THE OPIOID LITIGATION UNICORN*

Nicolas P. Terry**

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“I don’t expect a dime, but I’d like to see someone’s hide on the fence for allowing this to happen.”

I. INTRODUCTION

More than forty state attorneys general and innumerable counties, cities, and tribal nations are either investigating or actively litigating over-promotion and related claims against opioid manufacturers and other participants in the opioid prescription drug supply chain. Following multidistrict litigation

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** Hall Render Professor of Law, Executive Director, Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law. Research supported by Indiana University’s Addictions Grand Challenge. Email: npterry@iupui.edu. Some of the opinions expressed herein are based on Nicolas Terry & Aila Hoss, Opioid Litigation Proceeds: Cautionary Tales from The Tobacco Settlement, HEALTH AFFAIRS BLOG (May 23, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180517.992650/full. I express my thanks to Valerie Blake for her thoughtful comments on an earlier draft and to Emily Beukema and Colleen Whiting for their research and editorial assistance.

(MDL) consolidation, approximately one thousand cases are before Judge Daniel Polster in the Northern District of Ohio. For some, the Cleveland litigation overseen by Judge Polster seems to have almost mythic properties. For example, a New York Times headline asked, “Can This Judge Solve the Opioid Crisis?” At first sight, the opioid litigation seems to embrace the properties often expected of major (including mass tort) personal injury litigation, such as finding the truth, expressing righteous indignation, allocating blame, deterrence, and redistributing ill-gotten moneys to those the alleged tortious conduct has hurt.

This Article argues that these and other expectations surrounding the opioid litigation require some recalibration. There is no doubt that some of this enthusiasm has been generated by parallels drawn to the 1998 Tobacco Master Settlement Agreement (MSA). However, those parallels themselves need tempering. More importantly, the role of opioid litigation needs a context broader than pharmaceutical misconduct—one that better expresses the broader issues causative of and raised by the opioid overdose epidemic. While the goals that underpin the litigation are important, they are relatively minor compared to the broader features of the opioid epidemic, particularly the opioid overdose crisis. These are issues that litigation—or even an exceptionally well-crafted settlement—are unlikely to solve.

The arguments advanced here are, first, that concentrating on the MDL litigation may endorse the flawed gateway or vector analysis of the opioid overdose epidemic. Second, any compensation derived from successful prosecution of the litigation (or, more likely, its settlement)—while not insignificant—is more likely to enrich the plaintiffs (politically) and their attorneys (financially) than make a major impact on the social and healthcare costs already incurred or begin to cure the adverse social determinants of health that underpin the epidemic. Third, even when measured against the flawed tobacco settlement of 1998, any settlement is unlikely to have a positive long-term impact or any major public health role after the checks have been written and cashed. Overall, this Article takes the pessimistic position

2. Id.; see also Eric Heisig, Ohio Governments Say They Won’t Argue Specific Prescriptions Were Improper in 2019 Opioid Trial, CLEVELAND.COM (Oct. 24, 2018), https://www.cleveland.com/court-justice/2018/10/ohio-governments-say-they-wont-argue-specific-prescriptions-were-improper-in-2019-opioid-trial.html (suggesting that the total has risen to more than 1,000).


5. See infra notes 87–96 and accompanying text.
that this “litigation unicorn” will deflect attention from the true causes of the opioid overdose epidemic, thereby averting appropriate remediation while creating an improbable expectation that the settlement will fund either necessary treatment programs for those suffering from opioid use disorder (OUD) or their children suffering from neonatal abstinence syndrome (NAS).

The Article proceeds as follows: first, there is a brief sketch of the federal MDL litigation and some competing state court claims. Second, the tobacco litigation and settlement of the 1990s are compared, with particular attention paid to the dispositions of damages collected. Third, and the core of the Article, is a discussion of “blaming” litigation and how that may perpetuate the opioid epidemic’s stigmatizing moral defect narrative. Fourth, the Article takes a deeper dive into the barriers facing those in Cleveland trying to hammer out a settlement with particular attention paid to potential remedies.

II. MDL AND OTHER OPIOID LITIGATION

Various cities, counties, states, and tribal nations (political units) have sued the manufacturers and distributors of prescription opioids and face suit on a variety of factual claims based on numerous doctrinal theories. Central to the litigation, however, are two allegations. First, the manufacturers overstated the benefits and downplayed the risks of the use of their opioids while aggressively marketing them (the overpromotion claim); and second, that the distributors failed to monitor or detect suspicious orders (the diversion claim).

These are not the first lawsuits brought against the opioid manufacturers. Rebecca Haffajee and Michelle Mello have detailed various allegations made by individual patients and political units beginning in the early 2000s. The individual patients—they argue—faced considerable barriers to success based upon product liability theories such as “design” allegations (i.e. failure to

6. See infra notes 10–57 and accompanying text.
7. See infra notes 58–97 and accompanying text.
8. See infra notes 98–140 and accompanying text.
9. See infra notes 141–212 and accompanying text.
12. Id.; see generally Andrew Kolodny et al., The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction, 36 ANN. REV. PUB. HEALTH 559 (2015).
include an antagonist ingredient) and failure to warn about addiction risks, as well as misrepresentations about the drugs’ safety. These barriers included FDA approval—tending to negate defective design or warning claims—or protection of the latter under the Learned Intermediary Rule.

Increasingly, plaintiffs are basing their claims on allegations of overpromotion and diversion. These claims owe at least some of their conceptualization to suits brought and settled in the mid-2000s by states and the federal government alleging that the opioid manufacturers had engaged in various misdeeds such as misbranding, unlawful off-label use marketing, Medicaid fraud, and failing to avert diversion. This litigation is highly complex in its own right, and such complexity is further amplified by the MDL frame and dynamics surrounding powerful “repeat player” law firms representing the plaintiffs. The litigation also has to deal with the sheer number of plaintiffs and the heterogeneity of damages suffered.

In December 2017, the United States Judicial Panel on Multidistrict Litigation held that “the actions in this litigation involve common questions of fact, and that centralization in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation.” At that time, the MDL Panel consolidated most federal claims (then already numbering over four hundred) in the Northern District of Ohio before U.S. District Judge Daniel Polster. Thereafter, additional political units have joined the litigation.
Not all the plaintiffs have been so willing to participate in the Cleveland litigation. For example, plaintiffs representing NAS infants have sought to have a separate MDL for that cohort on the basis that “the interests of the governmental and corporate parties represented by the MDL leadership are fundamentally in conflict with those of these infants.”\(^{24}\) Not only did the MDL panel deny this centralization request,\(^ {25} \) but it subsequently ordered that the NAS infants’ claims should be consolidated in the Cleveland litigation.\(^ {26} \) Another cohort that is seeking to distinguish itself is the combination of 448 Native American tribes, some of whom are plaintiffs in the MDL litigation. The tribes argue that they have been disproportionately injured during the opioid epidemic, with an overdose mortality rate in some areas six times the percentage of non-Hispanic whites.\(^ {27} \) The tribes, too, have argued that the state plaintiffs have not adequately represented their interests.\(^ {28} \)

The defendant type is also expanding. For example, intermediaries in the drug supply chain such as pharmacy benefit managers are being added to the lawsuits.\(^ {29} \) A notable absentee from the plaintiff ranks is the federal government. In March 2018, the United States Department of Justice filed a statement of interest requesting Judge Polster grant it time to consider whether the federal government would participate in the litigation,\(^ {30} \) eventually deciding only to enter as an amicus.\(^ {31} \)

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\(^ {25} \) In re Infants Born Opioid-Dependent Products Liability Litig., 350 F. Supp. 3d 1377, 1381 (J.P.M.L. 2018).

\(^ {26} \) Transfer Order, In re Nat’l Prescription Opiate Litig., MDL No. 2804 *J.P.M.L. Dec. 6, 2018).

\(^ {27} \) Brief Amici Curiae of 448 Federally Recognized Tribes in Opposition to Defendants’ Motions to Dismiss Tribal Claims, In re Nat’l Prescription Opiate Litig., MDL No. 2804, at *2 (J.P.M.L. Oct. 5, 2018).

\(^ {28} \) Id.

\(^ {29} \) Casey Ross, A South Texas County Drags PBMs into Nationwide Lawsuit over Opioids, STATNEWS (Feb. 26, 2018), https://www.statnews.com/2018/02/26/texas-pbm-opioid-lawsuit.


MDL transfers permit “coordinated or consolidated pretrial proceedings” and are designed “to avoid duplication of discovery, to prevent inconsistent pretrial rulings, and to conserve the resources of the parties, their counsel and the judiciary.” In practice, MDL transfers are designed to encourage settlement. There have been several scheduled settlement conferences, there are reports of ongoing talks between the parties, and, somewhat optimistically, Judge Polster originally informed the parties that he wanted to see a settlement in 2018.

The MDL statute requires a remand back to the originating federal district courts. However, in practice the cases are often moved along (or at least nudged towards settlement) by holding some bellwether trials to further narrow down the issues in dispute and their commonality (or lack thereof) across the consolidated cases. In April 2018, Judge Polster set an aggressive timetable, ordering a March 2019 trial date for three combined cases filed in Ohio. However, in August 2018, he delayed those trials until September 2019. The judge is already on record stating that he considers even limited bellwether litigation necessary, noting that it was “necessary to do it, and [they’re] doing it, but it’s not a substitute or replacement in any way” for moving towards a settlement. Judge Polster’s optimism should be contrasted with that of the Oklahoma Attorney General, who in a state court filing opined, “The MDL settlement process is stuck in glue and the first trial in the

35. 28 U.S.C. § 1407(a).
MDL has been moved back to at least September 2019... and it will be moved back again.”

One difficult issue which has already arisen in preparation for the bellwether trials is the extent to which the plaintiffs will attempt to prove a causal nexus between their overpromotion claim and the writing of specific prescriptions. The defendants requested that the plaintiffs identify specific patients and prescriptions, and tie those to specific allegations of defendant misfeasance. The plaintiffs’ response was that “all prescriptions for opioids [in the bellwether cities and counties]... were influenced by Defendants’ deceptive marketing.” Thus, at least in the bellwether trials, plaintiffs have declined to make arguments about individual prescriptions, relying instead on aggregate proof based on the pattern of activities and behaviors.

Parallel to the MDL cases, some states and other political units continue along a different path, proceeding independently in their own local courts, arguing theories as diverse as state law false claims and deceptive or unfair consumer practices. These independent state claims not only feature additional theories of recovery or defendant cohorts (even malpractice cases against individual doctors), but also illustrate divergent tactics, as the

42. Id. at *2.
43. See id. at *3.
political units apparently believe they will receive better results before their own courts and see advantage in trying to reach judgment or settlement ahead of the MDL cases.\textsuperscript{48} Suffolk County, New York, has even filed suit against members of the Sackler family, who own Purdue Pharma\textsuperscript{49} and reportedly have a net worth of $13 billion.\textsuperscript{50}

More than forty state attorneys general are either investigating\textsuperscript{51} or actively litigating claims against participants in the drug supply, claims that may end up consolidated in Cleveland or proceed to trial more locally.\textsuperscript{52} Those, too, are the subject of ongoing settlement talks.\textsuperscript{53} Some political units, including some tribal nations concerned that consolidation will hurt their cases,\textsuperscript{54} have raised unsuccessful objections to the MDL transfer.\textsuperscript{55} It is unclear whether the defendants will agree to any settlement other than a global one that includes all plaintiffs.\textsuperscript{56} However, forcing all parties into a mandatory class action would be quite controversial.\textsuperscript{57}

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\textsuperscript{49} Cassandra Basler, Suffolk County Sues Purdue Pharma Family over Opioids, WSHU (Oct. 25, 2018), http://www.wshu.org/post/suffolk-county-sues-purdue-pharma-family-over-opioids#stream/0.


\textsuperscript{54} Fisher, Cleveland, supra note 44.

\textsuperscript{55} In re Nat’l Prescription Opiate Litig., supra note 11.

\textsuperscript{56} Fisher, Plaintiff, supra note 34.

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III. THE TOBACCO COMPARISON

From their inception, the opioid claims could be compared to most of the high-profile public health mass litigation cases of the past fifty years—cases from the products liability asbestos cases of the 1980s, to public nuisance actions against gun manufacturers and sellers, to consumers arguing links between fast food and health issues such as obesity. However, most attention has been lavished on comparisons with the tobacco litigation of the 1990s. In particular, the political unit opioid plaintiffs have been eyeing the large settlement big tobacco reached with the states, while some plaintiffs’ attorneys are even reprising their roles in the later litigation. There are many parallels to the tobacco litigation, but there are also equally salient differences. As is well known, products liability cases brought by individuals against the tobacco industry generally were unsuccessful. Allegations of defective design typically failed because there was no feasible alternative design, and few courts endorsed the idea of intrinsically dangerous products being defective. Indeed, only recently has

64. See, e.g., Hosford v. BRK Brands, Inc., 223 So. 3d 199, 199 (Ala. 2016) (finding insufficient evidence for existence of safer, practical, alternative design for an ionization smoke alarm).
the FDA acquired regulatory authority over tobacco products and aggressively pursued industry practices. The other classic product liability claim—one for failure to warn—was generally unavailable because of federally required warnings. During this time, the tobacco industry conducted a public relations offensive defending the safety of their products.

The litigation “dam” was finally breached in Cipollone v. Liggett, Inc. when the Supreme Court adopted a somewhat narrow reading of the preemptive effect of The Public Health Cigarette Smoking Act of 1969 and permitted claims traditionally brought under state law, including express warranty, intentional fraud and misrepresentation, or conspiracy. Shortly thereafter, the executives of the big tobacco companies found themselves in a Congressional hearing being publicly blamed for the health consequences of smoking. Afterwards, whistleblower documents—arguably showing that the industry had known of the risks of smoking for decades and suppressed evidence—took center stage.

Political unit claims began in 1994 when Mississippi became the first state to sue tobacco firms to recover its Medicaid costs attendant to treating smokers, followed by other state claims for losses incurred by their public insurance programs. In total, the attorneys general of forty-six states brought

suit. In November 1998, the states and the major tobacco companies settled the litigation in what is referred to as the Master Settlement Agreement (MSA).

Subsequently, in United States v. Philip Morris USA, Inc., the federal government prevailed against the cigarette manufacturers and tobacco trade organizations on a variety of Racketeer Influenced and Corrupt Organizations Act (RICO) allegations relating to misleading and deceptive marketing practices. The government was less successful as far as pleaded remedies such as disgorging profits, although the district court did rule that the companies had to publish five corrective statements in the media and on their product packaging.

After Cipollone and the disclosure of thousands of pages of industry documents, actions by individual smokers or their survivors have seen more success. The epicenter has been Florida, with these individual actions prompted by the 2006 decertification of a class action by the Florida Supreme Court. The court allowed the class members to pursue their claims individually while preserving some of the common liability findings. Thousands of claims resulted, with plaintiffs winning large numbers of multi-million dollar judgments. An additional line of cases has also opened, following a Supreme Court ruling that state consumer protection claims alleging that descriptions of some cigarettes as “light” or “low tar” were not preempted by the Federal Cigarette Labeling and Advertising Act. Plaintiffs have been less successful in preserving large punitive damage awards upon

77. Id.
78. 449 F. Supp. 2d 1 (D.D.C. 2006);
79. Id. at 1; see also United States v. Philip Morris USA Inc., 566 F.3d 1095, 1095 (D.C. Cir. 2009) (affirming district court ruling in large part against manufacturer).
80. Philip Morris, 566 F.3d at 1095.
82. Engle v. Liggett Grp., 945 So.2d 1246, 1246 (Fla. 2006).
83. Id. at 1269–70.
appeal, although in 2017, the Supreme Court of Florida held that an award of thirty million dollars was not unconstitutionally excessive.

From the standpoint of those engaged in the opioid litigation, the most interesting aspect of the tobacco story is the MSA of 1998. The MSA provided that the states would receive approximately $246 billion during the first twenty-five years of the settlement with payments continuing in perpetuity thereafter. The MSA also included some explicit public health remedies, including limitations on certain advertising and marketing to children, the creation of a research and educational foundation focused on teen smoking and smoking cessation, and the dissolution of certain tobacco industry initiatives that combated research findings about the dangers of smoking.

The recitals under the MSA contained language suggesting the purpose of the settlement and the intended use of its proceeds by the states. However, the agreement contained no specific or detailed language requiring the states to use the proceeds for specific tobacco-related or public health purposes. In practice, only a very small percentage of the settlement funds have been used to encourage smoking cessation or otherwise address public health priorities. For example, a 2007 report from the United States Government Accounting Office found that, on average, states allocated just thirty percent of their annual settlement receipts to healthcare (including funding Medicaid, CHIP, and making payments to providers) and 22.9 percent to cover budget deficits. States have also used these funds for education and infrastructure projects. Only 3.5 percent has been used for tobacco control. Ironically, South Carolina and North Carolina even used MSA funds to assist tobacco growers.

88. Master Settlement Agreement, supra note 76.
89. Id. at 29.
91. See, e.g., Master Settlement Agreement, supra note 76, at 1–2 (“P]ursuant to terms which will achieve for the Settling States and their citizens significant funding for the advancement of public health measures . . . .”).
as demand slowed. A six-state study argued that “far less is being spent on tobacco control and health programs than would have been anticipated in view of the states’ tort claims against the companies.” This is despite evidence that the funding of tobacco control has an extremely strong return on investment. Another study concluded that “MSA resources have been significantly diverted from tobacco control and treatment into other state policy activities.” The tobacco litigation and settlements raise significant issues regarding the opioid litigation and the use of potential settlement funds, addressed in detail below.

IV. THE HEART OF THE UNICORN: PERPETUATING MORAL DEFECT

Clearly there are strong retributive and deterrent motives behind the opioid litigation. As the City of Chicago’s corporation counsel stated, “We brought suit because we recognized that the companies had to both be held accountable for their long-term marketing practices that really created this market and fostered a misleading attitude toward these drugs as pain management . . . [a]nd then to make sure that they reform the industry going forward.”

These motives and related emotions are equally understandable. The headline-grabbing metric surrounding the overdose epidemic has been the death toll, estimated at almost fifty thousand for 2017. Sadly, that number does not include the almost incalculable familial and economic disruptions.

95. Frank A. Sloan et al., States’ Allocations of Funds from the Tobacco Master Settlement Agreement, 24 HEALTH AFF. 220, 224 (2005).
throughout the entire country. The former includes direct and indirect harms caused to family members, including those born with NAS and increases in imprisonment. The price tag for the latter is estimated to have been one trillion dollars between 2001 and 2016, and is projected at another five hundred billion dollars from 2016 to 2020.

The healthcare system—including the pharmaceutical companies and others in the opioid prescription drug supply chain—must bear considerable responsibility for the increase in OUD and the opioid overdose epidemic. For example, the marketing of the pain medication OxyContin® as “non-addictive” clearly influenced clinicians. Health insurers and managed care providers were also complicit, as they favored pharmaceutical approaches to pain over more expensive multidisciplinary approaches. Even healthcare regulators should bear some responsibility for designating pain as the “fifth vital sign” and introducing pain management into reimbursement-impacting patient satisfaction scores. Even law enforcement should not escape scrutiny. For example, a bipartisan Congressional investigation of “opioid-dumping” into West Virginia not only reported “failures in distributors’ anti-diversion efforts” but also “uncover[ed] gaps in the DEA’s


enforcement posture, both related to its capabilities nationwide and its oversight in West Virginia.”

Equally, whatever one’s judgment about the relative responsibility of the pharmaceutical industry in causing the opioid overdose crisis, clearly it has failed to deliver any useful solutions. Indeed, there are segments of the industry that seem to view the crisis not as an opportunity to repair damage, but as one for great profit. For example, Matthew Rosenberg and his colleagues noted very large increases in the prices of almost all formulations of the overdose-reversal drug naloxone—increases of 244% to 3,797% during 2006–2017. A 60 Minutes investigation showed that one brand-name formulation containing a few cents of naloxone cost over $4,000.

Tort litigation—while not an explicitly punitive or criminalizing model—still promotes a “blame frame” rather than a system-reform frame. Yet, considerable care must be taken in apportioning blame. The current opioid crisis notwithstanding, its seriousness is only the most recent of several waves of addiction. The opioid crisis is one which has substantially morphed over the past three to four years. In 2016, just over nineteen thousand persons died of overdoses associated with prescription opioids, and there has been some relative stability over the prior five years. In contrast, almost thirty thousand people died of overdoses associated with synthetic opioids (predominately Fentanyl) in 2017, a massive spike over the same time period (a twenty-two-fold increase from 2002 to 2017).

The opioid litigation or—at least its rhetoric—is built on the same fundamental misunderstandings of the opioid overdose epidemic as calls for additional criminalization. First, it adopts a stigmatizing “moral defect” frame which assigns causality to drug users and their suppliers, junkies, dealers, and


114. Id.
drug lords—albeit modified by substituting in patients with prescriptions—prescribers, pharmacy benefit managers, pharmacies, and pharmaceutical manufacturers. Second, the recent shift from medically-sourced prescription opioids to illicit synthetics is explained by the oft-criticized vector model or gateway analysis of the epidemic. That model argues that, having become addicted to opioid painkillers, those with OUD moved to illicit synthetics as the prescribing of opioids was curtailed or the prices of the illicit synthetics dropped below those of diverted prescriptions drugs.

Like most explanations of this “wicked problem,” there is a grain of truth in the vector model. One study found that 79.5 percent of heroin users previously had used prescription opioids; however, the same study found that only 3.6 percent of prescription opioid users transitioned to heroin. The real problem with the vector model is in suggesting a simple cause and effect model to explain a far more complex problem. The real causes of the opioid crisis are social determinants of health, which are defined as “the complex, integrated, and overlapping social structures and economic systems that are responsible for most health inequities.” Thus, insofar as it places the blame for the opioid overdose epidemic at the feet of pharmaceutical manufacturers and distributors, the opioid litigation is misappropriating a public health narrative to serve its own purposes. Indeed, it fully endorses the vector model, as it must do, in attempting to place responsibility for the harm caused by illicit synthetics on the manufacturers of prescription opioids.

Adopting a blame-based model implicates not only defendants but also plaintiffs. Inevitably, defendants will attempt to shift any alleged responsibility to their physician customers, patients, and to the latter’s

116. See id. at 183.
“addict” patients. Indeed, two of the national defendants have sued drug dealers and Internet pharmaceutical sites (“illegal supply chain defendants”) in an attempt to shift the blame for opioid diversion.\textsuperscript{122}

Shifting blame to patients can be accomplished by arguing lack of causation. For example, that the defendant’s condition was not caused by the defendant’s overpromotion but by the plaintiff’s pre-existing addiction or some blameworthy conduct. For example, in the well-known case of\textit{Price v. Purdue Pharma Co.},\textsuperscript{123} an opioid manufacturer successfully argued that the doctor-shopping plaintiff was guilty of illegal conduct.\textsuperscript{124} The court agreed, noting “[h]is violation of the law is not merely a condition, but instead an integral and essential part of his case and the contributing cause of his alleged injury.”\textsuperscript{125} Similarly, in\textit{Inge v. McClelland},\textsuperscript{126} the court used the “wrongful conduct” rule to deny a claim against a pharmacist on various over-supply theories because the prescriptions were procured by the plaintiff in a conspiracy with a nurse practitioner.\textsuperscript{127} Notwithstanding, some courts take a somewhat less draconian approach and apply comparative fault even in the case of a plaintiff’s criminal conduct.\textsuperscript{128}

Any success that individuals or political units in opioid litigation enjoy will come at a high price—misdirecting the public and policymakers away from the current epidemic (caused by illicit synthetics) and the fundamental problem: the social determinants of health. Further, in endorsing a blame/monetary forfeit model, the litigation will preserve the moral defect model and the stigmatization that accompanies it.

At some level, the opioid litigation also will perpetuate the recycling of “supply-side and criminal-justice approaches” rather than “an expanded public health response.”\textsuperscript{129} State attorneys general pursuing pharmaceutical manufacturers can recycle their tough-on-crime rhetoric, claiming “Purdue’s


\textsuperscript{123} 920 So. 2d 479 (Miss. 2006).

\textsuperscript{124} \textit{Id}. at 479.

\textsuperscript{125} \textit{Id}. at 485.

\textsuperscript{126} 257 F. Supp. 3d 1158 (D.N.M. 2017).

\textsuperscript{127} \textit{Id}. at 1158; see also \textit{In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.}, MDL No. 1203, 2009 WL 902351, at *1–2 (E.D. Pa. Apr. 2, 2009).

\textsuperscript{128} See, e.g., Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cty., 773 S.E.2d 627, 627 (W.Va. 2015).

\textsuperscript{129} Herzberg et al., \textit{supra} note 112, at 409.
pattern is pretty clear. It is a bad company.”

Further, if the “problem” is overprescribing, then the “solutions” must be supply-side strategies. These strategies, which some of the major commissions who have reported on the opioid overdose epidemic have endorsed, include supply-side interventions such as limitations on prescribing, opioid reimbursement reforms, and the expansion of Prescription Drug Monitoring Programs (PDMPs).

Obviously these strategies will be of limited effectiveness in the face of the illicit synthetics epidemic, and clearly they fail to address underlying social determinants.

Worse, such supply-side strategies themselves have negative consequences. Although the vector model is flawed as an underlying explanation of the epidemic, there is good evidence that opioid demand is inelastic, and those who find it harder to acquire prescription drugs will turn to street drugs such as fentanyl.

Second, there is concern that supply-side strategies designed to reduce overutilization will overcompensate and encourage the undertreatment of pain. Risks of undertreatment are already particularly high among racial minorities, women, and older adults. For example, according to Substance

130. The State’s Emergency Motion to Show Cause for Purdue’s Intentional Disregard of Two Court Orders and Failure to Provide Witness as Ordered by the Court, Oklahoma ex rel. Hunter v. Purdue Pharma L.P., No. CI-2017-816, at *3 (Okla. Dist. Ct. Aug. 20, 2018).


134. See generally Rebecca L. Haffajee et al., Mandatory Use of Prescription Drug Monitoring Programs, 313 JAMA 891, 891 (2015).


Abuse and Mental Health Services Administration (SAMHSA) almost half of older Americans suffer from chronic pain, with the incidence increasing with age.\textsuperscript{139} Mark Rothstein has argued that “[d]esperately ailing patients who legitimately need medical relief from serious pain should not be the latest unintended victims of societal opioid abuse.”\textsuperscript{140}

Third, there should be concern that successful litigation or a settlement favoring the plaintiffs will distract policymakers and their constituents from the far more challenging policy objectives—and their funding—that need to be addressed. As discussed in the next sections, the resolution of the litigation likely will have only a minimal role in “solving” the crisis.

V. THE OPIOID LITIGATION: BARRIERS AND POTENTIAL REMEDIES

It is important at the outset to moderate expectations for the opioid litigation. There are massive complexities standing in the way of successful litigation or settlement. These complexities are spread across multiple dimensions and include the parties’ allegations and causes of action, evidence, the proper parties, and remedies. First, as Rebecca Haffajee and Michelle Mello have pointed out, there are some key doctrinal and evidentiary barriers facing the plaintiffs.\textsuperscript{141} Before a jury, the defendants no doubt will strongly emphasize that their products were FDA-approved (potentially fatal in a product liability suit and still salient in an overpromotion case) and adverse patient behaviors such as doctor-shopping.\textsuperscript{142} Furthermore, with the important exception of the recent allegations that the Sacker family owners of Purdue Pharma orchestrated overpromotion,\textsuperscript{143} in contrast to the 1990s tobacco litigation, there have not been whistleblowers coming forward with insider information or leaked documents.\textsuperscript{144} Moreover, as already noted, the opioid plaintiffs may be unwilling (for privacy reasons) or unable to prove a nexus between alleged overpromotion or diversion and a specific prescription order.

\textsuperscript{140} Mark A. Rothstein, The Opioid Crisis and the Need for Compassion in Pain Management, 107 AM. J. PUB. HEALTH 1253, 1254 (2017).
\textsuperscript{141} See Haffajee & Mello, supra note 13, at 2303.
\textsuperscript{142} See supra notes 123–127 and accompanying text.
\textsuperscript{143} See David Armstrong, Purdue’s Sackler Embraced Plan to Conceal OxyContin’s Strength from Doctors, Sealed Deposition Shows, STAT (Feb. 21, 2019), https://www.statnews.com/2019/02/21/purdue-pharma-richard-sackler-oxycontin-sealed-deposition/.
\textsuperscript{144} Haffajee & Mello, supra note 13, at 2303–04.
or patient overdose. Some non-manufacturer defendants have already put the court on notice that plaintiffs’ theories of recovery against them are thin. In late 2018, two pharmacy chains characterized plaintiffs’ claims as calling for “a boundless expansion of tort doctrine that Ohio law does not countenance.”

Second, the relatively small number of defendant opioid manufacturers and others in the distribution chain are not in the same financial league—by a wide margin—as the tobacco industry. Although cigarette sales in the United States have declined considerably over the years, big tobacco’s revenue numbers are increasing, exceeding $93 billion in 2016. United States prescription opioid revenue peaked in 2015 at $8 billion. By the time administrative costs and attorney’s fees are deducted—and proceeds spilt between hundreds of plaintiffs—the settlement may not resemble the jackpot some are expecting. Importantly, this assumes that there will be substantial assets to collect. In an August 2018 filing in his state law action against the opioid manufacturers, the Oklahoma Attorney General argued, “Purdue is trying to buy time so it can move assets and employees overseas . . . and either file bankruptcy or leave an empty shell here in the United States for all of the victims of its corporate greed.”

Third, there are salient procedural considerations between the tobacco and opioid claims that may impact the scope of litigation and the timing or amount of settlement. The successful tobacco actions were relatively simple; they were brought by states to recoup their additional Medicaid costs and by the federal government to punish clearly abhorrent behavior by the tobacco companies. Even so, it took half a decade to settle the state tobacco suits and more than a decade before the federal government’s trial victory was translated into remedial action. In the opioid litigation, the number of MDL

145. See supra notes 41–44 and accompanying text.
146. Objections to the Magistrate Judge’s Report & Recommendation Regarding the Motion to Dismiss the Second Amended Complaint by Defendants CVS Indiana, CVS RX Services, Rite Aid of Maryland, Walgreen, Walgreen Eastern, and Walmart at 1, In Re Nat’l Prescription Opiate Litig., No. 1:18-op-45090-DAP (N.D. Ohio Nov. 2, 2018).
plaintiffs, already well over one thousand,\footnote{Fisher, supra note 57.} continues to grow. Equally, the number of non-MDL state claims is growing, some of which likely now will reach verdict before the MDL bellwether cases begin. As already noted, it will be difficult to bring these claims within any global settlement.\footnote{See supra notes 45–57 and accompanying text.} Reportedly, there are also growing tensions between states whose attorneys general are filing in state court and their smaller political units who have filed in federal court and then been swept up in the MDL.\footnote{Daniel Fisher, Cities vs. States: A Looming Battle for Control of High-Stakes Opioid Litigation, FORBES (Mar. 28, 2018 10:30 AM), https://www.forbes.com/sites/legalnewsline/2018/03/28/cities-vs-states-a-loomin...e3cc4b5d.} Finally, although some of their claims will be difficult to pursue because of “blameworthy” personal behavior,\footnote{See supra notes 121–27 and accompanying text.} it is unclear how many individual patients, their families, or children born with NAS may bring individual or class actions, in what is likely to be an enduring imitation of the tobacco litigation playbook.

Fourth, estimates vary as to the cost of the opioid crisis, rendering problematic any rational basis for calculating damage awards. A November 2017 report from the Council of Economic Advisors estimated that for just one year, 2015, the economic cost of the opioid crisis was $504 billion.\footnote{WHITE HOUSE, COUNCIL ECON. ADVISOR, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 1 (Nov. 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.} A 2018 study estimated costs between 2001–2017 at over one trillion dollars,\footnote{Economic Toll, supra note 102.} with projected costs of five hundred billion dollars through 2020.\footnote{Ryan M. Brewer & Kayla M. Freeman, Cumulative Economic Damages from 15 Years of Opioid Misuse Throughout Indiana, 93 IND. BUS. REV. (2018), http://www.ibrc.indiana.edu/ibr/2018/spring/article1.html.} A study focused on Indiana estimated that the state—one of the most severely affected—had suffered $43.3 billion in losses.\footnote{Complaint for Violation of the New Jersey False Claims Act, N.J.S.A. 2A:32C-1, Et Seq., as Well as Other Claims at ¶ 17, Porrino v. Purdue Pharma (N.J. Super. Ct. Ch. Div. 2017).} Plaintiffs are also beginning to create profiles of financial impact. For example, New Jersey’s complaint against Purdue Pharma estimates that, since 2008, its Medicaid vendors, workers compensation program, and employee and retiree health plans have paid well over $290 million for opioids.\footnote{Electronic copy available at: https://ssrn.com/abstract=3308838} The City of Tacoma, in its lawsuit against several pharmaceutical manufacturers, alleged that the opioid crisis has increased the City’s spending across healthcare, social services, emergency services, and public safety and has implemented a new tax in order
to raise ten million dollars a year to fund opioid response efforts.  In its 2018 lawsuit, New York City is claiming five hundred billion dollars to offset opioid costs. Overall, and as the ripples of the opioid epidemic spread and even merge with other public health problems, it is extremely difficult to find a rational limit to the damages caused. Do you draw the line at Medicaid costs? Law enforcement costs? Prisons and jail costs? The growing rates of Hepatitis C/HIV caused by heroin use? The intergenerational harms caused by NAS?

Finally, how should any damage “pie” be allocated? The heterogeneous nature of the losses that individual political units have suffered—and the question of whether damages awarded to political units should be tied directly to prescription drugs or reflect the broader cost of addictions—likely make any kind of metric such as a per capita share of any settlement quite problematic.

Aside from these distinct problems, the opioid litigation and any potential settlement raise broader issues. Contemporary mass tort actions are not “normal” lawsuits. They feature “repeat player” attorneys who have forged deep relationships with MDL judges, and exhibit commercial—even industrial—traits. For example, Elizabeth Burch and Margaret Williams have detailed the impact of lead plaintiff attorneys in MDL litigation and how “defendants can take advantage of lead attorneys’ control over settlement negotiations to strike deals that benefit the leaders and the defendant, but not the claimants.” This is of particular importance as the lead attorneys will likely receive at least twenty-five percent of any recovery. Even the financing of such litigation has been revolutionized since the time of the tobacco settlement, with dedicated financial services businesses—often with


ties to lead attorneys—funding litigation with their interests potentially overtaking those of the claimants. In the MDL litigation, these apparent conflicts of interests led to Judge Polster ordering attorneys to disclose any such relationships to the court.

The pressure to settle also comes at the cost of transparency. There is already concern over how some information about the pharmaceutical companies in the MDL litigation is being kept out of public view. And, there is no doubt that any settlement will bring with it all manner of confidentiality mandates. Barry Meier even blames the secrecy surrounding earlier settlements with opioid manufacturers by the federal government and some states, claiming it “allowed a containable crisis to mushroom into catastrophe.”

Questions of differential pressures to settle also raise some difficult timing issues. Are we at the beginning, middle, or end of the opioid epidemic crisis? In late 2018, the Secretary of Health and Human Services opined that the country was “beginning to turn the tide.” Positive statements were based on preliminary CDC data showing a 2.2 percent decline in drug overdose deaths. However, even if that data proves accurate, it still shows over half the states posting an increase in overdose deaths. Also, a 2018 McKinsey report argued that the number of persons suffering from OUD is likely to be an underestimate, with the actual number being between four and six million persons.

166. See text accompanying infra notes 177–178.
170. Id.
171. Sarun Charumilind et al., Why We Need Bolder Action to Combat the Opioid Epidemic, MCKINSEY & CO. (Sept. 2018), https://www.mckinsey.com/industries/healthcare-
Compensation aside, the other purpose of litigation is deterrence. While some may want any settlement to include a clear statement of fault, the defendants (as was the case with the tobacco manufacturers in the MSA) are likely to resist any such admission, particularly with millions of potential individual plaintiffs waiting in the wings. In fact, as a group, these defendants seem to have been unfazed by some strong deterrent messages. Back in 2007, Purdue Pharma and some of its senior executives pleaded guilty to federal charges of drug misbranding, agreeing to pay $34.5 million in penalties. In 2008, the opioid manufacturer McKesson Corporation settled a federal government claim that it had failed to report suspicious sales of controlled substances and paid $13.25 million in civil penalties. Nine years later, however, the same company paid $150 million to settle almost identical allegations, also agreeing to suspend sales from some of its distribution centers for a period of years and institute an enhanced compliance program.

Fines and damages aside, these companies seem relatively unworried. In contrast, much of the tobacco companies’ secrecy and campaigns against scientific evidence of links to lung cancer and other serious diseases likely can be explained by their fear of government regulation. The opioid manufacturers are already so subject. Indeed—albeit not without controversy—in November 2018 the FDA approved new, even more powerful, opioids. Related to deterrence is transparency. However, so far, the MDL litigation has shed little sunlight on the inner workings of the drug companies. The plaintiffs sought comprehensive data from the DEA’s ARCOS database, but the United States Justice Department would only release a subset, and then only under systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic.

173. U.S. DEP’T JUST., OFF. PUB. AFF., McKESSON CORPORATION AGREES TO PAY MORE THAN $13 MILLION TO SETTLE CLAIMS THAT IT FAILED TO REPORT SUSPICIOUS SALES OF PRESCRIPTION MEDICATIONS (2008).
conditions of confidentiality.  

Notwithstanding the various litigation difficulties faced by plaintiffs and the very real problems of achieving a global settlement, it has to be assumed that eventually a settlement of some sort will be reached. Any settlement likely will have two components. First, there will be a monetary component, giving rise to questions about how the sums collected will be used. Second, there will be a public health component, with provisions designed to reduce the negative impact of the opioid crisis and, probably, to reduce the possibility of another addiction crisis.

As to the first, prior actions are instructive. For example, in 2016, Indiana’s Attorney General used moneys recovered from a settlement of off-label and deceptive marketing of non-opioid drugs by pharmaceutical companies to equip first responders with naloxone. In contrast, West Virginia used proceeds from its 2004 settlement with Purdue Pharma to fund the state’s police academy fitness center and other remodeling at the academy. The latter example raises a sobering question—will any opioid judgment or settlement funds be applied to opioid relief or will they, like the MSA tobacco funds, be diverted from public health purposes to general tax funds?

As with the tobacco settlement, it seems unlikely that anything beyond aspirational statements would be mutually agreeable to all the plaintiffs. As a result, the question will become one for the political units. There are tools that states can use to protect the funds. For example, following the tobacco settlement, some states passed supplantation laws essentially prohibiting the use of tobacco moneys to replace existing funding for programs such as


178. See generally Herzberg et al., supra note 112, at 409.


181. See supra notes 91–97 and accompanying text.
smoking cessation or healthcare. A few states used ballot initiatives in an attempt to balance competing demands. Louisiana voters approved Amendment 2, which allocated seventy-five percent of tobacco monies to a trust fund providing college scholarships, funds for school districts, and health programs. Some states went further and sought to shelter some of the tobacco monies in separate funds dedicated to tobacco control or other public health initiatives. For example, Florida committed to allocate monies to tobacco control, although it then reduced the spending because of a budget crisis. Hawaii created a special fund into which settlement funds were to be deposited and split the proceeds between the state general and reserve funds, tobacco prevention (12.5 percent), and University healthcare facilities (twenty-six percent). Maine created the Fund for a Healthy Maine and committed fifty million dollars per year to the fund that was to be used (without supplantation) for healthcare and public health programs, including smoking cessation and control. Increasingly, however, the state has diverted funds to pay for Medicaid.

In general, the economies of the states are healthier than at any time since the great recession. With increased tax revenue and larger federal contributions, they have partially rebuilt their rainy-day funds. However, Medicaid spending continues to increase, and the upper Midwest and southern states that are among the hardest hit by the opioid epidemic are

184. Sloan et al., supra note 95, at 223–25.
185. HAW. REV. STAT., § 328L-2(b) (2015).
showing slower growth. Some states may take the opportunity to cabin opioid litigation funds for the treatment of those with OUD, caring for children suffering from NAS, and the building of community resilience. Sadly, however, it is likely that some states will use the money for general revenue purposes or for unproductive opioid measures such as criminal law enforcement. Politicians will claim a massive victory over the “evil” drug companies that caused the epidemic, but those who suffered—or continue to suffer—are unlikely to see the spoils of war. Such a result would be unfortunate and a lost opportunity. Addiction crises are not only not new, but additional crises continue to break like waves; witness the recent increase in hospitalizations because of amphetamine use. However, federal and state responses to these crises tend to emphasize supply-side models (such as criminalization or prescription monitoring) rather than preventative public health strategies. In fact, public health at both the federal and state level remains chronically underfunded. Per capita funding at the state level is low and is often flat, year-over-year, far less than spending on healthcare or law enforcement.

The second probable component of any opioid litigation settlement will be non-monetary—some commitment placed on the defendants to change their behavior and reduce or reverse the adverse effects of their practices. For example, in the tobacco settlement, the manufacturers agreed to restrict advertising and sponsorships, particularly those that targeted youth. Further, the MSA used a “volume adjustment,” a hydraulic model providing

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a mechanism that would reduce the damages to be paid if the number of

In a February 2018 hearing, Judge Polster reportedly announced the following:

What I’m interested in doing is not just moving money around, because this is an ongoing crisis. What we’ve got to do is dramatically reduce the number of the pills that are out there and make sure that the pills that are out there are being used properly. Because we all know that a whole lot of them have gone walking and with devastating results.  

An obvious analogue to the tobacco settlement would be sharp curtailment of opioid marketing. However, Purdue Pharma has already announced it will cease marketing opioids, stating that it had “restructured and significantly reduced [its] commercial operation and will no longer be promoting opioids to prescribers.” This approach also misses the fact that opioids are not tobacco-like, but are FDA-approved pharmaceuticals subject to labeling and marketing restrictions that clearly have a place in the national formulary. Further, reductions in consumption are being promoted using different models such as limitations on prescribing, opioid reimbursement reforms, and the expansion of Prescription Drug Monitoring Programs (PDMPs).

There is also a very real public health cost associated

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201. See text accompanying supra notes 15–17.
204. See generally Haffajee et al., supra note 134, at 891–92.
with reducing the supply of prescription opioids, such as drug seekers turning to far more dangerous illicit drugs such as fentanyl.\textsuperscript{205}

A better approach might be to hold the settling drug companies responsible for a proportion of the cost of supplying the harm-reducing drug naloxone or the drugs used in evidence-based, medication-assisted treatment (methadone, naltrexone, and buprenorphine), thus tying their ultimate responsibility to the continuing costs of the crisis. Indeed, in September 2018, Purdue Pharma made a $3.4 million grant to a Pittsburgh nonprofit to develop a low-cost naloxone nasal spray in a move that was disparaged by MDL plaintiffs’ lawyers as a publicity stunt.\textsuperscript{206}

One model that the states might adopt would be something akin to New York’s opioid “tax.” In March 2018, the New York legislature included an annual one hundred million dollar excise tax on companies who manufacture or distribute opioids in the state. The tax is imposed on the basis of market share with the proceeds placed into a “stewardship fund” designed to finance behavioral health programs.\textsuperscript{207} In July 2018, a trade group representing distributors filed suit in federal district court, arguing the tax was unconstitutional,\textsuperscript{208} and drug manufacturers subsequently filed similar lawsuits.\textsuperscript{209} Reportedly, a substantial number of states are considering a similar approach to pay for their treatment and prevention.\textsuperscript{210}

The most obvious problem with the New York approach is that the costs incurred by states, cities, and counties are caused by the non-medical use of street drugs, and deaths from synthetic drugs have already overtaken those


from prescription drugs. As a result, tying damages to prescription drug
distribution may have little positive public health impact. Further, while these
types of proposals seem to be appropriate and proportional, they do little to
build resilience or prepare for the next addiction crisis to hit the United States
(likely to be addiction to benzodiazepines) and the needs for early diagnosis
and treatment that almost inevitably will follow.

VI. CONCLUSION

More than two million Americans suffer from substance use disorder, more than half a million died from drug overdoses between 1999 and 2015, and current projections suggest an annual death toll approaching seventy thousand. This is an epidemic that is affecting multiple demographics as it morphs from a prescription-drug epidemic impacting older rural whites to an illicit drug epidemic increasingly impacting urban communities of color. It is a scourge destroying families and placing public services under extraordinary pressure.

As such, it is not difficult to understand the motivations behind the opioid litigation in its many forms and venues. Indeed, there is every reason to demand that those who profited from aspects of the epidemic should pay for some of its amelioration. Neither would there be many who would object to hard-hit communities receiving an injection of funds to rebuild and provide for those who are suffering. And while allocating blame through litigation risks giving credence to the moral defect theory, those suffering with OUD likely will prefer the blame shifting from themselves to those in the pharmaceutical distribution chain.


Unfortunately, litigation is a blunt instrument that—to the extent it is effective at all—is best suited to well prescribed, narrow claims between individuals or between an individual and a corporation. Litigation does not scale well, and it is not a good tool for remedying mass social ills. It is also extremely inefficient both in its procedural costs (including attorneys’ fees and other expenses) and a lack of timely resolution that almost guarantees that any recovery will be too late to help those who are currently suffering. For example, the California lead paint litigation began in 2000, and it was not until 2018 that the Supreme Court denied certiorari.217 The asbestos cases, the longest running mass tort litigation in the United States, never produced a global settlement.218

As a result, the question raised at the beginning of this Article about a judicial solution to the opioid crisis is relatively easy to answer. Any compensatory payments will be too little, too late, and, if history is any predictor, unlikely to be distributed to those actually harmed. Additionally, the opioid litigation is tied to relatively limited views of the opioid crisis (prescription opioids—not illegal synthetics such as fentanyl) and its remediation (supply-side strategies). And while there is plenty of blame to go around, adopting a blameworthy frame—as litigation must—perpetuates the moral defect narrative of addiction. Worse, liability of those in the pharmaceutical chain of distribution will be analogous to the criminalization of the addicted, a similarly short-term disparagement of some actors which fails to address root causes and evidence-based, public health approaches to society’s cycles of addiction.

Of the MDL plaintiff political units, sixty percent have above-average poverty rates.219 If the MDL litigation and its state court fellow travelers are to achieve anything positive other than rewarding plaintiffs’ lawyers and adding a few million dollars to states’ general funds, any settlement must address the negative social determinants of health that lie at the root of the opioid epidemic and build healthier environments that will reduce the likelihood of future addiction crises.


218. STEPHEN J. CARROLL ET AL., ASBESTOS LITIGATION 1, 47 (2005).