortiously concealed information about the health effects of smoking—“will have res judicata effect in those [individual] trials.” *Id.* at 1257 n.4, 1269. As a consequence, so-called “*Engle*-progeny” claimants could bring individual suits without relitigating these core issues.

Not surprisingly, defendants appealed the res judicata findings. Many rounds ensued, but, in *Philip Morris USA, Inc. v. Douglas*, 110 So. 3d 419, 436 (Fla. 2013), the Florida Supreme Court eventually rejected the defendants' objections, and the U.S. Supreme Court subsequently denied certiorari, see *Philip Morris USA Inc. v. Jordan*, 139 S. Ct. 1261 (2019) (mem.).

As of October 2018, tobacco companies reported that they faced 2,300 pending *Engle*-progeny lawsuits and that they “had already paid judgments totaling more than \$800 million.” Petition for a Writ of Certiorari at 4, 11, *Jordan*, 139 S. Ct. 1261 (No. 18-551), 2018 WL 5437861. As of July 2019, out of 258 cases tried, there was a 50-50 split with 102 plaintiff verdicts, 102 defense verdicts, and 54 mistrials. See Email from Mark Gottlieb, Exec. Dir., Pub. Health Advoc. Inst., Northeastern Univ. Sch. of L., to Robert L. Rabin, A. Calder Mackay Professor of L., Stanford L. Sch. (July 30, 2019) (on file with authors); see also Altria Grp., Inc., Annual Report (Form 10-K), item 8, at 87 (Feb. 25, 2020) (reporting that, as of January 2020, 134 *Engle*-progeny cases involving Philip Morris had been tried, and, of those, “[s]eventy-seven verdicts were returned in favor of plaintiffs and six verdicts . . . that were initially returned in favor of plaintiffs were reversed post-trial or on appeal and remain pending”). For more on *Engle*, see generally Daynard & Gottlieb, *supra*, at 18; and J.B. Harris, *Engle v. Liggett: Has Big Tobacco Finally Met Its Match?*, FLA. BAR J., Nov. 2012, at 17.

79. Michael Janofsky, *Mississippi Seeks Damages from Tobacco Companies*, N.Y. TIMES (May 24, 1994), <https://perma.cc/QDG9-XY3F>; Rabin, *supra* note 8, at 1735 & n.52 (describing the “pioneering venture”).

and ample expertise. Indeed, rather than litigating the cases in-house, Mississippi and the other states that followed in its footsteps entered into contingency-fee contracts with experienced plaintiff-side attorneys.⁸⁰

But Moore's brainchild was, in many ways, distinct from *Castano*.⁸¹ Most importantly, the suit was not based on product liability law, since the state, of course, had never purchased cigarettes, had never smoked, and, logically, couldn't fall ill.⁸² Instead, Mississippi sought relief on equitable grounds, asserting that the industry's deceptive and misleading conduct constituted a wrong *against the public* as well as against those who actually smoked.⁸³ Mississippi thus sought to recoup the public funds that it had spent treating impoverished smokers. As Moore put it: "While I cannot bring [deceased smokers] back, . . . I can spare Mississippi taxpayers from paying medical bills that are the tobacco companies' responsibility."⁸⁴

The theory was novel, and the claim that the state's interest was independent of, and distinct from, the interest of an individual smoker was wholly untested.⁸⁵ But, tested or not, the idea caught on. In the months and then years that followed, state after state followed Mississippi's lead.⁸⁶ As they did, theories of recovery swelled, ultimately coming to include claims for civil conspiracy, fraud, public nuisance, and deceptive marketing, alongside claims that the defendants had run afoul of numerous state and federal statutes including the civil Racketeer Influenced and Corrupt Organizations (RICO) Act, the Sherman Act, and a bevy of consumer-protection laws.⁸⁷

80. See CURTIS WILKIE, *THE FALL OF THE HOUSE OF ZEUS: THE RISE AND RUIN OF AMERICA'S MOST POWERFUL TRIAL LAWYER* 58-59 (2010) (describing the public-private partnership); Michael L. Rustad, *Smoke Signals from Private Attorneys General in Mega Social Policy Cases*, 51 DEPAUL L. REV. 511, 518-20, 523-24, 527 (2001).

81. Moore actually gives his law school classmate, Mike Lewis, credit for the initial idea. See Debbie Elliott, *What Has Changed Since the Tobacco Settlement?*, NPR (Nov. 16, 2008, 3:38 PM ET), <https://perma.cc/RL5U-YKQ5>.

82. Rabin, *supra* note 67, at 337 (explaining this distinction).

83. "A similar theory, wrongfully profiting at the expense of the public, undergirded claims of conspiracy and consumer fraud, particularly those targeted against industry tactics aimed at making smoking attractive to underage youths." *Id.*

84. Janofsky, *supra* note 79 (quoting Moore).

85. See Rabin, *supra* note 67, at 337 ("[T]hese theories were largely untested, and the claim that the state's interest was independent of and distinct from the individual smoker's generally rested on a shaky foundation.").

86. After Mississippi filed suit, Minnesota, Florida, West Virginia, and Massachusetts were next in line. *Massachusetts Files Suit Against Tobacco Industry*, N.Y. TIMES (Dec. 20, 1995), <https://perma.cc/H723-HPRK>. Like dominoes falling, by the summer of 1997, the vast majority of states had opted to initiate claims. Rabin, *supra* note 67, at 338.

87. See Rabin, *supra* note 67, at 337-38, 337 n.30 (sketching the relevant causes of action).

The claims were also sufficiently robust to survive pretrial skirmishes.⁸⁸ This was crucial, for once the claims survived motions to dismiss, plaintiffs were entitled to discovery—and once discovery commenced, the companies' many secrets spilled out. The resulting picture was devastating. Among other stratagems, the discovery process revealed that the industry had supported research designed to spread disinformation about the hazards of smoking, manipulated cigarettes' nicotine content, and specifically cultivated children, adolescents, and teens as "replacement" smokers (waiting in the wings, once the current crop of users expired).⁸⁹ Documents also underscored the extent to which the industry's public statements, which had for so long denied or minimized the hazards of smoking, were recklessly made and incontrovertibly false.⁹⁰

Ultimately, facing the unpredictability of litigation, spiraling legal fees, anxious shareholders, and an unrelenting drumbeat of negative publicity, the industry blinked.⁹¹ Initially, the parties considered an ambitious \$368.5 billion global settlement agreement, which would have given the industry broad immunity from future class action suits, and, in return, increased cigarettes taxes, subjected nicotine to regulation by the Food and Drug Administration (FDA), and created firm targets for curtailing underage smoking, among other restrictions.⁹² But that agreement required congressional approval, and efforts to obtain that approval stalled.⁹³ Undeterred, the parties forged ahead to make private peace.

Beginning in July 1997, the four major tobacco companies (Brown & Williamson, Lorillard, Philip Morris, and R.J. Reynolds) settled serially with the four states (Mississippi, Florida, Texas, and Minnesota) that were closest to trial.⁹⁴ (Indeed, the settlement with Minnesota came *during* trial, in the midst

88. Henry Weinstein & Jack Nelson, *Untested Theory Becoming Tobacco Firms' Top Threat*, L.A. TIMES (Aug. 4, 1996), <https://perma.cc/F4NQ-VXL5> (noting that, in 1995, judges in Mississippi and Minnesota denied defendants' motions to dismiss).

89. See Barry Meier, *Remaining States Approve the Pact on Tobacco Suits*, N.Y. TIMES (Nov. 21, 1998), <https://perma.cc/7G8V-YNK8>; Appellee's Answer Brief, Cross-Appeal Initial at 3-4, 7-12, Philip Morris USA Inc. v. Skolnick, 171 So. 3d 747 (Fla. Dist. Ct. App. 2015) (No. 4D13-4696), 2014 WL 5881848.

90. See Rabin, *supra* note 67, at 339 (describing the release of previously secret documents which "told a tale of industry deceit and indifference to public health considerations").

91. See PRINGLE, *supra* note 24, at 9, 230, 281 (discussing the contemporaneous stresses on the industry, including legal fees that exceeded \$600 million per year).

92. Rabin, *supra* note 67, at 338-41, 338 n.34 (describing the initial agreement, which ultimately grew in size and ambition, before collapsing under its own weight).

93. See BRANDT, *supra* note 20, at 427-29.

94. Fittingly, Mississippi forged the first settlement, pocketing \$3.4 billion over twenty-five years. The settlement was reached less than a week before the state's trial was set to commence. Barry Meier, *Acting Alone, Mississippi Settles Suit with 4 Tobacco Companies*, *footnote continued on next page*

of the parties' closing arguments.⁹⁵) To these states, tobacco companies shelled out some \$40 billion, to be paid out over twenty-five years.⁹⁶ Within a year, in November 1998, the companies and the forty-six remaining states negotiated a \$206 billion MSA of all outstanding health care reimbursement claims.⁹⁷

D. Individual Claims Revived

Meanwhile, in 1996, as the state claims were being contested, a personal injury lawsuit in Florida—*Carter v. Brown & Williamson Tobacco Corp.*, brought on behalf of a former air-traffic controller who lost half of a lung to cancer—

N.Y. TIMES (July 4, 1997), <https://perma.cc/2ZEW-3N5Q>. Liggett, which controlled just 2% of the U.S. market, had settled previously, on March 20, 1997. As part of that settlement, the states dropped their claims and, in return, Liggett agreed to relinquish 25% of its annual pretax income over the next twenty-five years, turn over incriminating documents (including, controversially, notes Liggett lawyers had taken while attending joint legal defense meetings with other companies' lawyers), and, going forward, label all its cigarette packages with a warning that "smoking is addictive." See MOLLENKAMP ET AL., *supra* note 30, at 57, 120; PRINGLE, *supra* note 24, at 242-44.

95. Pam Belluck, *Tobacco Companies Settle a Suit with Minnesota for \$6.5 Billion*, N.Y. TIMES (May 9, 1998), <https://perma.cc/DFW6-J5TH>.

96. Rabin, *supra* note 67, at 340.

97. Rabin, *supra* note 8, at 1737; BRANDT, *supra* note 20, at 432-34; *46 States and Territories Approve Settlement with Tobacco Companies: The States' Settlement*, 14 ANDREWS TOBACCO INDUS. LITIG. REP., Jan. 1999, at 3, 3 (noting that the MSA was also signed by Washington, D.C., and five territories).

One additional government action merits attention: In 1999, the federal government brought a massive civil RICO case against the industry. Centered on claims that the companies had conspired to deceive the American public about the dangers of smoking, the case initially sought to recoup the roughly \$289 billion the federal government had spent over the years on smoking-related care for Medicare patients, federal employees, and veterans. Marc Lacey, *Tobacco Industry Accused of Fraud in Lawsuit by U.S.*, N.Y. TIMES (Sept. 23, 1999), <https://perma.cc/W9H2-6RXF>; *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 32 (D.D.C. 2006), *aff'd in part and vacated in part per curiam*, 566 F.3d 1095 (D.C. Cir. 2009). The action was significantly narrowed, though, when a divided panel of the D.C. Circuit ruled that RICO authorizes only "forward-looking remedies"—and effectively took disgorgement off the table. *United States v. Philip Morris USA, Inc.*, 396 F.3d 1190, 1197-98 (D.C. Cir. 2005). Undeterred, the federal government pressed on, and in September 2004, the federal case made its way to trial, which was, itself, a nine-month marathon featuring some 14,000 exhibits and testimony from more than 200 witnesses. *Philip Morris USA Inc.*, 566 F.3d at 1106. At the trial's end, Judge Gladys Kessler of the D.C. District Court penned a blistering 1,742-page judgment. Among other things, that judgment branded the tobacco companies racketeers, found that they had engaged in mail and wire fraud, barred them from misrepresenting cigarettes' health and safety profile, barred them from packaging cigarettes as "low tar" or "light," and compelled them to disseminate certain corrective statements. *Philip Morris USA, Inc.*, 449 F. Supp. 2d at 851, 923-45.

finally broke the industry's forty-year winning streak.⁹⁸ At the time, some greeted Carter's victory (of \$750,000 in compensatory damages) by declaring that the case marked a decisive shift in litigant strategy and juror sentiment.⁹⁹ But the actual picture has been murkier.

In the decade immediately following *Carter*, numerous plaintiffs asserted individual claims. But it was more trickle than torrent—and, for plaintiffs, results were mixed.¹⁰⁰ Some notched impressive trial court victories, and some of these successes, such as *Henley v. Philip Morris, Inc.*,¹⁰¹ *Boeken v. Philip Morris, Inc.*,¹⁰² and *Williams v. Philip Morris Inc.*,¹⁰³ mostly survived the appellate process. But at least half went down in defeat.¹⁰⁴ Underscoring plaintiffs' long odds and hard road: As of January 2007, experts reported that “[d]efendants have paid judgments in just six individual smoking and health lawsuits ever.”¹⁰⁵

Over the past decade, this trend has endured.¹⁰⁶ Apart from the more than 250 *Engle*-progeny trials in Florida (which, via *res judicata*, are simplified in key respects¹⁰⁷), there have been roughly a dozen cases tried to verdict, mostly

98. See Rabin, *supra* note 67, at 331, 344; Rabin, *supra* note 8, at 1741; Brown & Williamson Tobacco Corp. v. Carter, 680 So. 2d 546 (Fla. Dist. Ct. App. 1996) (per curiam); *Grady Carter*, PBS: FRONTLINE, <https://perma.cc/XE9B-WK87> (archived Jan. 27, 2021).

99. E.g., Suein L. Hwang, Milo Geyelin & Alix M. Freedman, *Jury's Decision Stuns Industry; Verdict Sinks Tobacco Stocks*, WALL ST. J. (Aug. 12, 1996, 11:37 AM ET), <https://perma.cc/68ND-N6HP> (to locate, click “View the live page”) (quoting Michael Pertschuk as stating that the *Carter* verdict demonstrated that “[t]he climate of opinion, as reflected by how juries are prepared to vote, has shifted”).

100. See Rabin, *supra* note 8, at 1741-42 (describing filing trends and win rates); Daynard & Gottlieb, *supra* note 78, at 22 (reporting that, between 1998 and 2001, “about 30 percent of verdicts handed down in [tobacco] cases involving individual claims were in favor of plaintiffs”).

101. 9 Cal. Rptr. 3d 29 (Ct. App. 2004); Patrick Luff, *Regulating Tobacco Through Litigation*, 47 ARIZ. ST. L.J. 125, 152-53 (2015) (discussing *Henley*).

102. 26 Cal. Rptr. 3d 638, 645, 687 (Ct. App. 2005) (reducing punitive damages to \$50 million, where the jury had initially awarded \$3 billion).

103. 176 P.3d 1255, 1257-58 (Or. 2008) (reinstating the plaintiff's award of nearly \$80 million in punitive damages).

104. See *supra* note 100.

105. Brief of Amici Curiae Tobacco Control Health Resource Center Division of the Public Health Advocacy Institute, Inc. & the Tobacco Control Legal Consortium in Support of Respondents at 2, *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008) (No. 06-4666), 2007 WL 5613807.

106. As of December 2018, for example, approximately 111 non-*Engle*, individual tobacco cases were pending in the United States against R.J. Reynolds, Lorillard, and Brown & Williamson, combined. BRIT. AM. TOBACCO, TRANSFORMING TOBACCO: ANNUAL REPORT AND FORM 20-F 2018, at 193, 198 (n.d.), <https://perma.cc/9VV8-H2MD>.

107. In *Engle*-progeny cases, a plaintiff need not individually prove that smoking causes disease, that cigarettes are addictive and unreasonably dangerous, and that defendants

footnote continued on next page

in Massachusetts, and, as before, the scorecard is split.¹⁰⁸ Plaintiffs surely fare better than they did in the first forty years of tobacco litigation, and the occasional large verdict even makes news.¹⁰⁹ But, as we explain in more detail in Part IV.B.1 below, even buoyed by damning documents and aided by attorneys who are now better capitalized and more sophisticated than the outmatched advocates of the earlier era,¹¹⁰ smokers' cases continue to be vigorously defended, and litigation against the tobacco industry remains risky, expensive, and time-consuming.¹¹¹

II. Opioid Litigation

A. The Early Days: "OxyContin Is Our Ticket to the Moon"¹¹²

The early history of opioid abuse in the United States is, by now, fairly well known.¹¹³ With great fanfare, Purdue Pharma sought and obtained approval for OxyContin in late 1995.¹¹⁴ At the time, it was "heralded as a

obscured cigarettes' health effects. *Engle v. Liggett Grp., Inc.*, 945 So. 2d 1246, 1276-77 (Fla. 2006). For more on *Engle*, see note 78 above.

108. This data—on file with the authors—was generously supplied by Mark Gottlieb of the Public Health Advocacy Institute.
109. *E.g.*, Emily Field, *11th Circ. Won't Undo \$41 M Verdict for Engle Smoker*, LAW360 (Mar. 24, 2020, 9:27 PM EDT), <https://perma.cc/4KH4-TUYG> (to locate, click "View the live page") (involving an *Engle*-progeny suit in Florida); Daniel Siegal, *RJ Reynolds Hit with \$12.5M Verdict in Widow's Engle Trial*, LAW360 (Feb. 19, 2020, 2:48 PM EST), <https://perma.cc/7KGJ-WS2C> (to locate, click "View the live page") (same); Jack Queen, *RJR, Philip Morris Owe \$157M to Smoker's Widow, Jury Says*, LAW360 (Nov. 15, 2019, 10:00 PM EST), <https://perma.cc/9XYB-8NBF> (to locate, click "View the live page") (same); Daniel Siegal, *Philip Morris Hit with \$9.6M Verdict in Mass. Smoker's Trial*, LAW360 (Sept. 27, 2019, 6:45 PM EDT), <https://perma.cc/W3MZ-GY6L> (to locate, click "View the live page") (involving a Massachusetts lawsuit); Chris Villani, *RJ Reynolds Hit with \$300K Verdict in \$45M Cancer Trial*, LAW360 (Feb. 4, 2019, 2:55 PM EST), <https://perma.cc/T8CM-D5GJ> (to locate, click "View the live page") (same).
110. For these shifts in financing, sophistication, specialization, and firm size, see Stephen C. Yeazell, *Re-financing Civil Litigation*, 51 DEPAUL L. REV. 183, 199-200, 207, 216-17 (2001). For how plaintiffs now can draw on the damning documents unearthed in the state litigation, see Daynard & Gottlieb, *supra* note 78, at 18.
111. According to the Altria Group, apart from the *Engle*-progeny cases, sixty-eight tobacco-related suits against Philip Morris went to verdict from 1999 to December 2019, roughly three per year. Altria Grp., Inc., *supra* note 78, item 8, at 85. Of those, Philip Morris prevailed forty-four times, achieving a win rate of 65%. *Id.*
112. BARRY MEIER, PAIN KILLER: AN EMPIRE OF DECEIT AND THE ORIGIN OF AMERICA'S OPIOID EPIDEMIC 41 (2d ed. 2018) (capitalization altered) (quoting Raymond Sackler, a founder of Purdue Pharma).
113. As journalist Barry Meier aptly put it: "Every catastrophe, natural or man-made, has a beginning. For the opioid crisis, the seed was a drug called OxyContin." *Id.* at xi.
114. Phillip J. Wininger, Note, *Pharmaceutical Overpromotion Liability: The Legal Battle over Rural Prescription Drug Abuse*, 93 KY. L.J. 269, 269 (2004); Patrick Radden Keefe, *The* footnote continued on next page

‘wonder’ drug that would change how pain, mankind’s oldest and most persistent medical enemy, was treated.”¹¹⁵ To be sure, OxyContin’s sole active ingredient—oxycodone—was not new. Twice as powerful as morphine, oxycodone was initially synthesized in 1916.¹¹⁶ But OxyContin was nevertheless thought to represent a significant breakthrough over its predecessors—chiefly, Percocet, Percodan, and Tylox—in that it contained a novel time-release mechanism.¹¹⁷ This mechanism meant one pill would slowly and continuously release its oxycodone over time. (“Contin” was short for continuous.¹¹⁸) That, in turn, meant that one pill could contain a much larger dose of oxycodone than its conventional rivals and also provide relief over a longer period.¹¹⁹ This time-release mechanism was responsible for one more thing, too. 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.”¹²⁰

Family That Built an Empire of Pain, NEW YORKER (Oct. 23, 2017), <https://perma.cc/HFB5-CKNT>.

115. MEIER, *supra* note 112, at xi.

116. U.S. GEN. ACCT. OFF., GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 29 (2003) [hereinafter 2003 GAO REPORT], <https://perma.cc/4U8D-85VQ>; Keefe, *supra* note 114.

117. MEIER, *supra* note 112, at 8-9. Unlike its conventional rivals, OxyContin also did not contain an over-the-counter pain reliever, such as aspirin or acetaminophen. *Id.* at 8.

118. Keefe, *supra* note 114.

119. For more on the drug’s supposed advantage, see *id.*; Joseph B. Prater, Comment, *West Virginia’s Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U. L. REV. 1409, 1413 (2006); and 2003 GAO REPORT, *supra* note 116, at 8-9. In terms of OxyContin’s strength, the most potent Percocet pill contains ten milligrams of oxycodone (plus acetaminophen), whereas OxyContin contains up to eighty milligrams per pill. Sally Satel, *Painful Correction*, FORBES (Sept. 6, 2004), <https://perma.cc/8YGP-5SDZ>.

120. Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), <https://perma.cc/6926-NCGJ>. Reportedly, the FDA decision “was not based on findings from clinical trials, but a theory that drug abusers favored shorter-acting painkillers because the narcotic they contained was released faster and so produced a quicker ‘hit.’” *Id.* Even this untested claim wasn’t enough for Purdue, however. In 2007, the drugmaker admitted that it trained sales representatives to tell doctors that OxyContin was less addictive and less prone to abuse than its competitors, and going still further, at least one 1998 Purdue promotional video falsely boasted that the rate of addiction for opioid users treated by doctors is “much less than 1%.” Katherine Eban, *OxyContin: Purdue Pharma’s Painful Medicine*, FORTUNE (Nov. 9, 2011, 7:00 AM PST), <https://perma.cc/CK6H-9CYA> (to locate, click “View the live page”).

Whether true or not, the pitch—combined with Purdue’s extraordinarily aggressive marketing—worked.¹²¹ Within just a few years of its approval, OxyContin became the nation’s most prescribed Schedule II narcotic.¹²² Sales skyrocketed from \$45 million in 1996 to \$1.5 billion in 2002 and to almost \$3 billion in 2009.¹²³ Another way to measure it: By 2001, the drug accounted for 90% of Purdue’s total prescription sales, and physicians were writing over 7 million OxyContin prescriptions annually.¹²⁴

Even as sales were soaring, however, a storm was brewing. In time, doctors started to discover that, for many, OxyContin supplied only eight hours of pain relief, rather than the touted twelve—meaning many patients needed more OxyContin, more often, than initially thought.¹²⁵ Some patients who took relatively low doses were finding themselves hooked.¹²⁶ And, most ominously, many patients realized that they could crush the pills and then snort the dust or mix it with water and inject it, for not just the cessation of pain, but, rather, for an electric, heroin-like high.¹²⁷ Plaintiffs’ lawyers, and eventually prosecutors, took note.

121. For more on Purdue’s aggressive and often dishonest marketing efforts, see 2003 GAO REPORT, *supra* note 116, at 16-28; and *Evaluating the Propriety and Adequacy of the OxyContin Criminal Settlement: Hearing Before the S. Comm. on the Judiciary*, 110th Cong. 88-90 (2007) [hereinafter *2007 Senate Hearing*] (statement of John L. Brownlee, U.S. Attorney, Western District of Virginia).

122. Patrick O’Leary, *Credible Deterrence: FDA and the Park Doctrine in the 21st Century*, 68 FOOD & DRUG L.J. 137, 166 (2013). The Controlled Substances Act (CSA) classifies drugs into five schedules based on, among other things, their utility, danger, and potential for abuse. Schedule I drugs, such as heroin, have a high potential for abuse and dubious medicinal value and are thus unlawful; Schedule II drugs have the highest potential for abuse of any lawful drug; and Schedule III through V drugs present successively lower risks. See 2003 GAO REPORT, *supra* note 116, at 2 n.6; *Drug Scheduling*, U.S. DRUG ENF’T ADMIN., <https://perma.cc/4PUF-DNDK> (archived Jan. 27, 2021).

123. Eban, *supra* note 120.

124. 2003 GAO REPORT, *supra* note 116, at 9, 31 tbl.2.

125. The *Los Angeles Times* identified this problem in 2016, finding that OxyContin “wears off hours early in many people,” and when it does, “patients can experience excruciating symptoms of withdrawal, including an intense craving for the drug.” Harriet Ryan, Lisa Girion & Scott Glover, “You Want a Description of Hell?” *OxyContin’s 12-Hour Problem*, L.A. TIMES (May 5, 2016), <https://perma.cc/42HE-QVBL>. The investigation also revealed that “Purdue has known about the problem for decades. Even before OxyContin went on the market, clinical trials showed many patients weren’t getting 12 hours of relief.” *Id.*

126. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009); U.S. FOOD & DRUG ADMIN., FULL PRESCRIBING INFORMATION: OXYCONTIN § 5.1 (rev. 2016) (noting that addiction to Oxycontin can occur even “at recommended doses” and even “in patients appropriately prescribed Oxycontin” (capitalization altered)).

127. Francis X. Clines & Barry Meier, *Cancer Painkillers Pose New Abuse Threat*, N.Y. TIMES (Feb. 9, 2001), <https://perma.cc/4V5F-9D35> (explaining that by February 2001 some
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B. The First Wave: 2001 Through 2013

The first wave of opioid litigation dates from 2001 through 2013. It featured both individually initiated claims, which tended to founder, and government-initiated claims, which enjoyed modest success.

1. Individual claims

By all accounts, the first suit of the first wave was a wrongful death action filed against Purdue in Scioto County, Ohio, on April 25, 2001, on behalf of Jackie Renee Burton, a twenty-eight-year-old mother of two from McDermott, Ohio, who had died of an OxyContin overdose on April 25, 1999.¹²⁸ Mostly targeting Purdue, these early suits were, like Burton's, generally straightforward: Plaintiffs, who were typically coping with and seeking compensation for addiction or the loss of a loved one, alleged that OxyContin was accompanied by inadequate warnings, that it was defectively designed, and that Purdue had failed to exercise reasonable care in the painkiller's design, marketing, and promotion.¹²⁹ Essentially, plaintiffs asserted that Purdue "deceived potential users of OxyContin by relaying

had "learned to circumvent [the drug's] slow time-released protection and achieve a sudden, powerful morphine-like high"; 2003 GAO REPORT, *supra* note 116, at 2-3, 9 (explaining that news reports of "abuse and diversion began to surface in 2000"); Charles B. Camp, *Millions Sold, Office by Office: Strategy Targeted Busy Doctors, Hit Kentucky Oxycontin Sales—and Abuse—Boomed, Revealing the Risk of a "Blockbuster" Narcotic*, LEXINGTON HERALD-LEADER (Ky.), Aug. 17, 2003, at A1 ("By 2001, OxyContin was known as 'Hillbilly Heroin,' coveted by Appalachian junkies."). There is some evidence that Purdue knew about the problem earlier than all that—by the late 1990s. Meier, *supra* note 120.

128. See Complaint ¶¶ 3, 38, *Burton v. Purdue Pharma L.P.*, No. 01CIB005 (Ohio Ct. C.P. Scioto Cnty. Apr. 25, 2001), 2001 OH C.P. Ct. Pleadings LEXIS 16 [hereinafter *Burton Compl.*]; Lisa Taylor, *Jackie Renee Burton Parlin*, FIND A GRAVE (May 17, 2001), <https://perma.cc/WR3Y-ECKW>. The suit, discussed in more detail at note 320 below, was dropped eighteen months later. *First OxyContin Lawsuit Dismissed: Burton v. Purdue Pharma*, 18 ANDREWS PHARM. LITIG. REP., Nov. 2002, at 10; Ryan Scott Ottney, *OxyContin Company Pleads Guilty*, PORTSMOUTH DAILY TIMES (Ohio), May 11, 2007, at A1. For more on the "first wave," see Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2301 (2017); and Abbe R. Gluck, Ashley Hall & Gregory Curfman, *Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis*, 46 J.L. MED. & ETHICS 351, 353-54 (2018).
129. Gluck et al., *supra* note 128, at 353; Haffajee & Mello, *supra* note 128, at 2301; see, e.g., *Howland v. Purdue Pharma L.P.*, No. CV01 07 1651, slip op. at 8-10 (Ohio Ct. Com. Pl., Butler Cnty. July 23, 2002); *McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449, 451 (W.D. Va. 2004). Some lawsuits (including *Burton*) added express- and implied-warranty claims. E.g., *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 787-88 (S.D. W. Va. 2001); *Burton Compl.*, *supra* note 128, ¶¶ 53-61. Some (including *Burton*) also included statutory claims, primarily under state consumer-protection acts. *McCallister*, 164 F. Supp. 2d at 787; *Burton Compl.*, *supra* note 128, ¶¶ 64-67.

positive information while downplaying the known adverse and serious health effects.”¹³⁰

Between April 2001 and January 2007, over 1,400 such suits were initiated.¹³¹ But these suits confronted—and were frequently confounded by—a number of obstacles, and they rarely survived motions for summary judgment.¹³² Most notably, it was, and remains, difficult to show that a drug approved by the FDA is defectively designed.¹³³ Warning claims were tricky, partly owing to the learned-intermediary doctrine, which provides that, with a handful of exceptions, once a drug manufacturer has reasonably warned a physician of the drug’s danger, the manufacturer has fulfilled its disclosure obligations.¹³⁴ Warning claims also, on occasion, ran aground on causation, as it was difficult for plaintiffs to show that a *better* warning would have altered the physician’s decision to prescribe OxyContin, rather than a rival painkiller.¹³⁵

130. *Burton Compl.*, *supra* note 128, ¶ 21.

131. *In re OxyContin*, 833 N.Y.S.2d 357, 358 (Sup. Ct. 2007) (discussing the court’s “1,117 OxyContin drug cases”); 2003 GAO REPORT, *supra* note 116, at 10 (“According to Purdue, as of early October 2003, over 300 lawsuits concerning OxyContin were pending against Purdue, and 50 additional lawsuits had been dismissed.”); Paul Schott, *Opioid Crisis Fuels Massive Litigation Against Purdue Pharma*, STAMFORD ADVOC. (updated Nov. 2, 2018, 4:52 PM), <https://perma.cc/6H9F-J8NM> (reporting on “about 1,400 civil lawsuits” against Purdue that were initiated during this period).

132. Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1163 (2014) (“Purdue has pursued a policy of refusing to settle individual lawsuits and has prevailed at the summary judgment stage in most of them.”).

133. For the various obstacles that complicate the assertion of drug-based design-defect claims, see generally Michael D. Green, *Prescription Drugs, Alternative Designs, and the Restatement (Third): Preliminary Reflections*, 30 SETON HALL L. REV. 207 (1999). Owing to these obstacles, design-defect claims lodged against Purdue tended to founder. See, e.g., *Cornelius v. Cain*, No. CACE 01-020213(02), 2004 WL 48102, at *5 (Fla. Cir. Ct. Jan. 5, 2004) (“There is . . . no evidence of a design defect in OxyContin.”).

134. Of course, the learned-intermediary doctrine provides a shield only if the manufacturer supplies an *adequate* warning to the physician. If not, the doctrine should not protect the manufacturer from liability. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) & cmts. b, e (AM. L. INST. 1998). For an example of how the doctrine was used to defeat early opioid claims, see *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 706-08 (E.D. Ky. 2003).

135. See, e.g., *Bodie v. Purdue Pharma Co.*, 236 F. App’x 511, 520-21 (11th Cir. 2007) (finding that the plaintiff’s warning claim “must fail” because the plaintiff’s physician testified “that his decision to prescribe OxyContin . . . did not hinge upon the product literature (be it adequate or inadequate) that was provided to him by Purdue”); *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 556 (N.D. Tex. 2006) (granting Purdue’s motion for summary judgment “[b]ecause plaintiffs have failed to show that an adequate warning would have changed Dr. Danshaw’s decision to prescribe OxyContin”); *Timmons v. Purdue Pharma Co.*, No. 8:04-cv-1479, 2006 WL 263602, at *4 (M.D. Fla. Feb. 2, 2006) (granting Purdue’s motion for summary judgment because plaintiffs’ treating
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Beyond that, many plaintiffs—who admittedly abused narcotics—were thwarted by the wrongful-conduct rule, a common law invention that holds that a plaintiff “cannot maintain a tort action for injuries that are sustained as the direct result of his or her knowing and intentional participation in a criminal act.”¹³⁶ In addition, causation was often a problem because some seeking compensation simultaneously took *numerous* pain medications, which made pinning the blame on any single drugmaker difficult.¹³⁷ Last but not least, Purdue was also quick to stigmatize plaintiffs—and, in briefs and public arguments, missed no opportunity to emphasize individual victims’ own shortcomings and personal responsibility for their current plights.¹³⁸ Indeed, as one plaintiffs’ lawyer who represented some 5,000 clients in suits against Purdue during this period recalls: “Blame the patient’ was the basic foundation of their defense.”¹³⁹

Alongside these individual cases, plaintiffs’ lawyers also filed class actions. Indeed, less than one month after *Burton’s* April 25, 2001, initiation, the first class action was filed in Putnam County, West Virginia, seeking damages on

physicians claimed to be independently aware “of the [relevant] risks of addiction” and “[n]one of them purport[ed] to say that had the written warnings and promotional materials contained different rates of addiction, it would have made a difference in their selection of Oxycontin”).

136. *Greenwald v. Van Handel*, 88 A.3d 467, 472 (Conn. 2014). For more on the wrongful-conduct rule, including its origin and justification, see *Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo County*, 773 S.E.2d 627, 629-33 (W. Va. 2015); and Samuel Fresher, Comment, *Opioid Addiction Litigation and the Wrongful Conduct Rule*, 89 U. COLO. L. REV. 1311, 1312-26 (2018). For opioid cases stymied by the doctrine, see, for example, *Foister*, 295 F. Supp. 2d at 704-05; and *Price v. Purdue Pharma Co.*, 920 So. 2d 479, 486 (Miss. 2006) (en banc).
137. See, e.g., *McCauley v. Purdue Pharma L.P.*, 331 F. Supp. 2d 449, 452 (W.D. Va. 2004); *Ewing v. Purdue Pharma, L.P.*, No. 02-cv-00150, 2004 WL 1856002, at *1-2 (W.D. Va. Aug. 19, 2004).
138. For example, Purdue opened its brief before the Ohio Supreme Court in 2004: “Ms. Howland is a convicted felon. She has been convicted of numerous counts of deceptively obtaining OxyContin and hydrocodone and has a history of forging prescriptions for numerous prescription drugs” Brief on the Merits of Appellants Purdue Pharma L.P., Purdue Pharma, Inc., the Purdue Frederick Co., Purdue Pharmaceuticals. L.P., the P.F. Laboratories, Inc. & PRA Holdings, Inc. at 2, *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141 (Ohio 2004) (No. 03-1538), 2004 WL 5284775. Elsewhere, Purdue’s general counsel Howard Udell intoned: “When you ignore safety warnings and take an otherwise safe and effective product in an irresponsible and illegal manner, no personal injury lawyer will be able to help you cash in on your own misconduct by suing the product’s maker.” *W. Va. State Court Enters First Merits-Based Dismissal of OxyContin Suit: Allen v. Purdue Pharma*, 18 ANDREWS PHARM. LITIG. REP., Sept. 2002, at 12.
139. Telephone Interview with Paul J. Hanly, Jr., Leadership, Simmons Hanly Conroy (Dec. 12, 2019).

behalf of all persons who had obtained or ingested OxyContin in the state.¹⁴⁰ But these filings fared no better. Particularly in the wake of the Supreme Court's 1997 decision in *Amchem Products, Inc. v. Windsor*,¹⁴¹ Purdue insisted, and courts generally accepted, that class treatment was not appropriate, given that, as one court put it, "[t]he class is riddled with individual issues," thus defeating the exacting commonality, predominance, and typicality requirements of Rule 23(b).¹⁴²

In sum, as years of hard-fought opioid litigation drew to a close, plaintiffs had remarkably little to show for it. In April 2003, Purdue's general counsel, Howard Udell, crowed that "no OxyContin plaintiff has prevailed in any of the lawsuits Purdue has been forced to defend."¹⁴³ In December of the same year, Purdue issued a press release with the headline "65-0," touting the company's unbroken winning streak.¹⁴⁴ By 2004, the *American Lawyer* reported that Purdue had secured the dismissal of more than seventy suits and not a single suit—not one—had made it to trial.¹⁴⁵ And, in May 2007, the *New York Times* reported that Purdue "had defeated hundreds of lawsuits from patients

140. *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 787 (S.D. W. Va. 2001) ("Plaintiffs filed a class action complaint on May 18, 2001 in the Circuit Court of Putnam County, West Virginia, on behalf of persons who have obtained and ingested OxyContin (the drug) from a prescription written in West Virginia or from pharmacies or physicians in the state.").

141. 521 U.S. 591 (1997).

142. *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 598 (S.D. Ohio 2003). These individual issues included:

the reason why each class member's physician prescribed OxyContin®; whether that physician relied on the package inserts, and if so, which version . . . ; whether the class member took the OxyContin® as prescribed; [and] whether the termination of the OxyContin® was consistent with the package inserts and whether the class member followed the termination regime prescribed by his or her physician

Campbell v. Purdue Pharma, L.P., No. 02-cv-00163, 2004 WL 5840206, at *6 (E.D. Mo. June 25, 2004); see, e.g., *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 575 (W.D. Va. 2007) (recognizing that "class certification has been generally denied in OxyContin claims"); *Hurtado v. Purdue Pharma Co.*, No. 12648/03, 2005 WL 192351, at *16 (N.Y. Sup. Ct. Jan. 24, 2005) (observing that "no state or federal court has been sustained in maintaining a class action for OxyContin users").

143. *OxyContin Maker Boasts of Six Suits' Demise in Two Months: Couch v. Purdue Pharma*, 19 ANDREWS PHARM. LITIG. REP., Apr. 2003, at 9; see also *Some OxyContin Suits Dropped*, CHARLESTON DAILY MAIL (W. Va.), Aug. 2, 2003, at 9A ("Purdue Pharma said it has not paid any settlements involving dismissed cases and no cases have resulted in judgments against the company.").

144. Press Release, Purdue Pharma, 65-0: OxyContin® Cases Against Purdue Pharma Dismissed at Record Rate (Dec. 1, 2003) (on file with authors). The press release continued: "In none of the cases has the company paid anything to the plaintiffs in settlement. No personal injury case involving OxyContin has ever been decided against the company." *Id.*

145. Heather Smith, *Bar Talk: The Pain Continues*, AM. LAW., Jan. 2004, at 51.

claiming that they became addicted to OxyContin.”¹⁴⁶ To be sure, even by that time, Purdue’s record wasn’t exactly unblemished: In 2007, Purdue paid \$75 million to settle the claims of some 5,000 individuals, who were represented by the New York law firm Simmons Hanly Conroy.¹⁴⁷ But the settlement was shielded by a strict confidentiality provision, and the fact of the payment didn’t make news.¹⁴⁸

2. Public litigation

Aside from these personal injury and wrongful death suits initiated by patients or filed on their behalf, there were two other strands of litigation. These, for Purdue, were arguably more ominous. The first such strand dates back to June 11, 2001, when West Virginia’s attorney general initiated a *parens patriae* action based on the company’s promotion and distribution of OxyContin to state residents.¹⁴⁹ With public nuisance, negligence, antitrust, and consumer-protection claims, the suit accused Purdue of coercive and deceptive marketing and sought a range of penalties, including injunctive relief, damages sufficient to reimburse the state for the medical costs it had incurred, and the creation of a medical monitoring fund to assist in the prevention and remediation of OxyContin abuse.¹⁵⁰ After much public wrangling, on November 5, 2004, West Virginia and Purdue ultimately settled the claims for \$10 million, with no admission of fault.¹⁵¹

News of that settlement apparently prompted another twenty-six states and the District of Columbia to initiate copycat litigation against Purdue, asserting that the company neglected to disclose the diversion and addiction

146. Barry Meier, *Narcotic Maker Guilty of Deceit over Marketing*, N.Y. TIMES (May 11, 2007), <https://perma.cc/3CYB-NVU5>.

147. Andrew Joseph, *A Veteran New York Litigator Is Taking on Opioid Makers. They Have a History*, STAT (Oct. 10, 2017), <https://perma.cc/BT6A-XHSH>. According to attorney Paul Hanly, his firm was able to succeed where so many others failed because a coinciding criminal investigation (described below) was putting pressure on Purdue, and, unlike other firms that were outgunned, his firm wasn’t. *Id.* Two-dozen lawyers and staff worked on the case, and his firm invested millions in the litigation. *Id.* With these resources, Hanly’s team deposed dozens of witnesses and obtained millions of pages documents. *Id.*

148. See Esmé E. Deprez & Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, BLOOMBERG BUSINESSWEEK (Oct. 5, 2017, 1:00 AM PDT), <https://perma.cc/FVM5-Q5H5>.

149. For more on that action, *West Virginia ex rel. McGraw v. Purdue Pharma L.P.*, No. 01-C-137S (W. Va. Cir. Ct. June 11, 2001), see Ausness, *supra* note 132, at 1146-49.

150. See *id.* at 1148-49; *West Virginia Sues to Stop OxyContin Abuse: McGraw v. Purdue Pharma*, 17 ANDREWS PHARM. LITIG. REP., Aug. 2001, at 4.

151. Landon Thomas Jr., *Maker of OxyContin Reaches Settlement with West Virginia*, N.Y. TIMES (Nov. 6, 2004), <https://perma.cc/SVU8-R5QB>.

risks associated with the drug.¹⁵² Purdue settled those claims in May 2007, agreeing to pay \$19.5 million.¹⁵³

Also in May 2007, Purdue's criminal troubles came to a head. Following a six-year investigation,¹⁵⁴ the Department of Justice charged Purdue and three of its executives—including its general counsel, Howard Udell (who had touted Purdue's seeming invincibility just a few years before)—with violating the Federal Food, Drug and Cosmetic Act by introducing a misbranded drug into interstate commerce.¹⁵⁵ The three executives pled guilty to misdemeanor charges and agreed to pay more than \$34 million in fines.¹⁵⁶ The same day, Purdue pled guilty to a felony charge and agreed to pay more than \$600 million in criminal and civil fines, forfeitures, and civil penalties, after admitting that, “with the intent to defraud or mislead,” it falsely advertised OxyContin as “less addictive” and “less subject to abuse” than its more traditional rivals.¹⁵⁷

At the same time, Purdue entered into a court-ordered judgment with California and other states. Pursuant to that judgment, Purdue agreed not to make “misrepresentations with respect to OxyContin's potential for abuse, addiction, or physical dependence” and pledged to “implement and maintain an

152. See Ausness, *supra* note 132, at 1149. “Diversion” refers to the “transfer of any legally prescribed controlled substance from the person for whom it was prescribed to another person for any illicit use.” U.S. DEP’T OF HEALTH & HUM. SERVS., *FACING ADDICTION IN AMERICA: THE SURGEON GENERAL’S REPORT ON ALCOHOL, DRUGS, AND HEALTH*, glossary at 2 (2016), <https://perma.cc/GK2F-ZECX>.

153. Ausness, *supra* note 132, at 1149; Shannon Henson, *Purdue Pharma Settles with States over OxyContin*, LAW360 (May 8, 2007), <https://perma.cc/X534-VF4D> (to locate, click “View the live page”).

154. *2007 Senate Hearing*, *supra* note 121, at 10 (statement of John L. Brownlee, U.S. Attorney, Western District of Virginia) (“We initiated this in 2001. We spent 4 years going through millions of records, conducting hundreds of interviews.”).

155. Meier, *supra* note 146; Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx*, 12 J. HEALTH CARE L. & POL’Y 119, 143 (2009).

156. *2007 Senate Hearing*, *supra* note 121, at 84 (statement of John L. Brownlee, U.S. Attorney, Western District of Virginia). The executives also “were placed on supervised probation for 3 years [and] ordered to perform 400 hours of community service.” *Id.* That said, the \$34 million fine likely packed a muted punch as Purdue “picked up the tab.” Eban, *supra* note 120.

157. Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <https://perma.cc/33U6-EDC6>. The time period covered by the pleas ran from 1995 to mid-2001. *Id.* According to U.S. Attorney Brownlee, the \$600 million “reflect[ed] 90 percent of the company’s profit on the sale of OxyContin during the time period of the offense.” *2007 Senate Hearing*, *supra* note 121, at 84 (statement of John L. Brownlee, U.S. Attorney, Western District of Virginia). For the breakdown of where, exactly, the \$600 million went, see *id.* at 99.

abuse and diversion detection program that required its employees and contractors to report potential activities related to abuse and diversion.”¹⁵⁸

Then, in the fall of 2007, Kentucky got in on the act. In October 2007, the state’s attorney general filed suit against Purdue and Abbott, charging that the defendants’ sales representatives marketed and promoted OxyContin as “less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications” even though company officials knew that those assertions were “false or misleading.”¹⁵⁹ Kentucky insisted that those misrepresentations kept physicians and patients from accurately weighing the drug’s risks—and led more physicians to prescribe the drug more often, and to more patients, than they would have, had they been accurately informed.¹⁶⁰ After years of wrangling, that litigation, too, settled, this time for \$24 million.¹⁶¹ At the time, Purdue announced that the Kentucky settlement—which ended a decade of litigation with public entities—cleared the decks and allowed for a fresh start.¹⁶² But, in fact, all that was the calm before the storm.

C. The Second Wave: 2014 to the Present

Initiated by both states and local governments, the latest wave of opioid litigation commenced in July 2014.¹⁶³ Grounded in a range of claims, including public nuisance, RICO, negligence, fraudulent misrepresentation, fraudulent concealment, state statutory violations, and unjust enrichment, the suits seek to recoup the social and financial impact of opioid addiction and dependence.¹⁶⁴ Compared to the first wave of opioid litigation, this second

158. Complaint for Permanent Injunction, Abatement, Civil Penalties & Other Equitable Relief at 2, *California v. Purdue Pharma L.P.*, No. 19 STCV19045 (Cal. Super. Ct. June 3, 2019).

159. *In re Oxycontin Antitrust Litig.*, 821 F. Supp. 2d 591, 594 (S.D.N.Y. 2011) (quoting Amended Complaint); see also Samira Jafari, *Maker of OxyContin Is Sued for Millions*, DAILYBREEZE (updated Sept. 6, 2017, 11:31 AM), <https://perma.cc/U8EY-LFXX>.

160. *Oxycontin Antitrust Litig.*, 821 F. Supp. 2d at 594, 597.

161. David Armstrong, *Purdue’s Sackler Embraced Plan to Conceal OxyContin’s Strength from Doctors, Sealed Deposition Shows*, STAT (Feb. 21, 2019), <https://perma.cc/77M8-FSCE>. The settlement required Kentucky’s attorney general to “completely destroy” the Purdue documents in its possession. *Id.*

162. *Kentucky Settles Lawsuit with OxyContin Maker for \$24 Million*, CBS NEWS (Dec. 23, 2015, 5:11 PM), <https://perma.cc/R7Z2-TXVL>. There was a slow burn of litigation between the Kentucky suit and the start of the second wave. For a discussion, see Carr et al., *supra* note 15, at 208-09.

163. Richard C. Ausness, *The Current State of Opioid Litigation*, 70 S.C.L. REV. 565, 566 n.2 (2019).

164. For more on the particular causes of action, see *id.* at 567-91; and Nino C. Monea, *Cities v. Big Pharma: Municipal Affirmative Litigation and the Opioid Crisis*, 50 URB. LAW. 87, 130-43 (2019).

wave differs in terms of scope (far broader), volume (far larger), and visibility (far greater).

As to scope, plenty of arrows continue to be aimed at Purdue, the (now-bankrupt) maker of OxyContin and the company that “supercharged opioid addiction.”¹⁶⁵ But this latest wave of litigation implicitly recognizes that, while OxyContin’s footprint is large and its responsibility is great, its actual *market share* is, and has long been, quite modest.¹⁶⁶ Cognizant of that reality, second-wave plaintiffs have looked far beyond Purdue to a dense web of opioid manufacturers, distributors, and retailers.

Additional manufacturers named in this second wave include Insys, the maker of Subsys, a potent fentanyl pain reliever (which has filed for bankruptcy and also entered into a deferred prosecution agreement);¹⁶⁷ Endo, the maker of (among others) Opana ER Percodan and Percocet;¹⁶⁸ Teva, an Israeli generics manufacturer;¹⁶⁹ Mallinckrodt Pharmaceuticals, another large maker of generics;¹⁷⁰ and Johnson & Johnson (J&J), the maker of a fentanyl skin patch marketed under the brand name Duragesic.¹⁷¹ Plaintiffs generally assert that, in their aggressive marketing, these manufacturers exaggerated opioids’ benefits and soft-pedaled the painkillers’ risks.¹⁷²

165. CHRIS MCGREAL, *AMERICAN OVERDOSE: THE OPIOID TRAGEDY IN THREE ACTS* 273 (2018).

166. Indeed, Purdue accounted for approximately 3% of all opioids prescribed from 2006 through 2012. Scott Higham, Sari Horwitz & Steven Rich, *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST (July 16, 2019, 5:19 PM PDT), <https://perma.cc/TL58-DNJC>.

167. Nate Raymond, *Opioid Manufacturer Insys Files for Bankruptcy After Kickback Probe*, REUTERS (June 10, 2019, 3:24 AM), <https://perma.cc/E7PQ-FA6V>. Insys’s operating subsidiary has also pled guilty to fraud charges. Nate Raymond, *Unit of Drugmaker Insys to Plead Guilty to U.S. Opioid Bribe Scheme*, REUTERS (June 7, 2019, 3:09 AM), <https://perma.cc/YUV4-754S>.

168. Plaintiffs’ Memorandum of Law in Opposition to “Generic Manufacturers’” Motion for Partial Summary Judgment at 5, *In re Nat’l Prescription Opiate Litig.*, No. 17-md-2804 (N.D. Ohio Aug. 13, 2019), ECF No. 2251.

169. Josh Nathan-Kazis, *Teva and Endo Stock Are Falling Because Opioid Suits Aren’t Going Away*, BARRON’S (July 15, 2019, 10:19 AM ET), <https://perma.cc/79D9-H3FH>; David Segal & Isabel Kershner, *“Nobody Thought It Would Come to This”: Drug Maker Teva Faces a Crisis*, N.Y. TIMES (Dec. 27, 2017), <https://perma.cc/UA4L-VRGQ>.

170. Alexander Gladstone, Jared S. Hopkins & Juliet Chung, *Mallinckrodt Pitches at Least \$1.6 Billion Opioid Settlement, Generics Unit Bankruptcy*, WALL ST. J. (updated Feb. 24, 2020, 10:00 PM ET), <https://perma.cc/776M-Z626> (to locate, click “View the live page”).

171. Jan Hoffman, *Johnson & Johnson Ordered to Pay \$572 Million in Landmark Opioid Trial*, N.Y. TIMES (updated Aug. 30, 2019), <https://perma.cc/F2CV-J5D5>.

172. See, e.g., Summit County & City of Akron’s Omnibus Memorandum in Opposition to Defendants’ Motions to Dismiss at 1, *Nat’l Prescription Opiate Litig.*, No. 17-md-2804 (June 22, 2018), ECF No. 654.

On the distributor side, the litigation chiefly targets AmerisourceBergen, Cardinal Health, and McKesson—three companies that collectively distribute roughly 85% of the drug supply in the United States.¹⁷³ Plaintiffs assert that these distributors (essentially, the middlemen between manufacturers and retailers) failed to take reasonable steps to monitor, report, and detect suspicious shipments.¹⁷⁴ Central to these claims is the fact that the Controlled Substances Act (CSA) imposes various obligations on distributors.¹⁷⁵ Among other things, the CSA and accompanying regulations compel distributors to maintain “effective control against diversion of particular controlled substances,”¹⁷⁶ “design and operate a system” to identify “suspicious orders,”¹⁷⁷ and inform federal authorities of these suspicious orders when they come to light.¹⁷⁸ Plaintiffs assert that, notwithstanding these statutory, regulatory, and (in plaintiffs’ view) complementary common law requirements, the distributors stood idly by and pumped massive quantities of opioids into the health care system.

Finally, retailers—including such household names as Walmart, Walgreens, and CVS—are also in plaintiffs’ crosshairs.¹⁷⁹ Plaintiffs’ theories of liability against retailers resemble those discussed directly above.¹⁸⁰ In the federal multidistrict litigation (MDL), for example, plaintiffs allege that, like distributors, retailers breached their CSA-imposed obligation “to guard against”

173. For the 85% figure, see MAJORITY STAFF OF H. ENERGY & COMMERCE COMM., 115TH CONG., RED FLAGS AND WARNING SIGNS IGNORED: OPIOID DISTRIBUTION AND ENFORCEMENT CONCERNS IN WEST VIRGINIA 6, 30 (2018) [hereinafter RED FLAGS], <https://perma.cc/N9DX-UM4H>.

174. For a brief summary of claims against the distributors, see *West Virginia v. McKesson Corp.*, No. 2:17-cv-03555, slip op. at 1-2 (S.D. W. Va. Feb. 15, 2018).

175. Distributors’ ability to obtain an annual “registration” from the Drug Enforcement Administration (DEA) hinges on their fulfillment of these responsibilities. 21 U.S.C. § 822.

176. *Id.* § 823(b)(1), (e)(1).

177. 21 C.F.R. § 1301.74(b) (2020).

178. *Id.* “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

179. Walgreens, in particular, is reported to have handled 13 billion pills during the period from 2006 to 2012—“one out of every five oxycodone and hydrocodone pills shipped to pharmacies across America.” Jenn Abelson, Aaron Williams, Andrew Ba Tran & Meryl Kornfield, *At Height of Crisis, Walgreens Handled Nearly One in Five of the Most Addictive Opioids*, WASH. POST (Nov. 7, 2019), <https://perma.cc/LAT8-4KY9>; Emily Field, *Pharmacies Can’t Escape Public Nuisance in Opioid MDL*, LAW360 (Jan. 27, 2020, 5:37 PM EST), <https://perma.cc/7E44-PYZ8> (to locate, click “View the live page”).

180. *See, e.g.*, First Amended Complaint at 344-74, *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio Apr. 26, 2018), ECF No. 344 (alleging that the pharmacy defendants, including Walgreens, Walmart, CVS, and Costco Pharmacy, violated their duties under the CSA).

opioids' diversion¹⁸¹ and also failed to heed numerous red flags that should have indicated customers were seeking opioids for illicit use.¹⁸²

This second-wave litigation is proceeding along two separate, though sometimes overlapping, tracks: (1) a federal MDL (where scores of federal cases are consolidated), and (2) numerous state courts, scattered across the country. As to the former, the vast majority of local government actions, including some 2,700 suits initiated by cities, municipalities, counties, Indian tribes, and hospitals, are in federal court.¹⁸³ Pursuant to 28 U.S.C. § 1407, these federal actions have been swept together for pretrial proceedings into MDL No. 2804 before Judge Dan A. Polster in the U.S. District Court for the Northern District of Ohio.¹⁸⁴ At the same time, hundreds of additional cases—many filed by state attorneys general—are pending in state courts.¹⁸⁵ Mississippi, of tobacco-litigation fame, kicked off this state litigation in 2015,¹⁸⁶ and, in the years since, every state save Nebraska has followed Mississippi's lead.¹⁸⁷ Under *Mississippi ex rel. Hood v. AU Optronics Corp.*, states suing under their *parens patriae* powers cannot be forced to litigate in federal court,¹⁸⁸ while under *Postal Telegraph*

181. *Id.* at 302-03 (quoting 21 C.F.R. § 1301.71(a)).

182. *Id.* at 302-04. Such claims have so far survived summary judgment. *See, e.g.*, Order at 3, *Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804 (Sept. 4, 2019), ECF No. 2569 (ruling that plaintiffs had amassed sufficient evidence for a reasonable jury to conclude that “(1) Walgreens failed to maintain effective controls against diversion; and (2) these failures were a substantial factor in producing the alleged harm suffered by Plaintiffs”). State governments litigating outside the MDL have supplemented the above with claims under both state common law and state consumer-protection statutes. *See, e.g.*, Amended Complaint at 95-111, *Florida v. Purdue Pharma L.P.*, No. 2018-CA-001438 (Fla. Cir. Ct. Nov. 16, 2018) (alleging violation of two Florida state consumer-protection laws in addition to public nuisance, negligence, and civil conspiracy claims).

183. For a roster of MDL participants, see *Content Details: 17-2804-In Re: National Prescription Opiate Litigation*, U.S. GOV'T PUBL'G OFF., <https://perma.cc/M9VQ-JE42> (archived Oct. 24, 2020) (listing party names). For the 2,700 figure, see *In re Nat'l Prescription Opiate Litigation*, 956 F.3d 838, 841 (6th Cir. 2020).

184. The MDL was created in December 2017, when, with some 200 federal lawsuits pending in scattered district courts, the U.S. Judicial Panel on Multidistrict Litigation (JPML) granted plaintiffs' motion to consolidate and created MDL No. 2804, transferring the decentralized litigation then pending to Judge Polster's Cleveland courtroom. *In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d 1375 (J.P.M.L. 2017). Ohio got the nod because it is centrally located, is home to one of the largest wholesale drug distributors, and is particularly hard hit by the crisis. *Id.* at 1379.

185. Brief of Appellants at 5, *In re Nat'l Prescription Opiate Litig.*, No. 19-4097 (6th Cir. Feb. 7, 2020), ECF No. 44 [hereinafter Appellants' Sixth Circuit Br.] (“In addition to cases in the MDL, several hundred cases brought by states and political subdivisions are pending in state courts across the country.”).

186. Carr et al., *supra* note 15, at 208-09.

187. Grant Schulte & Geoff Mulvihill, *Nebraska's AG Is Lone Holdout in Pursuing Opioid Cases*, ASSOCIATED PRESS (June 12, 2019), <https://perma.cc/Q4F6-65EX>.

188. 571 U.S. 161, 164, 176 (2014).

Cable Co. v. Alabama, states are not even considered citizens for the purposes of diversity jurisdiction (and so may not even have had the *option* of filing in federal court, absent a federal question).¹⁸⁹ Thus, the checkerboard nature of this litigation is seemingly inevitable.¹⁹⁰

As of the time of this writing, only one state suit has proceeded to trial. Initiated by the State of Oklahoma, and focused on a sole defendant—J&J—that proceeding culminated in a \$465 million judgment after the court found that J&J engaged in a deceptive marketing campaign designed to convince Oklahoma doctors and the public that opioids were safe for the long-term treatment of chronic, nonmalignant pain and that this “false, misleading, and dangerous marketing” caused “exponentially increasing rates of addiction [and] overdose deaths,” which ravaged the Sooner State.¹⁹¹ Meanwhile, over in the MDL, a trial that would have pitted two Ohio counties—Summit and Cuyahoga—against a grab bag of manufacturers and distributors was set to start in the early fall of 2019.¹⁹² But it was cancelled at the eleventh hour, after the parties reached a \$260 million settlement.¹⁹³

More broadly, though, litigation continues in fits and starts. Judge Polster has long expressed his fervent desire for a quick and comprehensive settlement,¹⁹⁴ and he even certified a highly controversial “negotiation class” to

189. 155 U.S. 482, 487 (1894).

190. As of June 2019, Alabama was the only state to join the MDL. Amanda Bronstad, *Alabama Attorney General Voluntarily Dismisses Opioid Case*, AM. LAW. (June 13, 2019, 6:37 PM), <https://perma.cc/WLW9-5J4Z> (to locate, click “View the live page”). It subsequently dismissed its lawsuit after Judge Polster questioned whether he had jurisdiction. *Id.*

191. *State ex rel. Hunter v. Purdue Pharma L.P.*, No. CJ-2017-816, 2019 WL 4019929, at *12 (Okla. Dist. Ct. Aug. 26, 2019). The case initially took aim at Purdue and Teva, in addition to J&J, but both settled prior to trial (the former for \$270 million, the latter for \$85 million). Lenny Bernstein, *Oklahoma, Teva Pharmaceuticals Reach \$85 Million Settlement in Opioid Case*, WASH. POST (May 26, 2019, 6:51 PM PDT), <https://perma.cc/YT3J-64NH>. After the bench trial, the court initially ordered J&J to pay \$572 million but that sum was reduced after a math error was discovered. For more on the Oklahoma litigation, see Michelle M. Mello & Nora Freeman Engstrom, *Stanford Legal Experts on the Oklahoma Opioids Verdict and Ongoing Litigation*, SLS BLOG (Aug. 28, 2019), <https://perma.cc/ZF5Q-ULK5>. For the math error, see Colin Dwyer & Jackie Fortier, *Oklahoma Judge Shaves \$107 Million off Opioid Decision Against Johnson & Johnson*, NPR (updated Nov. 21, 2019, 4:00 PM ET), <https://perma.cc/BX44-W4HC>. On January 13, 2020, Oklahoma filed yet another lawsuit, this time against McKesson, Cardinal Health, and Amerisource Bergen. Lenny Bernstein, *Oklahoma Files Suit Against Three Major Opioid Distributors*, WASH. POST (Jan. 13, 2020, 11:19 AM PST), <https://perma.cc/XZLN-YNVZ>.

192. Eric Heisig, *Here’s Where Opioid Litigation Stands After Cuyahoga, Summit Counties Reach \$260 Million Settlement*, CLEVELAND.COM (updated Oct. 22, 2019), <https://perma.cc/Y6YN-KP4P>.

193. *Id.*

194. *See In re Nat’l Prescription Opiate Litig.*, 927 F.3d 919, 923 (6th Cir. 2019) (“The district court presiding over this potentially momentous MDL has repeatedly expressed a
footnote continued on next page”

advance that objective.¹⁹⁵ But, in September 2020, a divided panel of the Sixth Circuit reversed that certification determination.¹⁹⁶ And, generally, notwithstanding Judge Polster’s resolve, a sweeping settlement does not seem imminent.¹⁹⁷ Says plaintiffs’ lawyer Joe Rice, who is helping to quarterback the litigation for plaintiffs: “We still want a global settlement. We’re a long way from being through.”¹⁹⁸

III. A Tale of Two Products and Two Litigations

Over the past sixty years, the U.S. legal system has confronted a rising tide of litigation initiated by those alleging serious injury from their exposure to a wide range of toxic (or allegedly toxic) substances, from Agent Orange, DES, Bendectin, MER-29, and asbestos, to Zyprexa, fen-phen, Vioxx, talcum powder, Roundup, and Risperdal.¹⁹⁹ Arguably, tobacco and opioids are distinct among these tragic episodes: Both products are highly addictive and were sold in extraordinarily high quantities. Both were the subject of aggressive (and highly misleading) marketing campaigns.²⁰⁰ Both have imposed an economic

desire to settle the litigation before it proceeds to trial.”). Indeed, Judge Polster’s abiding interest in a settlement has stirred some controversy: On September 14, 2019, numerous defendants filed an unusual motion to disqualify Judge Polster citing, among other things, his “singular focus on, and substantial involvement in, settlement discussions.” Memorandum in Support of Motion to Disqualify Pursuant to 28 U.S.C. § 455(a) at 1-2, *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804 (N.D. Ohio Sept. 14, 2019), ECF No. 2603-1. The motion was denied. *Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 4686815, at *1 (Sept. 26, 2019), *aff’d*, Order at 1, *In re Nat’l Prescription Opiate Litig.*, No. 20-3075 (6th Cir. July 16, 2020), ECF No. 54-2.

195. *In re Nat’l Prescription Opiate Litig.*, 332 F.R.D. 532, 556 (N.D. Ohio 2019) (capitalization altered), *rev’d*, 976 F.3d 664 (6th Cir. 2020). For more on this unconventional mechanism, see note 276 and the accompanying text below.
196. *Nat’l Prescription Opiate Litig.*, 976 F.3d at 677. In so holding, the court concluded “that the negotiation class ordered by the district court simply is not authorized by the structure, framework, or language of Rule 23.” *Id.* at 675-76.
197. Complicating any settlement is the problem that not all *possible* plaintiffs have initiated claims. Thus, even a settlement with all current plaintiffs would leave the defendants exposed to further filings. For discussion of this complication as well as certain parties’ innovative effort to address it, see note 276 and the accompanying text below.
198. Press Release, Motley Rice LLC, Opioid MDL Track One Cases Settle on Eve of Openings, Joe Rice Leads Negotiations (Oct. 24, 2019), <https://perma.cc/S9QZ-LNVB>.
199. For a sense of how these cases have grown in size and importance, consider that MDLs now make up roughly 37% of the federal civil docket and that mass-tort MDLs comprise a remarkable 95% of that total. Nora Freeman Engstrom, *The Lessons of Lone Pine*, 129 YALE L.J. 2, 7 (2019) (collecting statistics).
200. One difference, of course, is that, in the tobacco context, the ads were aimed at smokers; in the opioid context, the ads were aimed chiefly at physicians. For the extraordinarily aggressive marketing of cigarettes, see Frank J. Chaloupka, Ellen J. *footnote continued on next page*

toll that runs in the trillions of dollars. Both product manufacturers profited handsomely from the products' sales (though, to be fair, even in OxyContin's heyday, profits from cigarette sales swamped opioid earnings).²⁰¹ And neither has been confined in terms of geography, race, gender, or social class—albeit, for both, the poor and less educated segments of the population have been hardest hit.²⁰²

In this Part, we focus on both episodes, chronicling three key ways that the two products—and the litigations they engendered—are, variously, different and alike, as well as the *implications* of these points of divergence and convergence. Subpart A considers the attributes of the two products at issue. Subpart B maps and then evaluates the different regulatory environments the products inhabit. Finally, Subpart C traces the various ways the litigants and litigation are similar and diverge.

A. Product Attributes

This Subpart catalogs the attributes of cigarettes and prescription painkillers—and, in particular, evaluates the products' relative susceptibility to substitution, social utility, and price sensitivity. This comparative exercise unmaskes the extraordinary difficulties that confront a policymaker in attempting to address the opioid epidemic. Whereas policymakers can—and by all accounts have—made a big dent in the tobacco problem by using tried-and-true supply-side mechanisms (such as excise taxes and MSA-induced price hikes) alongside place-of-use restrictions (such as bans on smoking in bars, in restaurants, and on flights),²⁰³ the opioid problem is thornier. Place-of-use

Hahn & Sherry L. Emery, *Policy Levers for the Control of Tobacco Consumption*, 90 KY. L.J. 1009, 1033 (2002). For opioid marketing, see the sources cited in note 121 above.

201. Experts estimate that, between 1996 and 2019, OxyContin generated \$35 billion in revenue for Purdue and \$4 billion for the Sackler family. Benjamin Soskis, *Why Haven't Major Institutions Cut Ties with the Sackler Family?*, WASH. POST (Mar. 15, 2019, 6:15 AM PDT), <https://perma.cc/GHM3-6HFE>. For the extraordinary profitability of tobacco companies, even today, see Jennifer Maloney & Saabira Chaudhuri, *Against All Odds, the U.S. Tobacco Industry Is Rolling in Money: Profits Are Booming, Despite Government Regulation, Huge Legal Settlements and Fewer Smokers*, WALL ST. J. (Apr. 23, 2017, 1:31 PM ET), <https://perma.cc/36VE-DSZE> (to locate, click "View the live page").

202. For smoker demographics, see note 11 above. Likewise, "[l]ower-income individuals, including those on Medicaid and the uninsured, are more likely to misuse opioids and have opioid use disorder than the general U.S. population." ROBIN GHERTNER & LINCOLN GROVES, U.S. DEP'T OF HEALTH & HUM. SERVS., *THE OPIOID CRISIS AND ECONOMIC OPPORTUNITY: GEOGRAPHIC AND ECONOMIC TRENDS 1* (rev. 2018), <https://perma.cc/2CDW-XKDD> (footnote omitted).

203. Smoking rates have trended sharply downward over the past sixty years, from roughly one-in-two Americans to one-in-seven Americans. See *supra* notes 8, 11 and accompanying text. Owing in part to that steep drop in tobacco use, "there are now more former smokers than there are current smokers" alive in the United States. HHS
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restrictions in the opioid realm are obviously of zero benefit; a pill can be popped anywhere. And opioids' relative price insensitivity (traceable, in part, to the mediating role of public and private insurance), their high social utility (particularly for the most vulnerable individuals in need of palliative care), and the ever-present threat that any meaningful supply-side restriction will simply backfire and drive users to even more dangerous black-market alternatives all conspire to dramatically complicate the opioid-problem policy response.

1. Product substitution

Tobacco and opioids first differ when it comes to product substitution—and their substitutes' differential susceptibility to a meaningful regulatory response. There are, on the whole, few substitutes for cigarettes. “Few substitutes” is not the same as “no substitutes,” however, and, particularly in recent years, one substitute in particular—the e-cigarette, which burst onto the scene a little more than a decade ago²⁰⁴—has started to draw sustained attention.²⁰⁵

Particularly among the young, there is a significant worry that, as smoking rates drop, rates of e-cigarette use rise. Both trends are in evidence: Since 2014, among U.S. youth, e-cigarettes have surpassed—and come to dominate—traditional cigarettes.²⁰⁶ In recent years, the trend has continued and the gap has widened: As of 2019, roughly five times as many high schoolers reported using e-cigarettes, as compared to their combustible counterparts (27.5% versus 5.8%).²⁰⁷ Juul claims the largest share of the youth market—and,

RETROSPECTIVE, *supra* note 11, at 12. For the role of price hikes, see notes 236-37 and the accompanying text below. For the role of place-of-use restrictions, see HHS RETROSPECTIVE, *supra* note 11, at 777, 792-95.

204. U.S. DEP'T OF HEALTH & HUM. SERVS., SURGEON GENERAL'S ADVISORY ON E-CIGARETTE USE AMONG YOUTH 1 (2018) [hereinafter SURGEON GENERAL'S ADVISORY], <https://perma.cc/3DDU-YA5L> (“E-cigarettes entered the U.S. marketplace around 2007 . . .”).

205. To be sure, the extent to which e-cigarettes are truly a *substitute* for conventional cigarettes is debatable. It seems likely that a high proportion of e-cigarette users would not use *any* cigarette if e-cigarettes had not been invented and aggressively marketed—and many who smoke e-cigarettes also smoke conventional cigarettes, which suggests that the e-cigarettes are not so much a substitute as a supplement. Patricia J. Zettler, Natalie Hemmerich & Micah L. Berman, *Closing the Regulatory Gap for Synthetic Nicotine Products*, 59 B.C. L. REV. 1933, 1948-49 (2018) (“Currently, . . . the majority of people who use e-cigarettes are *also* smoking.”); Micah L. Berman, *Tobacco Litigation, E-Cigarettes, and the Cigarette Endgame*, 13 NE. U. L. REV. 219, 232 (2021) (reporting that “most adult e-cigarette users are also *dual users* of cigarettes”).

206. SURGEON GENERAL'S ADVISORY, *supra* note 204, at 1.

207. The study gauged use in the “past 30 days.” *Youth and Tobacco Use*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/2AT9-WPDU> (archived Oct. 26, 2020).

at least until recently, its popularity was surging: From 2016 to 2017, the company's sales increased some 600%.²⁰⁸

E-cigarettes' popularity is deeply disquieting. The health effects of vaping are, as yet, uncertain.²⁰⁹ But there is evidence that nicotine can harm the developing brain (and a single Juul "pod" contains roughly as much nicotine as an entire pack of cigarettes)²¹⁰ and that the aerosol inhaled by vapers can expose users and those nearby to any number of harmful substances.²¹¹ In addition, an e-cigarette habit may serve as an onramp to acquiring a conventional cigarette habit (although it's also possible that, for others, e-cigarettes may serve as an off-ramp *away* from conventional cigarettes, to potentially salutary effect).²¹² All to say: Substitution in the cigarette realm is of consequence, and, in fact, e-cigarettes' rising popularity is starting to generate its *own* high-profile response, including from the FDA (which is cracking down on products that particularly appeal to children);²¹³ from states and municipalities (which are levying new taxes on e-cigarettes and starting to impose age restrictions on purchase);²¹⁴ and from myriad public and private

208. SURGEON GENERAL'S ADVISORY, *supra* note 204, at 2.

209. NAT'L ACADS. OF SCIS., ENG'G & MED., PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 1 (Kathleen Stratton, Leslie Y. Kwan & David L. Eaton eds., 2018) (reporting that "e-cigarettes are likely to be far less harmful than combustible tobacco cigarettes" but that their "absolute risks . . . cannot be unambiguously determined" and their "[l]ong-term health effects . . . are not yet clear").

210. Karen Cullen, Andrea S. Gentzke, Michael D. Sawdey, Joanne T. Chang, Gabriella M. Anic, Teresa W. Wang, MeLisa R. Creamer, Ahmed Jamal, Bridget K. Ambrose & Brian A. King, *e-Cigarette Use Among Youth in the United States, 2019*, 322 JAMA 2095, 2096 (2019); *How Much Nicotine Is in JUUL?*, TRUTH INITIATIVE (Feb. 26, 2019), <https://perma.cc/P2PE-Y5Z2>.

211. Cullen et al., *supra* note 210, at 2101. In addition, vaping has been linked to EVALI, short for "e-cigarette or vaping product use associated lung injury." Molly Wolf & Laura K. Rock, *EVALI: New Information on Vaping-Induced Lung Injury*, HARV. MED. SCH.: HARV. HEALTH BLOG (updated Apr. 4, 2020, 8:39 AM), <https://perma.cc/LYK2-AFNH>. An inflammatory lung response, EVALI has been associated with over 2,800 hospitalizations and at least 68 deaths. *Id.* That said, most cases of EVALI appear to involve THC-based, rather than nicotine-based, products. See Jonathan Corum, *Vaping Illness Tracker: 2,602 Cases and 59 Deaths*, N.Y. TIMES (updated Jan. 13, 2020), <https://perma.cc/D77B-Z3WX>.

212. NAT'L ACADS. OF SCIS., ENG'G & MED., *supra* note 209, at 11 ("[T]he evidence suggests that while e-cigarettes might cause youth who use them to transition to use of combustible tobacco products, they might increase adult cessation of combustible tobacco cigarettes.").

213. Emily Field, *FDA Begins Crackdown on Illegally Marketed E-Cigarettes*, LAW360 (Feb. 6, 2020, 4:54 PM EST), <https://perma.cc/BW6X-35BZ> (to locate, click "View the live page").

214. Elaine S. Povich, *Vaping Craze Prompts New State Taxes*, PEW CHARITABLE TRS.: STATELINE (Aug. 19, 2019), <https://perma.cc/M3M6-LEV5>. For additional measures enacted by states and municipalities, see Corum, *supra* note 211.

litigants (who have filed scores of claims alleging that Juul's e-cigarettes are defectively designed and deceptively marketed).²¹⁵

But even with all that, the cigarette substitution problem pales in comparison to its counterpart in the opioid arena. In the latter case, an individual may start down the road of addiction and dependence using an FDA-approved, physician-prescribed opioid for her bad back, bum knee, or aching tooth. But the line from use to dependence to addiction is blurry, and addiction, once ignited, can be fed and fueled by a range of cheaper black-market alternatives, including street drugs—chiefly, heroin and illicit fentanyl—that have no counterpart in the tobacco context.²¹⁶

The above pathway (from prescription pills to street drugs) is apparent in studies that have explored how heroin users got their start: The American Society of Addiction Medicine estimates that four out of five heroin users started with prescription pills.²¹⁷ It is also evident in national data. Recent years have witnessed a decline in physicians' propensity to prescribe opioids. Between 2000 and 2010, the number of U.S. prescriptions for oral opioids more than doubled, until, in 2010, prescription rates topped out at 81.2 prescriptions per 100 persons per year.²¹⁸ But then (perhaps not coincidentally, at just the

215. The federal suits have been consolidated into a recently formed MDL. See *In re Juul Labs, Inc., Mktg., Sales Pracs. & Prods. Liab. Litig.*, 396 F. Supp. 3d 1366 (J.P.M.L. 2019). For the state litigation, see, for example, Matthew Santoni, *Pa. Is Latest State to Claim Juul Marketed E-Cigs to Teens*, LAW360 (Feb. 10, 2020, 8:13 PM EST), <https://perma.cc/5FQA-SDFX> (to locate, click "View the live page"). For a round-up of additional recent activity, see Altria Grp., Inc., *supra* note 78, item 8, at 93.

216. Fentanyl is a Schedule II FDA-approved opioid. Prescribed for serious pain, prescription fentanyl comes in the form of lozenges or transdermal patches. However, a large black market for illicit fentanyl has developed, and this illicitly produced fentanyl, which is synthesized in clandestine laboratories mostly in China and Mexico, is overwhelmingly responsible for the ongoing fentanyl epidemic. U.S. DRUG ENF'T ADMIN., U.S. DEP'T OF JUSTICE, DEA-DCT-DIR-032-18, 2018 NATIONAL DRUG THREAT ASSESSMENT 21-22 (2018), <https://perma.cc/QQ35-MYXD>. Most heroin is also illegally imported, frequently from Mexico. *Id.* at vi, 11.

217. See Am. Soc'y of Addiction Med., *Opioid Addiction: 2016 Facts and Figures 2* (2016), <https://perma.cc/6S9K-M2CV>. We are unaware of a study that estimates the proportion of fentanyl users who began with prescription painkillers. See Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, 6 J.L. & BIOSCIENCES, June 9, 2020, at 2 n.7. There is some evidence that, particularly recently, some individuals might be sidestepping prescription gateway drugs altogether. Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 183 (2018); Chen et al., *supra* note 2, at 2.

218. See Sarpatwari et al., *supra* note 4, at 464 ("From 2000 to 2010, the number of prescriptions for oral opioid analgesics rose 104%."); 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 CDC MORBIDITY & MORTALITY WKLY. REP. 697, 698 (2017) (offering the 81.2 figure).

time Purdue reformulated OxyContin to make it harder to crush, break, or dissolve), prescription rates suddenly dipped.²¹⁹ By 2015, that figure was down to 70.6 prescriptions per 100 persons.²²⁰ And “[s]ince 2015, the estimated number of opioid analgesic prescriptions dispensed from U.S. outpatient retail pharmacies . . . [has] fallen by 24 percent.”²²¹ Almost certainly as a consequence, it appears that the death rate involving *prescription* opioids has started to plateau.²²²

Unfortunately, alongside that promising prescription-opioid story, there has been a concomitant (and, evidence suggests, causally related) rise in the use of heroin and adulterated or illicitly manufactured fentanyl.²²³ There has also been a corresponding (and again, according to most, causally related) surge in fatalities.²²⁴ Heroin and fentanyl overdose deaths have skyrocketed in recent years, to the point that, by 2016, fentanyl was the leading cause of overdose deaths.²²⁵

219. For a discussion of Purdue’s controversial (and suspiciously timed) innovation, see Bethany McLean, *Bitter Pill*, VANITY FAIR (Aug. 2019), <https://perma.cc/N3XF-YBVK>.

220. Guy et al., *supra* note 218 (offering the 70.6 figure); see also Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D. on the Agency’s 2019 Policy and Regulatory Agenda for Continued Action to Forcefully Address the Tragic Epidemic of Opioid Abuse (Feb. 26, 2019) [hereinafter Gottlieb Statement], <https://perma.cc/KG9C-74GW> (“The estimated total morphine milligram equivalents (MMEs) per prescription peaked in 2010, at 950 MMEs, before falling to 905 MMEs in 2015.”).

221. Gottlieb Statement, *supra* note 220.

222. *Overdose Death Rates*, *supra* note 1. Note, however, that any progress may be short-lived, as evidence suggests that COVID-19 is causing a surge in opioid deaths. See Rohrich, *supra* note 1.

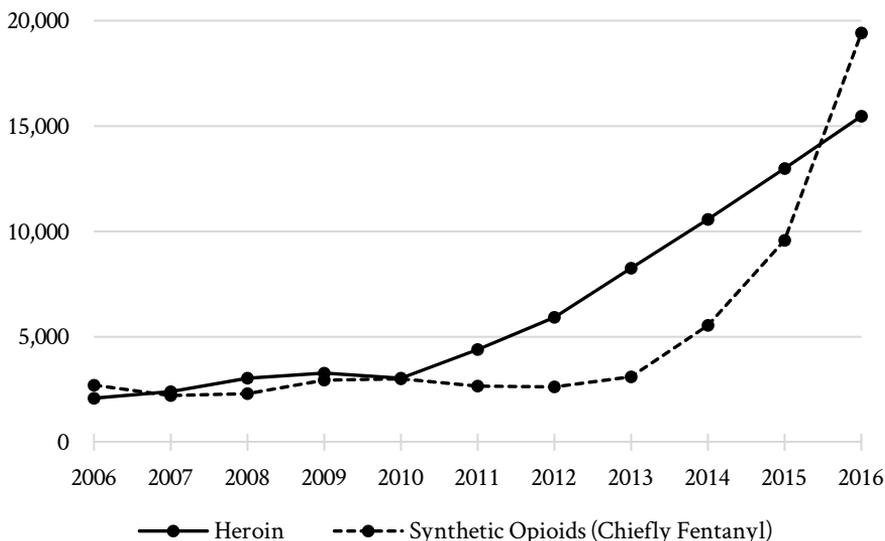
223. See COUNCIL OF ECON. ADVISERS, THE ROLE OF OPIOID PRICES IN THE EVOLVING OPIOID CRISIS 9, 30-31 (2019), <https://perma.cc/4WL2-984H> (tracing the rise in heroin and fentanyl use to the drop in the supply of prescription opioids and the reformulation of OxyContin); Keenan, *supra* note 15, at 74 (same); see also Pradip K. Muhuri, Joseph C. Gfroerer & M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ DATA REV., Aug. 2013, at 1, 1 (“Anecdotal reports and localized small-scale studies have suggested that some individuals who had been abusing OxyContin® switched to heroin after the reformulation in late 2010 that made OxyContin more difficult to crush.”). There is also some anecdotal evidence that limits on the supply of prescription opioids are encouraging some to experiment with other controlled substances, including crystal meth. Timothy Williams, *In a Town Where Meth Is Eclipsing Opioids, Everyone Feels the Pain*, N.Y. TIMES (Mar. 28, 2020), <https://perma.cc/C576-2NUR>.

224. See, e.g., William N. Evans, Ethan Leiber & Patrick Power, *How the Reformulation of OxyContin Ignited the Heroin Epidemic* 1, 19 (Nat’l Bureau of Econ. Rsch., Working Paper No. 24475, 2018) (concluding that “the rapid rise in the heroin death rate since 2010 is largely due to the reformulation of OxyContin”).

225. *Fentanyl and Other Synthetic Opioids Drug Overdose Deaths*, NAT’L INST. ON DRUG ABUSE (May 29, 2018), <https://perma.cc/736X-745X> (reporting that, in 2016, synthetic opioids, primarily fentanyl, eclipsed prescription opioids as the most common drugs involved
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Figure 1

U.S. Annual Fatalities Attributable to Heroin and Synthetic Opioids, 2006-2016



Data source: U.S. DRUG ENF'T ADMIN., U.S. DEP'T OF JUST., DEA-DCT-DIR-032-18, 2018 NATIONAL DRUG THREAT ASSESSMENT 17 fig.23, 28 fig.34 (2018), <https://perma.cc/QQ35-MYXD>.

The implications of all the above are profound. Compared to tobacco, the clear path an opioid user might travel—from regulated product to readily available yet more lethal black-market alternative—exponentially complicates the public-health response to the opioid crisis. In tobacco, to reiterate, there is some product substitution (from cigarettes to other products, chiefly e-cigarettes). *But all substitutes are legal.*²²⁶ This means that a motivated

in overdose deaths). Two additional facts further complicate matters. First, in the United States, heroin is typically injected. Compared to oral ingestion, injection (often using dirty syringes) spreads disease and puts the user at a much higher risk of overdose. NAT'L ACADS. OF SCIS., ENG'G & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 203, 210 (Richard J. Bonnie, Morgan A. Ford & Jonathan K. Phillips eds., 2017). Second, the move from prescription opioids to heroin is a one-way street; for a number of reasons (including price and ease of acquisition), those who graduate to the latter don't tend to go back to the former. *Id.* at 210-11.

226. In addition to substitution via e-cigarettes, there is a black market for cigarettes. In the United States, this black market consists primarily of "cigarette arbitrage" in the form of bootlegging from low-tax localities to high-tax localities. Thus, in the United States, even "black market" cigarettes were purchased (initially) from regulated sellers; their resale is just unregulated. NAT'L RSCH. COUNCIL, UNDERSTANDING THE U.S. ILLICIT
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policymaker can choke off access to cigarettes while simultaneously and effectively regulating the use of possible substitutes—by levying taxes, imposing *ex ante* regulation (including age restrictions on purchase), and by green-lighting (and, in some cases, even initiating) *ex post* tort litigation—using conventional, tried-and-true mechanisms.²²⁷ *In tobacco, the supply-side regulation of substitutes has real power and bite.*

By contrast, a policymaker who chokes off access to prescription opioids risks sending many users to already-illegal black-market alternatives—i.e., illicit fentanyl and heroin. Owing to this illegality, the only strategies at policymakers' disposal to reduce the supply of these alternatives are squarely within the criminal realm: increasing interdiction, redoubling the efforts of state and federal law enforcement, and upping charges and extending prison time to crack down further on traffickers, dealers, users, and middlemen. To date, such criminal sanctions have been notoriously ineffective and highly counterproductive. The upshot is this: If one restricts the legal sale of tobacco or nicotine, one has notched a victory for public health. If, on the other hand, one restricts the legal sale of opioids, at least in the short term, death rates might rise.²²⁸

TOBACCO MARKET: CHARACTERISTICS, POLICY CONTEXT, AND LESSONS FROM INTERNATIONAL EXPERIENCES 2 (Peter Reuter & Malay Majmundar eds., 2015). The size of this secondary market is unclear. See MICHAEL LAFAIVE, TODD NESBIT & SCOTT DRENKARD, MACKINAC CTR. FOR PUB. POL'Y, CIGARETTE TAXES AND SMUGGLING: A 2016 UPDATE 8 (2016) (finding that cigarettes bootlegged to avoid taxes may account for more than half of cigarettes consumed in New York, with lower numbers in other states); KEVIN DAVIS, MATTHEW FARRELLY, QIANG LI & ANDREW HYLAND, N.Y. STATE DEP'T OF HEALTH, CIGARETTE PURCHASING PATTERNS AMONG NEW YORK SMOKERS: IMPLICATIONS FOR HEALTH, PRICE, AND REVENUE 5 (2006) (reporting that, in 2004, 57% of surveyed smokers in New York purchased cigarettes from low-tax or untaxed sources such as nearby states or Indian reservations at least once, and that 37% did so regularly); Mark Stehr, *Cigarette Tax Avoidance and Evasion*, 24 J. HEALTH ECON. 277, 280 (2005) (estimating that 9.6% of cigarettes purchased from 1985 to 2001 were purchased without paying state taxes); LUK JOOSSENS, DAVID MERRIMAN, HANA ROSS & MARTIN RAW, HOW ELIMINATING THE GLOBAL ILLICIT CIGARETTE TRADE WOULD INCREASE TAX REVENUE AND SAVE LIVES 2 (2009) (finding that illicitly produced or sold cigarettes account for 9.8% of those consumed across all high-income countries).

227. See *supra* notes 213-14 and accompanying text (outlining recent governmental action to regulate e-cigarettes); see also *supra* note 215 and accompanying text (discussing litigation against Juul by state attorneys general).

228. See generally Allison L. Pitt, Keith Humphreys & Margaret L. Brandeau, *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 AM. J. PUB. HEALTH 1394 (2018) (predicting that policies to curtail prescription opioids will, at least in the short term, increase fatalities by causing some to turn to more dangerous alternatives).

2. Social utility

Further confounding a policymaker's response to the opioid epidemic is the matter of social utility. Smoking has little social utility.²²⁹ It can, therefore, be responsibly curtailed using blunt instruments. From a public-health perspective, less smoking is an unalloyed good. By contrast, opioids *do* have social utility. They offer significant therapeutic benefits, particularly for the alleviation of acute or cancer-related pain, in the course of palliative care, or for the long-term treatment of opioid-use disorder.²³⁰ Thus, for opioids, unlike cigarettes, reduction strategies need to be fine-tuned and carefully calibrated. By depriving vulnerable patients of necessary medication, a slashing, lurching, or across-the-board response may well exacerbate the nation's public-health crisis.

3. Price sensitivity

The third dimension in which tobacco and opioids differ—and the third way that addressing the opioid problem is more complex than addressing the tobacco problem—is price sensitivity, and, more to the point, the extent to which policymakers (or manufacturers) can responsibly and effectively raise prices to curtail demand.

Even though tobacco is addictive, demand for tobacco products is sensitive to price.²³¹ Numerous studies conducted at different times and evaluating different populations have convincingly shown that an increase in the price of tobacco products leads, inexorably, to a drop in tobacco use.²³² Indeed,

229. Smoking is not wholly without utility, as it suppresses one's appetite, relieves stress, and also gives many users at least a fleeting sense of pleasure and contentment. But smoking's social disutility far outweighs its utility, and even for individual smokers, there is a time inconsistency in preference, as many smokers, who might derive pleasure from each individual cigarette, simultaneously want to quit smoking. *Smoking Cessation: Fast Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/L8F4-SYJQ> (archived Oct. 26, 2020) (reporting that, as of 2015, 68% of adult smokers "said that they wanted to quit").

230. See NAT'L ACADS. OF SCIS., ENG'G & MED., *supra* note 225, at 194-95, 198.

231. Because of the addictive nature of tobacco, "demand is more price responsive in the long run than in the short run." Frank J. Chaloupka, Ayda Yurekli & Geoffrey T. Fong, *Tobacco Taxes as a Tobacco Control Strategy*, 21 TOBACCO CONTROL 172, 175 (2012); see also T.R. Goldman, *Health Policy Brief: Tobacco Taxes*, HEALTH AFFS. (Sept. 19, 2016), <https://perma.cc/PSM9-H48G> ("[T]he long-term impact on reducing tobacco use through higher taxes can be twice as much as the short term.").

232. E.g., Frank J. Chaloupka, Teh-wei Hu, Kenneth E. Warner, Rowena Jacobs & Adya Yurelki, *The Taxation of Tobacco Products*, in TOBACCO CONTROL IN DEVELOPING COUNTRIES 237, 244, 267 (Prabhat Jha & Frank J. Chaloupka eds., 2000) (explaining that an expansive literature clearly shows that "increases in the prices of cigarettes and other tobacco products significantly reduce cigarette smoking and other tobacco use"); Chaloupka et al., *supra* note 231, at 175 (explaining that numerous studies have
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researchers have quantified the relationship, consistently finding that boosting prices by 10% reduces smoking anywhere from 3% to 5%—and that young smokers and low-income individuals are particularly affected.²³³

This price elasticity arms policymakers with a pair of powerful tools. First, policymakers can directly raise the price of cigarettes by imposing taxes on cigarettes' sale. Recognizing this, all fifty states, the District of Columbia, the federal government, and numerous municipalities have levied tobacco taxes.²³⁴ Though they take disparate forms, and though, too, these taxes are undeniably regressive (because smokers are disproportionately poor), these levies are widely believed to be one of the most powerful weapons in policymakers' public-health arsenal.²³⁵

In addition to levying taxes directly, policymakers can also reduce demand by inducing cigarette manufacturers to raise their *own* prices. This, in fact, was just what the MSA accomplished; one of its key provisions—which entitled states to a portion of manufacturers' future revenue (rather than, say, a chunk of their cash on hand)—led cigarette companies to boost prices by more than

"consistently found that increases in . . . prices on tobacco products lead to reductions in tobacco use"); Rabin, *supra* note 8, at 1730 & n.36 (explaining that a "legion of economists" has found that smokers are "quite sensitive to price increases").

233. HHS RETROSPECTIVE, *supra* note 11, at 789 (reporting on studies that find particular price sensitivity among teens and low-income individuals). Anything that reduces teenagers' propensity to smoke is particularly beneficial because nearly 90% of adult smokers acquired the habit by the time they turned eighteen. Thus, if individuals don't begin smoking by the time they are eighteen, they very likely won't ever start. HHS RETROSPECTIVE, EXECUTIVE SUMMARY, *supra* note 7, at 13.

234. For a catalog of various states' excise and sales taxes, see Campaign for Tobacco Free Kids, State Excise and Sales Taxes Per Pack of Cigarettes: Total Amounts & State Rankings (2020), <https://perma.cc/V8J9-Z7QS>.

235. For the fact that the taxes take disparate forms, see *id.* For smokers' relative poverty, see note 11 above. Not all see the taxes' regressive nature as a negative, however. See INST. OF MED., NAT'L ACADS. OF SCI., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 187 (Richard J. Bonnie, Kathleen Stratton & Robert B. Wallace eds., 2007). For the fact that these taxes are regarded as powerful policymaking tools, see Pearl Bader, David Boisclair & Roberta Ferrence, *Effects of Tobacco Taxation and Pricing on Smoking Behavior in High Risk Populations: A Knowledge Synthesis*, 8 INT'L J. ENV'T RSCH. & PUB. HEALTH 4118, 4119 (2011) ("Tobacco taxation . . . has been recognized as one of the most effective population-based strategies for decreasing smoking . . ."); and Steven A. Schroeder, *Tobacco Control in the Wake of the 1988 Master Settlement Agreement*, 350 NEW ENG. J. MED. 293, 296 (2004) (reporting that "tobacco taxes" are one of two reforms that most effectively "reduce the harm caused by the use of tobacco"). As an added benefit, funds generated by the tobacco taxes can be (and, in some states, are) plowed into smoking-cessation programs. STATE System Excise Fact Sheet, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/Q37S-ZCYL> (archived Oct. 26, 2020) (noting that, in 2020, state governments will receive \$27 billion from tobacco taxes and settlements and spend \$740 million of that sum on tobacco-control programs).

\$1.10 per pack between 1998 and 2000.²³⁶ As one might expect, these price increases triggered a nontrivial, and highly salutary, drop in cigarette consumption and use.²³⁷

By contrast, when it comes to the availability of price as a policy lever, the opioid landscape is comparatively bleak. This is not because—as many assume—opioid consumption is wholly insensitive to price. To the contrary, it seems that opioid consumption (particularly among new users) is affected by consumers’ out-of-pocket costs.²³⁸ Underscoring the relationship, in fact, prescription opioid consumption surged just as consumers’ out-of-pocket costs plummeted, before both stabilized in 2010.²³⁹

236. For a concise explanation of the MSA’s unique structure, see Eric A. Posner, *Tobacco Regulation or Litigation?*, 70 U. CHI. L. REV. 1141, 1145 (2003) (book review). For the \$1.10 per pack increase, see TRUTH INITIATIVE ET AL., *BROKEN PROMISES TO OUR CHILDREN: A STATE-BY-STATE LOOK AT THE 1998 TOBACCO SETTLEMENT 20 YEARS LATER* 3 (2018), <https://perma.cc/7A49-HTBG>. There is, of course, a drawback to this arrangement as it gives states a perverse incentive to keep tobacco sales high. For a discussion, see BRANDT, *supra* note 20, at 435.

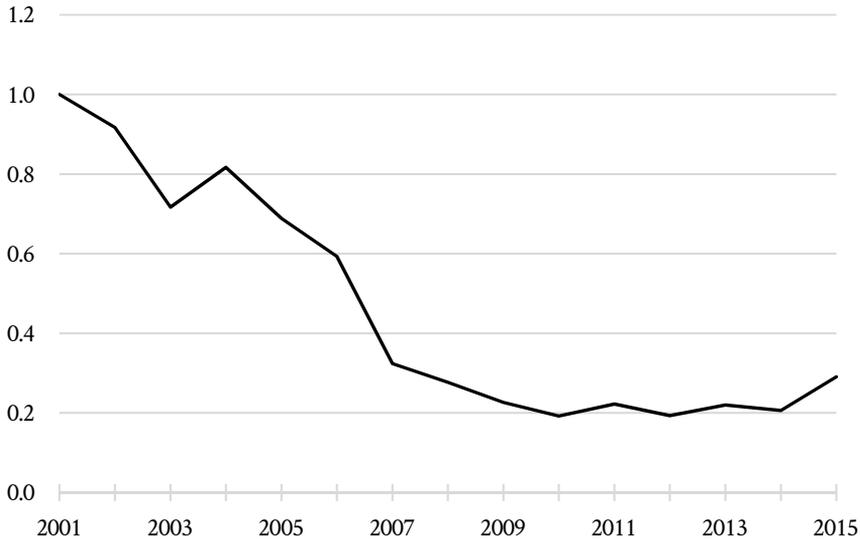
237. HHS RETROSPECTIVE, EXECUTIVE SUMMARY, *supra* note 7, at 18 (“The evidence is sufficient to conclude that litigation against tobacco companies has reduced tobacco use in the United States by leading to increased product prices . . .”); Frank A. Sloan & Justin G. Trogdon, *The Impact of the Master Settlement Agreement on Cigarette Consumption*, 23 J. POL’Y ANALYSIS & MGMT. 843, 852 (2004) (“The MSA and the separate state settlements have led to a significant decrease in smoking since their implementation. . . . Most of the effect . . . came through the associated retail price increases for cigarettes.”).

238. See generally Aparna Soni, Health Insurance, Price Changes, and the Demand for Pain Relief Drugs: Evidence from Medicare Part D, at 24 (Sept. 25, 2018) (unpublished manuscript), <https://perma.cc/W2ZB-8B6F> (finding that price affected new opioid users’, but not existing users’, demand for prescription opioids). Expense appears to work on the insurer side, too. Namely, if opioids were more expensive, insurers would presumably be less likely to steer patients to opioid-based painkillers. As it stands, there is evidence that insurers have channeled patients to (comparatively cheap) opioids, as opposed to pricier but less risky and potentially more efficacious therapies. Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricing, Less Addictive Painkillers*, N.Y. TIMES (Sept. 17, 2017), <https://perma.cc/SF5U-6RDD>; Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 763 (observing that the opioid crisis was fueled, in part, by the fact that “insurers preferred picking up the tab for opioids over pricier and more time-consuming approaches to pain management”).

239. “Between 2001 and 2010, the out-of-pocket price [of prescription opioids] fell by 81 percent before stabilizing.” COUNCIL OF ECON. ADVISERS, *supra* note 223, at 16. The reduction was, it appears, traceable to the introduction of Medicare Part D in January 2006, the increased supply of generics, and the rapid expansion of disability benefits during the period. *Id.* at 5-6, 16.

Figure 2

Indexed Out-of-Pocket Cost of Potency-Adjusted Prescription Drugs, 2001-2015



Note: Yearly price indices are calculated by dividing real total spending in a given year by the total number of morphine gram equivalents prescribed in that year. All prescriptions are converted into morphine gram equivalents based on the quantity of pills prescribed and their potency using the National Drug Code database.

Data source: COUNCIL OF ECON. ADVISERS, THE ROLE OF OPIOID PRICES IN THE EVOLVING OPIOID CRISIS 16 fig.6 (2019), <https://perma.cc/4WL2-984H>. Figure and note re-created with permission.

But, notwithstanding consumers' evident price sensitivity, the policymaker seeking to pull the opioid-price policy lever faces serious challenges. Opioid-specific sales taxes seem like a nonstarter: In all but two states, prescriptions are, currently, exempt from such charges.²⁴⁰ While it would be theoretically possible to create an opioid carveout from this well-established exemption, doing so is in some tension with states' longstanding tax practices. Opioid-specific excise taxes are potentially more promising. Indeed, more than a dozen states have recently considered bills that, if enacted, would levy taxes or fees on prescription painkillers, and a few states (New

240. Jennifer Dunn, *Sales Tax by State: Is Prescription and Nonprescription Medication Taxable?*, TAXJAR (Nov. 14, 2017), <https://perma.cc/NH6R-M4JY>.

York, Delaware, and Minnesota) have actually enacted such measures.²⁴¹ But the taxes are complicated and controversial, and their operation, effectiveness, and broader popularity remain uncertain.²⁴²

Meanwhile, following the MSA's script, it is possible that opioid manufacturers could be induced to increase their *own* prices. But, given the prevalence of privately and publicly supplied health insurance, if there *were* to be price hikes, it is governmental actors (such as Medicaid and Medicare) and first-party insurers (such as BlueCross and Aetna), not patients, who would predictably feel the pinch.²⁴³ Thus, if an opioid settlement were to replicate the MSA's price-hike structure, there would be something of a boomerang effect: A manufacturer forced to pay a monetary settlement to the state could simply pass on those costs through higher drug prices, which would, in turn, be paid mostly by the state.

Further complicating matters, the price policy lever works (or at least works best) only to the extent that the prescription medication is *purchased* from licit (rather than illicit) sellers who record the transaction and levy the tax. But currently, a sizable portion of those who misuse even *prescription* pain relievers obtain those painkillers from informal channels. In a recent survey of those who misused prescription pain medication, in fact, only one-quarter of respondents said they obtained their pain pills from physicians; more than half acquired their pills from a relative or friend for free.²⁴⁴ These "off-market" transactions are unlikely to be significantly affected by policymakers' tax strategy.

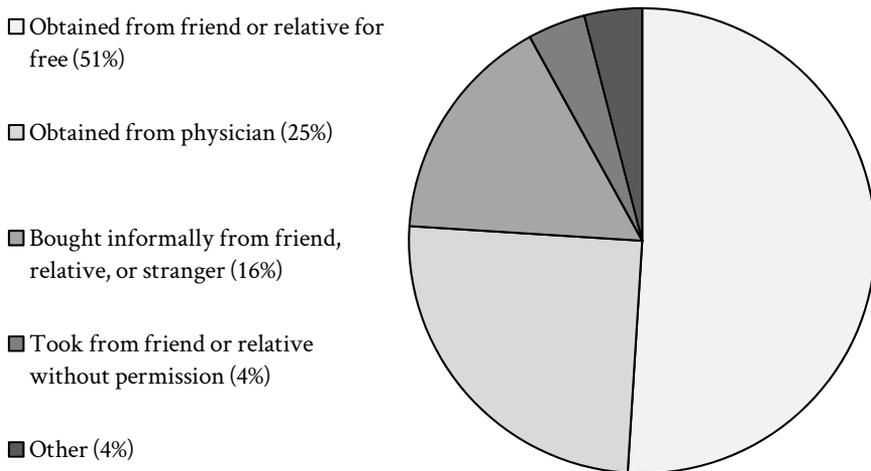
241. Nikki Bossert, Harley T. Duncan, Deborah Gordon & Nick Saye, *State Opioid Taxes*, 93 TAX NOTES ST. 1151, 1151-52 (2019).

242. See Ryan Prete, *States Ditching Opioid Taxes in Pursuit of One-Time Payouts*, BLOOMBERG TAX (Nov. 14, 2019, 1:46 AM PT), <https://perma.cc/6ZL6-WWCK>.

243. See Public Health Amici, *supra* note 15, at 17 (recognizing that a "key difference between tobacco and opioids is that the insurance market distorts the price of opioids"). In a recent survey, 84% of respondents reported that they, or a member of their household, had health insurance that helps pay for prescription drugs. NPR, ROBERT WOOD JOHNSON FOUND. & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, LIFE EXPERIENCES AND INCOME INEQUALITY IN THE UNITED STATES app. at 16 (2020). Currently, the coinsurance rate for hydrocodone is 50%. COUNCIL OF ECON. ADVISERS, *supra* note 223, at 18. That said, to the extent the cost of opioids rises for insurers, insurers might steer insureds away from these potent painkillers. Cf. *supra* note 238 (discussing insurers' price sensitivity).

244. Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Jan. 12, 2017), <https://perma.cc/T8YN-8VFU>. Another recent survey found that more than one in five adults with an opioid prescription self-reported having shared their painkillers with others. Alene Kennedy-Hendricks, Andrea Gielen, Eileen McDonald, Emma E. McGinty, Wendy Shields & Colleen L. Barry, *Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults*, 176 JAMA INTERNAL MED. 1027, 1027 (2016).

Figure 3
Sources of Misused Prescription Pain Medication



Data source: Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Jan. 12, 2017), <https://perma.cc/T8YN-8VFU> (providing annual averages from 2013 to 2014 for the most recent nonmedical use among users twelve or older).

Worse, anything that significantly boosts the out-of-pocket cost of prescription opioids would run into trouble along the dimensions we address in Subparts 1 and 2 above: Because the user can easily (but, often, tragically) satisfy her desire for a prescription opioid by switching to a black-market alternative (such as illicit fentanyl or heroin), measures that raise the cost of the former will predictably drive demand for the latter, to catastrophic effect. Meanwhile, because opioids (unlike cigarettes) have social utility for some patients (including those suffering from end-stage cancer and other serious maladies), upping the painkillers' cost is hardly an unalloyed good.

B. Regulatory Environments

Just as cigarettes and opioids have different product attributes, they also have been designed, manufactured, distributed, and marketed in very different regulatory environments. These divergent regulatory environments affect the

current landscape, as well as the strategies policymakers might use to curtail use and mitigate harm.²⁴⁵

Remarkably, despite clear recognition of the health risks of smoking, documented as early as 1964, Congress failed to regulate the tobacco industry until 2009. (Though the FDA tried to regulate the industry in 1996, its authority to do so was successfully challenged.²⁴⁶) Prior to 2009, the only direct federal regulation of tobacco products consisted of a ban on television advertising, a prohibition on smoking in certain areas (mostly, domestic flights and interstate buses), and the requirement that cigarette makers affix specified health warnings to cigarette packages and promotional messaging.²⁴⁷ Meanwhile, from the 1970s through the early 1990s, states and localities imposed various restrictions and regulations, including age limitations on purchase (stimulated, in part, by the 1992 Synar Amendment), bans on smoking in public establishments and workplaces, and excise taxes.²⁴⁸ But, even in those states that opted for “strict” requirements, the regulatory landscape was notably sparse.

In sharp contrast, the opioid environment is, and has long been, positively littered with laws and requirements. The pills must be (and have been) approved by the FDA as safe and effective for their intended use.²⁴⁹ They must be prescribed by licensed physicians “acting in the usual course of... professional practice.”²⁵⁰ The warning label that accompanies each pill must be

245. See Berman, *supra* note 15, at 1034 (observing that tobacco and opioids occupy very different regulatory environments).

246. For a discussion of the FDA’s experiment with regulation which came to an abrupt end with the Supreme Court’s decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 10 U.S.C., 15 U.S.C., and 21 U.S.C.), see note 378 and the accompanying text below.

247. See *Smoking & Tobacco Use: Legislation*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/TT78-6K3L> (archived Oct. 28, 2020) (noting that warning labels were required by the Federal Cigarette Labeling and Advertising Act of 1965, television advertising was banned by the Public Health Cigarette Smoking Act of 1969, and smoking on certain domestic flights was banned by Public Law No. 100-202 in 1987).

248. Enacted by Congress in 1992, the Synar Amendment conditioned states’ receipt of certain federal funds on their enactment of laws banning the sale of tobacco products to minors. 42 U.S.C. § 300x-26. For other activity, see INST. OF MED., NAT’L ACADS. OF SCIS., *SECONDHAND SMOKE EXPOSURE AND CARDIOVASCULAR EFFECTS: MAKING SENSE OF THE EVIDENCE* 110 tbl.5-1 (2010); Rabin, *supra* note 8, at 1721; and Dorie E. Apollonio & Stanton A. Glantz, *Minimum Ages of Legal Access for Tobacco in the United States from 1863 to 2015*, 106 AM. J. PUB. HEALTH 1200, 1201-04 (2016).

249. 21 U.S.C. § 355 (a), (d).

250. 21 C.F.R. §§ 1306.03(a), 1306.04(a) (2020); see also 21 U.S.C. § 829(a) (“[N]o controlled substance in schedule II . . . may be dispensed without the written prescription of a practitioner . . .”).

vetted, and any related advertising must be accurate, balanced, evidence-based, and consistent with FDA-approved prescription information.²⁵¹ Add to that, the Drug Enforcement Administration (DEA) imposes quotas on how many drugs may be distributed and also subjects distributors to a range of seemingly stringent requirements.²⁵² In addition, because opioids are Schedule II narcotics, distributors must report to the Attorney General “every sale, delivery or other disposal” of prescription opioids.²⁵³ These reports—which, collectively, compose the Automated Reports and Consolidated Ordering System (ARCOS) data and amount to a database tracing where every pill came from and where it was sold—are routed to the DEA and ostensibly permit the agency to “track controlled substances from the time they are manufactured until they are dispensed to consumers.”²⁵⁴ Finally, the Department of Justice, usually acting through U.S. Attorney’s offices, controls the misuse of pharmaceuticals through its initiation of both civil and criminal actions.²⁵⁵

The fact that opioids are comparatively comprehensively regulated has at least two implications. The first is concrete. The second, though less concrete, is perhaps of greater consequence.

First, opioids’ elaborate regulatory architecture arms opioid defendants with a possible argument: preemption. In opioids, more so than in tobacco, defendants may be able to argue—and, in a handful of cases, *have* successfully argued—that the federal statutory framework preempts, and thus compels the dismissal of, relevant claims.²⁵⁶ Even if that argument fails (because, so far,

251. For labeling, see 21 U.S.C. § 321(n); and 21 C.F.R. § 201.57. For advertising, see 21 C.F.R. § 202.1.

252. Among other things, distributors must obtain an annual “registration,” 21 U.S.C. § 822, and, in deciding whether to register an applicant, the Attorney General is obliged to consider, among other things, whether the applicant maintains “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels,” *id.* § 823(b)(1).

253. *Id.* § 827(d)(1). For the import of this Schedule II characterization, see note 122 above.

254. RED FLAGS, *supra* note 173, at 53.

255. Cuéllar & Humphreys, *supra* note 2, at 20. On top of the federal regulations noted above, state boards of pharmacy regulate and license pharmacists, while state licensure boards license and regulate physicians. *Id.* at 21.

256. *See, e.g.,* North Dakota *ex rel. Stenehjem v. Purdue Pharma L.P.*, No. 08-2018-cv-001300, 2019 WL 2245743, at *15 (N.D. Dist. Ct. May 10, 2019); *Caltagirone v. Cephalon, Inc.*, 190 A.3d 596, 597 (Pa. Super. Ct. 2018). *But see, e.g.,* Commonwealth *v. Purdue Pharma, L.P.*, No. 1884-cv-01808, 2019 WL 5495866, at *1, *3 (Mass. Super. Ct. Sept. 17, 2019) (citing *Merck Sharpe & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), and denying Purdue’s motion to dismiss). As noted below, in tobacco, the preemption question was authoritatively addressed in 1992 when, in *Cipollone v. Liggett Group, Inc.*, the Supreme Court held that the Public Health Cigarette Smoking Act of 1969 preempted certain common law failure-to-warn claims. *See* 505 U.S. 504, 524-25 (1992) (plurality opinion). But the Court left the door open for misrepresentation and deceit claims and had no occasion to address any broader framework of federal tobacco control legislation. *Id.* at
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courts have ruled that prescription drug manufacturers may be held liable for inadequate warnings, notwithstanding the FDA approval process²⁵⁷), in some states, a drug manufacturer may still be entitled to a rebuttable presumption that it is not liable for personal injuries, to the extent that the manufacturer complied with all federal requirements.²⁵⁸

Second, in opioids, an alphabet soup of federal governmental agencies (including the FDA, DEA, and Department of Justice) had significant authority to address the burgeoning opioid problem. In creating a comprehensive regulatory scheme, the legislative branch seemingly did its work. But numerous agencies nevertheless stood by, even as pill mills proliferated, the death toll spiked, and millions of painkillers were pumped into, and decimated, certain communities.²⁵⁹

Among other failings, from the beginning, the FDA permitted Purdue to boast (without evidence) that the delayed-release nature of its formula was “believed to reduce” its appeal to drug abusers.²⁶⁰ In addition, between 2009 and 2015, the FDA approved twenty-seven new opioids for sale,²⁶¹ via a process that’s since come under fire,²⁶² and simultaneously failed to ensure that a program designed to curb the excessive distribution of opioids actually worked.²⁶³ For its part, the DEA failed to monitor drug flows or diversion

530-31; Robert L. Rabin, *Territorial Claims in the Domain of Accidental Harm: Conflicting Conceptions of Tort Preemption*, 74 BROOK. L. REV. 987, 992 & n.27 (2009).

257. See *Albrecht*, 139 S. Ct. at 1676-79; *Wyeth v. Levine*, 555 U.S. 555, 568-73 (2009). Importantly, *Albrecht* limits impossibility preemption to cases where the defendant can “show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug’s label to include that warning.” 139 S. Ct. at 1678.

258. E.g., FLA. STAT. ANN. § 768.1256(1) (West 2020); MICH. COMP. LAWS ANN. § 600.2946(4) (West 2020).

259. For more on “pill mills” (a term for physicians, clinics, or pharmacies that prescribe or dispense controlled prescription drugs inappropriately or for nonmedical reasons), see Terry Spencer, *Florida’s “Pill Mills” Were a Gateway to the Opioid Crisis*, WUSF PUB. MEDIA (July 21, 2019, 11:18 AM EDT), <https://perma.cc/9Z4Q-SZTT>.

260. See *supra* note 120 and accompanying text.

261. See Chris McGreal, *Opioid Crisis: FDA’s Own Staff Demand Agency Halt Approval of New Painkillers*, GUARDIAN (Mar. 21, 2019, 4:59 EDT), <https://perma.cc/QD2J-L7Q6>.

262. *Id.*

263. Abby Goodnough & Margot Sanger-Katz, *As Tens of Thousands Died, F.D.A. Failed to Police Opioids*, N.Y. TIMES (updated Dec. 31, 2019), <https://perma.cc/Q7VQ-VNWF>. Known as the risk evaluation and mitigation strategy, or R.E.M.S., the program was started in 2007 to, among other things, train physicians to safely prescribe certain dangerous drugs. For more on the program and its limitations, see Noah, *supra* note 238, at 778-82.

trends,²⁶⁴ neglected to conduct even rudimentary criminal background checks of applicants,²⁶⁵ and, from 2003 to 2013, as the catastrophe mounted, inexplicably authorized a dramatic increase in oxycodone production.²⁶⁶ Finally, the Department of Justice also bears blame. Most notably, in 2007, when there was still time to stem this crisis, the Department of Justice's career prosecutors apparently wanted to indict Purdue executives on felony charges, but they were overruled by political appointees—and, when all was said and done, the executives merely got a slap on the wrist.²⁶⁷ The upshot is that, in opioids, unlike in tobacco, the scope and intensity of this calamity stands as a monument to the colossal failure of executive-branch personnel.²⁶⁸

C. Litigants and Litigation

Lastly, the third-wave tobacco and second-wave opioid litigation are also, in important ways, different and alike. The similarities are obvious enough: Both litigation episodes involve states and municipalities suing defendant manufacturers over a dangerous product in order to recoup those government funds expended because of the defendants' allegedly wrongful activity.²⁶⁹ Both

264. The DEA had ARCOS data within its grasp, which revealed the extent of the crisis. Yet a 2018 House Report concluded: "At the time the opioid epidemic was worsening, . . . DEA did not proactively use ARCOS data to investigate diversion trends." RED FLAGS, *supra* note 173, at 8.

265. OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF JUSTICE, REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATORY AND ENFORCEMENT EFFORTS TO CONTROL THE DIVERSION OF OPIOIDS 15 (rev. 2019).

266. *Id.* at 13; see also Sari Horwitz & Scott Higham, *Could the DEA Have Stopped the Opioid Epidemic by Cutting Off the Supply?*, WASH. POST (Dec. 28, 2019, 8:24 AM PST), <https://perma.cc/99LA-FA45>.

267. Barry Meier, *Why Drug Company Executives Haven't Really Seen Justice for Their Role in the Opioid Crisis*, TIME (June 15, 2018, 2:32 PM EDT), <https://perma.cc/KJZ7-979K>; Meier, *supra* note 120. For more on the penalties ultimately imposed, see notes 156-57 and the accompanying text above.

268. The FDA, for its part, has admitted as much. Gottlieb Statement, *supra* note 220 (stating that "the scope of the epidemic reflects many past mistakes and many parties who missed opportunities to stem the crisis, including the FDA"). By contrast, tobacco-side regulatory strategies (particularly public-place restrictions and excise taxes) have been very successful in reducing tobacco use. See *supra* notes 11, 203 (tracing the drop in cigarette usage); *supra* notes 234-35, 237, 326 and accompanying text (discussing effective tobacco control strategies). For a thoughtful discussion of strategies for closing the gap between regulatory enactments and regulatory enforcement in the opioids context, see Cuéllar & Humphreys, *supra* note 2, at 66-73.

269. Though cities' and municipalities' role in the tobacco litigation is often overlooked, some municipalities and cities (including such heavyweights as Los Angeles, San Francisco, San Jose, and New York) did bring suit against cigarette manufacturers. See, e.g., Jane Kay, *S.F. Will Scrutinize Tobacco Settlement*, S.F. GATE (updated Feb. 7, 2012, 4:00 PM), <https://perma.cc/84X2-4S49>; Henry Weinstein & Maura Dolan, *San Francisco Sues 6 Tobacco Firms*, L.A. TIMES (June 7, 1996), <https://perma.cc/B9T8-L8X8>; Sarah L.

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have relied on innovative and mostly untested legal theories. Both efforts were initiated only after individual suits, filed by hundreds of private plaintiffs, faced serious obstacles and experienced no (in tobacco) or very limited (in opioids) success. Both have featured private counsel working on behalf of state actors, pursuant to sometimes-controversial government/private-plaintiff-side partnerships. (Underscoring the litigations' linkages, numerous plaintiffs' lawyers who made a name for themselves spearheading tobacco litigation went on to lead the opioid charge.²⁷⁰) And, in both, the governmental plaintiffs are, for the most part, acting in concert, rather than going it alone. At the same time, however, the litigations differ in three key respects.

First, the plaintiffs differ. In the tobacco litigation, as noted above, municipalities and local governments did not stay on the sidelines entirely. Yet cities and municipalities were mostly bit players; with a few narrow exceptions, substate actors stood back and let state attorneys general speak for the states.²⁷¹ In the opioid litigation, by contrast, states have fractured into their constituent parts: Cities, counties, and municipalities were among the first to file, and these entities are, by most accounts, leading the litigation.²⁷²

The fact that opioid litigation includes so many—and so many varied—substate plaintiffs has complicated the action and, more to the point, seems destined to complicate the resolution of the action, significantly.²⁷³ To identify just one crucial implication: In tobacco, all the states lodged claims. Thus, the tobacco defendants could—and did—settle with those who had filed, and, upon inking those settlements, they achieved the goal of every defendant caught in mass tort's crosshairs: global peace. In the opioid litigation, by contrast, over 2,700 states, cities, counties, municipalities, tribes, and hospitals have sued the opioid manufacturers, distributors, and retailers.²⁷⁴ But these entities—while

Swan, *Plaintiff Cities*, 71 VAND. L. REV. 1227, 1234 n.22 (2018). Indeed, some cities and municipalities profited handsomely from these efforts. See Swan, *supra*, at 1233-34.

270. See Emily Field, *Motley Rice's Joseph Rice on the Opioid MDL and More*, LAW360 (Nov. 15, 2019, 8:25 PM EST), <https://perma.cc/N9V4-BLLT> (to locate, click "View the live page") (noting that Joseph Rice is co-lead counsel in the opioid MDL and also played a key role in tobacco litigation); Deprez & Barrett, *supra* note 148 (recognizing that Mike Moore and Steve Berman, both of tobacco fame, are helping to quarterback the opioid litigation).

271. Swan, *supra* note 269, at 1233-34 (observing that tobacco litigation was "mainly state-driven" (emphasis omitted)).

272. The current wave of opioid litigation was, fittingly, started by a substate actor, as the City of Chicago kicked off the second wave with a 2014 filing. Ausness, *supra* note 163, at 566 & n.2.

273. Perhaps not surprisingly, tensions have arisen between plaintiffs pursuing these parallel sets of claims. See, e.g., Jan Hoffman, *States Clash with Cities over Potential Opioids Settlement Payouts*, N.Y. TIMES (Aug. 5, 2019), <https://perma.cc/WHR4-BR7E>.

274. For the 2,700 figure, see note 183 above.

numerous—represent just a small fraction (on the order of 10%) of those actors who theoretically *could* sue for their opioid-related losses.²⁷⁵ This means that the opioid defendants could, theoretically, settle with all *current* litigants on Day 1 and, on Day 2, face another tidal wave of litigation. This prospect is, for defendants, genuinely terrifying—and is generating tremendous pressure to devise an unorthodox and boundary-pressing settlement that mitigates the concern by binding even absent complainants.²⁷⁶

Just as important, the defendants also differ. In tobacco, the plaintiffs took aim at cigarette manufacturers—and manufacturers alone—presumably because cigarette delivery was consolidated; the same company was responsible for production, distribution, and marketing. By contrast, opioid delivery is fragmented. Numerous actors (including manufacturers, distributors, and retail pharmacies, not to mention physicians) play a role in the provision of a single pill. Seizing on the chain-link nature of opioid distribution, as compared to tobacco plaintiffs, opioid plaintiffs are seeking compensation from a larger and more tangled web of defendants.

This fact, too, dramatically complicates the litigation by making it harder to assess each actor’s role in, and responsibility for, plaintiffs’ injuries. Among other implications, the chain-link nature of opioid distribution complicates questions of causation. (For example: Was the pill transfer from manufacturer *A* to distributor *B* the proximate cause of the municipality’s losses, if the municipality’s citizens actually acquired their pills, prescribed by doctor *C*, from retailer *D*?) And, more fundamentally, plaintiffs’ legal claims are stronger as to some categories of defendants and weaker as to others—and, even *within* categories, some defendants behaved more egregiously than others, whether judged by duplicity, irresponsibility, pill volume, or pill potency.²⁷⁷

275. See Joseph F. Rice, *Innovative Class Action Approach in Opioid Litigation Would Create a Beneficial and Coordinated Negotiating Class on Behalf of Communities Nationwide*, MOTLEY RICE: BLOG (June 14, 2019), <https://perma.cc/V57Y-RWJC>.

276. To address this complication, the parties have proposed—and Judge Polster initially approved—a plan to “create a Class for the sole purpose of negotiating and potentially settling with defendants engaged in nationwide opioids manufacturing, sales or distribution.” *Id.*; *In re Nat’l Prescription Opiate Litig.*, 332 F.R.D. 532, 556 (N.D. Ohio 2019), *rev’d*, 976 F.3d 664 (6th Cir. 2020). However, Judge Polster’s certification order was appealed to the Sixth Circuit, and a divided panel reversed, observing that “a new form of class action, wholly untethered from Rule 23, may not be employed by a court.” *Nat’l Prescription Opiate Litig.*, 976 F.3d at 672. For discussion of this unconventional mechanism, see generally Francis E. McGovern & William B. Rubenstein, *The Negotiation Class: A Cooperative Approach to Class Actions Involving Large Stakeholders*, 99 TEX. L. REV. 73 (2020).

277. For example, owing to Purdue’s aggressive (and often misleading) marketing, see *supra* note 121, and OxyContin’s seemingly defective design, see *infra* note 309 and accompanying text, claims against Purdue are particularly strong (or at least would be, absent bankruptcy).

Some defendants operated more (and others less) intensively in those parts of the country that have been hardest hit.²⁷⁸ And, unlike in tobacco, where all defendants remained solvent, some opioid defendants (so far, Insys and Purdue) have already filed for bankruptcy.²⁷⁹

Finally, the forums also differ. In 1998, after efforts to forge a congressionally approved tobacco settlement came to naught, the tobacco litigants reached agreement informally, in the shadow of widespread state-by-state litigation. Although the MDL vehicle—28 U.S.C. § 1407—had been invented and was in tentative use, no tobacco MDL was formed or, as far as we can tell, seriously contemplated, presumably because the mostly state-initiated suits, filed in state courts, were not removable and, as a consequence, resistant to federal consolidation.²⁸⁰ Because the tobacco cases were never consolidated, there was no “uber” judge to preside over, or put his or her imprint on, the tobacco controversy. Not so in the opioid litigation, where Judge Polster—with oversight responsibility for approximately 2,700 claims—has firmly taken the reins and is exerting enormous influence.²⁸¹

IV. Larger Lessons

Above, we canvassed the many obvious and not-so-obvious ways that tobacco and opioids—and the litigation each generated—are different and alike, as well as the implications of these points of divergence and convergence. In this final Part, we move beyond this comparative analysis to examine both episodes with a wider-angle lens. In so doing, we attempt to identify broader lessons that ought to inform policymakers’ response not just to the opioid crisis or to the tobacco problem, but also to future (as-yet-unidentified) public-health calamities. In particular, Subpart A analyzes what the MSA, which (mostly) closed the book on the tobacco litigation, got right and wrong and sets forth concrete suggestions concerning the structure of future aggregate settlements. Subpart B provides insights concerning the easily underestimated

278. The opioid epidemic has been unevenly felt across the United States. See, e.g., Austin Frakt, *Damage from OxyContin Continues to Be Revealed*, N.Y. TIMES (updated Apr. 16, 2020), <https://perma.cc/UEV3-U7MN>.

279. For Insys, see *supra* note 167 and accompanying text. For Purdue, see Jan Hoffman & Mary Williams Walsh, *Purdue Pharma, Maker of OxyContin, Files for Bankruptcy*, N.Y. TIMES (updated Sept. 17, 2019), <https://perma.cc/9L5T-P2UC>.

280. For a history of 28 U.S.C. § 1407, see generally Andrew D. Bradt, “A Radical Proposal”: *The Multidistrict Litigation Act of 1968*, 165 U. PA. L. REV. 831 (2017).

281. For Judge Polster’s significant influence, see Jan Hoffman, *Can This Judge Solve the Opioid Crisis?*, N.Y. TIMES (Mar. 5, 2018), <https://perma.cc/U5XZ-U3F2>. For the 2,600 figure, see Appellants’ Sixth Circuit Br., *supra* note 185, at 5. For the controversy certain of Judge Polster’s actions have engendered, see notes 194-95 above. For the 2,700 figure, see note 183 above.

power of aggregation. And Subpart C offers a theoretical perspective on the efficacy of tort litigation as a source of effective regulatory control.

A. What the MSA Got Wrong and Right

As discussed earlier, the state-initiated tobacco litigation culminated with a master settlement agreement, commonly called the MSA, agreed to by the four major tobacco companies and forty-six states plus five U.S. territories and the District of Columbia.²⁸² A complex and controversial document, the MSA extinguished states' current and future claims against the industry.²⁸³ In return, the industry agreed to provide to the states roughly \$206 billion over a twenty-five year period;²⁸⁴ restrict its advertising;²⁸⁵ abolish the Tobacco Institute, the Council for Tobacco Research, and the Center for Indoor Air Research;²⁸⁶ curtail its lobbying activity;²⁸⁷ furnish some \$1.5 billion to create a foundation to conduct a national public-education campaign to reduce tobacco use;²⁸⁸ and expand public access to internal documents.²⁸⁹

Many have conducted comprehensive MSA postmortems.²⁹⁰ That is not our project here. More narrowly, we focus on just two provisions: the state payments and disclosure requirements. One something of a disappointment and the other a great success, both provide crucial lessons that the opioid

282. See *supra* note 97 and accompanying text.

283. Sloan & Trogdon, *supra* note 237, at 843.

284. *Id.*

285. Among other provisions, the MSA banned billboard advertising, prohibited ads aimed at children and adolescents, and limited brand-name sponsorship of recreational activities. See W. KIP VISCUSI, *SMOKE-FILLED ROOMS: A POSTMORTEM ON THE TOBACCO DEAL* 38 (2002). There is evidence, however, that manufacturers have, at times, flouted these limitations. See Paul J. Chung, Craig F. Garfield, Paul J. Rathouz, Diane S. Lauderdale, Dana Best & John Lantos, *Youth Targeting by Tobacco Manufacturers Since the Master Settlement Agreement*, HEALTH AFFS., Mar./Apr. 2002, 254, 260-62.

286. VISCUSI, *supra* note 285, at 38. However, the industry retained “the freedom to form new trade associations.” *Id.*

287. *Id.*

288. TRUTH INITIATIVE ET AL., *supra* note 236, at 3 (describing the creation of this organization, initially named the American Legacy Foundation and now called the Truth Initiative, and reporting “[t]he latest evidence shows the truth® campaign prevented over 2.5 million youth and young adults from smoking from 2015 to 2018—and many millions more over the life of the campaign”).

289. See *infra* notes 296-98.

290. E.g., Frank Sloan & Lindsey Chepke, *Litigation, Settlement, and the Public Welfare: Lessons from the Master Settlement Agreement*, 17 WIDENER L. REV. 159 (2011); TRUTH INITIATIVE ET AL., *supra* note 236; Walter J. Jones & Gerard A. Silvestri, *The Master Settlement Agreement and Its Impact on Tobacco Use 10 Years Later: Lessons for Physicians About Health Policy Making*, 137 CHEST 692 (2010).

litigants, as well as other future litigants and public-health advocates, would be wise to heed.

The short of it is that the \$206 billion payment—or, more accurately, states' use and expenditure of the \$206 billion payment—has left much to be desired. At the time the MSA was inked, there was a broad consensus that the billions of dollars flowing into state coffers would be spent on smoking prevention and cessation programs and on covering tobacco-related health care costs.²⁹¹ But the MSA did not go so far as to *require* the states to spend their monies on particular programs. And without any such requirement, states exercised substantial discretion. More bluntly, states took the money pouring in, and they cannibalized it, mostly for matters altogether unrelated to tobacco use or public health.²⁹² At the end of the day, only a small fraction of the \$206 billion was spent as intended, and, with this broad diversion, states undermined (if not entirely defeated) one of the litigation's principal objectives.²⁹³ Largely for this reason, “many public health experts regard the MSA as a colossal failure, a capitulation that protected the tobacco industry's interests more than it did public health.”²⁹⁴

291. See Jim Estes, Opinion, *How the Big Tobacco Deal Went Bad*, N.Y. TIMES (Oct. 6, 2014), <https://perma.cc/6NQH-FP25> (“While a requirement that the states use these funds as intended was not written into the agreement, it was anticipated that they would do so.”); Michael Janofsky, *Tiny Part of Settlement Money Is Spent on Tobacco Control*, N.Y. TIMES (Aug. 11, 2001), <https://perma.cc/W7QZ-9KLH> (describing attorneys' “expectation that a large part” of the \$206 billion “would pay for tobacco-use prevention programs”); Vanessa O'Connell, *States Siphon Off Bigger Share of Tobacco Settlement Money*, WALL ST. J. (Oct. 9, 2003, 12:53 AM ET), <https://perma.cc/MWS7-QP5Q> (to locate, click “View the live page”) (quoting Senator John McCain as stating: “The clear impression conveyed to everyone when this deal was cut was that the money would be used for tobacco education and treatment.”).

292. In New York, for example, \$700,000 paid for a public golf course's sprinkler system; in Virginia, \$12 million went to lay fiber-optic lines for broadband cable; and, not to be outdone, North Carolina doled out \$42 million to tobacco farmers for “modernization and marketing.” See Estes, *supra* note 291 (discussing the New York and North Carolina examples); Howard Markel, Opinion, *Burning Money*, N.Y. TIMES (Aug. 22, 2005), <https://perma.cc/448Z-5XJA> (discussing the Virginia example). On the other hand, there is an argument in the states' defense: In the past, states paid medical costs out of revenues that might otherwise have gone to public housing, parks, roads, libraries, technology upgrades, and so forth. Why shouldn't the states now be free to spend—at least in part—on those public necessities, which previously got shortchanged?

293. TRUTH INITIATIVE ET AL., *supra* note 236, at 1 (“Over the past 20 years, from FY 2000 to FY 2019, the states have spent just 2.6 percent of their total tobacco-generated revenue on tobacco prevention and cessation programs.”); *id.* (“In the current budget year, Fiscal Year 2019, the states will collect \$27.3 billion in revenue from the tobacco settlement and tobacco taxes. But they will spend only 2.4 percent of it—\$655 million—on programs to prevent kids from smoking and [to] help smokers quit.”).

294. GIFFORD, *supra* note 59, at 8; *id.* at 216 (observing that the MSA “has widely been judged, even among the most ardent advocates of the litigation, to have been a disappointment and a lost opportunity”).

The MSA's transparency provisions fared differently. The MSA contained a pair of provisions to promote public transparency. The first compelled the manufacturers to support applications for the dissolution of nearly all protective orders.²⁹⁵ This meant, in effect, that the millions of documents that the industry had coughed up in the course of discovery would no longer be shielded from scrutiny. The second required each participating manufacturer to maintain, for a dozen years at its own expense, a website on which all released documents would be posted.²⁹⁶ Combined into the Legacy Tobacco Documents Library (now called the Truth Tobacco Industry Documents), these materials have become an indispensable resource for legions of historians of science, medicine, technology, business, and consumer culture.²⁹⁷ On this score, "there is a broad consensus that the [MSA]... succeeded beyond expectations."²⁹⁸

In the opioid context—and in other contexts going forward—litigants ought to learn from the above failure and success. To the extent possible, when litigants *intend* for monies to be spent for particular purposes, litigants should devise—and judges ought to demand that litigants devise—settlements that *formally* restrict the use of the funds, to ensure that the money the litigation generates isn't diverted or squandered but, rather, tangibly advances the public interest.²⁹⁹ At the same time, the MSA's transparency measures ought to be celebrated and replicated. Meaningful transparency mandates need to become de rigueur in large aggregate, class, and global settlements, in order to establish accountability and advance our collective understanding of how public-health calamities take root.

295. Transparency Amici, *supra* note 15, at 10.

296. *Id.* at 11.

297. *Id.* at 11-12; *Truth Tobacco Industry Documents*, UCSF, <https://perma.cc/B3UV-KDB2> (archived Oct. 28, 2020); see also BRANDT, *supra* note 20, at 12 (explaining that, owing to these provisions, "we have come to know more about the internal operations of the tobacco industry than perhaps any other American big business in the last century"); Stanton Glantz, Opinion, *Lawsuits Against Companies Aren't Just About Getting Money. They're About Revealing the Truth.*, WASH. POST (Sept. 9, 2019, 1:34 PM PDT), <https://perma.cc/9S78-HXJG> (explaining that the repository includes nearly 15 million documents, has been accessed by more than 7 million users, and has contributed to 1,059 scientific papers, media reports, documentaries, and government publications).

298. Transparency Amici, *supra* note 15, at 8.

299. For a detailed discussion of possible ways to fulfill this objective, as well as potential objections and obstacles, see Berman, *supra* note 15, at 1052-58.

B. Aggregation's Impact

The second lesson points to the power of aggregation—and particularly the power of aggregation with surrogate plaintiffs. In both tobacco and opioid litigation, the immediate victims saw little success.³⁰⁰ It was only when claims were aggregated and states and cities stepped in that the tide turned.

1. Whether in tobacco or opioids, individual claims have mostly faltered

As indicated earlier, in the tobacco litigation, *no* individual plaintiff scored a successful outcome through the first forty years of litigation. Even after the MSA was forged, and even buoyed by the damning revelations the earlier litigation unearthed, individual tobacco tort claimants' success has been modest and new filings have slowed to a trickle.³⁰¹ Likewise, in the opioid realm, when it comes to individually initiated claims, plaintiffs have faced dauntingly long odds. Starting with Jackie Renee Burton's doomed 2001 wrongful death suit and continuing on for more than a decade, legions of individual plaintiffs tried—but failed—to hold opioid manufacturers to account.³⁰²

This monumental failure rate presents something of a puzzle. After all, on paper, both individual tobacco and opioid suits looked—and continue to look—quite promising. In the early years of tobacco litigation, plaintiffs were able to show that manufacturers sold an addictive and carcinogenic product without

300. Two words on terminology are warranted. First, when we speak of “aggregation,” we intend to broadly refer to actions that consolidate or collect claims; we do not speak only to that *formal* aggregation authorized by Federal Rule of Civil Procedure 23 or its state court counterparts. Second, when we speak of “success,” we speak narrowly—to cases won or settlements forged. There is no question that a few of the early tobacco plaintiffs who were defeated (or, more accurately, quit in exhaustion) *succeeded* in some respects. Thus, for instance, although neither *Cipollone* nor *Haines* resulted in a penny in payment, both created some at least arguably favorable precedent, generated positive press coverage, and unearthed documents that later litigants ultimately accessed and built upon. See Jeb Barnes, *In Defense of Asbestos Tort Litigation: Rethinking Legal Process Analysis in a World of Uncertainty, Second Bests, and Shared Policy-Making Responsibility*, 34 LAW & SOC. INQUIRY 5, 23 (2009) (cautioning that those who tally litigation's “success[es]” ought to broadly consider “movement building, agenda setting, and the transformation of the understanding of claims and appropriate solutions”).

301. The *Engle*-progeny cases in Florida aside. And even in that litigation, success has been far from guaranteed despite the boost of generic state supreme court findings on common questions of causation and misrepresentation. See *supra* note 78.

302. An exception is a major settlement plaintiffs scored in 2007. For discussion, see *supra* notes 147-48 and accompanying text. We know of no individual plaintiff who prevailed against Purdue on summary judgment or at trial.

including *any* warning about the health risks of smoking.³⁰³ Those actions got tougher once a warning was added in 1966, and then particularly after *Cipollone v. Liggett Group, Inc.*, in which the Supreme Court ruled that the Public Health Cigarette Smoking Act of 1969 preempted most failure-to-warn claims.³⁰⁴ But *Cipollone* contained a critical carveout, preserving actions alleging willful misrepresentation or fraudulent concealment, and that carveout seemingly left plenty of room for plaintiffs to operate.³⁰⁵ Even so, as noted above, tobacco plaintiffs alleging personal injuries continued to face—and, in fact, still face—relatively long odds.

The opioid story is similar. Granted, many opioid plaintiffs were not using the pills as directed, raising potential issues of comparative responsibility and, in certain states, the wrongful-conduct rule.³⁰⁶ Also true, unlike in the tobacco context, physicians, not consumers, were the targets of the industry's aggressive and misleading marketing.³⁰⁷ But even with those complications and caveats, respectable inadequate-warning claims were seemingly available.³⁰⁸ Further, on the design front, it was clear as early as 2000 that OxyContin was readily manipulated (in tort parlance, “foreseeably misused”) to be far more dangerous than was intended or advertised, and it is well established that manufacturers are *supposed* to account for the foreseeable misuse of their design.³⁰⁹ Thus, plaintiffs’ often-asserted claim that “[d]efendants failed to integrate a mechanism into OxyContin which would

303. Prior to 1966, tobacco companies placed no warnings on cigarettes. Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 SYRACUSE L. REV. 897, 901 (1988).

304. See 505 U.S. 504, 524-25 (1992) (plurality opinion).

305. *Id.* at 530-31. The carve out was meaningful because documents have come to light revealing the industry’s deceptive conduct. See *supra* note 90; *infra* note 377.

306. See *supra* notes 136, 138 and accompanying text. Some states would also view the plaintiffs’ intentional misuse as affecting (and defeating) proximate cause. *E.g.*, *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355-56 (S.D. Fla. 2003).

307. The fact that the misleading or inaccurate information was supplied to an intermediary, rather than the individual patient, arguably made it harder to prove causation: that plaintiff *A* would not have become addicted to product *B* if physician *C* had been better informed.

308. After all, even if package warnings were clear enough, the evidence suggests that “detailers” exaggerated the pills’ benefits and downplayed their risks. See 2007 Senate Hearing, *supra* note 121, at 88-90 (statement of John L. Brownlee, U.S. Attorney, Western District of Virginia).

309. *E.g.*, *Jurado v. W. Gear Works*, 619 A.2d 1312, 1317 (N.J. 1993) (“[T]he plaintiff in a design-defect products-liability suit may succeed even if the product was misused, as long as the misuse or alteration was objectively foreseeable.”).

prevent its time-release feature from being circumvented,” on the face of it, should have had legs.³¹⁰

In a products liability arena where plaintiffs have notched so many high-profile victories, what accounts for tobacco and opioid plaintiffs’ dismal individual showings? There are various culprits, but we see two as dominant: culture and cost.

Cultural norms were the first obstacle that stymied both tobacco and opioid plaintiffs.³¹¹ In most high-profile drug and medical device suits (whether involving DES, the Dalkon Shield, fen-phen, Vioxx, Zyprexa, pelvic mesh, or Risperdal), injury victims are generally clueless about the prospective defect that causes their eventual injury. Given this ignorance (and victims’ associated innocence), one can lose sight of the extent to which tort trials have long been—and remain—morality plays, characterized by competing autonomy/responsibility norms.

Yet the fact of the matter is that the American public has a deeply ingrained sense of, and devotion to, independence and freedom of choice.³¹² And, in the face of those cultural norms, a tobacco plaintiff who is aware of the risk but smokes anyway, and the opioid addict who consciously overmedicates (and engages in pill crushing or doctor shopping to boot), continue to be blamed and stigmatized by the American public. Indeed, in opinion polls, respondents continue to insist that tobacco use is the choice of the individual smoker, and respondents have *consistently* blamed smokers—rather than cigarette companies—for smoking-related deaths.³¹³

It’s perhaps no surprise, then, that when tobacco and then opioid cases hit courts, defense lawyers were able to translate these broader beliefs into a

310. *See, e.g.*, *Little v. Purdue Pharma, L.P.*, 227 F. Supp. 2d 838, 843 (S.D. Ohio 2002) (footnote omitted). Even when, in 2010, Purdue closed that door by reformulating OxyContin to make it crush-proof, the company remained vulnerable to claims of failure to adequately warn of the associated risks, buttressed by allegations that the company (and various middlemen) recklessly oversupplied the market.

311. It is important to note that cultural norms are not static, and litigation can play a major role in changing them. Indeed, as we show below, the state tobacco litigation, by all accounts, altered American’s conception of the tobacco industry and acceptance of, and tolerance for, smoking. Likewise, Timothy Lytton has convincingly shown how tort claims reframed the dominant understanding of clergy sexual abuse. *See* TIMOTHY D. LYTTON, *HOLDING BISHOPS ACCOUNTABLE: HOW LAWSUITS HELPED THE CATHOLIC CHURCH CONFRONT CLERGY SEXUAL ABUSE* ch. 4 (2008).

312. As Allan Brandt explains: “In American culture, the ability of individuals to take control over their behaviors and their health is the cornerstone of rational notions of personal responsibility.” BRANDT, *supra* note 20, at 341.

313. WILLIAM HALTOM & MICHAEL MCCANN, *DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS* 229 (2004) (aggregating poll data); THOMAS R. MARSHALL, *PUBLIC OPINION, PUBLIC POLICY, AND SMOKING: THE TRANSFORMATION OF AMERICAN ATTITUDES AND CIGARETTE USE, 1980-2016*, at 131-32, 132 tbl.6.1 (2016) (same).

winning legal strategy. In the early individual tobacco cases, industry lawyers regularly and successfully argued that “the smoker [was] the cause of her own demise.”³¹⁴ And, in opioids—consistent with Richard Sackler’s now-notorious 2001 directive—Purdue bent over backwards to paint plaintiffs in a negative light.³¹⁵ Both episodes, then, offer an important lesson concerning the extent to which “noninnocent” plaintiffs asserting product liability suits have struggled—and are apt to continue to struggle—in U.S. courts, powerful addiction evidence notwithstanding.

Second, when it comes to explaining defendants’ success, cost—and also lawyer capacity—are key.³¹⁶ In the early days, both tobacco and opioid litigation had a distinct David-versus-Goliath quality. Both tobacco and opioid defendants (chiefly Purdue) adopted bare-knuckled tactics and poured virtually unlimited resources into defense efforts. (Indeed, Purdue’s litigation budget was, in the company’s telling, actually unlimited.³¹⁷) Represented by the most prestigious corporate law firms, both tobacco and opioid defendants responded to claims (to quote Purdue’s general counsel) “vigorously and to the hilt.”³¹⁸

314. Note, *Plaintiffs’ Conduct as a Defense to Claims Against Cigarette Manufacturers*, 99 HARV. L. REV. 809, 810 n.8 (1986) (describing the “popular view,” which cigarette companies were able to harness and exploit); see also Sloan & Chepke, *supra* note 290, at 164 (describing various tactics and their success); BRANDT, *supra* note 20, at 341-46 (same).

315. Christopher Rowland, *Prescription Opioids Destroyed Families. Now, Victims Worry Addiction Stigma May Keep Them from Getting Justice*, WASH. POST (Dec. 2, 2019, 7:27 AM PST), <https://perma.cc/N5DM-CS9K> (“Purdue Pharma’s broad legal strategy echoed a position stated in an email by Richard Sackler, the former president and chairman of the family-owned company, in 2001[:]: ‘We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals.’”); Alexandra D. Lahav & Elizabeth Chamblee Burch, *Information for the Common Good in Mass Torts 12* (Oct. 2, 2020) (unpublished manuscript), <https://perma.cc/XE3N-2VZC> (explaining that, for years, “[o]pioid manufactures successfully defended themselves by pointing the finger at doctor-shopping plaintiffs with histories of criminal conduct”); see also *supra* notes 138-39 and accompanying text.

316. Even when one fast-forwards to the present day, costs continue to cast a significant shadow. Product liability suits alleging tobacco- or opioid-related injuries continue to be risky (for the reasons discussed above), time-consuming, vigorously contested, and highly dependent on extremely expensive expert testimony. Particularly in a world where the potential upside is limited (owing to some combination of noneconomic damage caps, due process restrictions on punitive damages, and contingency fee limits), the prospects of such individually initiated actions seem bleak.

317. Krysten Crawford, *Will \$45 Million in Legal Fees and a Take-No-Prisoners Litigation Strategy Save Purdue Pharma’s Wonder Drug?*, CORP. COUNS., Sept. 2002, at 178 (quoting Purdue’s COO, Michael Friedman, as stating that Purdue’s legal team was wholly unconstrained in its spending). Between 2001 and 2006, Purdue reportedly spent some \$400 million to vanquish OxyContin litigation. David Armstrong, *Secret Trove Reveals Bold “Crusade” to Make OxyContin a Blockbuster*, STAT (Sept. 22, 2016), <https://perma.cc/Z8GT-DK4X>.

318. *W. Va. State Court*, *supra* note 138, at 12 (2002) (quoting Howard Udell).

Both Big Tobacco and Purdue prided themselves on their refusal to settle even colorable claims and gloried in their willingness to wage wars of attrition and “win at all costs.”³¹⁹ Facing these well-heeled adversaries, plaintiffs’ lawyers in both the early tobacco and opioid suits were outmatched in nearly every conceivable way. Along the way, legions of plaintiffs’ lawyers (quite rationally) opted to voluntarily dismiss their claims rather than face the high cost, long odds, and certain pain of further litigation.³²⁰

2. Aggregation and the implications of proceeding with surrogates and en masse

Frustrated by losing and sensitive to the substantive and institutional weaknesses of individual claims, litigators ultimately turned to an alternative strategy: collective action by surrogate claimants, namely, in the case of tobacco, state attorneys general. It was, in retrospect, a brilliant pivot, for it neutralized both of the defense-side advantages that had, for so long, stymied tobacco litigation: culture on the one hand, cost and capacity on the other.³²¹

On the former, as Mississippi Attorney General Michael Moore—who helped pioneer the novel strategy—was quick to point out, states (unlike individual plaintiffs) had never smoked.³²² As nonsmokers, they were impervious to character assassination and insulated from an assumed-risk defense.³²³ Thus, as Moore put it: “State actions are not about personal

319. Crawford, *supra* note 317, at 182-84.

320. Illustrating the point, the first plaintiffs’ lawyer to sue Purdue over OxyContin was Joe Hale from Portsmouth, Ohio. SAM QUINONES, *DREAMLAND: THE TRUE TALE OF AMERICA’S OPIATE EPIDEMIC 199-201* (2015). Initially wary of taking on a pharmaceutical giant, Hale overcame his reluctance and filed a lawsuit on behalf of the late Jackie Burton. *Id.* Yet, though Hale filed suit with high hopes, “[a]fter a few court hearings with him at one table and six or eight well-dressed Purdue attorneys on the other,” Hale voluntarily dropped the suit on the eve of trial. *Id.* at 201. For examples in the tobacco context, see notes 62-63 and the accompanying text above.

321. The pivot also permitted private attorneys, who were routinely stigmatized and vilified, to step out of the spotlight in favor of public officials, who were somewhat less controversial. Michael McCann & William Haltom, *Seeing Through the Smoke: Adversarial Legalism and U.S. Tobacco Politics*, in *VARIETIES OF LEGAL ORDER: THE POLITICS OF ADVERSARIAL AND BUREAUCRATIC LEGALISM* 57, 73 (Thomas F. Burke & Jeb Barnes eds., 2018); see also Erichson, *supra* note 73, at 134 (“State governments seeking reimbursement, particularly as a group, carry a certain moral authority that private plaintiffs lack.”).

322. Mike Moore, *The States Are Just Trying to Take Care of Sick Citizens and Protect Children*, 83 A.B.A. J., Jan. 1997, at 53.

323. See Erichson, *supra* note 73, at 134 (recognizing that, in tobacco, “government suits sidestepped the cigarette makers’ favorite defense—that individual smokers should accept personal responsibility for choosing to smoke”).

responsibility; they are about corporate responsibility.”³²⁴ So framed, compared to individual actions initiated by smokers, state actions were significantly more popular with the American public.³²⁵

On the latter, with taxpayers, along with some of the country’s top plaintiffs’ lawyers, footing the bill, states were capable of surmounting even formidable cost barriers and going toe-to-toe with their well-heeled adversaries. And, on at least some scores, the story, for plaintiffs, had a satisfying ending, as the state-based MSA litigation culminated in the largest settlement in the history of American civil litigation. It was, perhaps, inevitable that opioid plaintiffs would ultimately seek to follow the same script.

Viewed through a wide-angle lens, the shift has substantial consequences for the *individual* victims of substance abuse. Plainly, the most apparent consequence is that, once governmental entities take the reins, tort may continue to serve its deterrent function (though that depends, in some measure, on the structure of any eventual settlement). But tort law does not, and logically cannot, serve its compensatory function—and, as a procedural-justice matter, surrogate actions leave direct victims on the outside looking in.

C. Value of Public-Health Litigation

Finally, both episodes yield broad insights regarding the relative merit of public-health litigation, while providing new support for what we call a catalyst theory.

Tobacco and opioid litigation both coincided with significant regulatory pushes and behavioral changes. On the tobacco side, state litigation occurred roughly contemporaneously with a number of major state and federal excise-tax increases, place-of-use restrictions (limiting where smokers could light up), a sharp uptick in educational messaging, and, as discussed in more detail below, an FDA effort to subject the industry to comprehensive regulatory control.³²⁶

Similarly, over the past few years, just as there has been a surge of litigation against opioid makers, distributors, and retailers, there has been a

324. Moore, *supra* note 322, at 53.

325. This is not to suggest that the state suits garnered overwhelming public support; they didn’t. But, as compared to individual suits, the state suits’ reception was much warmer. MARSHALL, *supra* note 313, at 132-35, 132 tbl.6.1, 135 tbl.6.2 (amassing data).

326. See Robert A. Kagan & William P. Nelson, *The Politics of Tobacco Regulation in the United States*, in REGULATING TOBACCO 11, 17-21 (Robert L. Rabin & Stephen D. Sugarman eds., 2001) (compiling major tobacco-control actions, including California’s 1998 decision to ban smoking in bars and the fact that, from “1988 through 1998, 38 states enacted substantial tax increases”); INST. OF MED., *supra* note 248, at 110-12 tbl.5-1 (compiling milestones in decreasing indoor use of tobacco and showing a surge of regulatory activity beginning in the early 1990s).

swell of (on the face of it, unrelated) public and private activity. This activity is evident on the federal level. The CDC has issued a new Guideline for Prescribing Opioids for Chronic Pain, which—in a sharp break from past policy—expresses a strong preference for nonopioid therapies.³²⁷ The Department of Justice is redoubling enforcement efforts.³²⁸ The Centers for Medicare and Medicaid Services are implementing strict coverage limits for prescriptions for opioid-naïve patients.³²⁹ Currently, the average prescription extends for approximately three weeks; under the new restrictions, opioid-naïve users will be limited to a seven-day supply.³³⁰ The FDA is spearheading a range of initiatives, including new efforts to stem the flow of illegal opioid shipments, prevent illicit internet sales, and clamp down on reckless distributors.³³¹ It's also updating guidance on the risks and benefits of opioid use and speeding the overdose-reversal drug naloxone to over-the-counter status.³³² The DEA has similarly (if belatedly) sprung into action. For decades, the DEA had access to ARCOS data that surfaced diversion trends, but it failed to make much use of this vital information.³³³ That is changing, however, and, within the past few years, the DEA has finally “begun to use the data proactively to generate leads.”³³⁴ Even our conflict-riddled Congress has responded with surprising vigor, as it enacted the Comprehensive Addiction and Recovery Act (CARA) in 2016 and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act into law in 2018.³³⁵

327. Press Release, Ctrs. for Disease Control & Prevention, CDC Releases Guideline for Prescribing Opioids for Chronic Pain, <https://perma.cc/8BK5-DJBY> (archived Oct. 28, 2020).

328. For example, the DOJ recently announced the creation of a new “Opioid Strike Force” dedicated to investigating and prosecuting “health care fraud schemes in the Appalachian region.” Press Release, U.S. Dep’t of Justice, Justice Department’s Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions (Oct. 25, 2018), <https://perma.cc/A32E-AZGR>. The DOJ has also announced the creation of a new fraud unit “that will run data analytics to identify opioid-related use trends.” RED FLAGS, *supra* note 173, at 58.

329. Soni, *supra* note 238, at 2-3.

330. *Id.* at 3.

331. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FDA, <https://perma.cc/MJL9-PRT8> (last updated Aug. 11, 2020) (to locate, select the “2019” drop-down).

332. *Id.*

333. See RED FLAGS, *supra* note 173, at 8.

334. *Id.* at 46.

335. For more on both enactments, see *Laws and Regulations, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN.* (updated Apr. 27, 2020), <https://perma.cc/TV35-VPEE>.

States are likewise taking new steps. Since 2016, more than a dozen states have passed mandatory prescription limits for opioid-naïve patients.³³⁶ In an effort to identify “possible ‘doctor shoppers’ (individuals who visit multiple prescribers or pharmacies to obtain numerous prescriptions),” as well as to surface inappropriate provider practices, all states have constructed databases that providers can—or, in some cases, must—access to show whether opioids have been previously prescribed to a particular patient.³³⁷ Many have passed new “Good Samaritan” laws to shield people who call for help for drug-related medical emergencies from being arrested for drug possession in most circumstances.³³⁸ And, as noted above, a few states are experimenting with opioid-specific taxes and fees.³³⁹

Finally, private actors have gotten in on the act. Dentists and physicians have begun to reform their prescription practices.³⁴⁰ Private insurance companies are also taking affirmative actions: Some, for example, are cutting off coverage for OxyContin altogether;³⁴¹ others are expanding access to nonopioid pain-management mechanisms;³⁴² and, like Medicare, still others are imposing new seven-day prescription limits.³⁴³ Manufacturers have also taken belated steps: In February 2018, for example, Purdue announced it would discontinue its opioid-promotion practices.³⁴⁴

336. Marilyn Bulloch, Rebecca Whitmore & David Whisenant, *Opioid Prescribing Limits Across the States*, PHARMACY TIMES (Feb. 5, 2019, 3:00 PM), <https://perma.cc/9ZN7-X87V>. Some states’ laws focus on duration and restrict initial prescriptions to seven, five, four, or three days. *Id.* Other states have limited not just pills’ duration but also their dosage. *Id.*

337. NAT’L ACADS. OF SCIS., ENG’G & MED, *supra* note 225, at 309; *see also* Andrew M. Parker, Daniel Strunk & David A. Fiellin, *State Responses to the Opioid Crisis*, 46 J.L. MED. & ETHICS 367, 367, 369 (2018).

338. Amanda Pustilnik, *The Law’s Responses to the Opioid Epidemic: Legal Solutions to a Unique Public Health, Criminal Law, and Market-Related Crisis*, in CONFRONTING OUR NATION’S OPIOID CRISIS: A REPORT OF THE ASPEN HEALTH STRATEGY GROUP 89, 104 (Alan R. Weil & Rachel Dolan eds., 2017).

339. *See supra* note 241 and accompanying text.

340. For example, private agreements between physicians and patients—often called “opioid contracts”—have proliferated. Mark A. Rothstein, *The Opioid Crisis and the Need for Compassion in Pain Management*, 107 AJPH PERSPS. 1253, 1253 (2017). Pursuant to these contracts, physicians who prescribe opioids for chronic pain require the patient to consent to a range of controls, including random drug testing and pill counts (to ensure that the patient is taking, rather than diverting, the medication). *Id.*

341. Blake Farmer, *Insurer to Purdue Pharma: We Won’t Pay for OxyContin Anymore*, NPR (Sept. 12, 2018, 4:12 PM ET), <https://perma.cc/Y9XR-F9TQ>.

342. NAT’L ACADS. OF SCIS., ENG’G & MED, *supra* note 225, at 308-09.

343. Soni, *supra* note 238, at 3.

344. Ben Poston, *Capping Years of Criticism, Purdue Pharma Will Stop Promoting Its Opioid Drugs to Doctors*, L.A. TIMES (Feb. 10, 2018, 7:00 PM), <https://perma.cc/Z34B-PBMP>.

An open—and crucial—question is whether we'd be seeing this swell of activity in the absence of the current litigation. We believe that the answer is no. We believe that the above suggests that, to an even greater extent than in the tobacco realm (where, at least by 1994, information about the adverse health effects of smoking—if not the knowledge or culpability of the industry—was well known), the opioid litigation has already succeeded in altering the behavior of certain institutional actors.³⁴⁵

This conclusion is both practically and theoretically significant. On the latter, the relationship between litigation and other regulatory activity has long been debated. To this point, though, much of that debate has been broad-brush and somewhat acontextual. Further, much of the debate has focused on whether litigation is *better* than regulation or *worse* than regulation, without recognizing that the two are not rivals; the question, in the real world, is often not either/or.³⁴⁶ The two often are symbiotic and synergistic—and, as a consequence, there is much to be gained in studying the complex *interaction* between the two: in mapping where and how regulation and litigation, at least sometimes, overlap and intersect.³⁴⁷

345. Regarding tobacco knowledge: Although tobacco-company executives famously swore in 1994 that they did not believe cigarettes were addictive and that the evidence that cigarettes caused lung cancer was “not conclusive,” some might say that the lung-cancer question was answered as early as 1964, when the Surgeon General issued his blockbuster report. See Philip J. Hiltz, *Tobacco Chiefs Say Cigarettes Aren't Addictive*, N.Y. TIMES (Apr. 15, 1994), <https://perma.cc/7EFT-QNF2> (for testimony); *supra* notes 23, 36 (for the Surgeon General's report). Regarding the opioid litigation's success in altering the behavior of certain actors, see Gluck et al., *supra* note 128, at 352 (highlighting various opioid-related reforms while observing that “[i]t is impossible to draw causal links, but it is highly unlikely that the attention the litigation has drawn to the crisis combined with the threat of impending resolution did not contribute”); and Hoffman, *supra* note 281 (quoting an expert who attributed Purdue's decision to discontinue its marketing efforts in part to “overwhelming pressure from Judge Polster”).

346. If one were to tally comparative advantages, tort law is inferior to regulatory activity in certain respects. It is both backward-looking and blunt. It can also be slow, unpredictable, nondemocratic, unduly incremental, “powerfully influenced . . . by ever-changing normative judgments about the scruples of the contestants,” and heavily dependent on “extraordinary investments [in] lawyering.” See Robert L. Rabin, *The Third Wave of Tobacco Tort Litigation*, in REGULATING TOBACCO, *supra* note 326, at 176, 200. For more institutional tallying, see generally Aaron J. Ley, *The Costs and Benefits of American Policy-Making Venues*, 48 LAW & SOC'Y REV. 91 (2014). For a cogent sketch of the current debate, as well as its limitations, see generally Timothy D. Lytton, *Using Litigation to Make Public Health Policy: Theoretical and Empirical Challenges in Assessing Product Liability, Tobacco, and Gun Litigation*, 32 J.L. MED. & ETHICS 556 (2004).

347. The complementarity and interdependence of tort litigation and administrative regulation has been a central theme in the work of Timothy Lytton. See e.g., TIMOTHY D. LYTTON, *OUTBREAK: FOODBORNE ILLNESS AND THE STRUGGLE FOR FOOD SAFETY* 13-15 (2019); Timothy D. Lytton, *Using Tort Litigation to Enhance Regulatory Policy Making: Evaluating Climate-Change Litigation in Light of Lessons from Gun-Industry and Clergy-Sexual-Abuse Lawsuits*, 86 TEX. L. REV. 1837, 1838-40 (2008) [hereinafter Lytton, *Enhance* footnote continued on next page

To be sure, sometimes, litigation has no discernable effect on regulatory activity.³⁴⁸ Sometimes (as in the case of firearms, for example) it has a counterproductive effect, insofar as it generates a legislative backlash.³⁴⁹ Sometimes, even, litigation can substitute for or crowd out regulatory action, essentially stopping political efforts in their tracks.³⁵⁰ Or, sometimes—as in the case of both tobacco and opioid litigation—it can *serve as a catalyst*. It can do this, we submit, by (1) drawing attention to the problem's existence; (2) uncovering otherwise concealed information to establish accountability and clarify the problem's origin, scope, and character; and, in so doing, (3) affect public opinion in such a way as to spur private activity and also make political action against a powerful industry more palatable.³⁵¹

First, litigation can draw attention to a problem. This was vividly seen with tobacco, where *New York Times* coverage of the health risks of smoking positively surged between May 1994, when Mississippi filed its pathbreaking action, and November 1998, when the MSA was executed, and even local news outlets followed the twists and turns of the state litigation in scrupulous

Regulatory Policy Making]; Timothy D. Lytton, *Clergy Sexual Abuse Litigation: The Policymaking Role of Tort Law*, 39 CONN. L. REV. 809, 812-14 (2007).

348. Even in the tobacco context, certain municipalities enacted early public-place restrictions in response to concerns about secondhand smoke exposure. These municipalities were seemingly reacting to information generated by public health experts; they were not obviously influenced by the tobacco litigation.
349. See Lytton, *Enhance Regulatory Policy Making*, *supra* note 347, at 1838 & n.6.
350. Arguably, *Obergefell v. Hodges*, 135 S. Ct. 2584 (2015), which ruled that same-sex couples have a constitutional right to marry, falls into this category.
351. In setting forth this “catalyst” theory, we draw from, and build upon, work by other prominent scholars. GERALD N. ROSENBERG, *THE HOLLOW HOPE: CAN COURTS BRING ABOUT SOCIAL CHANGE?* 25-30 (1991) (offering, though mostly dismissing, a theory of courts as “catalysts”); see also, e.g., Cuéllar & Humphreys, *supra* note 2, at 66-68 (observing that, sometimes, “civil litigation can contribute to spurring broader action,” in part because it is “capable of generating information [and] public attention”); Wendy E. Parmet, *Tobacco, HIV, and the Courtroom: The Role of Affirmative Litigation in the Formation of Public Health Policy*, 36 HOUS. L. REV. 1663, 1695 (1999) (“[L]itigation is more than simply the understudy for legislation. Litigation can also help lead to the enactment of legislation.”). See generally, e.g., Lytton, *Enhance Regulatory Policy Making*, *supra* note 347 (showing how litigation can, among other things, frame issues, generate policy-relevant information, and place the issue on the agenda of policymaking institutions); Mather, *supra* note 38, at 899, 912 (contending that tobacco litigation, in particular, “significantly influenced national policymaking” by, among other things, unearthing previously undisclosed information and generating media coverage that was harshly critical of the cigarette industry); Barnes, *supra* note 300, at 15, 23 (offering an account of how the asbestos litigation of the 1980s and early 1990s contributed to the “broader policy-making process”).

detail.³⁵² Opioid litigation has done much the same, as opioid filings—and associated revelations—have been prominently covered in the popular press.³⁵³

Second, in addition to drawing attention to a brewing problem, public-health litigation—and the reciprocal discovery at its contemporary core—can help to uncover documents and other evidence that permit courts and commentators to map the extent of the problem, trace its root causes, allocate responsibility, and assign blame.³⁵⁴

Tobacco litigation and opioid litigation again vividly illustrate the above narrative. In tobacco, it was litigation—starting with *Cipollone* and escalating throughout the state health care reimbursement suits—that established, once and for all, what the industry knew about the danger of its product.³⁵⁵ It was

352. MARSHALL, *supra* note 313, at 53 fig.3.1. Of course, not all of these stories focused on the pending litigation. Much of this coverage was focused on related matters, including secondhand smoke and emergent scientific studies that uncovered new evidence of the risks of smoking. For further discussion of the intense media coverage of the tobacco litigation, as well as the fact that “[m]edia coverage of the litigation was virtually all negative from the tobacco industry’s point of view,” see Mather, *supra* note 38, at 916-18, 923, 936. See also McCann et al., *supra* note 64, at 302-11, 307 fig.3 (empirically investigating media coverage during the relevant period and finding, among other things, a spike in invocations of the tobacco companies’ “[c]riminality” between 1991 and 1998).

353. See, e.g., Lauren A. Rousseau, *An Avalanche of Lawsuits Holds Hope for the Opioid Epidemic*, JURIST (Mar. 12, 2018, 4:45:28 PM), <https://perma.cc/A5M2-KZP9>.

354. For discussion and contemporary examples of litigation’s “information-forcing” role, see ALEXANDRA LAHAV, IN PRAISE OF LITIGATION 56-83 (2017); Lahav & Burch, *supra* note 315, at 7-13; Diego A. Zambrano, *Discovery as Regulation*, 118 MICH. L. REV. 71, 94-95 (2020); Nora Freeman Engstrom, *When Cars Crash: The Automobile’s Tort Law Legacy*, 53 WAKE FOREST L. REV. 293, 328-35 (2018); Barnes, *supra* note 300, at 7; Wendy Wagner, *Stubborn Information Problems & the Regulatory Benefits of Gun Litigation*, in *SUING THE GUN INDUSTRY: A BATTLE AT THE CROSSROADS OF GUN CONTROL & MASS TORTS* 271, 271, 275-76 (Timothy D. Lytton ed., 2006); Timothy D. Lytton, *Framing Clergy Sexual Abuse as an Institutional Failure: How Tort Litigation Influences Media Coverage*, 36 WM. MITCHELL L. REV. 169, 180-82 (2009); Lytton, *Enhance Regulatory Policy Making*, *supra* note 347, at 1845-46, 1852-54; Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 711-18 (2007); Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293, 302 (2007); Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2068-70 (2000) [hereinafter Rabin, *Reassessing*]; and Peter H. Schuck, *Mass Torts: An Institutional Evolutionist Perspective*, 80 CORNELL L. REV. 941, 951-53 (1995). For why the tort system stands at a comparative advantage when it comes to uncovering policy-relevant information, see Rabin, *Reassessing*, *supra*, at 2068-70.

355. See generally Cirese et al., *supra* note 54 (discussing revelations unearthed during the *Haines*, *Cipollone*, and Minnesota litigation, the last of which uncovered some 35 million pages of previously undisclosed material); BRANDT, *supra* note 20, at 440 (explaining that litigation revealed “the industry’s extensive knowledge of the harms of its product” and further opining that, were it not for the litigation, “the documents proving these charges would most certainly have remained in the industry’s legal vaults”); Rabin, *Reassessing*, *supra* note 354, at 2070 (explaining how the litigation uncovered information that drew a “sharply defined picture . . . of industry indifference
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litigation that laid bare the irresponsible steps that industry leaders took in the face of that knowledge (including spreading scientific disinformation, marketing to children, manipulating the nicotine content of cigarettes, and concealing information concerning the comparative risks of low tar and light cigarettes).³⁵⁶ And it was litigation that pulled back the curtain on how, exactly, the industry abused the litigation process—including through its perversion of the attorney-client privilege—in order to keep its activities under wraps.³⁵⁷

Though still ongoing, opioid litigation has similarly generated crucial information about the scope, causes, and character of the epidemic.³⁵⁸ Massachusetts’s suit against Purdue has surfaced stunning allegations about how the company penetrated medical practice and encouraged the reckless over-prescription of their marquee painkiller, OxyContin.³⁵⁹ Oklahoma’s trial against J&J, which involved the admission of more than 870 now-publicly-

to health concerns and suppression of information in the manufacturing and marketing of tobacco”); Lahav & Burch, *supra* note 315, at 11 (tracing how documents unearthed in the tobacco litigation and press coverage thereof significantly altered “public sentiment”).

356. BRANDT, *supra* note 20, at 440 (explaining that litigation revealed “the industry’s . . . concerted efforts to obscure” key facts concerning the health risks of smoking); GIFFORD, *supra* note 59, at 189-90 (“[U]ntil information came to light, at least indirectly, through the litigation process, Congress and the FDA were not fully aware that tobacco manufacturers had manipulated the nicotine content of cigarettes”); PRINGLE, *supra* note 24, at 171-74 (explaining and documenting that litigation “uncover[ed] a series of confidential documents . . . [which] put the lie to the notion, promoted by the companies, that they do not target youth”); Rabin, *supra* note 8, at 1750 (“[T]he full story of the industry’s conscious disregard for the health effects of its profit-making activity might never have become a part of the public record in the absence of the tort litigation.”); INST. OF MED., *supra* note 235, at 148 (“[T]he state Medicaid lawsuits and other tobacco litigation led to revelations of industry deception and duplicity and confirmed the industry’s role in fostering and perpetuating tobacco use.”); Lisa Bero, *Implications of the Tobacco Industry Documents for Public Health and Policy*, 24 ANN. REV. PUB. HEALTH 267, 267, 268 tbl.1 (2003) (explaining that the “internal tobacco industry documents,” which were unearthed in the course of tobacco litigation, gave “the public health community unprecedented insight into the industry’s motives, strategies, tactics, and data”); Mather, *supra* note 38, at 930-31 (describing the “critical” information the litigation unearthed).

357. PRINGLE, *supra* note 24, at 194-95; Transparency Amici, *supra* note 15, at 10; Ciresi et al., *supra* note 54, at 499-500, 506.

358. Opioid litigation’s information-forcing role is particularly notable because so much of what’s been disclosed to plaintiffs remains under seal. Benjamin Lesser, Dan Levine, Lisa Girion & Jaimi Dowdell, *How Judges Added to the Grim Toll of Opioids*, REUTERS (June 25, 2019, 1:00 PM GMT), <https://perma.cc/M858-GNW8>.

359. E.g., Brian Mann, *Opioid Litigation Brings Company Secrets into the Public Eye*, NPR (Mar. 13, 2019, 5:01 AM ET), <https://perma.cc/7TN8-NZSK>; Barry Meier, *Sackler Scion’s Email Reveals Push for High-Dose OxyContin, New LawsUIT Disclosures Claim*, N.Y. TIMES (Jan. 31, 2019), <https://perma.cc/R667-5ER7>.

available exhibits, further pulled back the curtain on the defendants' duplicitous marketing efforts and concerted "strategy" to "target[] high-opioid-prescribing physicians."³⁶⁰ Suits have revealed the extent to which the "big three" distributors (Cardinal Health, McKesson, and AmerisourceBergen) were derelict in their duties—including the fact that though they were legally obligated to monitor suspicious orders, they did not have meaningful programs to perform such oversight.³⁶¹ Last but not least, litigation has forced the public release of ARCOS data—the confidential database maintained by the DEA that maps where every pill originated and where it was sold.³⁶² Release of these data (which both manufacturers and the DEA fought furiously to prevent) has been deeply revelatory.³⁶³ Among other things, the ARCOS data reveal that a mind-boggling number of pills was sold from 2006 through 2012 (far more than had been previously estimated).³⁶⁴ It also permits journalists, researchers, health experts, and the public to measure and map the precise roots and contours of the opioid epidemic for the first time, while also identifying, with precision, which manufacturers, distributors, and retailers shipped the most pills to the hardest-hit communities.³⁶⁵

360. *State v. Purdue Pharma L.P.*, No. CJ-2017-816, 2019 WL 4019929, at *1, *4, *9-10 (Okla. Dist. Ct. Aug. 26, 2019).

361. Danny Hakim, William K. Rashbaum & Roni Caryn Rabin, *The Giants at the Heart of the Opioid Crisis*, N.Y. TIMES (Apr. 22, 2019), <https://perma.cc/7UH6-6VPY>.

362. See Jennifer D. Oliva, *Opioid Multidistrict Litigation Secrecy*, 80 OHIO ST. L.J. 663, 665-83 (2019). For more on the ARCOS database, see note 254 above.

363. For more on the DEA's and manufacturers' fierce objections to disclosure, see note 254 above. Even Judge Polster wanted the data kept under wraps (revealed to plaintiffs but subject to a blanket protective order). Unsatisfied, news outlets challenged the protective order and prevailed. *In re Nat'l Prescription Opiate Litig.*, 927 F.3d 919, 938 (6th Cir. 2019). For the *Washington Post's* account of its own litigation to access the database, see Joel Achenbach, *How an Epic Legal Battle Brought a Secret Drug Database to Light*, WASH. POST (Aug. 2, 2019, 9:13 AM PDT), <https://perma.cc/6B8Q-ABQX>.

364. For revelations buried within the ARCOS data, see generally Higham et al., *supra* note 166.

365. See, e.g., *Drilling into the DEA's Pain Pill Database*, WASH. POST (updated Jan. 17, 2020), <https://perma.cc/U5EM-KQJL>. The story of Tug Valley Pharmacy is similarly revealing. West Virginia leads the nation in fatal drug overdoses, and this Williamson, West Virginia, pharmacy had been described as "one of the most notorious of the pill mill[s]" in the embattled state. *Ballengee v. CBS Broad., Inc.*, 331 F. Supp. 3d 533, 538 (S.D. W. Va. 2018) (quoting the defendants' motion for summary judgment). Yet, for years, the pharmacy simply chugged along. Recently, however, the tide turned. The turnabout came when one of the nation's largest opioid distributors—McKesson—announced it was ending shipments of controlled substances to Tug Valley, effective immediately. Why the change of heart? A member of McKesson's leadership team "read the plaintiffs' brief" in a lawsuit filed against the pharmacy, which included testimony from the pharmacy's owner indicating that Tug Valley "filled more than 150 prescriptions daily from one pain clinic alone." *Id.* at 543 (quoting the defendants' motion for summary judgment). Soon after that, Tug Valley was shuttered for good.

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Third and finally, litigation (fortified by the damning disclosures uncovered in discovery) can help to shape public opinion and, ultimately, stimulate private, political, and regulatory activity.³⁶⁶ Once again, both the tobacco and opioid litigation appear to illustrate this dynamic.

To be sure, our conclusions are tentative, as pointing a causal arrow between litigation and regulatory action is fraught; even showing what “caused” public opinion to shift is dicey (in fact, the simple matter of documenting a shift in public opinion is difficult, because few pollsters ask the same questions over time). Nevertheless, with those important caveats, provisional evidence suggests that, throughout the mid- and late 1990s, as the states battled the tobacco industry, and as media coverage of the scandalous revelations the tobacco litigation unearthed filled the airwaves, Americans’ trust of Big Tobacco “plummeted to extremely low levels.”³⁶⁷

The plight of Philip Morris is revealing. As of 1990, before *Castano* or the initiation of the state Medicaid litigation, a *Fortune* magazine survey found that Philip Morris was the second most admired corporation in the United States.³⁶⁸ By 1999, however, the *Wall Street Journal* reported that, based on a large nationwide survey, Philip Morris had the “worst reputation in America.”³⁶⁹ Soon thereafter, the company announced plans to change its name to the Altria Group.³⁷⁰ The switch was needed, executives explained, “to reduce

Travis Crum, *Tug Valley Pharmacy Closes After Controversy*, LOGAN BANNER (updated May 29, 2018), <https://perma.cc/2D3A-X949>.

366. For how public opinion shapes policy generally, and tobacco policy in particular, see MARSHALL, *supra* note 313, at 6-18, 121-22.

367. McCann et al., *supra* note 64, at 314 (reporting on a Harris poll). Or as the *New York Times* put it in 1997, “in the last three years, as tobacco companies have faced a steady drip-drip-drip of disclosures about deceptive marketing practices, public opinion has shifted forcefully against the tobacco industry.” Kevin Sack, *For the Nation’s Politicians, Big Tobacco No Longer Bites*, N.Y. TIMES (Apr. 22, 1997), <https://perma.cc/LLG3-F2NA>; see also HHS RETROSPECTIVE, *supra* note 11, at 32 (“During this period, tobacco companies lost credibility in the eyes of the public.”); DAN ZEGART, CIVIL WARRIORS: THE LEGAL SIEGE ON THE TOBACCO INDUSTRY 224-25 (2000) (remarking that, by 1997, “[s]uddenly the air was full of real hatred toward the cigarette men”); McCann & Haltom, *supra* note 321, at 74 (explaining that tobacco litigation—and sympathetic media coverage thereof—accompanied “dramatic drops in public opinion polls regarding ‘trust’ in the industry”); Mather, *supra* note 38, at 925 (concluding that tobacco litigation shifted public opinion against the tobacco industry).

368. Sarah Smith, *America’s Most Admired Corporations*, FORTUNE, Jan. 29, 1990, at 58, 62.

369. Ronald Alsop, *Harris Interactive Survey Indicates Fragility of Corporate Reputations*, WALL ST. J. (updated Feb. 7, 2001, 12:01 AM ET), <https://perma.cc/SZ3V-9HNV> (to locate, click “View the live page”); Ronald Alsop, *The Best Corporate Reputations in America: Johnson & Johnson Turns Up Tops*, WALL ST. J., Sept. 23, 1999.

370. John Schwartz, *Philip Morris to Change Name to Altria*, N.Y. TIMES (Nov. 16, 2001), <https://perma.cc/2S8S-D3VZ>.

the drag on the company's reputation that association with the world's most famous cigarette maker has caused."³⁷¹

Public opinion polls also paint a portrait. From 1980 to 1996, the percentage of Americans with an unfavorable opinion of the tobacco industry rose significantly, from 58% to 75%.³⁷² By March 1997, one public opinion poll found that 92% of Americans believed that "tobacco companies know [smoking] causes cancer even if they do not admit it."³⁷³ And, by the fall of 1999, as media accounts trumpeted the "rout of the new evil empire,"³⁷⁴ a nationwide poll found that a strong majority of Americans (69%) believed the industry ought to be regulated.³⁷⁵

As public perception soured, political support for the industry, which had been a longstanding bulwark of immunity from restrictive regulation, evaporated.³⁷⁶ This shift in public opinion—combined with the unflattering revelations that contributed thereto—by all accounts opened the door to an important round of regulatory activity.³⁷⁷ Indeed, when the FDA asserted its

371. *Id.*

372. Mather, *supra* note 38, at 923-24 (reporting Roper poll data).

373. Sack, *supra* note 367; see also Ceci Connolly & John Mintz, *For Cigarette Industry, a Future Without GOP Support*, WASH. POST (Mar. 29, 1998), <https://perma.cc/3HYA-DKR4> (reporting that, by 1998, "a huge majority of Americans—polls place it between 70 and 80 percent—mistrust the cigarette companies, viewing them as greedy executives profiting from kids").

374. *Rout of the New Evil Empire*, ECONOMIST (Nov. 4, 1999), <https://perma.cc/X7SY-DN7Q>.

375. MARSHALL, *supra* note 313, at 112; McCann & Haltom, *supra* note 321, at 74-75 (explaining that tobacco litigation—and sympathetic media coverage thereof—accompanied "increases in support for FDA regulation").

376. See HHS RETROSPECTIVE, *supra* note 11, at 32 ("Momentum from the states' lawsuits . . . turned the political tide against the tobacco industry in the mid-1990s, and their influence in Congress weakened."); Sloan & Trogon, *supra* note 237, at 854 (explaining that the third wave of litigation and resulting settlement "weaken[ed] the companies' political clout in opposing future legislation aimed at tobacco control"); Connolly & Mintz, *supra* note 373 (reporting, as of March 1998, that "[t]he once-mighty makers of cigarettes have seen a vast reservoir of political support evaporate").

377. Mary H. Cooper, *Regulating Tobacco*, 4 CQ RESEARCHER, Sept. 1994, at 3 ("As the evidence of tobacco's harmfulness mounts, public opinion has turned increasingly against tobacco. State and local ordinances banning smoking in public buildings and raising excise taxes on cigarettes have spread across the country."); see also INST. OF MED., *supra* note 235, at 125 ("The exposure of the tobacco companies' deceptive marketing practices not only resulted in widespread criticism of the industry but also created a new justification for legal action and regulation."); McCann et al., *supra* note 64, at 314 ("The dramatic change in public attitudes toward tobacco corporations was critical to the success in winning legislative authorization of FDA regulatory control over tobacco . . ."); Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. HEALTH POL. POL'Y & L. 769, 777, 788 (1999) (stating that, as a "consequence" of the third wave of litigation—and the information it unearthed—"public attitudes toward the industry have become

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(albeit short-lived³⁷⁸) authority to regulate the tobacco industry in 1996, the FDA “justifie[d]” its action on its review and compilation of three decades of previously hidden internal tobacco-company documents, many of which were unearthed in litigation, and nearly all of which spoke to the industry’s knowledge and intent.³⁷⁹

Though less far along, the opioid story is, by all accounts, similar.³⁸⁰ As the opioid litigation has matured, public condemnation has gradually shifted from users and abusers to other contributors.³⁸¹ Reflecting this evolution, a 2016 poll—which predated the December 2017 formation of MDL No. 2804—found

substantially more negative” and that “[t]he resulting public antipathy toward the industry has certainly encouraged more stringent regulatory restrictions”).

378. The Supreme Court ultimately ruled that the FDA overstepped its authority. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000), *superseded by statute*, Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 10 U.S.C., 15 U.S.C., and 21 U.S.C.).
379. *Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination*, 61 Fed. Reg. 44,619, 44,628-29, 44,637-45, 44,854-913 (Aug. 28, 1996); *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 172 (Breyer, J., dissenting) (explaining that the FDA’s regulatory action was justified because “the FDA recently has gained access to solid, documentary evidence” concerning the manufacturers’ knowledge and intent); Brief for the Petitioners at 5, 7, *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (No. 98-1152), 1999 WL 503874 (stating that the FDA’s decision to regulate tobacco was largely based on the manufacturers’ own previously hidden documents that revealed that manufacturers “intend[ed] their products to affect the structure and function of the body” and manipulated nicotine); DAVID KESSLER, *A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY* 205-06, 229, 258-60 (2001) (discussing how various smoking guns unearthed in the course of litigation influenced the FDA’s thinking and hardened its resolve); Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 STAN. L. & POL’Y REV., Winter 1997, at 63, 76 (“On February 25, 1994, FDA Commissioner David Kessler, relying primarily on a document discovered in the *Cipollone* case . . . report[ed] that the FDA had received ‘mounting evidence’ that ‘the nicotine ingredient in cigarettes is a powerfully addictive agent’ and that ‘cigarette vendors control the levels of nicotine to satisfy this addiction.’ He suggested that these conclusions, if established in an administrative or judicial proceeding, would justify regulating cigarettes as a drug” (footnote omitted) (quoting the *Tobacco Products Litigation Reporter*)).
380. Monea, *supra* note 164, at 99 (explaining how litigation has drawn attention to “the role corporate actions played in the opioid epidemic, countering the narrative that the fault lies entirely with addicted persons”); Rousseau, *supra* note 353 (contending that opioid “lawsuits have shown [sic] a spotlight on the deceptive marketing practices of the pharmaceutical industry” and that, in so doing, the litigation has “provide[d] support for government regulation that is clearly needed to curb excessive prescribing by doctors, misleading marketing behaviors of pharmaceutical companies, and irresponsible drug distribution”).
381. *See* Lahav & Burch, *supra* note 315, at 12-13 (tracing how information “produced during discovery” has “shift[ed] blame” from addicts to corporate actors).

that only 10% of respondents believed that pharmaceutical companies were “mainly responsible” for prescription painkiller abuse.³⁸² But, by 2019, a poll asking a similar question found that a full 63% of respondents believed that pharmaceutical companies bore “[a] great deal” of blame for the opioid crisis, and, in fact, respondents assigned more blame to pharmaceutical companies than to any other possible culprit.³⁸³ And, in a replay of the plummeting reputation of tobacco companies seen in the 1990s, an August 2019 poll found that the pharmaceutical industry had replaced the federal government as the most negatively viewed industry.³⁸⁴

By drawing attention to the problem and uncovering the vital (and otherwise hidden) information that maps the problem’s size and establishes responsibility for its creation and perpetuation, litigation thus does not stand as an either/or alternative to more traditional regulatory mechanisms. It (at least sometimes) works hand-in-glove with other governmental and private reforms and, indeed, provides the spark necessary to ignite complementary regulatory activity.³⁸⁵ For this reason, the commentators who insist, for example, that “litigation is not a substitute for the hard work needed in fighting this crisis” or that “looking for someone to blame for the epidemic might be less useful than figuring out how to stop it” are not wrong per se.³⁸⁶ But they entirely miss the point. The question is not whether litigation will, standing alone, *solve* the opioid crisis. It won’t. Nor is the question whether litigation ought to *supplant* other policy reform efforts. It shouldn’t. The question is whether litigation is apt to meaningfully contribute to a solution. Drawing on the lessons of tobacco litigation, we believe it is.

382. HARVARD T.H. CHAN, SCH. OF PUB. HEALTH, AMERICANS’ ATTITUDES ABOUT PRESCRIPTION PAINKILLER ABUSE 3 (2016), <https://perma.cc/WD6Z-GZZ8>.

383. Mike Stobbe & Emily Swanson, *AP-NORC Poll: Many Blame Drug Firms for Opioid Crisis*, ASSOCIATED PRESS (Apr. 25, 2019), <https://perma.cc/U9GM-EAKF>.

384. Justin McCarthy, *Big Pharma Sinks to the Bottom of U.S. Industry Rankings*, GALLUP (Sept. 3, 2019), <https://perma.cc/7J28-X5E2>. According to Gallup: “Americans’ net ratings for the pharmaceutical industry have never been lower,” and, in recent history, “few industries have been rated lower than the pharmaceutical industry’s current -31 net rating.” *Id.* In discussing the reason for this harsh assessment, Gallup cited, among other scandals, the industry’s role in fueling the opioid crisis and opined that “[t]he industry’s rating likely will not recover until its role in the opioid epidemic is addressed.” *Id.*

385. Rabin, *supra* note 8, at 1750 (observing that tort litigation against the tobacco industry uncovered information about the industry’s activities, which caused a spike in public disapproval—and that this disapproval “could have contributed to the political climate” in which regulatory measures, including excise taxes, were enacted).

386. *See, e.g.*, Robin Newhouse, *Lawsuits Are No Solution to the Opioid Crisis*, LAS VEGAS SUN (Mar. 1, 2018, 2:00 AM), <https://perma.cc/FV4X-TPHX>; Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, ATLANTIC (June 2, 2017), <https://perma.cc/D96C-YUS2>; *see also* Charles Fain Lehman, *Suing Big Pharma Won’t Fix the Drug Crisis*, NAT’L REV. (Apr. 10, 2019, 6:30 AM), <https://perma.cc/534Q-BQZ9>.

Conclusion

Opioid litigation is arguably the most complicated litigation ever to hit American courts. In looking ahead to how the opioid MDL and accompanying state court cases should be resolved, it is sensible to look back to the *second* most complex and hotly contested civil action in American history: tobacco.

This comparison is useful because tobacco and opioids are, in many ways, similar: Both products are highly addictive and extremely dangerous, and both were sold in extraordinarily high quantities. Both were the subject of aggressive, duplicitous, and lavishly funded marketing campaigns. And both have imposed economic and human tolls that almost defy comprehension.

Yet, as we have shown, tobacco and opioids are also different products in critical respects—particularly with regard to their susceptibility to substitution, social utility, and price sensitivity. The regulatory environments tobacco and opioids inhabit and the litigation they’ve generated also diverge in meaningful ways. By highlighting these differences, and analyzing their significant implications, this Article extracts the relevant lessons from tobacco as they apply to the ongoing opioid epidemic. These concrete lessons should inform—and, in some instances, chasten—litigants, health care providers, and state and federal policymakers as they seek to fashion an appropriate and effective response to the ongoing and urgent opioid epidemic.

At the same time, the Article has moved beyond this comparative analysis, to abstract further out and identify lessons that ought to inform not just the disaster du jour but also future, as yet unidentified, public-health calamities. Among these larger lessons, three stand out.

First, judges and juries are judgmental. They have regarded as morally suspect individual plaintiffs who can be portrayed as bearing some responsibility (however tangential) for their current plight. To neutralize this suspicion and skepticism, aggregation of claims—and the involvement of “innocent” state and local governments—is key. As such, aggregation does not merely alter the size or structure of litigation; it also changes its complexion and character.

Second, the MSA was a mixed bag. In some respects—namely, its transparency provisions—it exceeded expectations. In other respects—namely, states’ widespread diversion of monies, intended for public-health purposes, to other uses—the MSA is rightly derided as a disappointment and a missed opportunity. Going forward, the lawyers inking, and the judges, magistrates, and special masters overseeing, significant settlements would be wise to heed and build upon the MSA’s successes while learning from past mistakes.

Third, the tobacco and opioid experiences contribute to our collective understanding of the role of tort litigation in promoting public health. They show that litigation and regulation are not necessarily rivals or substitutes. Instead, tort litigation can, at least some of the time, complement—and, under certain conditions, catalyze—broader regulatory strategies.