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A SETTLEMENT IN CRISIS: HOW *IN RE OPIOID* LITIGATION FAILS TO PUT PEOPLE BEFORE CORPORATIONS

Since 1999, 932,000 people in the United States have died from a drug overdose.¹ In 2021 alone over 100,000 people died from a drug overdose.² Seventy-eight percent of those overdoses involved opioids.³ As the opioid epidemic has torn families apart and decimated American communities, the natural response is to find someone to blame. State and local governments, Native-American tribes, labor unions, insurance companies, hospitals, and individuals have all pointed the finger at the same culprits: opioid manufacturers and distributors.⁴

The result—over 3,000 state and local governments alongside Native American tribes joined *In Re Opiate Litigation*,⁵ a multidistrict litigation, alleging “improper marketing of and inappropriate distribution of various prescription opiate medications into cities, states and towns across the country.”⁶ On February 25, 2022, five years after these actions were first centralized in the Northern District of Ohio, the “Big Three” distributors (“the Distributors”)—McKesson, AmerisourceBergen, and Cardinal Health—finalized a \$21 billion settlement for their role in the opioid crisis.⁷ This perspective analyzes the two main provisions of the opioid settlement—the abatement fund and Clearinghouse provisions—and compares them to equivalent provisions in the Tobacco Master Settlement Agreement (“tobacco settlement”). This juxtaposition highlights that while the opioid Global Settlement Agreement (“opioid settlement”) took a cue from the tobacco settlement agreement’s ineffective abatement fund provisions, the opioid settlement failed to mirror the

¹ *The Drug Overdose Epidemic: Behind the Numbers*, CENTERS DISEASE CONT. & PREVENTION (Jun. 1, 2022), <https://www.cdc.gov/opioids/data/index.html>.

² *Id.*

³ *Drug Overdose Deaths in the U.S. Top 100,000 Annually*, CENTERS DISEASE CONT. & PREVENTION (Nov. 17, 2021), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm

⁴ *Opioids*, NAT’Y ASSOC. OF ATT’YS GEN. (last visited Oct. 2, 2022); *See also* Roger Michalski, *MDL Immunity: Lessons from the National Prescription Opiate Litigation*, 69 AM. U. L. REV. 175, 179 (2019).

⁵ *Id.*

⁶ *In Re Nat’y Opiate Litig.*, 290 F.Supp.3d 1375, 1377 (J.P.M.L. 2017).

⁷ Associated Press, *J&J, Distributors Finalize \$26B Landmark Opioid Settlement*, U.S. NEWS & WORLD REP. (Feb. 25, 2022), <https://www.usnews.com/news/health-news/articles/2022-02-25/j-j-distributors-finalize-26b-landmark-opioid-settlement>.

biggest strength of the Tobacco Master Settlement Agreement: strong, robust transparency provisions.

Comparing the provisions in the opioid settlement to similar provisions in prior litigation is useful. Because the “[o]pioid litigation is arguably the most complicated litigation ever to hit American courts . . . it is sensible to look back to the *second* most complex and hotly contested civil action in American history: tobacco.”⁸ Comparing the tobacco settlement to the opioid settlement is helpful because the lingering memory of the tobacco settlement shaped the opioid settlement,⁹ and the settlements were structured similarly with both creating abatement funds and implementing transparency provisions.¹⁰

Abatement Funds

The abatement fund provisions in *In Re Opioid Litigation* show a lesson learned from the tobacco settlement. The tobacco settlement, despite its monumental size, is largely regarded as a failure because majority of the \$246 billion settlement was not spent on anti-smoking initiatives or remedial measures.¹¹ The opioid agreement, however, allocates funds to states, counties, and cities through a formula that accounts for the population of the state and the number of opioid-related deaths, residents with a substance use disorder, and opioid pills delivered over the course of the epidemic.¹² Unlike the funds in the tobacco settlement, the funds in the opioid settlement *must* be used for opioid remediation.¹³ If states spend any money for a non-remedial purpose, they are required to report the amount spent and what the money was used for.¹⁴ The reported information is published for the public to see.¹⁵ The Global Settlement

⁸ Nora Freeman Engstrom & Robert L. Rabin, *Pursuing Public Health Through Litigation: Lessons from Tobacco and Opioids*, 73 STAN. L.REV. 285, 362 (2021) (alteration added) (emphasis in original).

⁹ See Calleen Walsh, *Learning the Hard Way*, THE HARV. GAZETTE (Aug. 4, 2021) <https://news.harvard.edu/gazette/story/2021/08/applying-lessons-learned-from-the-tobacco-settlement-to-opioid-negotiations/> (noting that the reason that cities and counties were involved in the MDL a direct result of the mismanagement of the tobacco Master Settlement Agreement funds).

¹⁰ See generally Walsh, *supra* note 9; *The Master Settlement Agreement*, NAT’Y ASSOC. OF ATT’YS GEN. (last visited Oct. 23, 2022), <https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement/>.

¹¹ Walsch, *supra* note 9.

¹² *Opioids*, NAT’Y ASSOC. OF ATT’YS GEN. (last visited Oct. 2, 2022) <https://perma.cc/VN8H-CX23>.

¹³ See generally Distributor Settlement Agreement (Exhibit E) (Mar. 25, 2022) chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://nationalopioidsettlement.com/wp-content/uploads/2022/03/Final_Distributor_Settlement_Agreement_3.25.22_Final.pdf (listing core strategies and approved uses for abatement strategies).

¹⁴ *Id.*

¹⁵ *Id.*

also includes an enforceability provision.¹⁶ If a state does not spend the settlement funds appropriately, the distributors do not have to pay the state any more.¹⁷ Despite the comparative success of the abatement funds and the large sum that must be paid by the distributors, the abatement fund alone cannot guarantee corporate responsibility.¹⁸ Transparency provisions, on the other hand, can be a tool to establish corporate responsibility in settlements.

Transparency Provisions

A ten-year court order lists the transparency provisions of the Global Settlement, requiring distributors to (1) create a Controlled Substance Monitoring Program (“CSMP”) to better prevent diversion of controlled substances,¹⁹ and (2) create “a centralized and independent Clearinghouse to provide all three distributors and state regulators with aggregated data and analytics about where drugs are going and how often, eliminating blind spots in the current systems used by distributors.”²⁰ The Clearinghouse is also responsible for “develop[ing] uniform reporting recommendations for potential implementation by state regulators . . . to allow the Injunctive Relief Terms and state and federal laws in a uniform and consistent manner.”²¹

Transparency provisions are crucial to the success of the opioid agreement and public health litigation at large. Transparency provisions alone will not prevent the next health crisis because the “growth of profits at the expense of public health, is endemic in pharmaceutical markets.”²² But, litigation historically acts as a catalyst for public policy.²³ It does so by

- (1) drawing attention to the problem’s existence; (2) uncovering otherwise concealed information to establish accountability and clarify the problem’s original scope and character; and, in so doing, (3)

¹⁶ *Id.* at 34-35.

¹⁷ *Id.*

¹⁸ Lenny Bernstein, *McKesson, Nation’s Largest Drug Distributor, to pay \$150 million in Fines in Opioid Settlement*, THE WASHINGTON POST (Jan. 18, 2017), <https://www.washingtonpost.com/news/to-your-health/wp/2017/01/18/mckesson-nations-largest-drug-distributor-to-pay-150-million-in-fines-in-opioid-settlement/>. (The McKesson’s settlements with the Drug Enforcement Agency (DEA) are an example of a cautionary tale. In 2008, McKesson reached a \$13.2 million settlement with the DEA after failing to report suspicious narcotics orders. McKesson “continued to fail to report suspicious orders between 2008 and 2012 and did not fully implement or follow the monitoring program.” As a result, the company settled with DEA and had to pay a \$150 million fine nine years later).

¹⁹ See generally Distribution Settlement Agreement, *supra* note 15 at Exhibit P.

²⁰ *Opioids*, NAT’Y ASSOC. OF ATT’YS GEN. (last visited Oct. 2, 2022) <https://perma.cc/VN8H-CX23>.

²¹ Distribution Settlement Agreement *supra* note 19, at P-33.

²² Liza Vertinsky, *Pharmaceutical (Re)capture*, 20 YALE J. HEALTH POL’Y, L. & ETHICS 146, 208 (2021).

²³ Freeman et al., *supra* note 23, at 354 (2021).

affecting public opinion in such a way as to spur private activity and also make the political action against a powerful industry more palatable.²⁴

The tobacco settlement demonstrates the power of transparency provisions, of which it contained two.²⁵ The first transparency provision “compelled [tobacco] manufacturers to support applications for the dissolution of nearly all protective orders,” which in effect unsealed discovery and left Big Tobacco subject to public scrutiny.²⁶ The second transparency provision required each manufacturer “to maintain, for a dozen years at its own expense, a website in which all released documents would be posted” and publicly available.²⁷ These repositories were “an indispensable resource”²⁸ because they revealed “tobacco companies had known for decades that smoking caused cancer” and still continued to target young children in their campaigns.²⁹ These documents showed “a conspiracy intended to defraud the American public” and showed the path Big Tobacco paved towards a public health crisis.³⁰ As a result, “there is broad consensus” that the transparency provisions in the tobacco settlement “succeeded beyond expectations.”³¹

The tobacco transparency provisions shine a light on the inadequacy of the opioid settlement equivalent: the Clearinghouse provisions. The opioid settlement’s transparency provisions do not adequately uncover concealed information, establish accountability, or clarify the distributor’s involvement in the opioid crisis. Discovery was not unsealed in the opioid settlement; however, it is unclear what documents were in discovery that could be unsealed because Judge Polster, the presiding judge in the MDL, directed attorneys to forgo discovery and begin settlement discussions at the beginning of the case.³² Still, the opioid settlement could have included a provision like the provision in the tobacco settlement requiring the creation of a repository for industry documents.³³

²⁴ *Id.*

²⁵ *Id.* at 344.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ Jim Carrier, *One Final Look Inside the Archive that Exposed Big Tobacco*, THE WASHINGTON POST (Aug. 26, 2021), https://www.washingtonpost.com/outlook/minnesota-tobacco-document-depository/2021/08/25/cdc1ecfc-050c-11ec-a654-900a78538242_story.html.

³⁰ *Id.*

³¹ *Id.*

³² Elizabeth W. De Leon, *The Opioid Crisis or Climate Change: Which is More Likely to Succeed Under the Tobacco Litigation Model*, 8 TEX. A&M L. REV. 27, 49 (2021).

³³ Freeman et al., *supra* note 23, at 344.

The absence of such a transparency provision is shocking because “the importance of publicizing companies’ internal documents is not unique to the tobacco litigation, as it was also recognized as a sign of success in the mass asbestos product litigation.”³⁴ The importance of such transparency provisions has also been recognized in other opioid settlements. Johnson & Johnson³⁵ and McKinsey were both required to turn over corporate documents that highlighted their role in the opioid crisis to an independent third party for publicly available, online publication.³⁶ Instead, the Clearinghouse provisions of the opioid settlement require the CSMP to create and implement drug diversion efforts, collect data on those efforts, and report that data to the Clearinghouse. Setting aside the irony of asking the distributors to effectively govern themselves, the opioid settlement states “[a]ll data provided to the Clearinghouse shall be confidential.”³⁷ The Distributors’ information “may not be provided to any other entity or individual outside those expressly contemplated by the Injunctive Relief Terms,” and the agreement mainly “contemplates” state governments.³⁸ The Clearinghouse data is not retroactive—it only collects data from the time that the CSMP is formed and after.³⁹ Furthermore, the data that it does create is not publicly accessible.⁴⁰

The transparency provisions in the opioid settlement are undeniably weaker than those in the tobacco settlement, though they should have been stronger. Unlike the tobacco industry before the tobacco settlement, the opioid market has always been heavily regulated.⁴¹ Nevertheless, the alphabet soup of government

³⁴ *Id.*

³⁵ See Walsh *supra* note 9.

³⁶ Office of Attorney General Maura Healey, *AG’s Office Secures \$573 Million Settlement With McKinsey for ‘Turbocharging’ Opioid Sales and Profiting From the Epidemic*, MASS.GOV (Feb. 4, 2021) <https://www.mass.gov/news/ags-office-secures-573-million-settlement-with-mckinsey-for-turbocharging-opioid-sales-and-profiting-from-the-epidemic> (“McKinsey is required to turn over tens of thousands of internal documents detailing its work for Purdue Pharma and other opioid companies for public disclosure online.”)

³⁷ *Id.* at P-36.

³⁸ *Id.* at P-36.

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ *Id.* at 335-36 (“[T]he opioid environment is, and has long been, positively littered with laws and requirements. The pills must be (and have been) approved by the FDA as safe and effective for their intended use. They must be prescribed by licensed physicians ‘acting in the usual course of . . . professional practice.’ The warning label that accompanies each must be vetted, and any related advertising must be accurate, balanced, evidence-based, and consistent with FDA-approved prescription information. The Drug Enforcement Administration (DEA) imposes quotas on how many drugs may be distributed and also subjects distributors to a range of seemingly stringent requirements. Because opioids are Schedule II narcotics, distributors must report to the Attorney General ‘every sale, delivery or other disposal’ of prescription opioids. These reports—which, collectively, compose the Automated Reports and Consolidated Ordering System data (ARCOS) data and amount to a database tracing where every pill came from and where it was sold—are routed to the DEA and

agencies regulating opioids and the many statutes and regulations on the books governing the approval and distribution of narcotics failed to stop an opioid crisis of epic proportions.⁴² Some argue this proves government regulation is ineffective and the free market is the only cure.⁴³ Such an argument, however, overlooks the fact that the opioid crisis is a case of regulatory capture “by companies who saw an opportunity to profit from cultivating the business of pain and growing the market for opioids to treat pain.”⁴⁴ Because the opioid industry is particularly vulnerable to the interests of Big Pharma, successful litigation must create barriers to pharmaceutical influence on legislation and regulations.⁴⁵

One such barrier to industry influence is public accountability and private action, both of which can be shaped by litigation. Consequently, transparency provisions are significant because they help legislators and the public know who to blame, sway public opinion, and ignite private action against powerful industries.⁴⁶ Releasing information to the public can also lead to “moral and cultural shifts.”⁴⁷ Polling has shown that litigation surrounding the crisis has increased awareness of the opioid epidemic; however, it has not shifted the public’s perception of addicts’ blameworthiness.⁴⁸ While the public understands the outrageous actions of Big Tobacco because the settlements made their company documents public, we are unable to assign that same level of blame to the Distributors when discovery is sealed and similar provisions are forgone.⁴⁹ Without cognizable proof of corporate wrongdoing, the public will continue to stigmatize addicts as people who played an active role in their addiction, rather than as victims of corporate greed.⁵⁰ Without such a “moral and cultural shift[]” of blame from the individual to the corporation, we lose the public—a key group who can help hold legislatures accountable and prevent pharmaceutical interests from recapturing our laws and agencies.⁵¹ Perhaps, the most egregious aspect of the opioid settlement is that it hands over legislative power to the Distributors.

ostensibly permit the agency to ‘track controlled substances from the time they are manufactured until they are dispensed to consumers’).

⁴² *Id.*

⁴³ Vertinsky, *supra* note 22, at 223.

⁴⁴ *Id.* at 159, 208.

⁴⁵ *Id.* at 219.

⁴⁶ Freeman et al., *supra* note 23, at 254.

⁴⁷ Elizabeth Chamblee Burch & Alexandra Lahav, *Information for the Common Good in Mass Torts*, 70 DEPAUL L. REV. 345, 356 (2021).

⁴⁸ De Leon, *supra* note 32, at 57.

⁴⁹ See Burch & Lahav, *supra* note 47, at 356-57.

⁵⁰ *Id.*

⁵¹ Burch & Lahav, *supra* note 47, at 356.

The Distributors work hand-in-glove with the Clearinghouse and Clearinghouse Advisory Panel “to develop uniform reporting recommendations for potential implementation by state regulators.”⁵² The opioid agreement even embraces that the requirement is intended “to benefit the Injunctive Relief Distributors and the Settling States.”⁵³

The Clearinghouse provisions should have placed a barrier between the Distributors and legislators to prevent further regulatory capture. Instead, the opioid settlement paves the way. While the settlement provisions of *In Re Opioid Litigation* are resolved, its provisions, much like those of the Tobacco Master Settlement Agreement, can teach us many valuable lessons. Furthermore, these lessons are not yet moot as potentially one of the last big opioid settlements has yet to be finalized.⁵⁴ CVS Health Corp., Walgreens Boots Alliance Inc., and Walmart Inc. have agreed to pay more than \$12 billion to resolve thousands of lawsuits alleging mishandling of opioids.⁵⁵ These plaintiffs ought to demand transparency provisions that require strong separation between legislators and the Distributors, unseal discovery documents, and actively increase corporate accountability.

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⁵² NAT’Y ASSOC. OF ATT’YS GEN., *supra* note 12, at P-32.

⁵³ *Id.*

⁵⁴ Jeff Feely et al., *CVS, Walgreens and Walmart Agree to Pay \$12 Billion To Settle Opioid Epidemic Lawsuits*, FORTUNE (Nov. 2, 2022), <https://fortune.com/2022/11/02/cvs-health-agrees-to-pay-5-billion-to-settle-opioid-lawsuits%E2%80%A2>

⁵⁵ *Id.*