Settling the Score: Maximizing the Public Health Impact of Opioid Litigation

REBECCA L. HAFFAJEE† & MICHAEL R. ABRAMS‡

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I. INTRODUCTION

Despite rising media coverage and public awareness, the opioid crisis continues to outpace efforts to mitigate its harms.[1] The Centers for Disease Control and Prevention most recently estimated that drug overdoses took 70,237 lives in 2017, an increase of almost ten percent over the previous year, with nearly 48,000 of such deaths attributable to opioids.[2] While illicit opioids are

† Rebecca L. Haffajee, JD, PhD, MPH, is a policy researcher at RAND Corporation and an adjunct assistant professor of health management and policy at the University of Michigan School of Public Health. She practiced regulatory health care law and now evaluates the public health impacts of behavioral health policies, including those targeting opioids.

‡ Michael R. Abrams, JD, is a 2019 graduate from the University of Michigan Law School currently serving as a judicial law clerk.

[1] *See* Allison L. Pitt et al., *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic*, 108 AM. J. PUB. HEALTH 1394, 1398 (2018) (modeling policy impact to find that "[f]or some policies and time horizons, the increase in heroin--related deaths may exceed the reduction in opioid pill-related addiction deaths, despite overall gains in quality of life"); Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in the Next Decade*, STAT (June 27, 2017), https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ [https://perma.cc/6BRS-C7UA] (averaging expert forecasts of opioid overdose deaths to conclude that the peak of the crisis has not passed).

[2] *Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/statedeaths.html [https://perma.cc/FYU9-M3D7] (last updated June 27, 2019).

responsible for a growing share of opioid overdose deaths,[3] many individuals' opioid misuse and addiction originated from prescription painkiller use.[4] A concerning overlap between prescription opioid and illicit opioid use exists, such that "the prescription opioid epidemic could at least double the number of heroin users in the United States by 2025."[5]

The crisis's historic rates of addiction and overdose have prompted a panoply of legal and public health responses. Federal and state administrative agencies have prioritized monitoring, enforcement, spending programs related to opioid prescribing, and, more recently, addiction treatment.[6] Law enforcement agencies are acting in tandem in the criminal realm, prosecuting a mix of defendants, including corporate executives, pharmaceutical retailers, physicians, pharmacists, and persons with opioid addiction.[7] Nonprofit

[3] *See* Puja Seth et al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulant—United States, 2015–2016*, 67 CTRS. FOR DISEASE CONTROL & PREVENTION: MORBIDITY & MORTALITY WKLY. REP. 349, 349 (2018). The most significant contributor to the rise in opioid deaths was notoriously dangerous synthetic opioids like fentanyl, followed by heroin. *Id.* at 350–51, 352, 353. "Fentanyl, an opioid 80 times more potent than heroin, was brought to market in the United States as Duragesic® by Janssen Pharmaceuticals. . . . In the early 1990s, drug dealers began mixing fentanyl with heroin to produce a greater high. . . . By 2016, [for example,] half of overdose deaths in Illinois were fentanyl-related." Richard D. deShazo et al., *Backstories on the US Opioid Epidemic. Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. MED. 595, 599 (2018) (internal footnotes omitted).

[4] *See* Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2301 (2017) (citing RICHARD J. BONNIE ET AL., NAT'L ACAD. SCIS., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE (2017)); JONAKI BOSE ET AL., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2017 NATIONAL SURVEY ON DRUG USE AND HEALTH 20–22 (2018).

[5] BONNIE ET AL., *supra* note 4, at 213–14.

[6] *See generally The Federal Response to the Opioid Crisis: Hearing Before the S. Health, Educ., Labor, and Pensions Comm.*, 115th Cong. (2017) (statement of Dr. Francis Collins, Director, National Institutes of Health) (describing how federal agencies, including HHS, SAMHSA, CDC, NIH, and FDA, are responding to the crisis). *See also* Stephen Barlas, *U.S. and States Ramp Up Response to Opioid Crisis*, 42 PHARMACY & THERAPEUTICS 569, 569 (2017) (noting that state agencies "have been just as active" as federal ones, expanding prescription monitoring and access to overdose-reversal medication).

[7] *See, e.g.*, Rachel L. Rothberg & Kate Stith, *The Opioid Crisis and Federal Criminal Prosecution*, 46 J.L. MED. & ETHICS 292, 295–97 (2018) (describing DEA and DOJ criminal prosecutions related to opioids, including the criminal case of Purdue Pharma executives, and other cases against medical providers); Y. Tony Yang & Rebecca L. Haffajee, Commentary, *Murder Liability for Prescribing Opioids: A Way Forward?*, 91 MAYO CLINIC PROC. 1331, 1331 (2016) (discussing a novel theory of criminal liability in the opioid context, where a physician is charged with murder for opioid overdose deaths that resulted from reckless prescribing practices); Katie Zezima & Sari Horwitz, *Federal, State Authorities Step Up Fentanyl Prosecutions as Drug Drives Spike in Overdoses*, WASH. POST (June 7, 2018), https://www.washingtonpost.com/national/federal-state-authorities-step-up-fentanyl-

organizations and charitable foundations are fundraising and publishing reports to mitigate opioid harms.[8] Private sector corporations are donating profits to these efforts and seeking to innovate other potential products that treat pain non-addictively or effectively manage addiction.[9]

Garnering substantial attention is the spate of lawsuits brought against the companies responsible for supplying the prescription opioid market. The litigation examines the connection between the products manufactured, distributed, and marketed by major pharmaceutical brands (and approved for safety by the Food and Drug Administration (FDA)) and the millions of persons addicted to opioids.[10] The scope and frequency of the lawsuits, as well as their public health emphasis, prompt comparisons to the massive tobacco litigation of the 1990s.[11] That litigation ultimately brought the four largest cigarette manufacturers to the table to negotiate a "Master Settlement Agreement" (MSA) worth hundreds of billions.[12] Whether the opioid litigation will resolve similarly remains to be seen.

Indeterminacy notwithstanding, the potential significance of a global opioid settlement agreement cannot be understated. On the one hand, an MSA could bring substantial money—much more than the federal government has yet invested even taking into account its latest Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities

prosecutions-as-drug-drives-spike-in-overdoses/2018/06/07/5631edd0-69c0-11e8-bf8c-f9ed2e672adf_story.html [https://perma.cc/FV32-ACMU].

[8] *See, e.g.*, *The Opioid Epidemic*, ARNOLD VENTURES, https://www.arnoldventures.org/work/the-opioid-epidemic/ [https://perma.cc/FH76-6BEB]; *Substance Use Disorders & Recovery: Our Approach*, CLINTON FOUND., https://www.clintonfoundation.org/our-work/clinton-health-matters-initiative/programs/substance-use-disorders-recovery/our-approach [https://perma.cc/9VAQ-WA5S].

[9] *See, e.g.*, *Aetna Foundation to Support States in Fight Against the Opioid Epidemic*, AETNA FOUND. (Feb. 13, 2018), https://news.aetnafoundation.org/press-release/health-care-equity/aetna-foundation-support-states-fight-against-opioid-epidemic [https://perma.cc/875R-PWT4]; *Cardinal Health Foundation Awards over $3 Million to More than 70 Nonprofit Organizations to Fight the Opioid Epidemic Across Appalachia*, CARDINAL HEALTH (June 19, 2018), http://cardinalhealth.mediaroom.com/GenRx_grants [https://perma.cc/J4ZR-2DU2]; *McKesson Announces New Initiatives, Launches Foundation to Help Fight Nation's Opioid Epidemic*, MCKESSON (Mar. 29, 2018), https://www.mckesson.com/about-mckesson/newsroom/press-releases/2018/new-initiatives-fight-opioid-epidemic/ [https://perma.cc/JHK7-HLCS].

[10] *See* Haffajee & Mello, *supra* note 4, at 2301 (describing how lawsuits allege opioid products "were defectively designed," and manufacturers "failed to adequately warn about addiction risks" or "withheld information about their products' dangers").

[11] *See, e.g.*, Derek Carr et al., *Reducing Harm through Litigation Against Opioid Manufacturers? Lessons from the Tobacco Wars*, 133 PUB. HEALTH REP. 207, 207 (2018); Nicolas Terry & Aila Hoss, *Opioid Litigation Proceeds: Cautionary Tales from the Tobacco Settlement*, HEALTH AFF. BLOG (May 23, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180517.992650/full/ [https://perma.cc/XEU3-MF7F].

[12] Carr et al., *supra* note 11, at 207–08.

(SUPPORT) Act—and change behavior to ameliorate opioid harms.[13] On the other hand, such an agreement could actually fail to promote public health goals if it mimics the use of funds from the tobacco MSA.[14]

But, history does not have to repeat itself. This Article responds to skeptics of a potential global opioid settlement agreement by proposing terms that would further public health goals. While a blockbuster agreement is uncertain, it appears increasingly likely that an MSA of some sort will be reached in the multi-district litigation where the emphasis has been on improving health and other life outcomes in the midst of the crisis. This Article proceeds by providing an overview of the opioid litigation in Part II. Part III discusses lessons that can be drawn from past settlements—both the tobacco MSA and prior smaller opioid settlements. Part IV conceptualizes what form an MSA might take, outlining how damages and behavior change components could be structured to maximize public health benefits. Part V offers some concluding thoughts.

II. THE OPIOID LITIGATION, IN BRIEF

At the federal, state, and local levels, plaintiffs are pursuing litigation to hold pharmaceutical industry interests accountable for the costs of the opioid epidemic.[15] The diverse array of claimants includes private classes of consumers; hospitals and healthcare organizations; the federal government; state attorneys general; and local and tribal governments.[16] The defendants are

[13] *See* Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018) [hereinafter SUPPORT Act]; German Lopez, *Trump Just Signed a Bipartisan Bill to Confront the Opioid Epidemic*, VOX (Oct. 24, 2018), https://www.vox.com/policy-and-politics/2018/9/28/17913938/trump-opioid-epidemic-congress-support-act-bill-law [https://perma.cc/4LVP-H5L7] (noting that "the law [does] not provide a significant increase in spending for the opioid crisis at all," but "authorizes some relatively small grant programs"); Haffajee & Mello, *supra* note 4, at 2305 (listing productive ways the settlement terms could be structured, such that an agreement "hold[s] real hope for arresting the opioid epidemic").

[14] *See* Carr et al., *supra* note 11, at 209–10 (contending that the tobacco MSA funds were misused, and arguing that "[f]ew reasons exist to believe a similarly styled opioid MSA would produce better results" than the tobacco MSA did); Terry & Hoss, *supra* note 11 (cautioning that "[s]takeholders should not wait for the worst aspects of the tobacco settlement to be replayed," and generally critical that "plaintiffs and their lawyers seem keen to capture funds now").

[15] *See generally* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117 (2014); Abbe R. Gluck et al., *Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis*, 46 J.L. MED. & ETHICS 351 (2018); Haffajee & Mello, *supra* note 4.

[16] *See* Haffajee & Mello, *supra* note 4, at 2302–04; *West Virginia Hospitals Sue Opioid Companies; Want Damages*, MOD. HEALTHCARE (Apr. 30, 2019), https://www.modernhealthcare.com/providers/west-virginia-hospitals-sue-opioid-companies-want-damages [https://perma.cc/3BMG-LET3].

largely pharmaceutical manufacturers, distributors, and retailers.[17] Depending on the defendant, the suits differ in theories of liability asserted. Among other claims, manufacturers are accused of misrepresenting the addictive nature of opioid products in marketing campaigns and detailing efforts, and failing to adequately warn consumers about the potential for addiction;[18] distributors are alleged to have violated federal duties to monitor and report suspicious prescription ordering activity;[19] retailers are sued for negligently filling suspicious prescription orders despite "red flags."[20] The actions also vary in the relief sought. Beyond just money damages, the government plaintiffs typically seek to enjoin the defendants' future conduct: forbidding the companies from continuing their misrepresentations of the risks posed by opioid treatment of chronic pain or failing to report suspicious prescriptions and requiring restitution payments for any profits gained from these illegal practices.[21]

[17] *See* Haffajee & Mello, *supra* note 4, at 2301–04. Some recent cases also name healthcare industry groups as defendants, as well as pharmacy benefit management companies. *See, e.g.*, Amended Complaint and Jury Demand at 36, Cty. of Webb v. Purdue Pharma, L.P. et al., 1:18-op-45175-DAP (N.D. Ohio Sept. 17, 2018); Complaint at 62–70, Employer-Teamsters Local Nos. 175 & 505 Health & Welfare Fund et al. v. Purdue Pharma L.P. et al., 1:18-OP-45446 (N.D. Ohio Apr. 17, 2018); Complaint at 2–5, City of Charleston v. Joint Comm'n on Accreditation of Health Care Orgs., 2:17-cv-04267 (S.D. W. Va. Nov. 2, 2017);.

[18] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 223 (2009). For a history of marketing and public representations by manufacturers and their connection to the addiction epidemic, see generally *id.*; MINORITY STAFF OF S. HOMELAND SEC. & GOVERNMENTAL AFFAIRS COMM., 115TH CONG., INSYS THERAPEUTICS AND THE SYSTEMIC MANIPULATION OF PRIOR AUTHORIZATION (Comm. Print 2017); and Charles Ornstein & Ryann Grochowski Jones, *Opioid Makers, Blamed for Overdose Epidemic, Cut Back on Marketing Payments to Doctors*, PROPUBLICA (June 28, 2018), https://www.propublica.org/article/opioid-makers-blamed-for-overdose-epidemic-cut-back-on-marketing-payments-to-doctors%C2%A0 [https://perma.cc/2HH3-52PM].

[19] *See* Nora Freeman Engstrom et al., *Suing the Opioid Companies*, STAN. L. SCH. BLOGS: LEGAL AGGREGATE (Aug. 30, 2018), https://law.stanford.edu/2018/08/30/q-and-a-with-mello-and-engstrom/ [https://perma.cc/3UP6-MC8S] (describing the claims against distributors as alleging a failure "to monitor, detect, investigate, and report suspicious orders of prescription drugs, even though reasonably prudent suppliers would have done so and the federal Controlled Substances Act requires suppliers to maintain effective controls against diversion of controlled substances to illicit markets").

[20] Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. MED. 7, 31 (2016) (describing how doctors may be liable for violating the Controlled Substances Act when "ignor[ing] many warning signs and red flags and consciously eschew[ing] performing the most rudimentary screening that would have revealed many . . . patients' ruses") (quoting United States v. Katz, 445 F.3d 1023, 1031 (8th Cir. 2006)).

[21] *See, e.g.*, Complaint at 100–01, State *ex rel.* DeWine v. Purdue Pharma, No. 2017CL261 (Ross Cty. Ct. C.P. May 31, 2017); Complaint at 51–52, State v. Purdue Pharma, No. 512018CA001438CAAXWS (Fla. Cir. Ct. May 15, 2018); Complaint at 85, State v.

Defendants have responded in turn by challenging the chain of causation between their own conduct and the intervening actions of healthcare providers and patients.[22] Further, manufacturers often raise preemption defenses, arguing that the FDA's approval of the drugs for safety preempts state-based claims.[23] During the early 2000s, the first wave of opioid litigation characterized by personal injury suits waged against Purdue Pharma was largely subsumed by these defenses.[24] More generally, the imbalance of resources between the individual plaintiffs and the well-resourced pharmaceutical industry defendants often proved fatal.[25] The ongoing current wave, however, appears more viable.[26] Those cases, currently being litigated, can be grouped into two categories: class action suits and suits in which a government is plaintiff.[27] The class action vehicle helps level the resources brought to bear by parties and allows plaintiffs to overcome some of the procedural obstacles faced by the first wave of individual suits. For example, demonstrating the causal connection between a manufacturer's business practices and an alleged harm is generally easier for a group of hundreds of similarly situated people than at the individual level.[28] With a state or local government as the plaintiff, the injury is redefined

Purdue Pharma L.P., No. 3AN-17-09966CI (D. Alaska Oct. 30, 2017). *See generally* Haffajee & Mello, *supra* note 4.

[22] Gluck et al., *supra* note 15, at 357 (citing Memorandum in Support of Defendant McKesson Corporation's Motion to Dismiss Plaintiff's Complaint at 1, 15, Kanawha Cty. Comm'n v. Rite Aid of Maryland, Inc., No. 2:17-cv-01666 (S.D. W. Va. 2017); Memorandum in Support of Defendant McKesson Corp.'s Motion to Dismiss Complaint at 13–16, Cabell Cty. Comm'n v. AmerisourceBergen Drug Corp., No. 3:17-cv-01665 (S.D. W.Va. Apr. 11, 2017)).

[23] Gluck et al., *supra* note 15, at 357 (citing Memorandum of Law in Support of Defendant Purdue's Demurrer at 17, State v. Purdue Pharma L.P., No. 30-2014-00725287-CU-BT-CXC (Sup. Ct. Ca. 2015); Memorandum in Support of the Purdue Defendants' Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim at 1, Ohio *ex rel.* DeWine v. Purdue Pharma L.P., No. CV-17 CI 000261 (Ross Cty. Ct. C.P. Sept. 8, 2017)).

[24] *See* Haffajee & Mello, *supra* note 4, at 2304. For representative cases from this period of litigation, see Andrew Joseph, *A Veteran New York Litigator Is Taking on Opioid Makers. They Have a History*, STAT (Oct. 10, 2017), https://www.statnews.com/2017/10/10/opioid-lawsuits-paul-hanly/ [https://perma.cc/G6QX-522N] (describing suits filed on behalf of individual plaintiffs beginning in 2003, but noting that prior to a landmark 2007 settlement, "case after case against the [manufacturer of OxyContin] failed" in part because "[e]arlier lawsuits were brought by firms with fewer resources representing just a few patients" and defensive "hurdles" like FDA-approval and intervening causes "tripped up lawsuits").

[25] *See* Haffajee & Mello, *supra* note 4, at 2304; Ausness, *supra* note 15, at 1120.

[26] *See* Haffajee & Mello, *supra* note 4, at 2301, 2304 (describing how the "formidable barriers" faced by the first wave of litigation "persist today," but noting that "[t]he tide may turn for such lawsuits" as class action and government cases are bolstered by epidemiological data from the crisis' growth).

[27] *See id.* at 2304.

[28] *Id.*

as one to public coffers and environment, avoiding some of the causation challenges and affirmative defenses that stymied individual claims.[29]

A significant milestone in the wave of government suits that could pave the way towards a tobacco litigation-like MSA was the consolidation of over 150 cases brought by state and local governments in federal court under multidistrict litigation (MDL) in the northern district of Ohio in December 2017.[30] While it is difficult to generalize about the many different suits with unique complaints, numbering over 2000 as of September 2019,[31] they consistently seek compensation for the damage arising from improper marketing and distribution of prescription opioid medications into cities, states, and towns across the nation.[32] Plaintiffs allege the defendants are responsible for opiate diversion into their communities;[33] violated Racketeer Influenced and Corrupt Organizations (RICO) statutes, consumer protection laws, and state analogues to the Controlled Substances Act (CSA).[34] The lawsuits also regularly assert common

[29] *Id.* ("Because the government itself is claiming injury and seeking restitution . . . these suits avoid defenses that blame opioid consumers or prescribers [and they] garner substantial publicity.").

[30] Transfer Order at 1–4, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804-DAP (N.D. Ohio Dec. 12, 2017). N.D. Ohio was chosen from several options due to its "strong factual connection to this litigation" after it "experienced a significant rise in the number of opioid-related overdoses in the past several years and expended significant sums in dealing with the effects of the opioid epidemic." *Id.*

[31] Andrew Joseph, *Purdue Pharma Filed for Bankruptcy. What Does It Mean for Lawsuits Against the Opioid Manufacturer?*, STAT (Sept. 16, 2019), https://www.statnews.com/2019/09/16/if-purdue-pharma-declares-bankruptcy-what-would-it-mean-for-lawsuits-against-the-opioid-manufacturer [https://perma.cc/TZ4E-5JXT]. Indeed, one facet of this difficulty is the many different methods by which the complainants calculate damages. For example, New Jersey's complaint against Purdue Pharma estimates $290 million has been spent from state coffers on opioids (including Medicaid, workers' compensation, and employee and retiree health programs). Terry & Hoss, *supra* note 11. By contrast, the City of Tacoma estimated damages by quantifying how "the opioid crisis has increased the city's spending across health care, social services, emergency services, and public safety," and has implemented a new tax increase to raise $10 million annually to fund opioid spending. *Id.*

[32] Transfer Order, *supra* note 30, at 1.

[33] "[D]iversion" refers to "the unlawful channeling of regulated pharmaceuticals from legal sources to the illicit marketplace." James A. Inciardi et al., *Mechanisms of Prescription Drug Diversion Among Drug-Involved Club- and Street-Based Populations*, 8 PAIN MED. 171, 171 (2007). Diversion is a major factor contributing to the opioid epidemic and can be both exacerbated or minimized by the conduct of pharmaceutical companies. *See* Kathryn L. Hahn, *Strategies to Prevent Opioid Misuse, Abuse, and Diversion that May Also Reduce the Associated Costs*, 4 AM. HEALTH & DRUG BENEFITS 107, 111 (2011); Nora D. Volkow & Thomas A. McLellan, Commentary, *Curtailing Diversion and Abuse of Opioid Analgesics Without Jeopardizing Pain Treatment*, 305 JAMA 1346, 1346 (2011).

[34] *See supra* notes 21, 23 and accompanying text; Haffajee & Mello, *supra* note 4, at 2302–03; Gluck et al., *supra* note 15, at 353, 355.

law claims of public nuisance, negligence, negligent misrepresentation, fraud, and unjust enrichment.[35]

The federal judge overseeing the MDL, Judge Dan Aaron Polster, has garnered attention for an unorthodox approach: implementing an aggressive trial schedule and explicitly calling for a major settlement agreement.[36] While his tactics may be overly ambitious given the litigation's complexities and even overreaching for a court of law, they do weigh in favor of a potentially significant MDL settlement.[37] But questions remain about which parties that settlement might involve, and whether it will be on the same historic scale as the tobacco MSA.[38] A global settlement that resolves the pending liability comprehensively could appeal to both sides: the pharmaceutical industry could avoid extensive, costly, and image-battering suits, while government plaintiffs could gain sorely needed resources, perhaps swiftly.[39] The private plaintiffs' firms litigating on behalf of state attorneys general and local governments mostly on a contingency basis, however, may have perverse incentives to maximize their profits over costs, rather than achieve the most just outcome for their clients.[40]

MDL settlement prospects are limited by challenges unique to the posture of the litigation. Hundreds of opioid cases are not subsumed in the MDL, and rather reside—often by design to gain local tactical advantages—in state or tribal courts.[41] This complicates the endgame of an MSA, given that the

[35] *See supra* notes 21, 23 and accompanying text; Haffajee & Mello, *supra* note 4, at 2302.

[36] *See generally* Jan Hoffman, *Can This Judge Solve the Opioid Crisis?*, N.Y. TIMES (Mar. 5, 2018), https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html [https://perma.cc/CYF8-ZJFF]; Jeff Overley & Emily Field, *Opioid MDL Judge Sets Litigation Plan, Bashes DEA*, LAW360 (Apr. 11, 2018), https://www.law360.com/articles/1009123/opioid-mdl-judge-sets-litigation-plan-bashes-dea [on file with *Ohio State Law Journal*].

[37] Hoffman, *supra* note 36 ("'These are bold things for a judge to say and it's exciting and intriguing to follow,' said Abbe R. Gluck, a professor at Yale Law School . . . . 'But to say that his goals are ambitious would be an enormous understatement.'").

[38] *See* Gluck et al., *supra* note 15, at 360.

[39] *Id.* ("Defendants have an interest in a global settlement that resolves all their liability in one shot . . . [and] state Attorneys General[] will be attracted to early settlement and quick gains. . . .").

[40] *See* Andrew Harris et al., *Justice for Opioid Communities Means Massive Payday for Their Lawyers*, BLOOMBERG (July 25, 2018), https://www.bloomberg.com/graphics/2018-opioid-lawsuits/ [https://perma.cc/5H5A-MCN2]. Plaintiffs' attorneys on such cases work on a "contingency fee" basis, meaning they work the case for no-money-down in exchange for a stake in the award if successful. *See id.* The fees at stake in the opioids cases typically range between 25–33% of total recovery. *Id.* On the upper end of projections for the hypothetical value of the opioids litigation, this could mean a "$12.5 billion payday" for the plaintiffs' firms. *Id.*

[41] *See* Gluck et al., *supra* note 15, at 359 (describing how West Virginia and the Cherokee Nation sought "to avoid being pulled into the MDL" by emphasizing that state law predominates over their cases); Terry & Hoss, *supra* note 11 (speculating that "some cities

defendants' primary incentive to settle is to avoid drawn-out courtroom battles and costs by resolving *all* litigation simultaneously.[42] It may well be that the factors that drove the tobacco companies to the settlement table in the 1990s do not pose a sufficient degree of pressure on the opioid defendants.[43] Instead, opioid defendants might prefer to holdout for a bargain settlement or even opt for trial, especially since certain key plaintiff legal theories are novel and untested.[44] Despite these uncertainties, recent developments provide hope for an historic resolution.

III. LESSONS FROM PAST ADDICTIVE PRODUCT SETTLEMENTS

Should a comprehensive resolution to the opioid litigation materialize, an important objective at the forefront of Judge Polster's mind concerns the optimal forms of relief to maximize public health benefits.[45] Scholarly theories conflict regarding the value of litigation as a tool for regulation[46] and regarding the

are staying out of the federal MDL" because they are "betting on a higher payday before their state courts," given that the MDL will rack up "administrative costs and attorneys' fees" and damages will be "split among hundreds of plaintiffs")*; see also* Andrew Joseph, *Why Houston and Other Cities Want Nothing to Do with the Massive National Opioid Lawsuit*, STAT (Mar. 27, 2018), https://www.statnews.com/2018/03/27/houston-national-opioid-lawsuit/ [https://perma.cc/AB5T-XZQU].

[42] Hoffman, *supra* note 36 ("The defendants will most likely insist on a settlement that would resolve most, if not all, the state lawsuits as well as the federal ones.").

[43] Terry & Hoss, *supra* note 11 (noting that the following differences between the tobacco and opioid litigations "may yet encourage the defendants to litigate instead of settle or depress the settlement amount": the opioid manufacturers are fewer and of lesser value than "Big Tobacco" was; the "heterogeneous nature" of losses by opioids differ from the "relatively simple" tobacco cases; the MSA settlement talks were simplified because tobacco had "no health benefit," whereas any opioid settlement would be complicated by opioids' continued beneficial role in healthcare).

[44] *See* Jef Feeley, *Opioid Deal in West Virginia May Spur More Agreements*, BLOOMBERG (May 2, 2019), https://www.bloomberg.com/news/articles/2019-05-02/mckesson-settles-west-virginia-opioid-sales-claims-for-37-mln [https://perma.cc/XP88-M9NX]. For example, though many government plaintiffs assert claims against the major pharmaceutical distributors for violations of duties under the CSA, it remains an open question whether violations of the CSA can give rise to an independently enforceable cause of action. *See* Gluck et al., *supra* note 15, at 356. Similarly, claims against healthcare industry groups, like the Joint Commission, that argue collusion with pharmaceutical companies or against pharmaceutical benefit managers, or that argue negligent authorization of coverage for unnecessary prescriptions, are theories of first impression. *Id.* at 356–57. It also remains to be seen how far manufacturer's preemption defense, contending that FDA approval of opioid products preempts state-based tort liability, may extend. *See generally* Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1 (2015).

[45] *See* Hoffman, *supra* note 36.

[46] W.E. Parmet & R.A. Daynard, *The New Public Health Litigation*, 21 ANN. REV. PUB. HEALTH 437, 441, 446 (2000) (surveying the rise of affirmative litigation in public health campaigns to regulate firearms, lead paint, and tobacco, noting that some leading scholars

effectiveness (and fairness) of regulatory settlement agreements.[47] Two decades have passed since the 1998 Tobacco Master Settlement Agreement, allowing for retrospective assessment of the agreement's successes and failures. This Part considers those findings, as well as the terms of opioid settlements previously reached, to generate insights for a potential opioid MSA.

A. *The Tobacco Master Settlement Agreement*

After years of fruitless litigation, the four major tobacco manufacturers were finally forced to compromise when a coalition of forty-six state attorneys general and six other U.S. jurisdictions, rather than classes of private plaintiffs, rallied around a novel liability theory to recover government Medicaid and other costs incurred from spending on tobacco-related morbidity and mortality.[48] To help the states' case, damning whistleblower evidence, in the form of the Tobacco Papers, emerged to establish that tobacco companies knew of their products' addictive properties and nevertheless conspired to suppress this

believe "courts cannot create significant social change except in limited circumstances," while contending that "public health litigation . . . may at times play a constructive, if not decisive, role in the democratic struggle to protect the public's health"); *see also* Donald G. Gifford, *Impersonating the Legislature: State Attorneys General and Parens Patriae Product Litigation*, 49 B.C. L. REV. 913, 915 (2008) (arguing that product litigation aimed at regulating controversial markets subverts democratic processes); 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, 769 (1999) (concluding that "in general, public health goals are more directly achievable through the political process than through litigation," but that some circumstances are well-served by litigation campaigns that "stimulate[] a national debate" and "move the policy agenda").

[47] *See* Elizabeth Chamblee Burch & Margaret S. Williams, *Repeat Players in Multidistrict Litigation: The Social Network*, 102 CORNELL L. REV. 1445, 1449 (2017) (arguing that large MDL settlement dynamics mean that "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"); Andrew J. Haile & Matthew W. Krueger-Andes, *Landmark Settlements and Unintended Consequences*, 44 U. TOL. L. REV. 145, 175 (2012) (concluding that global settlements allow "defendants in regulatory litigation [to] effectively set public policy and even draft the language of legislation that state legislatures are then, for all practical purposes, required to enact"); Ryan D. Dreveskracht, *Forfeiting Federalism: The Faustian Pact with Big Tobacco*, 18 RICH. J. L. & PUB. INT. 291, 293, 315 (2015) (analyzing the tobacco MSA to conclude that state attorneys general reliance on litigation empowered "Big Tobacco" and displaced federalism's intended balance of powers).

[48] Arthur B. LaFrance, *Tobacco Litigation: Smoke, Mirrors and Public Policy*, 26 AM. J.L. & MED. 187, 187–93 (2000) (cataloging that from 1954 to 1994, when 813 private, state tort claims were filed against the tobacco industry, "[o]nly twice did courts find in favor of the plaintiffs," in part because of "a decades-long pattern of deliberate concealment, misrepresentation and deception by the tobacco companies." But, when AGs started bringing cases based on state Medicaid costs, they "broke the logjam of documentary deceit and concealment" and brought about "a sea change" in the litigation).

information and mislead consumers.[49] Settlement talks were initiated in 1996 and finalized in 1998 among the governments that were ultimately party to the litigation.[50] In exchange for tortious immunity, the agreement required industry to pay approximately $246 billion in penalties to state and local governments over a twenty-five year period,[51] plus an additional $9 billion per year in perpetuity thereafter, though it was virtually silent as to how those funds should be spent.[52] It also imposed injunctive requirements on tobacco marketing, particularly to young consumers.[53] The complex terms of the agreement have given rise to an entire body of case law litigating the scope of the settlement's requirements for each state that ratified it.[54]

The tobacco MSA marked a turning point in the decades-long campaign to regulate tobacco more stringently.[55] The settlement agreement stands as the largest ever settlement implemented in the U.S.[56] and has been characterized by anti-smoking advocates as "the most significant increase in spending on tobacco prevention and cessation in history."[57] The MSA's advertising enjoinders included mandatory funding for a massive "countermarketing" campaign led by the American Legacy Foundation.[58] To pay for the costs of the MSA, tobacco

[49] Peter Pringle, *The Chronicles of Tobacco: An Account of the Forces that Brought the Tobacco Industry to the Negotiating Table*, 25 WM. MITCHELL L. REV. 387, 387–88 (1999).

[50] Steven A. Schroeder, *Tobacco Control in the Wake of the 1998 Master Settlement Agreement*, 350 NEW ENG. J. MED. 293, 294 (2004).

[51] Terry & Hoss, *supra* note 11. *See generally* National Association of Attorneys General, *Master Settlement Agreement* (1998), http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf [https://perma.cc/23ZL-BSDV] [hereinafter *Master Settlement Agreement*] (presenting the most recent reprint of the MSA in full); TOBACCO CONTROL LEGAL CONSORTIUM, PUB. HEALTH L. CTR., THE MASTER SETTLEMENT AGREEMENT: AN OVERVIEW (2015), http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-msa-overview-2015.pdf [https://perma.cc/R6M4-LLWF] [hereinafter MSA OVERVIEW] (summarizing the terms and effects of the MSA).

[52] *See* MSA OVERVIEW, *supra* note 51, at 3. *See generally Master Settlement Agreement*, *supra* note 51.

[53] For example, the MSA famously marked the death of the "Joe Camel" advertising campaign. *See* Schroeder, *supra* note 50, at 294.

[54] *See generally* Robin Miller, *Validity, Construction, Application, and Effect of Master Settlement Agreement (MSA) Between Tobacco Companies and Various States, and State Statutes Implementing Agreement; Use and Distribution of MSA Proceeds*, 25 A.L.R.6th 435 (2007).

[55] Robert S. Wood, *Tobacco's Tipping Point: The Master Settlement Agreement as a Focusing Event*, 34 POL'Y STUD. J. 419, 425, 431 (2006) (concluding that the MSA was a "tipping event" that "represents genuine policy change" and that will "have lasting institutional impacts").

[56] Cheryl Healton, *The Tobacco Master Settlement Agreement—Strategic Lessons for Addressing Public Health Problems*, 379 NEW ENG. J. MED. 997, 997 (2018).

[57] Schroeder, *supra* note 50, at 295; *see also* MICHAEL PERTSCHUK, SMOKE IN THEIR EYES 221 (2001) ("[T]he single most fundamental change in the history of tobacco control in the history of the world.") (quoting Matt Myers of the Campaign for Tobacco-Free Kids).

[58] Schroeder, *supra* note 50, at 295 (identifying the prominent "truth" campaign as funded by the MSA).

companies raised prices on cigarettes significantly, initiating a corresponding decrease in demand that achieved, to a limited degree and albeit indirectly, the ultimate goal of smoking prevention and cessation.[59]

But even at the time of the settlement's implementation, there were critics skeptical of the litigation's capacity to bring about authentic policy change.[60] In the years since, policy advocates and researchers alike have widely criticized the MSA as failing to sufficiently reduce harms from tobacco, even though it did effectively impose a large monetary penalty against the industry.[61] Many argue that MSA funds were insufficiently tethered to the goal of reducing smoking rates and were instead diverted into state coffers for unrelated, inefficient purposes like servicing debt and closing budget shortfalls.[62] Further, because the states were granted MSA payments from tobacco companies prospectively in perpetuity, without spending stipulations, many states securitized their future payments into bonds for more immediate cash on hand.[63] For public health activists who hoped the MSA might mark the end of "Big

[59] *Id. But see* Gregory W. Traylor, Note, *Big Tobacco, Medicaid-Covered Smokers, and the Substance of the Master Settlement Agreement*, 63 VAND. L. REV. 1081, 1101–14 (2010) (arguing that the cigarette price increases caused by the MSA resulted in Medicaid-covered smokers essentially "footing the bill" of the tobacco manufacturers' MSA payments).

[60] LaFrance, *supra* note 48, at 189 (describing why the American Cancer Society filed a brief opposing the settlement agreement, and arguing that the costs of the settlement for "Big Tobacco" would be "passed on to an addicted consumer base," such that industry would "self-insure against the injuries it inflicts and continue its course of destructive conduct" without "genuine improvement in the nation's health").

[61] *See, e.g.*, Jayani Jayawardhana et al., *Master Settlement Agreement (MSA) Spending and Tobacco Control Efforts*, PLOS ONE 1, 15, 18 (2014) (using empirical methods to find "that MSA payments were negatively associated with overall measure of strength of tobacco control in states" because "the longer range objective of reducing tobacco use is often ignored when revenue allocation decisions are made by state legislatures"); Jim Estes, Opinion, *How the Big Tobacco Deal Went Bad*, N.Y. TIMES (Oct. 6, 2014), https://www.nytimes.com/2014/10/07/opinion/how-the-big-tobacco-deal-went-bad.html [https://perma.cc/6YMT-UBMB] (criticizing that states used MSA funds for projects such as construction of shipping docks, a public golf course sprinkler system, and a county jail, while projected to spend only 1.9% of MSA revenues on tobacco prevention programs in 2014).

[62] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-534T, STATES' ALLOCATIONS OF PAYMENTS FROM TOBACCO COMPANIES FOR FISCAL YEARS 2000 THROUGH 2005 6 (2007) (finding that, from 2000 to 2005, only 3.5% of total MSA revenues were spent on tobacco control programs, while 22.9% went towards state budget gaps, 7.1% towards "general purposes," and 6% towards "infrastructure"); Haile & Krueger-Andes, *supra* note 47, at 146 ("[I]n 2011 the states collectively used less than 2% of their annual MSA payments for smoking control and prevention programs."); Walter J. Jones & Gerard A. Silvestri, Commentary, *The Master Settlement Agreement and Its Impact on Tobacco Use 10 Years Later: Lessons for Physicians About Health Policy Making*, 137 CHEST 692, 697 (2010) ("It is clear that the MSA has not resulted in a[n] . . . intensification of state tobacco control efforts, because . . . MSA resources have been significantly diverted from tobacco control and treatment into other state policy activities.").

[63] *See* Schroeder, *supra* note 50, at 295.

Tobacco" forever, this financial symbiosis instead "created perverse incentives for the states to keep the tobacco industry financially healthy."[64] While there are some who view the benefits of the tobacco MSA as outweighing the costs,[65] several cautionary takeaways emerge that can be applied to a global opioid settlement.

B. *Past Opioid Settlements*

The specter of the tobacco MSA looms over the contemporary opioid litigation. The similar addictive properties of the substances and cumulative volume of cases brought by most state attorneys general, as well as local governments naturally raise comparisons between the opioid and tobacco litigation. Some fear that a global opioid settlement would fall prey to certain features embodied in the tobacco MSA that benefitted industry, failed to improve the public's health, or both.[66] Pointing to a handful of settlements from the first wave of opioid litigation, critics argue that there is already evidence that opioid settlements are ineffective as a direct public health response to opioid addiction (see Tables 1–3).[67] For example, in 2007, a multistate coalition of 27 state attorneys general reached a $19.5 million settlement agreement with Purdue.[68] The settlement is largely viewed as a failure, given its relatively paltry damages award and that the opioid epidemic only continued to accelerate afterwards.[69] Moreover, pharmaceutical companies apparently continued the

[64] *Id.* at 295 (quoting anti-smoking advocate Matt Myers as viewing the tobacco industry as the "winner" of the litigation because of the perverse incentives in the states' relationship with the manufacturers).

[65] *See, e.g.*, Michael Givel & Stanton A. Glantz, *The "Global Settlement" with the Tobacco Industry: 6 Years Later*, 94 AM. J. PUB. HEALTH 218, 224 (2004) ("Far from representing 'missed opportunities,' the global settlement proposal, the subsequent debates leading to its rejection, the MSA, the ongoing litigation in the area, and the policies that have been developed since 1997 have advanced tobacco control substantially.").

[66] *See* Terry & Hoss, *supra* note 11 ("How the settlement funds from the 1990s tobacco litigation have been distributed provides a cautionary precedent [for the opioid litigation]."); Carr et al., *supra* note 11, at 207 ("[A] similar agreement [to the tobacco MSA] in the [opioid] context would be unlikely to substantially reduce opioid-related morbidity and mortality absent contemporaneous comprehensive regulatory reform.").

[67] *See, e.g.*, Carr et al., *supra* note 11, at 208 (highlighting how "[d]espite these legal consequences" from the first wave of litigation, "some [opioid] manufacturers allegedly continued to use misleading and illegal practices" that gave rise to the second wave); Terry & Hoss, *supra* note 11 (criticizing West Virginia's use of settlement funds from a 2004 agreement reached with Purdue Pharma).

[68] *See* Consent Judgment at 14, State v. Purdue Pharma L.P., No. 07-2-00917-2 (Wash. Ct. Sup. May 9, 2007); *AG Files Judgment with Purdue Pharma Over Marketing of OxyContin*, OR. DEP'T JUST. (May 8, 2007), https://www.doj.state.or.us/media-home/news-media-releases/ag-files-judgment-purdue-pharma-marketing-oxycontin [https://perma.cc/E5FX-MH4T].

[69] Laura Strickler, *Drugmakers May Face More Legal Action over Opioid Epidemic*, CBS NEWS (Sept. 1, 2016), https://www.cbsnews.com/news/oxycontin-opioid-drug-

very practices that were litigated despite the settlement's inclusion behavior change requirements, namely making misrepresentations about the addictiveness of opioid products.[70] One attorney from the Oregon Attorney General's office, the office that led the coalition, recently testified to Congress that the settlement "did not require Purdue to take sufficient remedial action" because the government attorneys "did not fully appreciate the severity of the opioid epidemic and the long-lasting effects of Purdue's [OxyContin] promotion."[71]

A West Virginia case provides another example of missed opportunity. The state police received a $44 million portion of the criminal asset forfeiture payment made to the Department of Justice following its 2007 prosecution of Purdue Pharma executives.[72] A portion of that payment went to the construction of a 12,000 foot police academy training facility, featuring a gymnasium and combat training room, and remodeling projects including replacement of stucco exteriors with brick.[73] For skeptics of the public health value of settlement

makers-legal-action/ [https://perma.cc/6HSV-HYSY] ("The company had to pay nearly $20 million but there has been, in the words of one assistant attorney general, 'tremendous buyer's remorse' that the settlements did not extract more money, accountability or change in the prescribing culture.").

[70] Carr et al., *supra* note 11, at 208 ("Despite these legal consequences, some [opioid] manufacturers allegedly continued to use misleading and illegal practices. In 2015, Purdue settled lawsuits brought by New York and Kentucky alleging improper marketing of OxyContin—nearly the same allegations to which the company had pled guilty in federal court 8 years before.").

[71] *Examining the Opioid Epidemic: Challenges and Opportunities, Hearing Before the S. Comm. on Fin.*, 114th Cong. 11 (2016) ("Had I so known, I would have advocated for a settlement which would have required more extensive remedial action by Purdue to correct the inappropriate prescribing patterns for opioids. . . ."). *Id.* at 42.

[72] W. VA. GOVERNOR'S OFFICE, PLAN FOR A DRUG-FREE WEST VIRGINIA 6 (Jan. 2008), https://djcs.wv.gov/grant-programs/Specialized%20Programs/PPF/Documents/Purdue%20Pharma%20Plan.pdf [https://perma.cc/DG5F-52DF] [hereinafter W. VA. GOVERNOR'S REPORT] (documenting WVSP's portion of the asset forfeiture payment, noting that "[f]ederal asset forfeiture funds, considered to be proceeds of criminal activities, are often shared by the federal government with state and local law enforcement authorities that have contributed to the investigation and/or prosecution of federal crimes").

[73] Cathleen Moxley, *West Virginia State Police Open New Training Center*, WSAZ NEWSCHANNEL 3 (Apr. 24, 2012), https://www.wsaz.com/home/headlines/WV_State_Police_Open_New_Training_Center_148764835.html [https://perma.cc/97M3-9RNR]; Marianne Skolek, *West Virginia Uses OxyContin Settlement Money to Build Gym*, NAT'L PAIN REP. (Apr. 30, 2012), http://nationalpainreport.com/west-virginia-uses-oxycontin-settlement-money-to-build-a-gym-8814021.html [https://perma.cc/F9RT-VET6].

agreements, this provides a straightforward illustration of squandered opportunity[74] that hearkens back to a repetition of tobacco MSA mistakes.[75]

Reviewing more recent settlements, however, paints a more mixed picture. Several cases from the ongoing current wave of opioid litigation have settled and seem to indicate an ambition among the stakeholders to avoid repeating past mistakes. For example, in a 2015 Purdue Pharma $24 million settlement with the State of Kentucky (paid out over eight years),[76] funds are required by court order to go towards a public health fund for initiatives like addiction treatment.[77] Imposition of a "restricted fund" is one tactic for ensuring that settlement monies go towards meaningful and related purposes, and it improves upon the highly fungible state tobacco MSA payments. Moreover, embodying requirements in the court order, as opposed to the settlement agreement, renders the terms enforceable by the court itself—moving the settlement further from the law of contract and closer to something like a binding consent decree enforced by the judiciary.[78]

[74] The reality may be more nuanced. For an example of the critique, see West Virginia activist and journalist Marianne Skolek, whose daughter died from an OxyContin overdose, asking "if the families of those addicted and dying from West Virginia's prescription drug epidemic prefer dumbbells over drug treatment facilities." Skolek, *supra* note 73. But the funds the West Virginia State Police used for their training facility were exclusively from the Department of Justice (DOJ) criminal asset forfeiture payment, *not* the settlement, from Purdue Pharma. *See* W. VA. GOVERNOR'S REPORT, *supra* note 72, at 6–7. Those payments of seized criminal proceeds go directly to the state police budget as opposed to general state coffers. *Id.* Moreover, they are subject to strict regulatory guidelines from the DOJ, and in this case DOJ specifically pre-approved the funds' usage for "law enforcement training," "law enforcement equipment and operations," and "law enforcement facilities and equipment," in addition to "drug education and awareness programs." *Id.* While one might argue that all $44 million should have been spent on allaying West Virginia's addiction crisis, $5 million on facilities and renovations is not necessarily a scandal, given that "U.S. Department of Justice asset forfeiture funds are typically used to support general law enforcement purposes." *Id.* at 6.

[75] Terry & Hoss, *supra* note 11 (invoking the West Virginia State Police remodeling project as raising "a most sobering precedent" from the tobacco MSA).

[76] Settlement Agreement and General Release at 7–8, Kentucky *ex rel.* Conway v. Purdue Pharma L.P., No. 07-CI-01303 (Pike Cir. Ct. Dec. 22, 2015), https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf [https://perma.cc/3VXT-Q9MG].

[77] Agreed Judgment and Stipulation of Dismissal with Prejudice at 3–4, Kentucky *ex rel.* Conway v. Purdue Pharma L.P., No. 07-CI-01303 (Pike Cir. Ct. Dec. 22, 2015), https://ag.ky.gov/pdf_news/purduepharmaoxycontin.pdf [https://perma.cc/3VXT-Q9MG] ("[A]ny funds shall be placed in a restricted fund . . . for the use of public health initiatives, educational or public safety campaigns, reimbursement or financing of health care services and *infra*structure related to addiction prevention and treatment.").

[78] *See* Anthony DiSarro, *Six Decrees of Separation: Settlement Agreements and Consent Orders in Federal Civil Litigation*, 60 AM. U. L. REV. 275, 277–79 (2010) (explaining the sliding-scale distinctions between settlement agreement and consent decree, noting that "[t]he first distinction . . . is the mode of enforcement," such that "an injunction in the consent decree makes non-compliance with the settlement terms contempt of court" while "failure to comply with a settlement agreement is simply a breach of contract").

A more recent example of a state opioid litigation settlement in which funds have been earmarked for restricted purposes is that between the State of Oklahoma and Purdue Pharma.[79] The settlement, valued at about $270 million, requires that $102.5 million go to Oklahoma State University's center for addiction that specializes in research and education on addiction, and the Sackler family (not party to the suit) will donate an additional $75 million over five years to the center.[80] Approximately $60 million will go towards attorneys' fees, and $12.5 million will go directly to counties and municipalities to help pay for their costs attributable to the crisis.[81] Finally, $20 million has been earmarked to pay for addiction treatment medicines.[82] Although the overall amount of this settlement may have been lower than the costs of the crisis, due to bankruptcy threats posed by Purdue that would have significantly reduced any amounts recovered by Oklahoma,[83] the specific uses of the bulk of the funds to ameliorate opioid harms is a step in the right direction. Moreover, Purdue agreed to stop promoting opioids in Oklahoma in perpetuity.[84] The agreement may be an indication of industry defendants' increasing openness to settle.[85] Since Purdue reached its agreement with Oklahoma, manufacturer defendant Teva also settled with the State in the days leading up to trial in exchange for an $85 million payment.[86] In the same period, the West Virginia Attorney General's Office announced its own $37 million settlement with distributor McKesson, with funds limited to "support of state initiatives to combat the opioid epidemic."[87] That settlement has received criticism from some in the

[79] Consent Judgment as to the Purdue Defendants at 10, Oklahoma *ex rel.* Hunter v. Purdue Pharma L.P., No. CJ-2017-816 (Clev. Cty. D. Ct. Mar. 26, 2019), http://www.oag.ok.gov/Websites/oag/images/Consent%20Judgement.pdf [https://perma.cc/HXC9-P8LN].

[80] *Id.*; Jan Hoffman, *Purdue Pharma and Sacklers Reach $270 Million Settlement in Opioid Lawsuit*, N.Y. TIMES (Mar. 26, 2019), https://www.nytimes.com/2019/03/26/health/opioids-purdue-pharma-oklahoma.html [https://perma.cc/UL7R-GN3J].

[81] Consent Judgment as to the Purdue Defendants, *supra* note 79, at 10.

[82] *Id.*

[83] Hoffman, *supra* note 80.

[84] Consent Judgment as to the Purdue Defendants, *supra* note 79, at 8–9.

[85] *See* Francie Diep, *What Oklahoma's $270 Million Settlement with Purdue Pharma Means for the 1,000-Plus Opioid Cases Still Pending*, PACIFIC STANDARD MAG. (Mar. 27, 2019), https://psmag.com/news/what-oklahomas-settlement-with-purdue-pharma-means-for-opioid-cases [https://perma.cc/U4KA-VRDT].

[86] *Company Statement: Teva Reaches Agreement with State of Oklahoma to Resolve State's Claim Against the Company*, AP NEWS (May 26, 2019), https://www.apnews.com/Business%20Wire/e3cbd00425694f2eb6ba2725620022db [https://perma.cc/GN4R-BRSJ]. The settlement remains pending, and its terms unpublished, after the court insisted that "any provision of confidentiality needs to be stripped" and the agreement be published on the public docket. *See* Summary Order, Oklahoma *ex rel.* Hunter v. Purdue Pharma L.P., No. CJ-2017-816 (Clev. Cty. D. Ct. June 13, 2019) [on file with the author].

[87] Press Release, McKesson Reaches Settlement with State of West Virginia on Opioid Order Monitoring and Reporting, McKesson (May 2, 2019), https://www.mckesson

state—U.S. Senator for West Virginia Joe Manchin labelled it a "sweetheart deal" for McKesson—who view the payout as paltry when compared to West Virginia's opioid-related costs or even to Oklahoma's collection of hundreds of millions from Purdue.[88]

In addition to distinct approaches to settlement payments, some third wave opioid settlements impose novel behavior change requirements on pharmaceutical defendants. In particular, a series of settlements obtained by the Department of Justice (DOJ) implement innovative enjoinders that go beyond generic prohibitions against the litigated conduct. The first settlement arose from a 2012 investigation of Cardinal Health by several U.S. Attorneys' Offices and the DEA.[89] Prosecutors utilized a legal theory that increasingly appears in new opioid suits and many of the MDL actions: imposing liability against a major pharmaceutical distributor for failing to comply with "suspicious order" reporting requirements under the CSA.[90] To avoid litigation, Cardinal entered into an administrative agreement with the government to cooperate with the investigation.[91] The investigation culminated in settlement payments of $34 million and $10 million in 2016,[92] and reinforced several enjoinders included in an earlier 2012 settlement.[93] Those terms primarily included enhanced terms of

.com/about-mckesson/newsroom/press-releases/2019/mckesson-reaches-settlement-west-virginia-opioid-monitoring-reporting/ [https://perma.cc/A68Q-4CEE].

[88] *See* Feeley, *supra* note 44.

[89] *See* Cardinal Health, Inc. v. Holder, 846 F. Supp. 2d 203, 207–10 (D.D.C. 2012) (denying Cardinal's motion for a preliminary injunction to enjoin DEA's suspension of Cardinal's CSA license and detailing DEA's investigation into diversion of opioid medications at Cardinal's distribution facilities).

[90] *See Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act*, U.S. DEP'T JUST. (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act [https://perma.cc/2VER-ZLNT]. This theory of liability is particularly concerned with the issue of "diversion" of pharmaceuticals. *See id.*; Haffajee & Mello, *supra* note 34, at 2302–03.

[91] ADMINISTRATIVE MEMORANDUM OF AGREEMENT 2, 4–5 (2012), https://www.thehealthlawfirm.com/uploads/Cardinal%20Health%20-%20Memo%20of%20Agreement.pdf [https://perma.cc/9A5W-H3EB] [hereinafter 2012 CARDINAL MOA].

[92] SETTLEMENT AGREEMENT 5 (2016), https://www.bizjournals.com/tampabay/news/2016/12/23/cardinal-health-agrees-to-44m-settlement-in.html [on file with *Ohio State Law Journal*]; *Manhattan U.S. Attorney Announces $10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, Llc.*, U.S. DEP'T JUST. (Dec. 23, 2016), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-recovery-against-new-york [https://perma.cc/8ZDB-RRK9] [hereinafter 2016 CARDINAL AGREEMENT].

[93] *See* SETTLEMENT AGREEMENT, *supra* note 92, at 7 ("This Agreement is not intended to and does not supersede the obligations contained in the May 2012 Administrative Memorandum of Agreement.").

CSA compliance and internal corporate reforms that facilitate oversight of large orders of opioid medications.[94]

The DOJ achieved a similar result using the same theory of liability against another major pharmaceutical distributor: McKesson Corporation.[95] McKesson was originally investigated in 2008 and entered an agreement to pay a civil penalty for reporting violations.[96] McKesson continued to violate CSA reporting duties, however, particularly with regards to oxycodone and hydrocodone, giving rise to a renewed investigation.[97] That investigation culminated in a record-setting $150 million penalty for CSA violations.[98] Like Cardinal, McKesson faced punishment beyond just monetary fines and agreed to make consequential changes to its business practices.[99] Most significantly, McKesson implemented a "first of its kind" independent monitor system partnership with DEA to ensure compliance.[100] While McKesson's initial

[94] 2012 CARDINAL MOA, *supra* note 91, at 3–4. Specifically, Cardinal agreed to raise its quality control standards and processes, create a new corporate body for monitoring large volume orders of regulated pharmaceuticals, comply with more stringent monthly reporting requirements to the DEA, and a temporary suspension of its CSA license for distributing narcotic medications. *Id.*

[95] *McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, U.S. DEP'T JUST. (Jan. 17, 2017), https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders [https://perma.cc/8L6M-P2DN] [hereinafter *McKesson Press Release*].

[96] *Id.*

[97] *Id.*; ADMINISTRATIVE MEMORANDUM OF AGREEMENT 1, 2 (2017), https://www.justice.gov/opa/press-release/file/928476/download [https://perma.cc/EAJ9-WYMU] [hereinafter MCKESSON MOA].

[98] *McKesson Press Release*, *supra* note 95; SETTLEMENT AGREEMENT AND RELEASE 1, 6 (2017), https://www.justice.gov/opa/press-release/file/928471/download [https://perma.cc/2UL4-C7UQ].

[99] *McKesson Press Release*, *supra* note 95. Four McKesson distribution centers were subject to suspensions ranging from 1–3 years, MCKESSON MOA, *supra* note 97, at 5–7, and the company "agreed to enhanced [CSA] compliance terms for the next five years . . . [and] to specific, rigorous staffing and organizational improvements; periodic auditing; and stipulated financial penalties for failing to adhere to the compliance terms." *McKesson Press Release*, *supra* note 95.

[100] *McKesson Press Release*, *supra* note 95; *see also* COMPLIANCE ADDENDUM 1 (2017), https://www.justice.gov/opa/press-release/file/928481/download [https://perma.cc/H9KT-J4UF]. Under the system, McKesson is subject to "enhanced compliance," *McKesson Press Release*, *supra* note 95, with the CSA for a five-year period, using "customer specific" and geographic data to supplement its standard monthly reports. COMPLIANCE ADDENDUM, *supra* note 100, at 4. Its implementation required creation of multiple new corporate departments and committees for compliance, subject to special independence and compensation restrictions; new corporate training and ethics policies; an outside "Independent Review Organization," a three-member panel of experts on pharmaceuticals and substance control that conducts an annual audit. *See* COMPLIANCE ADDENDUM, *supra* note 100, at 1, 4–17, 22–30. The system reports back to the DEA throughout each process. *See id.* at 22–30.

bucking of its 2008 agreement with the government is paradigmatic of the settlement agreement critique, this subsequent agreement illustrates the potential to ingrain systemic change.

The federal government obtained several additional settlement agreements for CSA violations outside the distribution context that also reveal opportunities for meaningful accountability.[101] DOJ's $35 million settlement with Mallinckrodt, among the largest producers of generic oxycodone, was novel because it extended enforcement of CSA reporting requirements to a manufacturer.[102] Like Cardinal and McKesson, Mallinckrodt failed to report "suspicious orders" to the DEA and its lackluster system for monitoring such orders allegedly violated its legal duties.[103] Government enforcers in this investigation honed in on the pharmaceutical industry practice of offering "chargebacks"—essentially customized discounts offered to buyers based on downstream purchasing data.[104] Because the data is provided to the manufacturer *after* the sale of regulated medications has taken place, it was previously not provided to the DEA in CSA reports.[105] In what the DOJ termed a "groundbreaking" development, Mallinckrodt agreed to an unprecedented data sharing agreement with the DEA that includes downstream purchasing data, facilitating oversight on "the next level in the supply chain."[106]

The final examples of model settlement agreements come from DOJ's extension of the CSA theory to the retailer space. In 2017, DOJ obtained an $11.75 million settlement with Costco based on monitoring violations in their pharmacy outlets.[107] Costco pharmacies filled incomplete prescriptions, filled prescriptions from noncompliant practitioners, and failed to maintain proper records at stores and "central fill locations."[108] Like the previous agreements, this settlement required more than just payment: Costco invested more than

[101] *See generally Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, U.S. DEP'T JUST. (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders [https://perma.cc/2X23-SXQR] [hereinafter *Mallinckrodt Press Release*].

[102] *Id.* ("This is the first settlement of its magnitude with a manufacturer of pharmaceuticals resolving nationwide claims that the company did not meet its obligations to detect and notify DEA of suspicious orders . . . .").

[103] *Id.*

[104] *Id.*; ADMINISTRATIVE MEMORANDUM OF AGREEMENT 1–3, 5 (2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download [https://perma.cc/R542-69SM] [hereinafter MALLINCKRODT SETTLEMENT AGREEMENT].

[105] *See* MALLINCKRODT SETTLEMENT AGREEMENT, *supra* note 104, at 5.

[106] *Mallinckrodt Press Release*, *supra* note 101; *see also* MALLINCKRODT SETTLEMENT AGREEMENT, *supra* note 104, at 4–9.

[107] *See Costco Wholesale to Pay $11.75 Million to Settle Allegations of Lax Pharmacy Controls*, U.S. DEP'T JUST. (Jan. 19, 2017), https://www.justice.gov/opa/pr/costco-wholesale-pay-1175-million-settle-allegations-lax-pharmacy-controls [https://perma.cc/94E3-XS8Y].

[108] *Id.*

$100 million in a revamped pharmacy management system to facilitate CSA compliance, implemented a new internal audit system requiring internal corporate reorganization and external cooperation, and agreed to a three year period of unfettered DEA access to inspect facilities.[109] The same year, and under the same theory, DEA achieved a $3 million settlement with Safeway.[110] The investigation was triggered when DEA was tipped off to an internal theft of a large supply of hydrocodone.[111] Finding that the practices that allowed such a loss to go unreported were widespread across the company's pharmacies, DEA implemented similar compliance requirements as in the Costco agreement.[112]

Time will tell if the behavior change strategies deployed by the federal government will lead to better outcomes than in previous opioid settlements. The strategy, however, demonstrates that settlement agreements are more than mere payments and penalties to dispose of a lawsuit. They are a flexible tool that can incorporate systemic, enforceable terms of change, bounded only by the thoughtfulness and willingness of the contracting parties.

C. *Priorities in an Opioid Master Settlement Agreement*

Examples of previous public health regulatory settlements provide both aspirational and cautionary guidance on crafting effective terms for an opioid MSA. It is reasonable to assume that any settlement would include both monetary compensation and behavior change requirements. Other residual benefits of this type of public health litigation—even absent a settlement—include building public awareness about opioid harms and spurring other government activity, namely in the legislative and executive branches.[113] This part, however, focuses on master settlement monetary and behavior change components, conceptualizing what form and substance these components could take to maximize public health impacts. We also briefly address several related questions that complicate any such MSA, including what magnitude monetary damages might reach, which parties may negotiate the terms of a settlement, and how the terms would best be enforced.

[109] *See id.*

[110] *Safeway Pharmacies Pay $3 Million to Resolve Allegations Chain Failed to Timely Report Drug Diversion*, U.S. DEP'T JUST. (July 18, 2017), https://www.justice.gov/usao-wdwa/pr/safeway-pharmacies-pay-3-million-resolve-allegations-chain-failed-timely-report-drug [https://perma.cc/LE6A-ZZJD].

[111] *Id.*

[112] *See id.*; Nate Raymond, *Safeway to Pay $3 Million to Resolve U.S. Drug Probe*, REUTERS (July 18, 2017), https://www.reuters.com/article/us-safeway-probe/safeway-to-pay-3-million-to-resolve-u-s-drug-probe-idUSKBN1A32BB [https://perma.cc/4MPV-LB44] ("In addition to paying $3 million, Safeway will also implement a compliance agreement reached with DEA to prevent future notification lapses.").

[113] *See* Haffajee & Mello, *supra* note 4, at 2305; Jacobson & Warner, *supra* note 46, at 788–90; Parmet & Daynard, *supra* note 46, at 445.

1. *Monetary Damages*

a. *Damages Award Magnitude*

A settlement with the pharmaceutical industry cannot be expected to match the overall cost of the opioid epidemic, given that industry is only one of many contributing parties. However, the magnitude of overall epidemic costs provides benchmarks for the value of a master settlement.

Studies estimating the economic burden of the opioid epidemic vary widely.[114] Conservative estimates find annual costs increasing from around $75 billion in 2013 up to almost $100 billion in 2017, for a total cost of the epidemic since 2001 of $1 trillion.[115] More inclusive valuations find annual costs alone total half a trillion dollars, with compounded costs of the epidemic therefore in the multiple trillions.[116] The economic cost studies largely cluster around these two poles; whether or not a given study accounts for the value of lost lives largely accounts for the difference in cost magnitude estimated.[117] On the lower end, studies estimate costs by primarily valuing health care costs, looking to the disproportionate health care burdens imposed by people who misuse opioids relative to those who are similarly situated but do not.[118] On the upper end, studies also consider economic losses, such as foregone labor and criminal justice system costs, and noneconomic costs arising from lost lives.[119] In this

[114] *Compare* COUNCIL OF ECON. ADVISERS, EXEC. OFFICE OF THE PRESIDENT, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 8 (Nov. 2017) [hereinafter WHITE HOUSE REPORT] (finding an annual cost of $504 billion for 2015), *and* Laxmaiah Manchikanti et al., *Opioid Epidemic in the United States*, 15 PAIN PHYSICIAN ES9, ES10 (2012) (stating that Americans with persistent pain issues impose "financial costs ranging from $560 billion to $635 billion per year"), *with* Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 MED. CARE 901, 904 (2016) (estimating annual costs for 2013 at $78.5 billion), *and* Corey Rhyan, *The Potential Societal Benefit of Eliminating the Opioid Crisis Exceeds $95 Billion per Year*, ALTARUM (Nov. 16, 2017), https://altarum.org/sites/default/files/uploaded-publication-files/Research-Brief_Opioid-Epidemic-Economic-Burden.pdf [https://perma.cc/A3TN-UJ9M] (finding 2016 annual costs total around $95 billion dollars).

[115] *See* sources cited *supra* note 114; Corey Rhyan, *Economic Toll of Opioid Crisis in U.S. Exceeded $1 Trillion Since 2001*, ALTARUM (Feb. 13, 2018), https://alterum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001 [https://perma.cc/3WL8-NVNC].

[116] *See* WHITE HOUSE REPORT, *supra* note 114, at 8.

[117] *See id.* at 3 ("Previous studies and estimates fail to fully account for the lives lost to overdose.").

[118] *See* Carrie McAdam-Marx et al., *Costs of Opioid Abuse and Misuse Determined from a Medicaid Database*, 24 J. PAIN & PALLIATIVE CARE PHARMACOTHERAPY 5, 6 (2010).

[119] *See* WHITE HOUSE REPORT, *supra* note 114, at 3 ("Studies that only include healthcare expenditures typically capture none of the value of lives lost, and studies that account for earnings losses among those who die account for only a fraction of the loss from such mortality. . . . As earnings do not take into account other valuable activities in life besides work."); Howard G. Birnbaum et al., *Estimated Costs of Prescription Opioid*

latter category of studies that value lost lives, productivity losses from opioid fatalities represent the majority of the epidemic's costs.[120] By 2015, for example, 2 million "prime-age" workers were inactive due to opioid use, slowing economic growth by 0.6% and costing the economy an estimated $1.6 trillion.[121] The next greatest categories of costs are productivity losses from nonfatal opioid misuse, health care costs related directly to overdoses, indirect health care costs, criminal justice system administration, child and family assistance, and losses to the education system.[122]

When costs are broken down by sector of the economy, studies show that individuals and the private sector bear the majority of the burden, followed by the federal government, then by state and then local governments.[123] This breakdown finds that the federal, state, and local government portion of the burden has held at roughly half of costs per year, including half of the $95.8 billion cost in 2016 alone.[124] Compounded since 2001, this constitutes approximately $500 billion of the $1 trillion total costs—only projected to exponentially grow in the coming years.[125] Because the plaintiffs in the current wave of opioid litigation are typically the government itself, this metric could be a useful barometer for master settlement negotiations, assuming most or all government plaintiffs come to the table.[126] Added to this $500 billion from

Analgesic Abuse in the United States in 2001: A Societal Perspective, 22 CLINICAL J. PAIN 667, 671–73 (2006); Howard G. Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 PAIN MED. 657, 661–62 (2011); Florence et al., *supra* note 114, at 902–03; Ryan N. Hansen et al., *Economic Costs of Nonmedical Use of Prescription Opioids*, 27 CLINICAL J. PAIN 194, 195–98 (2011); Ben Gitis, *State-by-State: The Labor Force and Economic Effects of the Opioid Crisis*, AM. ACTION F. (Sept. 12, 2018), https://www.americanactionforum.org/project/opioid-state-summary/ [https://perma.cc/5ZCE-56Z2].

[120] *See* Rhyan, *supra* note 115.

[121] Gitis, *supra* note 119.

[122] *See* Rhyan, *supra* note 115.

[123] *Id.* (finding the individual costs are predominantly from lost wages; private sector from health care costs; federal, state, and local governments from additional expenditures on health care, social services, education, and criminal justice, as well as lost tax revenue).

[124] *See id.*

[125] *See id.*

[126] Indeed, even though the United States is not a party to the opioid MDL, it is formally participating in settlement negotiations as a designated "friend of the Court." *See* United States' Motion to Participate in Settlement Discussions and as Friend of the Court at 1, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804 (N.D. Ohio Apr. 02, 2018) (unopposed motion approved by Judge Polster on June 19, 2018); United States' Memorandum in Support of Its Motion to Participate in Settlement Discussions and as Friend of the Court at 3, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804 (N.D. Oh. Apr. 02, 2018) ("The United States' substantial financial stake in combatting the opioid epidemic has implications for the proper allocation of any monetary settlement of the claims asserted in the multi-district litigation."); Statement of Interest of the United States at 3, *In re* Nat'l Prescription Opiate Litig., No. 1:17-md-02804 (N.D. Oh. Mar. 01, 2018) [hereinafter Statement of Interest] (justifying the federal government's interest in the MDL by pointing to "substantial costs from the opioid epidemic," including the 2013 single-year estimate of total costs as

2001–2017 is the projected $250 billion from 2017–2020 incurred by governments—for a cumulative total of about $750 billion.[127] And this figure does not take into account future costs beyond 2020, which could be quite substantial, or individual costs that could be factored into a settlement as discussed in Part III.C.1.b.[128] In short, a realistic figure for the master settlement could reasonably reach at least $50 billion to hundreds of billions, similar to the tobacco MSA, if shared responsibility, other defenses, or bankruptcy threats do not reduce that sum substantially.[129]

b. *Compensating the "Injured Parties"*

Compensatory damages awarded in tort litigation are classically understood to serve competing goals: compensation, deterrence, and punishment or corrective justice.[130] In the public health and regulatory contexts, litigation damages are often also relied on by legislatures and executive agencies as a means for private enforcement of public regulations and mass injuries.[131] As in the tobacco litigation, the opioid litigation conceives of addiction to opioids as a kind of "mass" injury not unlike asbestos exposure, damages compensation for which shifts the costs of injuries from victims to responsible parties.[132] As

$78.5 billion and citing the Council of Economic Advisors' upper-end estimate, *supra* note 114).

[127] *See* Rhyan, *supra* note 114.

[128] Even estimates that place greater emphasis on the value of human life might more representatively quantify the true societal impact of the epidemic but are likely untenable in the context of a litigation resolution. *See* WHITE HOUSE REPORT, *supra* note 114, at 3–5 (noting that many federal administrative agencies each have unique metrics for valuing human life, that the superiority of any given method is contested, and that even the number of lives lost to opioids is itself uncertain).

[129] *See* Harris et al., *supra* note 40 (estimating an MDL settlement to reach $50 billion).

[130] Gary T. Schwartz, *Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice*, 75 TEX. L. REV. 1801, 1801 (1997) (describing the "major camps of tort scholars," some seeing "tort liability as an instrument aimed largely at the goal of deterrence, commonly explained within the framework of economics," and for others seeing "tort law as a way of achieving corrective justice between the parties").

[131] *See* David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 854 (1984) ("Although Congress and the states have enacted a host of regulatory programs in recent years, most of these programs delegate a significant portion of the public enforcement burden to private damage actions. . . . Such actions are . . . the sole means by which victims of mass exposure accidents may recover for their losses.").

[132] *See* Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. CIN. L. REV. 741, 753–62 (2003) (describing how the tobacco litigation relied on an innovative "public nuisance" theory); David Schwartz et al., *Opioid Litigation: What's on the Horizon*, LAW360 (Aug. 17, 2017), https://www.law360.com/articles/955070/opioid-litigation-what-s-on-the-horizon [on file with *Ohio State Law Journal*] ("Some have even forecast that [the opioid litigation] could be a mass tort the size of Vioxx or other high-profile cases").

in mass tort regulatory litigation, an opioid settlement should seek to achieve meaningful compensation for injured parties.[133]

Here, determining who is "injured" is not straightforward. The government plaintiffs represent and litigate on behalf of their constituents, but the injuries they allege are to public coffers and the public welfare.[134] This was the case in the tobacco litigation, where the attorneys general used costs to state Medicaid systems to finally force the tobacco industry to the negotiating table, and where the MSA payments were negotiated to remedy the states' injuries.[135] Even though pursuing government injuries provides a promising vehicle for successfully holding opioid industry actors accountable, private parties ought not be excluded from compensation considerations. The tobacco MSA teaches that state awards are unlikely to trickle down to the pocketbooks of the very individuals most directly injured by industry's wrongdoing.[136] And as aforementioned, individual costs from the opioid epidemic are substantial, estimated to roughly equal total government costs.[137]

Therefore, an opioid MSA, if negotiated successfully and equitably, would take a bifurcated approach to compensation. Ideally, a settlement award would be split between negotiated payments to the government plaintiffs and a system for direct compensation of injured individuals.[138] Articulating detailed

[133] Though, it is worth noting, even money going solely to state coffers would not be "wasted," given that money is fungible and the crisis has directly impacted many state and local governments' bottom lines. *See* Paula Seligson & Tim Reid, *Unbudgeted: How the Opioid Crisis Is Blowing a Hole in Small-Town America's Finances*, REUTERS (Sept. 27, 2017), https://www.reuters.com/article/us-usa-opioids-budgets/unbudgeted-how-the-opioid-crisis-is-blowing-a-hole-in-small-town-americas-finances-idUSKCN1BU2LP [https://perma.cc/E728-PKGY].

[134] *See* Statement of Interest, *supra* note 126, at 3–4.

[135] Parmet & Daynard, *supra* note 46, at 440 ("[T]he attorneys general sought compensation for the costs of smoking-related illnesses paid by the states . . . .").

[136] *See* Margaret A. Little, *A Most Dangerous Indiscretion: The Legal, Economic, and Political Legacy of the Governments' Tobacco Litigation*, 33 CONN. L. REV. 1143, 1191–92 (2001) ("[S]cholars have frankly acknowledged that the government's temptation to eat the citizens' lunch may be irresistible . . . [and] the government's interference with its citizens' compensatory claims . . . will violate the legal rights of the individual victims . . . ." (internal quotations omitted)); John Dunbar, *Tobacco Settlement Helps Everyone but Smokers*, CTR. FOR PUB. INTEGRITY (Dec. 8, 2000), https://www.publicintegrity.org/2000/12/08/3249/tobacco-settlement-helps-everyone-but-smokers [https://perma.cc/XZ2R-3Q4A] (last updated May 19, 2014).

[137] *See* Rhyan, *supra* note 115.

[138] Canada's opioid litigation provides an example. There, when consolidated consumer class actions against Purdue Pharma settled for $20 million (Canadian), the settlement agreement provided that after a $1 million payment to insurers, the remaining $19 million would be divided among affected members of the public who are approved for compensation by an appointed claims administrator. *See* OXYCONTIN AND OXYNEO NATIONAL SETTLEMENT AGREEMENT 15 (Mar. 8, 2017) (Can.), http://www.siskinds.com/cmsfiles/PDF/Pharmaceutical/Oxycontin/Oxy_Settlement_Agreement_Signed_March-8-17.pdf [https://perma.cc/Y4SQ-J73E] [hereinafter CANADIAN SETTLEMENT AGREEMENT]. The compensation program has not yet been implemented, as courts in each province had to

guidelines for either scheme is beyond the scope of this Article, but past missteps can help avoid future ones. Unlike in the tobacco MSA negotiations, the federal government could lead any comprehensive opioid MSA negotiations, be it as a party to the MDL or in its current capacity as a party to settlement negotiations.[139] The tobacco negotiations, which took place in a hurried and high-pressure context, illustrated the risk that state self-interests predominate over more targeted resolutions designed to serve tort litigation goals.[140] The federal government's involvement in a more measured negotiating environment could assist with alleviating conflicts of interest.

Individual compensatory schemes also raise a myriad of complex, though not insurmountable, issues related to fairness and administrability. An opioid victim's compensation fund overseen by a specially formed administrative body is an excellent option, and would not be without precedent.[141] Carefully crafted causation and evidentiary standards could ensure that injured applicants are not blocked from compensation if they misused their medications, while also warding off illegitimate claims and ensuring fairness for the pharmaceutical companies paying into the fund.[142] Depending on the category of claimant and

independently approve the settlement, and a Saskatchewan court denied approval pending revisions. *See* Perdikaris v. Purdue Pharma, 2018 SKQB 86, ¶¶ 71–72 (Can. Sask. Q.B.).

[139] *See supra* note 126 and accompanying text; U.S. GEN. ACCOUNTING OFF., GAO-01-851, TOBACCO SETTLEMENT: STATES' USE OF MASTER SETTLEMENT AGREEMENT PAYMENTS 10 (2001) (describing how an "earlier more far-reaching proposal[,]" which would have created a fund for the states administered by the federal government, fell through, leaving "states [to] resume[] negotiations" that led to the MSA, a "scaled-down version [that] did not require federal action to be implemented").

[140] *See* Dreveskracht, *supra* note 47, at 295–96 (2015) (describing how "a hurried three months of negotiations" led to the original 1997 settlement proposal, followed by the 1998 proposal that allowed for "non-settling states to participate . . . if they opted in within seven days—a time limit that 'offered almost no opportunity for public health critics to mount an effective response' and 'placed overwhelming economic and political pressure on attorneys general [sic] to join'") (quoting ALLAN BRANDT, THE CIGARETTE CENTURY: THE RISE, FALL, AND DEADLY PERSISTENCE OF THE PRODUCT THAT DEFINED AMERICA 431 (2007)).

[141] For example, the Canadian Settlement Agreement includes procedures for an administrative system for evaluating claims and assigning compensatory value to different injuries. CANADIAN SETTLEMENT AGREEMENT, *supra* note 138, at 36–44 (attaching Exhibit B, the Compensation Protocol, and Schedule A, the Claims Administration Protocol). The compensation protocol assigns applicants "points" based on their alleged injuries (Fatal overdose, 500 points; non-fatal overdose, 150 points; loss of custody of children, 100 points; loss of employment, 10–100 points based on income level; etc.), and the claims administration protocol provides guidelines for evaluating the sufficiency of an applicant's evidence. *Id.; see also* Jon D. Hanson et al., *Smokers' Compensation: Toward a Blueprint for Federal Regulation of Cigarette Manufacturers*, 22 S. ILL. U. L.J. 519, 535–50 (1998) (providing "real-world" models of compensation fund programs).

[142] *See generally* Michael R. Abrams, Note, *Renovations Needed: The FDA's Floor/Ceiling Framework, Preemption, and the Opioid Epidemic*, 117 MICH. L. REV. 143, 167–71 (2018) (outlining broadly a proposal for an Opioid Epidemic victim's compensation fund and surveying the administrative questions involved). *See also* Linda S. Mullenix & Kristen B. Stewart, *The September 11th Victim Compensation Fund: Fund Approaches to*

injury (wrongful death claim on behalf of victim's estate? healthy claimant seeking compensation for lost wages or health care costs? claimant presently seeking addiction services?), payment could take the form of direct monetary awards or subsidized services.[143] Indeed, similar proposals were put forward as resolutions to the tobacco litigation prior to the MSA's implementation.[144] The task of designing such a system, and formulating a government payment scheme that is sufficiently proscribed, is surely immense, but the result is vital for obtaining a litigation resolution that is directly tied to the crisis harms.

c. *Allocation of Settlement Funds*

Because the opioid crisis is ongoing and only worsening as measured by the prevalence and severity of many associated harms, Judge Polster has articulated the sage intention to carefully allocate potential settlement resources, including funds, in the negotiation process.[145] He hopes to meaningfully abate the opioid crisis now and going forward, rather than simply repair past harms.[146] Uniquely, he views comprehensive settlement as a vehicle to sweep aside procedural formalities and defenses inherent in litigation, and instead focus efforts on maximizing public health impact.[147] He sees the judiciary's role in the MDL as remedying perceived failures among other government branches to adequately address the crisis.[148]

So, what should an abatement fund designed to mitigate opioid nuisances prioritize? Adopting an epidemiological framework for public health harm prevention at three levels of exposure is helpful in prioritizing fund allocation. First, resources can be allocated to primary and secondary prevention, or towards preventing harms prior to individual opioid exposure or when individuals have been exposed but have not yet developed the disease of addiction, respectively.[149] Second, albeit more pressingly, resources can be

Resolving Mass Tort Litigation, 9 CONN. INS. L.J. 121, 126−150 (2002) (contrasting the causation and evidentiary approaches of major compensation funds); Palma J. Strand, Note, *The Inapplicability of Traditional Tort Analysis to Environmental Risks: The Example of Toxic Waste Pollution Victim Compensation*, 35 STAN. L. REV. 575, 608–18 (1983) (proposing an administrative compensation scheme for victims of toxic waste, using a "probabilistic causation approach").

[143] *See* Abrams, *supra* note 142, at 169.

[144] *See* Richard C. Ausness, *Compensation for Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 36 WAYNE L. REV. 1085, 1124–33 (1990); Donald W. Garner, *Cigarettes and Welfare Reform*, 26 EMORY L.J. 269, 314–21 (1977); Hanson et al., *supra* note 141, at 553–56.

[145] *See generally* Hoffman, *supra* note 36 (exploring the broad variety of resources Judge Polster is considering while exploring an opiate settlement).

[146] *See id.*

[147] *See id.*

[148] *See id.*

[149] *See generally* Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 18 ANN. REV. PUB. HEALTH 559, 565–

allocated to tertiary prevention efforts, or those that seek to prevent further harm to individuals in which opioid use disorders are firmly entrenched.[150] These tertiary prevention efforts aim to prevent overdose, progression of disease, and other adverse life outcomes resulting from addiction.[151]

Allocation of funds into tertiary prevention efforts will address many acute, severe harms of the epidemic, where an infusion of money intelligently allocated and on a magnitude not yet invested by the federal government and states could quickly save lives and avoid serious harms.[152] First, opioid overdose deaths have risen dramatically since 2000; from 2012 to 2016, these deaths increased 80% to reach 42,249 deaths (or almost 116 persons per day).[153] Indications suggest that opioid-specific deaths maintained or increased further in 2017–2018.[154] The most direct way to avert these deaths is by making naloxone, the opioid overdose-reversal drug which is highly effective when administered quickly, more widely available.[155] Many states and communities have already expanded access to naloxone by equipping first responders, family, and friends with the drug.[156] As well, Medicaid and other insurance expansions have made coverage for the product more robust and are correlated with decreased harms.[157] Nevertheless, access is still woefully inadequate—particularly given that the opioid overdoses attributable to synthetic fentanyl have increased most dramatically since 2012 (675% increase) and require a

69 (2015) (defining primary and secondary prevention strategies in the context of opiates); Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 HASTINGS L.J. 1621, 1631–34 (2016) (applying the primary and secondary prevention strategies described by Kolodny); John Strang et al., *Drug Policy and the Public Good: Evidence for Effective Interventions*, 379 LANCET 71 (2012) (describing similar holistic solutions to opioid addiction).

[150] Rebecca L. Haffajee & Richard G. Frank, *Making the Opioid Public Health Emergency Effective*, 75 JAMA PSYCHIATRY 767, 767 (2018).

[151] Kolodny et al., *supra* note 149, at 568–69.

[152] *See* SUPPORT Act, *supra* note 13; THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION & THE OPIOID CRISIS 8, 37–39 (2017).

[153] Haffajee & Frank, *supra* note 150, at 768 (2018); *see* Seth et al., *supra* note 3, at 349.

[154] *See* sources cited *supra* note 1.

[155] Haffajee & Frank, *supra* note 150, at 767.

[156] *Id.*; *see also* Rahi Abouk et al., *Association Between State Laws Facilitating Pharmacy Distribution of Naloxone and Risk of Fatal Overdose*, 179 JAMA INTERNAL MED. 805, 806 (2019).

[157] *See* Lisa Clemans-Cope & Marni Epstein, *Medicaid-Covered Opioid Overdose and Treatment Drugs Reveal the Growth of the Opioid Crisis*, URB. INST. (Mar. 27, 2018), https://www.urban.org/urban-wire/medicaid-covered-opioid-overdose-and-treatment-drugs-reveal-growth-opioid-crisis [https://perma.cc/X5JQ-VJVL]; Richard G. Frank et al., *Does Naloxone Availability Increase Opioid Abuse? The Case for Skepticism*, HEALTH AFF. (Mar. 19, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180316.599095/full/ [https://perma.cc/3ECF-RAJT]; Richard G. Frank & Carrie Fry, *Medicaid Expands Access to Lifesaving Naloxone*, COMMONWEALTH FUND (July 5, 2017), https://www.commonwealthfund.org/blog/2017/medicaid-expands-access-lifesaving-naloxone [https://perma.cc/8AJQ-S24Y].

naloxone dose at least five times greater than that typically available to be successfully reversed.[158] Conservatively estimating that about fifteen naloxone doses dispensed result in one life saved[159]—and given the statistics that between 2.1 and 6 million Americans have an opioid use disorder (OUD),[160] almost 150,000 emergency department visits were due to opioid overdoses in 2017,[161] and almost 48,000 opioid overdoses resulted in deaths in 2017[162]—likely millions of additional doses of naloxone are needed at costs that overwhelm states and localities.[163] Substantial amounts of settlement funds could go towards these costs, with the federal and allied state governments potentially stepping in to negotiate lower prices than the persistently high prices for naloxone.[164]

Another ripe opportunity for tertiary prevention fund investment is evidence-based opioid addiction therapy, particularly to rural areas. Only 20% to 40% of the millions with OUD receive addiction treatment, a fraction of whom receive evidence-based treatment.[165] A combination of medication and behavioral therapy, or medication-assisted treatment (MAT), is considered the gold standard for treating OUDs.[166] Clinical trials have demonstrated that three medications for OUD (MOUD)—methadone, buprenorphine, and extended release naltrexone—reduce opioid use, overdose, and other adverse health

[158] Haffajee & Frank, *supra* note 150, at 767–68.

[159] Frank & Fry, *supra* note 157.

[160] *See* Sarun Charumilind et al., *Why We Need Bolder Action to Combat the Opioid Epidemic*, MCKINSEY & CO. (Sept. 2018), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/why-we-need-bolder-action-to-combat-the-opioid-epidemic [https://perma.cc/JD64-34PD]; *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Sept. 2018), https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHFFR2017/NSDUHFFR2017.htm [https://perma.cc/3XKF-M3L3].

[161] *See* Alana M. Vivolo-Kantor et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses—United States, July 2016-September 2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 279, 281 (2018).

[162] *Drug Overdose Deaths*, *supra* note 2.

[163] Haffajee & Frank, *supra* note 150, at 767.

[164] *See* Ravi Gupta et al., *The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths*, 375 NEW ENG. J. MED. 2213, 2214–15 (2016); Frank & Fry, *supra* note 157.

[165] *See* Anna Lembke & Jonathan H. Chen, *Use of Opioid Agonist Therapy for Medicare Patients in 2013*, 73 JAMA PSYCHIATRY 990, 991 (2016); Brendan Saloner & Shankar Karthikeyan, *Changes in Substance Abuse Treatment Use Among Individuals with Opioid Use Disorders in the United States, 2004–2013*, 314 JAMA 1515, 1515 (2015).

[166] *See* Robert P. Schwartz et al., *Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009*, 103 AM. J. PUB. HEALTH 917, 920–21 (2013) (finding that "increased access to [buprenorphine, a drug often used for MAT,] . . . may have significantly contributed to the reduction in heroin overdose deaths [in Baltimore]"); Lembke & Chen, *supra* note 165, at 990 (discussing the efficacy of MAT-related therapy).

outcomes.[167] For example, methadone and buprenorphine treatment were associated with 53% and 37% reductions, respectively, in all-cause mortality among patients with OUD as compared to those receiving no MOUD in the twelve months following nonfatal overdose.[168] However, rural areas are particularly lacking in MAT and MOUD providers, with a majority of rural counties still lacking a physician with a buprenorphine waiver,[169] and many more lacking a methadone provider.[170] Also particularly lacking in robust MAT are criminal justice settings,[171] including when patients transition out of these settings and are at vastly increased risks for overdose.[172]

Barriers to more robust opioid addiction treatment abound and notably involve a lack of behavioral health and primary care practitioners willing or trained to provide this treatment.[173] But funding could directly address many of

[167] *See* Richard P. Mattick et al., *Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence*, 2014 COCHRANE DATABASE SYSTEMATIC REVS. 1, 19–20; Richard P. Mattick et al., *Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence*, 2009 COCHRANE DATABASE SYSTEMATIC REVS. 1, 10–11; Suzanne Nielsen et al., *Opioid Agonist Treatment for Patients with Dependence on Prescription Opioids*, 317 JAMA 967, 967 (2017); Suzanne Nielsen et al., *Opioid Agonist Treatment for Pharmaceutical Opioid Dependent People*, 2016 COCHRANE DATABASE SYSTEMATIC REV.S 1, 23; Schwartz et al., *supra* note 166, at 920. *See generally* Marc A. Schuckit, Review Article, *Treatment of Opioid-Use Disorders*, 375 NEW ENG. J. MED. 357, 361−366 (2016) (surveying MOUD treatments and efficacies).

[168] Marc. R. Larochelle et al., *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study*, 169 ANNALS INTERNAL MED. 137, 140 (2018).

[169] C. Holly A. Andrilla et al., *Geographic Distribution of Providers with a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update*, 35 J. RURAL HEALTH 108, 110 (2018); *see also* Rebecca L. Haffajee et al., *Characteristics of U.S. Counties with High Opioid Overdose Mortality and Low Capacity to Deliver Medications for Opioid Use Disorder*, 2 JAMA NETWORK OPEN e196373, at e196373 (2019).

[170] *See* Haffajee et al., *supra* note 169, at e196373; Rebecca L. Haffajee et al., *Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment*, 54 AM. J. PREVENTIVE MED. S230, S232–33 (2018); Jeffrey H. Samet et al., Perspective, *Methadone in Primary Care—One Small Step for Congress, One Giant Leap for Addiction Treatment*, 379 NEW ENG. J. MED. 7, 8 (2018).

[171] Sarah E. Wakeman & Josiah D. Rich, *Addiction Treatment Within U.S. Correctional Facilities: Bridging the Gap Between Current Practice and Evidence-Based Care*, 34 J. ADDICTIVE DISEASES 220, 221 (2015).

[172] Josiah D. Rich et al., *Methadone Continuation Versus Forced Withdrawal on Incarceration in a Combined US Prison and Jail: A Randomised, Open-Label Trial*, 386 LANCET 350, 351 (2015).

[173] *See* Brendan Saloner et al., *Moving Addiction Care to the Mainstream—Improving the Quality of Buprenorphine Treatment*, 379 NEW ENG. J. MED. 4, 4 (2018); Samet et al., *supra* note 170, at 7. *See generally* Haffajee et al., *supra* note 170, at S237–38 (addressing barriers for many healthcare providers to provide buprenorphine treatment); Sarah E. Wakeman & Michael L. Barnett, *Primary Care and the Opioid-Overdose Crisis—Buprenorphine Myths and Realities*, 379 NEW ENG. J. MED. 1 (2018) (providing solutions for mobilizing primary care providers to offer buprenorphine).

these barriers and expand treatment by financing: public payer coverage of MAT;[174] provider incentives to practice in rural areas;[175] clinician time and fees associated with MAT training;[176] updated curriculum changes in graduate and continuing medical education around opioid prescribing and addiction treatment;[177] infrastructure to provide MAT via telemedicine (assuming regulatory hurdles are overcome) and/or integrated care models;[178] and robust MAT provisions in criminal justice settings and upon transition into society.[179]

Additional financial investments that would address downstream harms involve reducing the incidence of infectious disease transmissions—an increasingly common comorbidity that accompanies opioid injection use.[180] For instance, Hepatitis C infections nationally, which had enjoyed a steady decline of 87% between 1992 and 2009, increased by 167% since 2010.[181] Outbreaks of HIV have also been connected to the opioid crisis,[182] for instance to injecting Opana in Scott County, Indiana.[183] These infections could be prevented or minimized with clean syringes (including at safe injection facilities),[184] MAT, and increased surveillance/detection efforts—all of which cost money.[185] For example, providing the approximately 700,000 persons with heroin use disorders who are potentially injecting with clean needles would cost $14 million per year.[186] Establishing safe injection facilities would be more controversial and costly,[187] but these facilities have been shown in a number of studies to reduce the incidence of infectious diseases and minimize overdose harms.[188]

[174] Haffajee et al., *supra* note 170, at S234–37; Emma Sandoe et al., *Policy Levers that States Can Use to Improve Opioid Addiction Treatment and Address the Opioid Epidemic*, HEALTH AFF. (Oct. 2, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180927.51221/full/ [https://perma.cc/5KZ9-2URZ].

[175] Haffajee et al., *supra* note 170, at S238.

[176] *See id.* at S236.

[177] *Id.* at S238.

[178] Haffajee & Frank, *supra* note 150, at 768; Y. Tony Yang et al., Commentary, *Telemedicine's Role in Addressing the Opioid Epidemic*, 93 MAYO CLINIC PROC. 1177, 1180 (2018).

[179] Wakeman & Rich, *supra* note 171, at 223.

[180] Haffajee & Frank, *supra* note 150, at 767.

[181] *Id.*

[182] Gregg S. Gonsalves & Forrest W. Crawford, *Dynamics of the HIV Outbreak and Response in Scott County, IN, USA, 2011–15: A Modelling Study*, 5 LANCET HIV E569, E569 (2018).

[183] *See* Philip J. Peters et al., *HIV Infection Linked to Injection Use of Oxymorphone in Indiana, 2014–2015*, 375 NEW ENG. J. MED. 229, 230 (2016).

[184] *See* Jennifer Ng et al., *Does Evidence Support Supervised Injection Sites?*, 63 CANADIAN FAM. PHYSICIAN 866, 866 (2017); Gonsalves & Crawford, *supra* note 182.

[185] Haffajee & Frank, *supra* note 150, at 767–68.

[186] *Id.* at 767.

[187] *See id.*

[188] *See* Jennifer Ng et al., *supra* note 184, at 866; German Lopez, *A Study Questioning the Evidence for Safe Injection Sites Has Been Retracted*, VOX (Aug. 22, 2018),

Finally, to reduce tertiary harms, settlement money could help support the growing number of children affected by opioid overdose and misuse.[189] After declining by almost 30% from 1999 to 2012, foster care rates have increased from 2012 to 2016 nationally by approximately 7%.[190] Most evidence from foster care administrators suggests this increase is largely attributable to parents with opioid addiction, some of whom overdose fatally, who are no longer able to care for their children.[191] As well, money could be invested into providing supports to reunite families torn apart by opioid addiction—including therapy, MAT, housing, and job supports for parents affected. Treatment for pregnant and postpartum mothers and babies with neonatal opioid withdrawal syndrome was addressed in the SUPPORT Act.[192]

Evidence-based upstream harm prevention efforts also are reasonable candidates for MSA fund allocation. These could include money for prescription drug monitoring programs (PDMP) that embody features shown to reduce high-risk opioid prescribing and even overdoses,[193] including building in technology to make referrals to addiction treatment providers and training providers to react to PDMP information without turning patients away.[194] Pain clinic regulation is also a viable candidate for fund infusion, where the evidence shows that when enforced, these laws reduce high-risk prescribing.[195]

https://www.vox.com/science-and-health/2018/8/22/17683364/safe-injection-sites-study [https://perma.cc/5VLK-CSF7].

[189] Haffajee & Frank, *supra* note 150, at 767.

[190] *Id.*; *see* U.S. DEP'T OF HEALTH & HUMAN SERVS., ADMIN. FOR CHILDREN & FAMILIES, CHILDREN'S BUREAU, THE AFCARS REPORT 1 (2018).

[191] *See generally* Julia Lurie, *Children of the Opioid Epidemic Are Flooding Foster Homes. America Is Turning a Blind Eye.*, MOTHER JONES (July/Aug., 2017), https://www.motherjones.com/politics/2017/07/children-ohio-opioid-epidemic [https://perma.cc/9HYV-B4DP] ("Largely because of the opioid epidemic, there were 30,000 more children in foster care in 2015 than there were in 2012 . . . .").

[192] SUPPORT Act, *supra* note 13, §§ 1005, 7061–65.

[193] David S. Fink et al., *Association Between Prescription Drug Monitoring Programs and Nonfatal and Fatal Drug Overdoses: A Systematic Review*, 168 ANNALS INTERNAL MED. 783, 788 (2018); Amanda I. Mauri et al., *The Association of State Opioid Misuse Prevention Policies with Patient and Provider Related Outcomes: A Scoping Review*, MILBANK Q. (forthcoming 2019).

[194] For an overview of PDMP and their effect on reducing opioid prescriptions, usage, dosages, and overdoses, see generally Thomas C. Buchmueller & Colleen Carey, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare*, 10 AM. ECON. J. 77, 82–86 (2018); Rebecca L. Haffajee et al., *Four States with Robust Prescription Drug Monitoring Programs Reduced Opioid Dosages*, 37 HEALTH AFF. 964, 972 (2018); Maria N. Wilson et al., *Effectiveness of Prescription Monitoring Programs in Reducing Opioid Prescribing, Dispensing, and Use Outcomes: A Systematic Review*, J. PAIN (forthcoming 2019). *See generally* Rebecca L. Haffajee, *Prescription Drug Monitoring Programs: Friend or Folly in Addressing the Opioid Overdose Crisis*, 381 NEW ENG. J. MED. 699, 699–701 (2019).

[195] *See* Tatyana Lyapustina et al., *Effect of a "Pill Mill" Law on Opioid Prescribing and Utilization: The Case of Texas*, 159 DRUG & ALCOHOL DEPENDENCE 190, 195 (2016); Lainie Rutkow et al., Original Investigation, *Effect of Florida's Prescription Drug Monitoring*

d. *Behavior Change Requirements*

Monetary relief is essential for offsetting the epidemic's considerable economic burden, but a master settlement's injunctive terms are just as vital. Monetary relief alone is likely incapable of reversing upwards trends of opioid addiction and overdose.[196] The only major settlement from the first wave of opioid litigation was largely inconsequential,[197] perhaps in part due its uninspired behavior change provisions. Any comprehensive settlement to the opioid litigation should include provisions that ensure transparency, monitoring, and enforceability.

One challenge that injunctive terms can remedy is the general opacity that surrounds government settlement agreements.[198] While funds secured through the work of the DOJ may be subject to disclosure requirements, state victories are generally less transparent.[199] Because settlement agreements are typically not published on public litigation dockets, discovering the exact terms agreed to between a state attorney general's office and a corporate defendant can be challenging.[200] Interested parties are often left only with press releases announcing that an agreement was reached, which may be skewed in the

Program and Pill Mill Laws on Opioid Prescribing and Use, 175 JAMA INTERNAL MED. 1642, 1646–48 (2015).

[196] *See* Carr et al., *supra* note 11, at 210 (arguing that a monetary penalty's most likely impact is increased pricing, but "such a result is unlikely to substantially affect opioid-related morbidity and mortality because health insurers, not consumers, pay most prescription drug costs").

[197] *See supra* notes 67–70 and accompanying text.

[198] David Luban, *Settlements and the Erosion of the Public Realm*, 83 GEO. L.J. 2619, 2648 (1995) ("Parties consummate settlements out of public view. The facts on which they are based remain unknown, their responsiveness to third parties who they may affect is at best dubious, and the goods they create are privatized and not public. Settlements are opaque.").

[199] W. VA. GOVERNOR'S REPORT, *supra* note 72, at 7 (explaining that "federal asset forfeiture funds are distinct from the settlement funds that were collected by the West Virginia Attorney General's Office" and that the spending plans for the former category of funds were being publicly outlined, while the latter were not, because of "strict U.S. Department of Justice guidelines"). Even at the federal level, however, settlement transparency remains a problematic area giving rise to reform efforts. *See Senators Warren and Lankford Introduce Truth in Settlements Act to Increase Transparency of Federal Agency Settlements*, ELIZABETH WARREN (May 16, 2017), https://www.warren.senate.gov/newsroom/press-releases/senators-warren-and-lankford-introduce-truth-in-settlements-act-to-increase-transparency-of-federal-agency-settlements [https://perma.cc/9JJ5-U87P].

[200] *See* Judith Resnik, *Uncovering, Disclosing, and Discovering How the Public Dimensions of Court-Based Processes Are at Risk*, 81 CHI.-KENT L. REV. 521, 555 (2006) (explaining that litigation dockets may not reflect that settlement was reached because rules of procedure allow parties to "conclude agreements by dismissals," meaning they arrive at a mutually agreeable resolution to the litigation, unilaterally file notices of dismissal with the court, and then outside of court "specify the relevant terms in contracts").

direction of flattering the party volunteering the information.[201] In other cases, nondisclosure provisions in the agreement may very well prohibit publication of the terms.[202] While the settlement terms themselves would reveal whether the funds were restricted to certain policy initiatives, that information is only useful to the extent that the funding can be traced, another impossible task if funds are liquidated into a state's general treasury. Any future opioid settlements could improve upon past agreements simply by including disclosure provisions for the agreements themselves and for expenditures of the funds.

Relatedly, a comprehensive settlement should include provisions allowing for public monitoring and enforcement of the agreement's requirement(s). DOJ's recent series of opioid settlements demonstrate how the agreements can require the creation of new corporate bodies dedicated to monitoring and compliance with settlement terms.[203] Moreover, the second wave settlements endorse an approach closer to a judicially enforceable consent decree as opposed to a purely private contract agreement.[204] An opioid settlement agreement should include a court order that would allow any state party to the agreement to bring a contempt of court action against any defendant that fails to fulfill its

[201] *See Mallinckrodt Press Release*, *supra* note 101; *McKesson Press Release*, *supra* note 95.

[202] Resnik, *supra* note 200, at 555 (noting that parties can "bargain for privacy/secrecy" by "conditioning [their] settlements on nondisclosure of information"); Luban, *supra* note 198, at 2649 (describing the "widespread practice of secret settlements"). Further, settlement secrecy provisions can enable further shrouding of litigation documents that would otherwise be public: "discovery confidentiality clauses are routinely included as a predicate to the initial disclosures," such that "settlement may hinge on agreements to make data inaccessible." Resnik, *supra* note 200, at 555–56; *see also* Luban, *supra* note 198, at 2649 (offering a typical example of secret settlement that includes "a promise of secrecy and the return of the discovery materials"). Indeed, this appears to have occurred in the opioid context during the West Virginia Attorney General's 2004 negotiations with Purdue Pharma. *See* David Armstrong, *Drug Maker Thwarted Plan to Limit OxyContin Prescriptions at Dawn of Opioid Epidemic*, STAT (Oct. 26, 2016), https://www.statnews.com/2016/10/26/oxycontin-maker-thwarted-limits/ [https://perma.cc/Q356-9QVB] (revealing previously sealed court documents from the case showing that settlement without admission of liability allowed Purdue to conceal damaging information about marketing practices exchanged during discovery); *see also* Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain [https://perma.cc/A7T5-7KZU] (detailing litigation between the State of Kentucky and Purdue Pharma that ended in a settlement that was a "coup" for Purdue, in part because "in settling, the company sealed from public view both [the company President]'s deposition and internal documents obtained through discovery").

[203] *See generally supra* notes 92–93, 98–100, 105, 108 and accompanying text (describing several pharmaceutical companies' settlement agreements with compliance requirements that include administrative oversight mechanisms).

[204] *See, e.g.*, *McKesson Press Release*, *supra* note 95.

obligations.[205] By requiring that states make public how opioid settlement funds are utilized, and then providing a mechanism for monitoring and enforcing the obligations of both the government and industry alike, an opioid master settlement could avoid some of the missteps of the tobacco MSA.

Of course, a comprehensive settlement would include a myriad of behavior change requirements beyond the broad structural suggestions outlined here. Enjoinders would require strict compliance with federal laws (including the CSA's reporting requirements and the FDCA's marketing requirements), constrain how funds can be spent, limit marketing and lobbying tactics around prescription opioids (both direct-to-consumer and to professionals), and establish the creation of new initiatives and programs devoted towards treating addiction, innovation of new pain and addiction therapies, and helping with structural determinants of disease (e.g., housing and employment services for those in recovery).[206] Just as the tobacco MSA ended advertising campaigns like "Joe Camel," and started public service marketing projects like the "Truth" campaign,[207] an opioid settlement should require the creation and funding of projects dedicated to addiction prevention and public and professional education.[208] By ensconcing these more specifically tailored initiatives in legal structures that require transparency, monitoring, and enforcement, the opioid settlement agreement programs will be accountable to the public and true to their intent.

IV. CONCLUSION

Litigation holds significant public health potential in addressing the opioid crisis if pursued intelligently and thoughtfully. The sheer magnitude and costs of opioid harms and lack of resources governments have to put or (in the case of the federal government) are willing to allocate towards them make clear the need for additional supports. Who better to contribute to these costs than companies that have profited tremendously from opioid analgesic sales and helped to create a population dependent and addicted to opioids for treatment of chronic pain and other conditions? The collateral damage from the influx in prescription opioid supply has only partially manifested and will expand into

[205] *See* DiSarro, *supra* note 78, at 282–86 (noting that contempt-of-court claims can be adjudicated more quickly and efficiently than breach-of-contract and provide more potential remedies).

[206] *See id.* at 286 (noting that the limitations on potential obligations in settlement agreements "are limited only by the creativity of the parties' counsel and the desires of the settling parties").

[207] *See* Schroeder, *supra* note 50, at 294–95.

[208] *See* ADDICTION SOLUTIONS CAMPAIGN, OPIOID SETTLEMENT PRIORITIES 5–13 (2018), https://addictionsolutionscampaign.org/wp-content/uploads/2018/05/Opioid-Settlement-Priorities_5.17.18.pdf [https://perma.cc/MS78-XJQT] (recommending that an opioid litigation settlement prioritize education campaigns on substance misuse and addiction, harm reduction and prevention strategies, and access to evidence-based treatment services).

the next generation as babies born with neonatal opioid withdrawal syndrome and children of parents with opioid addiction experience health and life costs, and society experiences long-term workforce deficits. While opioid manufacturers, distributors, and pharmacies are not solely to blame, their liability for public health harms that governments and individuals currently and in the future will bear is challenging to dispute given mounting epidemiological evidence and internal evidence of marketing and sales practices. Nevertheless, even as smaller settlements and a potential MSA are forthcoming, carefully earmarking monetary settlement funds and outlining behavior change requirements (as some past opioid settlements have done) are critical steps towards maximizing the value and impact of this litigation endeavor.

Of course, litigation is not a panacea. Continued efforts to achieve comprehensive legislative solutions to the opioid epidemic akin to and beyond the SUPPORT Act should be supported, along with other evidence-based and carefully crafted governmental and non-governmental activities. But an opioid MSA would not come at the opportunity cost of those efforts, as the various public health response fronts are not competing in a zero-sum game. Instead, an MSA could provide an infusion of funds and behavior changes needed to help finally turn the corner on the crisis's unrelenting expansion.

APPENDIX

Table 1: *Representative Opioid Settlements & Terms: Manufacturer Settlements*

Case	Plaintiffs	Defendants	Allegations	Settlement Terms (Monetary; Injunctive)
Manufacturer Settlements				
2007 Settlement between 27 State AGs and Purdue Pharma	Attorneys General for OR, AZ, AR, CA, CT, ID, IL, KY, LA, ME, MD, MA, MT, NE, NV, NM, NC, OH, PA, SC, TN, TX, VT, VA, WA, WI and DC	Purdue Pharma	Misrepresentations in off-label marketing of OxyContin Failure to adequately disclose OxyContin's risk for abuse and diversion	$19.5 million settlement payout, divided among the states
				Cease false, misleading, or deceptive claims regarding OxyContin Cease excessive or abusive advertising practices and all off-label marketing Establish internal abuse-and-diversion detection program
2015 Commonwealth of Kentucky v. Purdue Pharma L.P. (Kentucky state court)	Office of the Kentucky Attorney General	Purdue Pharma & Abbott Laboratories	Misrepresentations in marketing activities promoting OxyContin from 1996 to 2001	$24 million paid out in installments over eight years
				Court order implementing settlement agreement requires payments go to a restricted fund for public health initiatives including addiction treatment

Case	Plaintiffs	Defendants	Allegations	Settlement Terms (Monetary; Injunctive)
Manufacturer Settlements				
2017 Settlement between United States and Mallinckrodt	U.S. Department of Justice; U.S. Drug Enforcement Administration	Mallinckrodt LLC	Failure to identify and report suspicious orders to the DEA, particularly regarding oxycodone, in violation of the Controlled Substances Act (CSA) Additional CSA violations from recordkeeping practices at manufacturing plants	$35 million settlement payment Enter novel "parallel agreement" with the DEA to monitor and allow access to downstream purchasing information, or "chargeback" data Comply with additional monitoring and recordkeeping procedures to prevent diversion
2019 Settlement between State of Oklahoma and Purdue	Office of the Oklahoma Attorney General	Purdue Pharma	Overstatement of efficacy of opioid pain medications coupled with misrepresentation of risks of addiction Deceptive marketing; public nuisance; False Claims Act violations; Consumer Protection Act violations	$270 million settlement: $102.5M towards new center for addiction at Okla. State Univ. from Purdue; additional $75M donation to the Center directly from Sackler family; $60M in attorneys' fees; $12.5M directly to Okla. counties and municipalities; $20M towards supplying addiction treatment medications

Case	Plaintiffs	Defendants	Allegations	Settlement Terms (Monetary; Injunctive)
Manufacturer Settlements				
				Cease promotion and marketing of opioids in Oklahoma Assist law enforcement with any diversion investigations

Table 2: *Representative Opioid Settlements & Terms: Distributor Settlements*

Case	Plaintiffs	Defendants	Allegations	Settlement Terms (Monetary; Injunctive)
Distributor Settlements				
2015 Settlement between United States and Cardinal	U.S. Department of Justice; U.S. Drug Enforcement Administration	Cardinal Health	Failure to identify and report suspicious orders of opioid medications in violation of the CSA Failure to meet recordkeeping responsibilities under the CSA	$44 million in total payments to the United States Comply with CSA reporting requirements at temporarily heightened standard Implement new internal structures for monitoring compliance
2016 Settlement between United States and McKesson	U.S. Department of Justice; U.S. Drug Enforcement Administration	McKesson Corporation	Failure to comply with 2008 agreement with DOJ for reporting violations under the CSA, particularly regarding oxycodone and hydrocodone Inadequate design and implementation of detection and reporting system under CSA Failure to protect against diversion of narcotic medication at a dozen distribution centers	Comply with CSA reporting requirements at temporarily heightened standard Implement new internal structures for monitoring compliance Suspend operations at four distribution centers for period of 1–3 years Implement "first of its kind" internal monitoring system featuring independent review board Comply with heightened CSA standards for 5-year period

Table 3: *Representative Opioid Settlements & Terms: Pharmacy Retailer Settlements*

Case	Plaintiffs	Defendants	Allegations	Settlement Terms (Monetary; Injunctive)
Pharmacy Retailer Settlements				
2017 Settlement between United States and Costco	U.S. Department of Justice; U.S. Drug Enforcement Administration	Costco Wholesale; Costco Pharmacies	Improperly filled prescriptions that were non-compliant with CSA requirements Violating CSA recordkeeping provisions at pharmacies and distribution centers	$11.75 million settlement payment to the United States Invest in new pharmacy back-end management system to facilitate CSA compliance Implement internal audit system with 3-years of unfettered access for DEA inspections
2017 Settlement between United States and Safeway	U.S. Department of Justice; U.S. Drug Enforcement Administration	Safeway, Inc.	Alaska pharmacy locations lost track of tens of thousands of hydrocodone tablets due to inadequate monitoring Insufficient compliance with CSA monitoring requirements to prevent diversion at pharmacies across the company	Invest in new pharmacy back-end management system to facilitate CSA compliance Implement internal audit system with 3-years of unfettered access for DEA inspections Implement monitoring and reporting systems for CSA compliance Comply with heightened standards for temporary punitive period