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Mistakes were Made: Applying Lessons Learned from the Tobacco Master Settlement Agreement to the Opioid Settlement Agreement

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MISTAKES WERE MADE: APPLYING LESSONS LEARNED FROM THE TOBACCO MASTER SETTLEMENT AGREEMENT TO THE OPIOID SETTLEMENT AGREEMENT

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[1] Juris Doctor Candidate, Mitchell Hamline School of Law, 2021; Bachelor of Science in Environmental Science, Policy, and Management, University of Minnesota, Twin Cities. Elizabeth Orrick's passion for environmental science and public health stems from her work as a recycling coordinator for four local Minnesota communities, "It has been a privilege to dive deeper into the opioid issue and the impact this crisis has had on so many individuals and families," she said. Elizabeth Orrick extends her special thanks to Professor Laura Hermer, Mitchell Hamline School of Law, for her thoughtful instructions, guidance, and expertise throughout this paper.

I. INTRODUCTION

America has an ongoing and devastating opioid epidemic. In 2016, the Department of Health and Human Services shared that opioids accounted for more than 42,000 deaths.[2] Just one year later, more than 47,000 Americans died from an opioid overdose.[3] While the opioid crisis is certainly not a new phenomenon, the recent barrage of litigations sparked conversation around who should be blamed for this massive epidemic and how the blamed parties might be held responsible for the consequences of their actions.

America's opioid problem is a human-made public health crisis. As with most public health issues, more than one solution is needed to combat opioid addiction and alleviate the destructive impact opioids can have on individuals and communities. Proposed solutions to combat the crisis vary from guidelines for stricter prescribing habits for physicians[4] to ending the war on drugs and the criminalization of addiction.[5]

There may also be a need for ongoing treatment programs, needle exchange programs to combat the challenges of addiction,[6] research and development into the root causes of addiction,

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[2] *What is the U.S. Opioid Epidemic?*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.hhs.gov/opioids/about-the-epidemic/index.htm (last updated Sept. 4, 2019).
[3] Nat. Inst. on Drug Abuse, *Opioid Overdose Crisis*, NAT'L INSTS. OF HEALTH (May 27, 2020), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis [hereinafter NIDA].
[4] *See* Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 143 (2018) (providing an overview of prescription drug monitoring programs and the "current programmatic and legal posture of PDMPs, with focus on law enforcement access, criminal justice data integration, and the continued struggle to harmonize the law enforcement-driven design of prescription drug monitoring with its supposed public health mandate.").
[5] *See* Christine Minhee & Steve Calandrillo, *The Cure for America's Opioid Crisis? End the War on Drugs*, 42 HARV. J.L. & PUB. POL'Y 547 (2019) (arguing that policymakers thrive off the power from fear of addiction and that, despite the evidence that a public health approach would be more effective, those in power prefer to blame big pharma and continue prohibition on all drugs); *see also* Jelani Jefferson Exum, *From Warfare to Welfare: Reconceptualizing Drug Sentencing During the Opioid Crisis*, 67 U. KAN. L. REV. 941, 942 (2019) (arguing that the message around drug addiction is changing, and with this shift comes a need to recast "potential drug offenders as community members, rather than enemies.").
[6] *See* Ronald O. Valdiserri, *Ending HIV and Eliminating Hepatitis C: Unlikely Without Resolving America's Opioid Epidemic*, HEALTH AFFS. (May 28, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190522.888602/full/

and how to create less-addictive or, ideally, non-addictive alternatives. To see change, states might consider exploring and adopting several of these suggestions through legislative action while making significant changes to existing rules and regulations.

Although many have differing views on the best actions to combat the opioid crisis, perhaps the largest barrier to progressive change is obtaining ongoing and consistent funding. Despite cost estimates of the opioid crisis being difficult to predict accurately, a comprehensive plan will require a sizeable immediate expenditure and a continuing stream of support over at least a decade. For example, a comprehensive plan by Senator Elizabeth Warren, based on spending data from the HIV/AIDS crisis, proposes $100 billion in federal funding over ten years to fund first responders, public health departments, and local communities.[7]

While other plans and estimates vary, one thing is clear: change needs to happen, and it needs to happen now. Yet, large-scale legislation can be slow to enact, and federal funding can take years to secure. Therefore, the current opioid litigation is the best option for an immediate source of funding to begin fighting this crisis. This paper begins with a brief overview of the history of the opioid epidemic. It will include a discussion on how the opioid problem grew into the crisis we know and fear today.[8] The paper then moves into a synopsis of the current opioid litigation landscape and bellwether trials in Ohio.[9]

(citing cases of HIV outbreaks in rural areas such as Scott County, Indiana and stating that "the rates of acute hepatitis C virus (HCV) infection in the US have more than tripled between 2010 and 2016, largely as a result of increased injection drug use associated with our ongoing opioid epidemic.").

[7] Elizabeth Warren, *My Comprehensive Plan to End the Opioid Crisis*, Medium: Team WARREN (May 8, 2019), https://medium.com/@teamwarren/my-comprehensive-plan-to-end-the-opioid-crisis-9d85deaa3ccb.

[8] *See infra* Section II.A.

[9] *See infra* Section II.C.

Of course, this is not the first time that large scale litigation has raised such concerns about settlement expenditures. In many ways, the legal and public health issues raised in the current opioid litigation mirrors the concerns raised in the tobacco litigation of the 1990s.[10] What ultimately became the largest settlement agreement in United States' history, the tobacco litigation led to a payout of approximately $161.7 billion to settling states since 1998.[11]

This paper aims to detail lessons learned from the tobacco master plan settlement and identify critical differences between opioids and tobacco that should shape the outcome of a potential opioid settlement.[12] Finally, this paper concludes with a proposal for structuring a settlement plan that includes, at minimum, state-mandated spending requirements for states to develop a public-health centered plan to combat the opioid crisis in their communities.[13]

II. Creating a Crisis

A. A Brief History of the Opioid Crisis in the United States

The opioid epidemic in the United States can be traced as far back as the late 19th century.[14] While opiates have existed for much longer, historians track the first real large-scale abuse of opioids to the U.S. Civil War, where many soldiers turned to morphine to relieve

[10] *See infra* Section III.
[11] *Actual Annual Tobacco Settlement Payments Received by the States, 1998–2019*, CAMPAIGN FOR TOBACCO-FREE KIDS (Aug. 13, 2020), https://www.tobaccofreekids.org/assets/factsheets/0365.pdf.
[12] *Infra* Section III.A.
[13] *Infra* Section IV.A.
[14] Clinton Lawson, Opinion, *America's 150-Year Opioid Epidemic*, N.Y. TIMES, May 19, 2018, https://www.nytimes.com/2018/05/19/opinion/sunday/opioid-epidemic-history.html. The author discusses a newspaper article from the Clarence and Richmond Examiner, which highlighted a story of a young woman suffering from opioid addiction. The article from 1878 is titled: "A Beautiful Opium Eater" and discusses this young woman's "morphia mania" which ultimately led to her death. *See A Beautiful Opium Eater*, CLARENCE & RICH. EXAM'R & NEW ENG. ADVERTISER (Mar 23, 1878), https://trove.nla.gov.au/newspaper/article/62080789/5047385.

physical and mental pain and suffering.[15] Recognizing the emerging crisis of opiate addiction in America, states and federal government enacted the Pure Food and Drug Act of 1906, the Harrison Anti-Narcotic Act of 1914, and the Heroin Act of 1924 as a legislative attempt to regulate the production and distribution of opioids.[16] Additionally, in 1908, President Theodore Roosevelt appointed Hamilton Wright to be the nation's first Opium Commissioner.[17] These regulatory actions signify the first time in U.S. history that the government exhibited a hands-on approach to controlling drug consumption.[18]

Despite the government's efforts and oversight, more than a century later, America continues to experience devastating losses of life, with each year setting new death toll records.[19] The most recent data from the Centers for Disease Control and Prevention ("CDC") shows the number of deaths from opioid-related overdoses in 2017 is six times higher than in 1999, with an average of 130 Americans dying every day.[20] The addictive nature of opioids cannot be understated as roughly one-quarter of all patients who are prescribed opioids for chronic pain misuse them.[21] Yet, prescription opioids including OxyContin®, Vicodin®, codeine, and morphine are merely a class of opioids alongside synthetic opioids and the illegal drug heroin, all of which play a role in the crisis we see today.[22]

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[15] Nick Miroff, *From Teddy Roosevelt to Trump: How Drug Companies Triggered an Opioid Crisis a Century Ago*, WASH. POST (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/. Morphine addiction in veterans became so common that the term "soldiers' disease" was used to describe the affliction. *Id.*
[16] Lawson, *supra* note 14.
[17] Miroff, *supra* note 15.
[18] *See* Erik Grant Luna, *Our Vietnam: The Prohibition Apocalypse*, 46 DEPAUL L. REV. 483, 486 (1997) (claiming that until this century, "drug consumption was largely unfettered by government regulation.").
[19] *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Mar. 19, 2020) [hereinafter CDC, *Understanding the Epidemic*].
[20] *Id.*
[21] NIDA, *supra* note 3.
[22] *See id.*

The CDC recognizes the rise in opioid-related overdose deaths in three notable waves.[23] The first wave, beginning in the 1990s, is distinctly linked to an increase in the misuse of legal prescription opioids.[24] From 1997 to 2002, prescriptions for a newly formulated opioid named "OxyContin®" jumped from 670,000 to 6.2 million.[25] The zealous prescribing habits by doctors during this wave are linked to the shift from "opiophobia" to opioid acceptance after several research studies highlighted the failure of medical professionals to treat chronic pain properly and the general under-reliance on opioids as a method for such pain treatment.[26]

This shift coincided with one notable publication in the 1980s regarding the addictive nature of opioids.[27] The letter, submitted by Doctor Hershel Jick as a simple eleven-line note to the editor in the New England Journal of Medicine ("NEJM"), summarized a graduate student's calculation on the number of patients in the Boston University Medical Center's database that became addicted to narcotics.[28] The letter highlighted the finding that of the 11,882 hospitalized patients who received narcotics, there were only four instances of "reasonably well documented addiction."[29] The publication finished with one line that completely changed the trajectory for

[23] CDC, *Understanding the Epidemic*, *supra* note 19.
[24] *Id.*
[25] Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN & THERAPY 13, 16 (2018).
[26] *Id.* at 15.
[27] *Id.*
[28] Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980) https://www.nejm.org/doi/10.1056/NEJM198001103020221. This simple one paragraph letter is cited over 680 times in various medical journals, dental journals, surgical journals, and much more. The New England Journal of Medicine also published a letter in 2017 analyzing the various citations to the 1980 letter. *See* Pamela T.M. Leung, et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW. ENG. J. MED. 2194 (2017) https://www.nejm.org/doi/full/10.1056/NEJMc1700150. This analysis states that, "[o]f the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids." *Id.*
[29] Porter & Jick, *supra* note 28, at 123.

opioid use and abuse: "We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."[30]

This often miscited letter quickly became the tagline for large drug manufacturers, including Purdue Pharma. In 1998, amidst an aggressive marketing campaign, Purdue Pharma aired a commercial for OxyContin® using the "findings" from the letter to say that the rate of addiction among pain patients treated is much less than one percent.[31] Neglecting to mention the publication's narrow scope, Purdue's promotions claimed the risk of addiction to be extremely small, urging patients to trust their doctors and even offering "starter coupons" consisting of a free, limited-time prescription for OxyContin.[32] All the while, Purdue Pharma was also vigorously promoting opioids to health care professionals by sending promotional items like OxyContin stuffed animals and CDs with songs titled "Get in the Swing with OxyContin."[33]

During this time, campaigns to spread awareness on the benefits of opioids were in full force. In 1995, the American Pain Society launched the "pain as the fifth vital sign," urging medical providers to evaluate and treat pain symptoms based on uniform standards.[34] Building off the American Pain Society campaign momentum, the national non-profit Joint Commission compiled pain management standards and distributed them to health care organizations to improve their undertreatment of pain.[35] Additionally, the Drug Enforcement Agency promised

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[30] *Id.*
[31] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009).
[32] *Id.* at 221–22. These "starter coupons" are reminiscent of the coupons for free cigarettes and other tobacco products that were offered prior to their abolition in the Multistate Master Settlement Agreement.
[33] *Id.* at 222.
[34] *See* David W. Baker, *The Joint Commission's Pain Standards: Origins and Evolution*, JOINT COMM'N (May 5, 2017), https://www.jointcommission.org/-/media/tjc/documents/resources/pain-management/pain_std_history_web_version_05122017pdf.pdf?db=web&hash=E7D12A5C3BE9DF031F3D8FE0D8509580.
[35] *Id.*

that there would be less stringent regulation over opioid prescribers, allowing medical professionals to prescribe liberally and often at their own discretion.[36] By 2003, opioids were used for any type of pain management, and nearly half of all physicians prescribing opioids were primary care physicians, despite concerns by some that primary care physicians were not able to sufficiently follow up with chronic pain patients due to time constraints.[37]

While doctor prescribing habits played a critical role in the consequences of wave one, drug manufacturers remained the largest target for lawsuits.[38] The legal claims in these lawsuits ranged from fraud to negligence to violations of consumer protection statutes, yet the issue at the heart of all of these claims echoes the complaint heard today: drug manufacturers play a role in opioid addiction.[39] Despite best efforts by plaintiffs to blame the creators of these drugs, large drug manufacturers, including Purdue Pharma, were mostly successful in defending these claims without agreeing to a settlement.[40] In many cases, the courts granted summary judgment because the plaintiffs failed to make a causal connection between the manufacturers' aggressive campaigns and their resulting injury in the form of addiction.[41]

Beginning around 2010, states started to recognize the detrimental effects of opioid addiction, and many tightened prescribing regulations for pain clinics.[42] These restrictions ultimately led to a rise in heroin use, which is the hallmark of the second wave in opioid-related

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[36] Jones et al., *supra* note 25, at 16.
[37] Van Zee, *supra* note 31, at 222.
[38] *See* 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).
[39] *Id.* at 353.
[40] *Id.* ("Taking a no-settlement approach [defendants] avoided liability by placing the blame on the individual plaintiffs who brought the suit; by arguing that class actions largely ignored the individual medical records of patients who used their products[.]").
[41] *Id.*; *See, e.g.*, Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 554 (N.D. Tex. 2006).
[42] Abby Goodnough, *Opioid Prescriptions Fall After 2010 Peak, C.D.C. Report Finds*, N.Y. TIMES (July 6, 2017), https://www.nytimes.com/2017/07/06/health/opioid-painkillers-prescriptions-united-states.html.

deaths.[43] Heroin, a street drug made from morphine, quickly became a cheaper and faster alternative to prescription opioids for many. From 2010 to 2012, the death rate from heroin overdoses doubled while the death rate from prescription opioids decreased ever so slightly.[44] Although heroin existed well before 2010, studies suggest prescription opioid misuse is likely a leading factor in the rise of heroin use—approximately 80% of persons who use heroin reported that they previously abused opioid prescription painkillers.[45]

In 2013, the third wave in opioid-related deaths began with the rise in synthetic opioids such as fentanyl.[46] At 50–100 times more potent than morphine, the synthetic drug fentanyl is primarily used for treating the most severe pain, such as pain caused by cancer.[47] From 2013 to 2016, deaths linked to fentanyl increased from 1,919 deaths to 18,335 deaths, and by late 2016, 29% of all drug overdose deaths involved fentanyl.[48] The most recent study shows synthetic opioid deaths are still on the rise, with approximately 31,000 deaths linked to fentanyl in 2018.[49] While fentanyl is a legal prescription drug, as of 2020, most cases of fentanyl overdoses coalesce to illegally made fentanyl, which is often a mix of morphine and heroin, creating an even deadlier concoction.[50]

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[43] CDC, *Understanding the Epidemic*, *supra* note 19.
[44] ROSE A. RUDD ET AL., INCREASES IN HEROIN OVERDOSE DEATHS—28 STATES, 2010 TO 2012, 63(39) CDC: MORBIDITY & MORTALITY WKLY. REP. 849 (Oct. 3, 2014). Note the statistics cited in this report are based off of a mortality data from twenty-eight states.
[45] Kim Krisberg, *Fatal Heroin Overdoses on the Increase as Use Skyrockets: Health Officials Battling Opiate Epidemic*, 44 NATION'S HEALTH 1 (2014).
[46] CDC, *Understanding the Epidemic*, *supra* note 19.
[47] *Fentanyl*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html (last updated Mar. 19, 2020) [hereinafter CDC, *Fentanyl*].
[48] HOLLY HEDEGAARD ET AL., NAT'L VITAL STAT. REP., DRUGS MOST FREQUENTLY INVOLVED IN DRUG OVERDOSE DEATHS: UNITED STATES, 2011-2016, 1, 4 (2018).
[49] *Id.*
[50] CDC, *Fentanyl*, *supra* note 47.

In 2017, the Department of Health and Human Services ("HHS") declared for the first time that the opioid crisis is a national public health emergency.[51] With this declaration, HHS identified five priorities: (1) "improve access to prevention, treatment, and recovery support services"; (2) "target the availability and distribution of overdose-reversing drugs"; (3) "strengthen public health data reporting and collection"; (4) "support cutting-edge research on addiction and pain"; and (5) "advance the practice of pain management."[52] While critics argue that this declaration was no more than a symbolic statement without teeth, the declaration arguably helped bring this issue's enormity into the public sphere.[53]

The evolution of today's modern-day opioid epidemic presents unique challenges for policymakers and others involved. The crisis encompasses many complicating factors, and the stigma of addiction makes treatment options for those currently affected even more difficult. Policymakers, drug manufacturers, medical professionals, and similar groups all have a stake in the game, and each has differing opinions on how America should treat and manage opioids. However, the opioid epidemic did not happen overnight, and there is no one solution to fix this public health problem, nor is there just one party to blame. Yet, there remains a unanimous cry: change is needed.

[51] Press Release, U.S. Dep't Health & Hum. Servs., HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis (Oct. 26, 2017), https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.
[52] *Id.*
[53] *See* Exum, *supra* note 5 at 942. The author also speaks about the differences between the crack epidemic, which largely affected black communities, and compares the crisis response from the crack epidemic to the opioid epidemic, which appears to affect white communities at a higher rate. The author brings to light the racial disparities in punishment and administrative responses. *Id.* at 941–42.

B. The Estimated Economic Cost of Opioid Crisis on Communities

No state, county, or city is immune to the devastation opioids inflict on communities. While some areas see higher addiction rates based on their population's composition, all communities struggle with figuring out how to fund opioid treatment and addiction.[54] The Council of Economic Advisers estimates that, in 2015, the total economic cost of the opioid crisis was $504 billion, or 2.8% of the GDP.[55] 85% of this total cost is from fatal overdoses.[56]

Opioids inflict a tremendous burden on health care systems and local governments responsible for serving their community's needs. While the effects of opioids are far-reaching, some costs, such as state spending on health care, are easier to quantify.[57] According to one study, in 2013, "[t]he aggregate cost for these prescription opioid-related overdose, abuse, and dependence was over $78.5 ($70.1–$87.3) billion," of which, nearly two-thirds of this total are costs related to health care.[58] The financial burden of opioids is borne mainly by federal, state, and local governments.[59]

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[54] *See* Eric Levitz, *Did Americans Turn to Opioids Out of Despair—or Just Because They Were There?*, NY INTELLIGENCER (Jan. 16, 2018) (stating that "[b]etween 1999 and 2013, the death rate for white, middle-aged, working-class Americans increased by 22 percent. This explosion in premature deaths was driven by a surge in opioid overdoses, alcohol-related fatalities, and suicides.").

[55] COUNCIL OF ECON. ADVISERS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS (2017). This estimate is six times higher than the estimate before, signifying that the crisis is hard to quantify, and best estimates based on data may be much higher or lower than the numbers presented in the report.

[56] Sheryl A. Ryan, *Calculating the Real Costs of the Opioid Crisis*, 141(4) PEDIATRICS (2018), https://pediatrics.aappublications.org/content/141/4/e20174129.

[57] *See* Elizabeth Weeks & Paula Sanford, *Financial Impact of the Opioid Crisis on Local Government: Quantifying Costs for Litigation and Policymaking*, 67 U. KAN. L. REV. 1061 (2019) (discussing various economic studies on opioids).

[58] Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54(10) MED. CARE 901, 906 (2016) (health care costs in this article were estimated by identifying and observing Medicare and Medicaid health plan enrollees and comparing abuse or dependence case costs versus an "average" patient health care cost to determine excess annual health care costs).

[59] *Id.*

On the other hand, costs such as the burden on the criminal justice system and lost productivity are more challenging to quantify. These costs are often abstract and multi-factorial. Certainly, looking broadly at how many individuals are in prison based on a drug sentence is essential in calculating such costs. However, other factors such as property damage and loss from a drug related crime or population and employment data in areas significantly impacted by opioids should also be considered.[60] These costs are slightly obscure as they are often disconnected from the immediate destruction caused by the opioid epidemic. Some have also estimated costs by following reports on "criminal justice spending for drug crimes" and considering "(1) police protection, (2) legal and adjudication, (3) correctional facilities, and (4) property lost due to crimes." [61]It is estimated that criminal justice costs make up approximately 9.7% of all aggregate opioid spending costs.[62] A large portion of these costs, as one might expect, are borne by the public.[63]

It is also worth noting that, while the opioid crisis affects all communities, opioids may disproportionately affect certain groups of people, including people of color and Native American communities.[64] However, news articles and press releases regarding the impact of the epidemic have primarily featured white suburban families and focused on the "whiteness" of the

[60] *See* Howard G. Birnbaum, et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 FORENSIC PAIN MED. 657, 658–59 (2011) (describing and listing various data sources used to estimate societal costs of prescription opioid abuse); *see also* Florence et al., *supra* note 58, at 905–06 (discussing various methods used to calculate criminal justice costs and lost productivity costs).
[61] Florence et al., *supra* note 58, at 905.
[62] *Id.* at 902, 913.
[63] *Id.* at 908.
[64] *See* Abdullah Shihipar, Opinion, *The Opioid Crisis Isn't White*, N.Y. TIMES (Feb. 26, 2019), https://www.nytimes.com/2019/02/26/opinion/opioid-crisis-drug-users.html ("According to statistics collected by the Kaiser Family Foundation, black people made up 12 percent of all opioid-related fatal overdose victims in 2017, with 5,513 deaths, more than double the number in 2015."); *See also Native American Overdose Deaths Surge Since Opioid Epidemic*, AP NEWS (Mar. 14, 2018), https://apnews.com/81eb3ae96c2b4f6aae272ec50f0672d2 ("Native Americans and Alaska Natives saw a fivefold increase in overdose deaths between 1999 and 2015[.]").

epidemic.[65] This is likely, in part, because the opioid epidemic greatly impacted white communities, unlike other drug crises of the past, including the crack epidemic of the 1980s-1990s.[66]

Some also theorize that racial discrimination has played a protective role in black and Latino communities, as white patients may be more likely than people of color to be prescribed pain medications.[67] However, stating that the opioid epidemic is a "white" epidemic grossly overlooks the damage and pain Native American and communities of color experience daily.[68]

Finally, beyond the economic costs, opioids cause irrevocable destruction in families who experience the pain of watching their loved ones suffer from the cycle of addiction or experience the heartbreaking loss of a loved one after an opioid-related overdose.[69] These societal costs,

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[65] *See* Interview by Noel King with Andrew Kolodny, co-director of the Opioid Pol'y Rsch. Collaborative at Brandeis, in NPR NEWS (Nov. 4, 2017), https://www.npr.org/2017/11/04/562137082/why-is-the-opioid-epidemic-overwhelmingly-white. Dr. Kolodny compared the opioid epidemic to the crack epidemic and discussed why policy makers seem to take more of an interest in the opioid epidemic. Dr. Kolodny states that with the crack epidemic we got "a war on drugs and a crackdown on crime. What we're seeing now is a very different response now that we've got an addiction epidemic that's disproportionately white." *Id.*

[66] Shihipar, *supra* note 64.

[67] Interview by Noel King with Andrew Kolodny, *supra* note 65. Dr. Kolodny discussed his theory about why the opioid epidemic has affected white communities. He states:

> [D]octors prescribe narcotics more cautiously to their non-white patients . . . the black patient is less likely to be prescribed narcotics, and therefore less likely to wind up becoming addicted to the medication. So what I believe is happening is that racial stereotyping is having a protective effect on non-white populations.

[68] *See, e.g.*, Matt Irby, *The Opioid Crisis in Indian Country: The Impact of Tribal Jurisdiction and the Role of the Exhaustion Doctrine*, 43 AM. INDIAN L. REV. 353 (2018) (discussing the impact of the opioid crisis on Native American communities and how the failure of the federal government to protect these communities led the Cherokee Nation to file an action in tribal court); Suzette Brewer, *Tribes Lead the Battle to Combat a National Opioid Crisis*, HIGH COUNTRY NEWS (May 9, 2018), https://www.hcn.org/articles/tribal-affairs-tribes-lead-the-battle-to-combat-a-national-opioid-crisis ("As the opioid crisis continues to explode across the country[,] it has ravaged tribal communities from Alaska to Maine. Remote and isolated, with limited resources to combat the epidemic's relentless, creeping sprawl, Native Americans and Alaska Natives have been more severely impacted than any other demographic in the country."); *Opioids in Indian Country: Beyond the Crisis to Healing the Community: Hearing Before the Comm. on Indian Affairs*, 115th Cong. 17 (2018) (statement of Michael E. Toedt, MD, Chief Medical Officer of the Indian Health Services) (reporting that, in 2015, American Indians and Alaska Natives had the highest overdose rates and that it is possible that the numbers may even be higher than reported "because of misclassification of race and ethnicity on death certificates[.]").

[69] *See, e.g.*, Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. TIMES (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html?module=inline.

including the cost of reducing the quality of a person's life, or the cost of grieving for a lost loved one, are impossible to reasonably quantify.[70] While pain, loss, and grieving cannot be easily described by numbers, by implementing driven public health focused outcomes, communities may be able to prevent this unquantifiable pain from happening to other families. The costs that can be estimated can be used as tools for local policymakers when budgeting for a public health spending plan.

C. Opioid Litigation and Bellwether Trials

In 2017, litigators filed hundreds of prescription opioid cases in federal courts all across the United States.[71] The number significantly increased over the last several years as cities, counties, and states brought nearly 2,000 total lawsuits against major pharmaceutical companies, retailers, and drug distributors seeking compensation for the costs these communities have incurred from opioids. The majority of these cases have been consolidated into a multi-district litigation ("MDL") in the Northern District of Ohio to be presided over by Judge Polster, a federal judge in Cleveland.[72]

MDL litigation is a unique form of litigation approved under federal law.[73] The federal statute allows for the transfer and consolidation of proceedings by a judicial panel to a federal district court when the action involves "one or more common questions of fact" for the general purpose of judicial efficiency.[74] While the federal law does not give Judge Polster the authority

[70] Florence et al., *supra* note 58, at 908.
[71] Gluck et al., *supra* note 38 (describing the range of legal claims brought by hundreds of different plaintiffs).
[72] Jan Hoffman, *Groundwork is Laid for Opioids Settlement That Would Touch Every Corner of U.S.*, N.Y. TIMES (June 14, 2019), https://www.nytimes.com/2019/06/14/health/opioids-lawsuit-settlement.html.
[73] 28 U.S.C. § 1407 (2018).
[74] *Id.* § 1407(a).

to try the cases, he does have the power to conduct pretrial proceedings, including settlement proceedings.[75]

The location for the consolidation in this matter was selected, in part, because the Ohio region experienced higher-than-average opioid use and abuse in recent years and because the area is centrally located to defendants' headquarters.[76] In these cases, the plaintiffs are claiming several different legal theories from public nuisance to negligence to civil conspiracy.[77] While the theories of liability vary slightly, all claims center around the argument that opioid manufacturers grossly misrepresented the risks of these drugs, which in turn created or contributed to the current opioid crisis with deadly consequences.[78] In these cases, the defendants span the entire prescription drug chain, from drug manufacturers, distributors, retail shops, and physicians.[79] In particular, drug manufacturers are beginning to feel the strain from the wave of civil lawsuits, as one drug maker, Insys Therapeutics, already filed for bankruptcy, with others claiming they are not far behind.[80]

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[75] *Id.*

[76] *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1379 (J.P.M.L. 2017); *see also* HOLLY HEDEGAARD, ARIALDI M. MINIÑO, & MARGARET WARNER, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1997-2017 (2018) (noting that the states with the highest rates of death due to drug overdose were West Virginia (57.8 per 100,000), Ohio (46.3 per 10,000), Pennsylvania (44.3 per 100,000), the District of Columbia (44.0 per 100,000), and Kentucky (37.2 per 100,000)).

[77] *Key Questions the Oklahoma Opioid Verdict Didn't Answer*, LAW360 (Aug. 30, 2019), https://www.law360.com/articles/1194408/key-questions-the-oklahoma-opioid-verdict-didn-t-answer; Other theories of liability cited thus far include "negligence, fraudulent misrepresentation and fraudulent concealment, violation of consumer protection statutes, anti-racketeering acts (RICO), Medicaid fraud and false claims acts, [and] unjust enrichment." *Id. See also In re* Nat'l Prescription Opiate Litig., No. 19-3827, 2019 U.S. App. LEXIS 29054 (6th Cir. Sept. 25, 2019); *In re* Nat'l Prescription Opiate Litig. v. Purdue Pharma. L.P., No. 1:18-op-45459, 2019 U.S. Dist. LEXIS 101660 (N.D. Ohio Apr. 1, 2019).

[78] *See* Colin Provost & Paul Nolette, *The Opioid Litigation has More Than 2,000 Plaintiffs. Here's What that Means Behind the Scenes*, WASH. POST (Sept. 21 2019), https://www.washingtonpost.com/politics/2019/09/21/opioid-litigation-has-more-than-plaintiffs-heres-what-that-means-behind-scenes/.

[79] *See In re Nat'l Prescription Opiate Litig.*, 290 F. Supp. 3d at 1380–82.

[80] Vanessa Romo, *Insys Files for Chapter 11, Days After Landmark Opioid Settlement of $225 Million*, NPR NEWS (June 10, 2019), https://www.npr.org/2019/06/10/731363225/insys-files-for-chapter-11-days-after-landmark-opioid-settlement-of-225-million.

The few cases that remain in state courts set the stage for the potential settlement of the MDL. Of these cases, the majority settled before trial, including a settlement between Oklahoma and Purdue Pharma for $270 million in March of 2019.[81] Of the $270 million, approximately $200 million is set to fund a National Center for Addiction Studies and Treatment, while the remainder will be distributed to local governments.[82]

However, not all lawsuits reached a settlement, including the highly anticipated trial against Johnson & Johnson in Oklahoma in August 2019. The complaint by the State of Oklahoma against Johnson & Johnson centered on state tort law, claiming the drug company created a public nuisance.[83] The parties agreed on a few essential items, including that Oklahoma has a serious opioid crisis and that opioid prescription sales increased from 2011–2015.[84]

Following a seven-week trial where forty-two witnesses and 874 exhibits were presented, presiding Judge Balkman ruled that Johnson & Johnson helped fuel the intentionally false and dangerous marketing campaigns that caused increased rates of addiction and overdose deaths.[85]Judge Balkman found the defendant's marketing efforts "were intended to influence the prescribing behavior of physicians and, thus, increase Defendants' profits from opioids."[86] Further, he found that "[b]y no later than 2001, 'a significant number of Oklahoma physicians,

[81] Sean Murphy & Geoff Mulvihill, *Maker of OxyContin Agrees to $270M Settlement in Oklahoma*, AP NEWS (Mar. 26, 2019), https://www.apnews.com/f9db345d659a48bfbff33e6f4c394d0a.
[82] *Id.*
[83] Complaint at 27, State of Oklahoma v. Purdue Pharma L.P., No. CJ-2017-816 (W.D. Okla. 2017); *see also* Jan Hoffman, *Johnson & Johnson Ordered to Pay $572 Million in Landmark Opioid Trial*, N.Y. TIMES (Aug. 26, 2019), https://www.nytimes.com/2019/08/26/health/oklahoma-opioids-johnson-and-johnson.html. The theory of liability under this case is unique because public nuisance claims are usually brought in cases involving property disputes and often center around public health violations such as pollution.
[84] State of Oklahoma v. Purdue Pharma L.P., No. CJ-2017-816, 2019 WL 9241510, at *1 (Okla. Dist. Ct. Nov. 15, 2019) [hereinafter "Oklahoma Decision"].
[85] *Id.* at *12.
[86] *Id.* at *4.

the healthcare community, law enforcement, medical advisory boards, the [Drug Utilization Review] Board' and others in Oklahoma were 'being pushed and pushed and marketed [to] and misled' about opioids by Defendants."[87]

The remedy, Judge Balkman concluded, is an order to Johnson & Johnson to pay $572,102,028 to the State.[88] While the public nuisance theory of liability in this case could look somewhat different in other states as public nuisance laws can vary from state to state,[89] the finding that a drug manufacturer directly contributed to the crisis is a significant step forward.

Following these groundbreaking settlement and verdict decisions, settlement discussions for the MDL before Judge Polster are picking up speed. In September 2019, Purdue announced a potential agreement between the drug manufacturer and twenty-four states.[90] The proposed settlement agreement called for Purdue to file for bankruptcy and restructure the company into a public benefit trust that would continue to sell drugs under certain restrictions.[91] Under this proposal, Purdue would not need to admit to any wrongdoing.[92] The remaining twenty-six states are opting out based on the belief that this settlement does not hold the Purdue owners accountable.[93] Judge Polster's final settlement must be approved, whose comments suggest he would support a public-health-focused spending plan.[94]

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[87] *Id.* at *10.
[88] *Id.* at *15–21. Judge Balkman lists findings related to costs in this order to conclude that $572 million will reasonably cover the costs for opioid enforcement and abatement. Note that the remedy fell short of the plaintiff's original request of $17 billion. *See* Hoffman, *supra* note 83.
[89] *See* Oklahoma Decision at *11 ("Unlike other states' [public nuisance] statutes that limit nuisances to the 'habitual use or the threatened or contemplated habitual use of any place,' Oklahoma's statute simply says, 'unlawfully doing an act, or omitting to perform a duty.'").
[90] Faith Khalik et al., *Learning the Lessons of Tobacco: A Public Health Approach to the Opioid Settlements*, HEALTH AFFS.: BLOG (Sept. 26, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190925.554104/full/.
[91] *Id.*
[92] *Id.*
[93] *Id.*
[94] *Id.*

Judge Polster has also made it clear that an MDL settlement is both expected and encouraged. He also spoke about creating change and making a real difference in the opioid crisis. In his opening remarks in 2018, Judge Polster announced,

> [W]hat I'm interested in doing is not just moving money around, because this is an ongoing crisis. What we've got to do is dramatically reduce the number of pills that are out there and make sure that the pills that are out there are being used properly. . . . [W]e don't need a lot of briefs and we don't need trials . . . .[95]

However, in a year, the litigation has grown as more cities, counties, tribes, hospitals, and non-profits claim a stake in the battle.

The large and complex legal battle and lack of settlement agreements led Judge Polster to sign off on a first "bellwether" test trial in the Ohio federal courthouse, which took place in October 2019.[96] The trial was between Cuyahoga and Summit counties and five large drug manufacturers. These two counties have been particularly hard-hit by the crisis and currently have the nation's second-highest opioid overdose rate.[97] Before the trial was to occur, four of the five drug manufacturers and the two Ohio counties agreed upon a multi-million-dollar settlement, which may be telling of what is to come for other parties in the MDL. The deal will funnel $215 million directly to Cuyahoga and Summit counties from McKesson Corporation, Cardinal Health, AmerisourceBergen Corporation, and Teva Pharmaceutical Industries.[98]

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[95] George Somi & Ginsey Varghese, *Settlement Push for Opiate Litigation*, 36 ALTS. TO HIGH COST LITIG. 114, 121 (Sept. 2018) (quoting Transcript of Proceedings at 416, *In re* Nat'l Prescription Opiate Litig., MDL No. 2804, No. 1:17-CV-2804 (N.D. Ohio Jan. 9, 2018).
[96] Khalik et al., *supra* note 90.
[97] Sara Randazzo, *Last-Minute Opioid Deal Could Open Door to Bigger Settlement*, WALL ST. J. (Oct. 21, 2019), https://www.wsj.com/articles/four-drug-companies-reach-last-minute-settlement-in-opioid-litigation-11571658212.
[98] *Id.*

In the end, a global settlement agreement will likely go to a national fund to be distributed to a single "negotiating class" where the money will be split based on state population following approval by state leaders.[99] Additionally, communities or towns that have been notably more affected by the opioid crisis could see an additional sum of money, as approximately 15% of the total settlement is set aside in a separate emergency fund for such use.[100] While communities would be allowed to opt out if they desired, this is unlikely as the global settlement is being developed with many state officials and leaders' aid.[101]

III. THE EVOLUTION OF THE OPIOID LITIGATION COMPARED TO THE TOBACCO LITIGATION OF THE 1990'S

A. Creating the Tobacco Master Settlement Agreement: Mistakes to Learn From

In 1998, following a lengthy trial, the four largest tobacco manufacturers agreed to the Master Settlement Agreement (MSA) with forty-six states.[102] The participating States agreed to give up all future legal claims against these companies and in return, the tobacco manufacturers promised to make ongoing annual payments and restrict tobacco marketing and promotional campaigns.[103] The purpose of the initial litigation was not necessarily to create a settlement agreement, but instead to hold cigarette manufacturers accountable for the cost of tobacco on public health and to recoup Medicaid losses.[104]

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[99] Brian Mann, *Architecture for Possible Nationwide Opioid Settlement Unveiled*, NPR NEWS (June 14, 2019), https://www.npr.org/2019/06/14/732661209/architecture-for-landmark-nationwide-opioid-settlement-unveiled.
[100] *Id.*
[101] *Id.*
[102] TOBACCO CONTROL LEGAL CONSORTIUM, THE MASTER SETTLEMENT AGREEMENT: AN OVERVIEW 2, https://www.publichealthlawcenter.org/sites/default/files/resources/MSA-Overview-2018.pdf (last updated Nov. 2018).
[103] *Id.* at 3.
[104] *Id.* at 2.

The states' legal theories against the tobacco manufacturers included statutory claims such as violation of consumer protection laws, antitrust claims, and numerous fraud claims, among others.[105] Yet, instead of testing these theories, the states and tobacco manufacturers reached a global settlement, which effectively forced states to drop all legal claims in return for the largest civil settlement of $368.5 billion.[106] The MSA seemed to be the best solution for states to secure the funds to tackle this enormous crisis. To date, the MSA is the largest civil litigation settlement in American history.[107]

On paper, the MSA could be considered widely successful for it achieved many of the goals set out in litigation: restrict tobacco advertising to prevent youth addiction, prohibit lobbying against tobacco legislation, create tobacco prevention initiatives, and secure funding to improve public health.[108] From 1999 to 2020, cigarette manufacturers have paid out approximately $168.7 billion under this agreement.[109]

Yet, the MSA lacks in one key area: it does not specify how states must use the settlement money.[110] Instead, the settlement describes how the payments will be made into escrow with the ultimate spending decisions left to the state legislatures.[111] One MSA report shows that from 1998 to 2017, "the Settling States received over $126 billion in payments, however, less than 1 percent of these funds were earmarked for state tobacco prevention

[105] Robert L. Rabin, *The Tobacco Litigation: A Tentative Assessment*, 51 DEPAUL L. REV. 331, 337 (2002).
[106] *Id.* at 338.
[107] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 1.
[108] *Id.* at 3–4.
[109] TOBACCO FREE KIDS, ACTUAL ANNUAL TOBACCO SETTLEMENT PAYMENTS RECEIVED BY THE STATES, 1998-2020 https://www.tobaccofreekids.org/assets/factsheets/0365.pdf.
[110] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 5. (This report compares spending habits of big tobacco to state funding against big tobacco and finds that "tobacco companies spend $14 to market their products for every $1 the states spend to reduce tobacco use."); *see also* TOBACCO MASTER SETTLEMENT AGREEMENT 44–45 (1998), https://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf.
[111] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 8.

programs."[112] Currently, "Not a single state currently funds tobacco prevention programs at the level recommend by the [Centers for Disease Control and Prevention]."[113] There are few data available on what effect the MSA had on tobacco control, making it difficult to measure the agreement's success and hold tobacco manufacturers accountable.[114]

To say that the MSA did not impose any obligations on states would be a fallacy. For example, under the agreement, settling states agreed to establish a "Antitrust/Consumer Protection Tobacco Enforcement Fund" for the tobacco companies to pay into.[115] Yet, specific ongoing responsibilities of the settling states comprise approximately one page of the eighty-eight-page agreement. They outline only requirements for the attorney general of settling states to attend occasional meetings and manage the funds as they come in.[116] The agreement does not state how funds must be spent, and while a significant objective of the agreement is "to further the Settling States' policies regarding public health," the agreement does not outline public health approaches for States to take.

B. The Master Settlement Agreement: Comparing how States Spent Settlement Funds

The MSA resulted in initial payments, annual payments and strategic contribution payments to states participating in the settlement agreement.[117] The MSA mandated tobacco manufacturers to pay upfront payments for five years, followed by yearly payments continuing in

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[112] *Id.*
[113] *A State-By-State Look at the 1998 Tobacco Settlement 21 Years Later*, TOBACCO-FREE KIDS (Jan. 16, 2020), https://www.tobaccofreekids.org/what-we-do/us/statereport.
[114] Walter J. Jones & Gerard A. Silvestri, *The Master Settlement Agreement and Its Impact on Tobacco Use 10 Years Later*, 137(3) CHEST 692, 692 (2010).
[115] TOBACCO MASTER SETTLEMENT AGREEMENT, *supra* note 110 at 31-32

[116] *Id.* at 30–31.
[117] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 4.

perpetuity.[118] Eighteen states, however, chose to securitize MSA funds. In doing so, the states receive an upfront lump sum versus annual payments, resulting in secured funding but, overall, less money.[119] With large sums of settlement coming in and no strings attached to spending, many states used funds to pay back state budget deficits or focus on otherwise neglected areas of state spending such as infrastructure projects.[120]

Because of the lack of uniform spending requirements, states vary widely in how they spend MSA funds. To understand the general categories of spending, the General Accounting Office (GAO) issued a report on how thirteen different states use their MSA funds. The GAO found that the majority of the states allocated only 7% of the funds for the purposes of tobacco control while seven states actually allocated 6% of the funds to assist tobacco growers.[121] However, this is not to say that the MSA was in vain. All participating states allocated at least some money to tobacco control programs, with as many as ten states dedicating over 10% for tobacco control programs and purposes.[122]

Unfortunately, many states ebbed and flowed in their commitment to funding tobacco prevention and control. The desire to redirect MSA funds for unrelated purposes proved high for state policy officials. Even in states that seemed committed to funding tobacco control efforts eventually diverted funds for other causes.[123]

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[118] *Id*.
[119] *Id.* at 9.
[120] *Id.* at 5–6.
[121] GEN. ACCT. OFF., TOBACCO SETTLEMENT: STATES' USE OF MASTER SETTLEMENT AGREEMENT PAYMENTS 6–7 (2001).
[122] *Id.* at 31. The ten states include Colorado, Hawaii, Indiana, Maryland, Montana, Nebraska, Ohio, Vermont, Washington, and Wyoming.
[123] *See* Micah L. Berman, *Using Opioid Settlement Proceeds for Public Health: Lessons from the Tobacco Experience*, 67 U. KAN. L. REV. 1029, 1045–46 (2019) (discussing how states diverted MSA funds when the economies hit hard times).

1. Minnesota's Master Settlement Agreement Spending

In 1994, shortly after Mississippi filed a lawsuit against big tobacco, Minnesota became the second state to file a lawsuit.[124] The Minnesota settlement is particularly unique because the state was one of four states that did not sign onto the MSA but instead settled separately with big tobacco manufacturers.[125] In the end, under the settlement, the tobacco manufacturers agreed to pay out more than $6.5 billion to the state and Blue Cross and Blue Shield of Minnesota.[126]

Within one year of the settlement, the Minnesota Legislature created an endowment of approximately $20 million per year to prevent tobacco addiction in youth populations. This endowment, adequately titled The Minnesota Tobacco Use Prevention and Local Public Health Endowment, was trademarked under the name Target Market Organization (TMO).[127] Launched in 2000, this successful program included youth summit events, targeted marketing and media campaigns, sponsored concerts, and numerous school programs.[128] At the time, this Tobacco Prevention Initiative was Minnesota's only statewide tobacco prevention program.[129]

The Minnesota Department of Health (MDH) took charge of administering tobacco prevention programs.[130] Initial reports on the program showed that the program was "on track to

[124] Cathy Wurzer & Julia Franz, *Minnesota's Landmark Tobacco Settlement is 20 Years Old*, MPR NEWS (May 8, 2018), www.mprnews.org/story/2018/05/08/minnesotas-landmark-tobacco-settlement-is-20-years-old.
[125] Other states included Mississippi, Florida, and Texas. Frank A. Sloan et al., *States' Allocations of Funds from the Tobacco Master Settlement Agreement*, 24 HEALTH AFFS. 220, 220 (2005).
[126] Wurzer, *supra* note 123.
[127] David F. Sly et al., *The Outcome Consequences of Defunding the Minnesota Youth Tobacco-Use Prevention Program*, 41 PREVENTIVE MED. 503, 504 (2005) (discussing the creation of Minnesota's target market program for funding youth tobacco education programs).
[128] TOBACCO PREVENTION AND LOCAL PUBLIC HEALTH ENDOWMENT: ANNUAL REPORT TO THE LEGISLATURE 2002 ACTIVITIES, MINN. DEP'T HEALTH 4 (2002) (programs included open gym and computer time to various schools and other events "focused broadly on encouraging positive youth behaviors.").
[129] *Id.* at 2.
[130] *Id.*

reach the goal of a 30% reduction in youth tobacco use by 2005."[131] The University of Minnesota, along with experts from the MDH and other state agencies, worked together to develop measurable outcomes to track youth tobacco use over time.[132] Within two years of implementing the program, teen tobacco use was down 11%.[133]

Despite support by communities, the program was short-lived, and by the spring of 2003, the Minnesota Legislature completely phased out the TMO.[134] In 2005, researchers assessed the consequences of defunding the program by looking at surveyed households at random to see whether youth (ages 12–17) were likely to wear gear with a tobacco logo, what their general attitudes and beliefs were toward tobacco, and their intent, if any, to smoke.[135] The research showed that the cutback on funding and discontinuation of the TMO program resulted "in a marked increase in the risk of youth smoking" compared to youth smoking rates during the implementation of the program.[136]

While it is hard to say with certainty how successful the program might have been in eliminating tobacco addiction in youths and teens in Minnesota, an examination of trends immediately following the end of the TMO, and studies on youth intentions to smoke indicate that the discontinuation of the TMO was a mistake.

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[131] *Id.* at 5.
[132] *Id.* at 6–8. (Such outcomes included (1) proportion of youth who use tobacco; (2) initiation of smoking among youth; (3) youth self-reported cigarette consumption; (4) youth desire to begin smoking; (5) source of tobacco products for youth; (6) proportion of retailers selling tobacco to minors; (7) youth attitudes and beliefs toward tobacco use; (8) youth perception of the prevalence of smoking; (9) ability to refuse influences to use tobacco; and (10) exposure to secondhand smoke).
[133] *Id.* at 8.
[134] Sly et al., *supra* note 126, at 504.
[135] *Id.* at 507.
[136] *Id.* at 509.

However, Minnesota continues to receive settlement funding which has been used over the last twenty years for public health programs, Nice Ride bike sharing programs, and to help lessen the state's deficit.[137] Yet, the state has also been active in passing clean air ordinances, including the Minnesota Clean Air Act of 2007 which prohibits smoking in public indoor spaces.[138] Minnesota recently developed the Minnesota Comprehensive Tobacco Control Framework 2016–2021 which is primarily funded by the MDH, Clearway Minnesota,[139] and Blue Cross and Blue Shield of Minnesota—entities that received funding from the settlement.[140] The framework lays out a comprehensive tobacco control program which includes the creation of smoke-free policies, education and outreach, aid for current tobacco users, and various economic and social strategies.[141]

Minnesota, like many other states receiving tobacco settlement money, has not always used the funds for the intended purposes, however, legislative updates and the current tobacco framework show a dedication by the state to reduce tobacco use. While the State saw a decline in tobacco use from the years 2000–2017, the use of e-cigarettes and flavored tobacco products is on the rise, and the state is now attempting to find new ways to reduce youth exposure to tobacco.[142]

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[137] Wurzer, *supra* note 123.
[138] MINN. STAT. §§ 144.41–.417 (2019).
[139] Clearway Minnesota is a non-profit that was born out of Minnesota's tobacco settlement agreement. *See* MINNESOTA COMPREHENSIVE TOBACCO CONTROL FRAMEWORK 2016–2021, 10 (2016), https://www.health.state.mn.us/communities/tobacco/initiatives/docs/mnframework.pdf.
[140] *Id.* at 6.
[141] *Id.* at 9.
[142] MINN. DEP'T HEALTH, TEENS AND TOBACCO IN MINNESOTA: HIGHLIGHTS FROM THE 2017 MINNESOTA YOUTH TOBACCO SURVEY 17 (2017).

2. North Dakota's Master Settlement Spending

North Dakota was one of forty-six states signing on to the MSA, but the state chose not to allocate or spend MSA funding in the same manner as its neighbors. Instead, North Dakota allocated 100% of MSA funds to "water projects and bond payments," carving out 45% of the MSA funds to state infrastructure development projects shortly after the settlement.[143] By 2000, the state was cited in a CDC report for holding one of the worst ratings for tobacco control efforts.[144] However, even before the MSA, North Dakota had no existing statewide tobacco control programs.[145]

From 1999–2000, policy leaders and the then governor, Ed Schaefer, supported spending 45% of all funds on clean water and water-related projects.[146] While the American Heart and Lung Association did not disapprove of spending on clean water, leaders in the organizations pushed the state to limit using MSA funds for that purpose, but such spending limits were not created.[147]

North Dakota was also one of nine states to use MSA funding to supplement its educational funds by allocating money for school districts to complete much-needed improvements and increase teacher salaries.[148] North Dakota did dedicate some of the MSA funding to the largely successful Community Health Grant Program, which helped create an educational curriculum to teach students about the dangers of smoking.[149] From 2001–2005, the

[143] GEN. ACCT. OFF., *supra* note 120, at 39; Sloan et al., *supra* note 124, at 224.
[144] Sloan et al., *supra* note 124, at 224.
[145] *Id.* at 223–24.
[146] *Id.* at 224.
[147] *Id.*
[148] GEN. ACCT. OFF., *supra* note 120, at 37–38. The other eight states included Colorado, Connecticut, Kentucky, Louisiana, Maryland, Montana, New Hampshire, and Ohio.
[149] Sloan et al., *supra* note 124, at 224.

Community Health Grant Program increased funding using MSA dollars from $4.7 million to $6 million.[150]

In 2012, North Dakota passed the Smoke-Free Law, effectively prohibiting smoking in all enclosed public areas and areas of employment.[151] By 2014, however, North Dakota became one of two states to fund tobacco control programs at the minimum levels recommended by the Center for Disease Control and Prevention.[152] While North Dakota currently remains above the national average in cigarette use among both adults and high school students, the state allocates a portion of the money from the tobacco settlement toward tobacco prevention.[153] Specifically, in 2019, North Dakota received $53.6 million in revenue from the MSA, though allocated only $5.8 million to tobacco prevention.[154]

Recent efforts are laid out in North Dakota's Tobacco Prevention and Control Program (TPCP).[155] Under a partnership with forty-one different organizations, the TPCP created a comprehensive state plan which outlines strategies to reduce tobacco use in North Dakota.[156] Such efforts include cessation interventions, outreach and communication focused on prevention and creating new social norms, surveillance and evaluation, and implementing CDC best practices.[157] While the state has experienced budget cuts toward tobacco programs, legislative

[150] *Id.*
[151] N.D. CENT. CODE § 23-12-10.
[152] TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 5.
[153] Truth Initiative, *Tobacco Use in North Dakota 2019* (June 28, 2019), https://truthinitiative.org/research-resources/smoking-region/tobacco-use-north-dakota-2019.
[154] *Id.*
[155] *See* PRO. DATA ANALYSTS, THE STATE OF TOBACCO CONTROL IN NORTH DAKOTA: 2017–2019 (2019).
[156] *Id.* at 2.
[157] *Id.* at 7.

efforts to implement a tobacco price increase could bring an influx of funds to the state in the future.[158]

3. North Carolina's Master Settlement Agreement Spending

While states were not required to use the funds for any specific purpose, the idea behind the MSA was to fund tobacco control and prevention. Many states failed to use MSA spending for such public health purposes, but perhaps none failed quite as terribly as North Carolina. Using $42 million in MSA funding, North Carolina actually subsidized tobacco farmers with the intention of improving farming practices and marketing strategies under the guise of allocation to "economic development projects."[159] In total, the state used 75% of the funds for economic development and tobacco farming subsidies.[160]

Additionally, North Carolina created three institutional disburse MSA funds: (1) the Golden LEAF (Long-term Economic Advancement Foundation) to allocate funds to areas of the state that are dependent on tobacco farming and production, (2) The Tobacco Trust Fund (TTF) "charged with assisting tobacco farmers" among other tobacco-related sales purposes; and (3) the Health and Wellness Trust Fund (HWTF), "charged with addressing the health needs of vulnerable and underserved populations" among other treatment prevention programs.[161] While the state did divert approximately 25% of the MSA funds to health and wellness purposes through the HWTF, only 21% of the HWTF funding went toward youth tobacco use and

[158] *Id.* at 10.
[159] GEN. ACCT. OFF., *supra* note 120, at 27; 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?_r=0.
[160] GEN. ACCT. OFF., *supra* note 120, at 35.
[161] Alison Snow Jones et al., *Funding of North Carolina Tobacco Control programs Through the Master Settlement Agreement*, 97 AM. J. PUB. HEALTH 36, 37–38 (2007) (noting that the majority of MSA funds went to the Golden Leaf Foundation).

prevention.[162] The remainder went toward other state health initiatives such as obesity prevention.[163]

North Carolina, along with Kentucky and Virginia, is a large producer of the tobacco crop, with this region producing 74% of the United States' tobacco.[164] The MSA directly impacted tobacco manufacturers, who subsequently imposed the higher cost burden on tobacco farmers and producers. Thus, the purposes behind the subsidy was to prevent job loss from a major economic driver of North Carolina's economy.[165] However, because the state developed no long-term plans to move away from tobacco production, the MSA, in part, funded the continuation of tobacco farming.[166]

While funding for these groups continued, the state did eventually spend some funds on health programs. In 1999, a year after the MSA, the state contributed 10% of the MSA dollars to the American Cancer Society and the American Lung and Heart Associations for the purpose of tobacco control.[167] All the while, then-current Attorney General (now governor) Mike Easley pressed for diversion of funds to other non-tobacco related purposes. For example, in 2003, Easley pushed for a $65 million diversion in MSA funds to reduce the state budget deficit.[168]

The funding for tobacco prevention purposes continued as the state-sponsored teen-smoking prevention campaigns.[169] Yet, throughout the state's history, North Carolina lacked a

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[162] *Id.* at 39.
[163] *Id.*
[164] GEN. ACCT. OFF., *supra* note 120, at 34.
[165] *Id.*
[166] *See id.* at 36–37.
[167] Sloan, *supra* note 124, at 223. Note that this spending was in conjunction with the spending funding of tobacco farming.
[168] *Id.* at 223.
[169] *Id.*

dedication toward tobacco prevention programs and repercussions for tobacco. From 1991 to 2019, the State has kept cigarette excess tax at a steady five cents per pack despite the additional funds a higher tax could generate.[170] Currently, the state's cigarette tax is at $0.45, nearly a quarter of national average of $1.81.[171]

By 2017, the state doubled funding for tobacco prevention programs, bringing the total spending to $2.1 million.[172] While the increase certainly showed a dedication toward reducing tobacco use and, especially by youth, the total expenditure represents a small portion of funding received.[173] In the same year, the state "improved from 47th to 43rd among states in terms of the amount of money going toward tobacco-prevention programs."[174]

In 2019, North Carolina received $450.4 million from the tobacco settlement and taxes, yet allocated only $2.8 million in state funds to tobacco prevention.[175] Therefore, while North Carolina is dedicating more funds toward tobacco prevention, progress in tobacco control has been slow for the last twenty-one years.

C. Key Differences and Complicating Factors in the Opioid Litigation

To say the opioid crisis and potential opioid settlement mirrors the problems seen in the tobacco litigation is a simplistic understatement. The opioid crisis is caused by years of abhorrent marketing techniques by manufacturers, overzealous prescribing by health care professionals, criminalization of drug addiction by the federal government, creative and cheaper illegal drug mixtures by street dealers, and insufficient funding for treatment programs by states and

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[170] *Id.*
[171] Truth Initiative, *supra* note 152.
[172] Richard Craver, *Master Settlement Agreement Remains Flawed Enigma Even After 20 Years*, WINSTON-SALEM J. (Nov. 25, 2018).
[173] *See id.*
[174] *Id.*
[175] Truth Initiative, *supra* note 152.

communities. While opioid distributors may bear the costs of this issue through litigation, physicians, hospitals, pharmacies, law enforcement, and local governments also play a critical role in this issue.

Even if distributors could be held solely responsible, the financial differences between big tobacco and opioid distributors is so stark that it would be impossible for states to rely on continued funding by opioid distributors in the same way they might be able to with the MSA. For example, in 2016, "U.S. tobacco sales totaled $94.4 billion, prescription opioids, $8.5 billion."[176] Thus, it is unlikely that a potential opioid settlement will bring in the same level of funding as tobacco did, making even more important for states to allocate closer to 100% of funds from the settlement to treat opioid addiction.

Second, opioids serve an important purpose in the health care system. Opioids are approved by the Federal Drug Administration (FDA) as a safe drug to use for prescribed medical purposes.[177] While non-addictive options would certainly be ideal, opioids are highly effective pain care medications that, when taken appropriately, can make a tremendous difference in the life of a person suffering from chronic pain or cancer.[178] Preventing drug manufacturers from creating and distributing opioids is not an option as around fifty million Americans suffer from chronic pain, and many rely on prescribed opioids to relieve the burden on their lives.[179] The health benefit consideration of opioids is a factor that was simply not present in the tobacco

[176] Nicolas Terry & Aila Hoss, *Opioid Litigation Proceeds: Cautionary Tales from the Tobacco Settlement*, HEALTH AFFS. (May 23, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180517.992650/full/.
[177] *See generally Opioid Medications*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/information-drug-class/opioid-medications (last updated July 1, 2019).
[178] *See* David Leonhardt, Opinion, *The Benefit of Opioids*, N.Y. TIMES (Mar. 9, 2018), https://www.nytimes.com/2018/03/09/opinion/opioids-benefits.html.
[179] JAMES DAHLHAMER ET AL., PREVALENCE OF CHRONIC PAIN AND HIGH-IMPACT CHRONIC PAIN AMONG ADULTS—UNITED STATES, 2016, 67(36) CDC MORBIDITY & MORTALITY WKLY. REP. 1001, 1002 (Sept. 14, 2018).

litigation. While Alternative pain medication could help some with chronic pain, given the effectiveness of opioids, the drug must be available until equivalent less-addictive alternatives are approved and readily available.

Unlike the tobacco settlement, which allowed for a possible reduction in damages for reducing cigarettes sold in state, drug manufacturers cannot limit prescription medications to patients.[180] Thus, attempting to copy and paste the MSA's restrictive guidelines to the opioid settlement is simply not feasible. However, like the MSA, the opioid settlement can restrict marketing and promoting opioids to health care providers and patients, and fund awareness campaigns to try to minimize the use of opioids when an opioid might not be considered "medically needed."[181] For example, under the section aptly titled "permanent relief" the MSA states:

> No Participating Manufacturer may take any action, directly, or indirectly, to target Youth within any Settling State in the advertising, promotion or marketing of Tobacco Products, or take any action the primary purpose of which is to initiate, maintain, or increase the incidence of Youth smoking within any Settling State.[182]

While opioids are regulated under the FDA and thus subject to FDA advertising and promotion regulations, the FDA's role is primarily to ensure any advertisements are truthful.[183] Specifically, the FDA also requires any promotions and marketing efforts for opioids to be submitted through

[180] Terry & Hoss, *supra* note 175.
[181] The term "medically needed" continues to be debated. While this issue is outside the scope of this paper, it is important to note that, as the dramatic changes in opioid prescribing habits during the 1980's, 1990's, and early 2000's suggest, the concept of "medial necessity" in the context of pain relief is not absolute, and many researchers and physicians have differing viewpoints on what should and should not be considered "medically necessary." *See e.g.*, Linda A. Bergthold, *Medical Necessity: Do We Need It?*, 14 HEALTH AFFS. 180 (1995) (discussing how the term "medical necessity" has gained greater importance in the health care world and is used now to "control the use of scarce resources.").
[182] TOBACCO MASTER SETTLEMENT AGREEMENT, *supra* note 110, at 14.
[183] *See* HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP (2018), https://www.fda.gov/media/110587/download.

the FDA for review before public distribution.[184] Although some drug manufacturers agree to voluntarily change marketing policies,[185] the opioid settlement, like the MSA, could include strict restrictions on the public marketing of opioids.

There are also important legal differences and considerations as prescription opioids go through a heavily regulated health care system. Laws such as the Federal Food, Drug, and Cosmetic Act[186] and the Controlled Substance Act[187] regulate and control opioids on a broad scale. Unlike tobacco products, an individual of legal age[188] cannot walk into a gas station or market and purchase opioids. While opioid prescribing habits have changed over the years, a prescription is still necessary to access this medication.[189] In some ways, this change has sparked friction between policymakers who push for aggressive prescription regulations and doctors who are tasked with treating pain.[190] Therefore, unlike tobacco, the oversight and regulatory scheme for opioids will make it difficult to impose strict prohibitions on opioid manufacturers through a settlement agreement.

Finally, the path an opioid can take from prescription to an individual can be difficult to track. Addiction to opioids or heroin can start with a straightforward prescription for pain treatment. After a patient picks up an opioid prescription from their pharmacist, the path the

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[184] Van Zee, *supra* note 31, at 224.
[185] *See* Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, ATLANTIC (June 2, 2017) (noting that, following a multi-million-dollar settlement, Purdue acted by changing policies and providing a better notice of the addictiveness of opioids).
[186] 21 U.S.C. ch. 9, § 301 et seq.
[187] 21 U.S.C. ch 13, § 801 et seq.
[188] In the United States, the legal age for purchasing tobacco was eighteen years old. However, On December 20, 2019, the legal age increased to twenty-one under the amended Federal Food, Drug, and Cosmetic Act. *See* FED. DRUG ADMIN, NEWLY SIGNED LEGISLATION RAISES FEDERAL MINIMUM AGE OF SALE OF TOBACCO PRODUCTS TO 21, https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21.
[189] Jane C. Ballantyne, *Regulation of Opioid Prescribing*, 334(7598) BRIT. MED. J. 811, 812 (2007).
[190] *Id.*

opioid can take is often challenging to monitor and control.[191] Some may take the drug as prescribed and continue to get it refilled appropriately, while others may illegally sell their opioid prescription, making it nearly impossible to track and regulate.[192] Therefore, while imposing requirements on drug manufacturers through a settlement will likely help, the many paths an opioid can take makes it difficult to see change through these requirements alone.

IV. A PROPOSAL FOR STATES TO DIRECT POTENTIAL SETTLEMENT MONEY TO COMBAT THE GROWING OPIOID CRISIS

A. Setting forth State Obligations in Settlement Plan

As the opioid settlement and promises of tens of billions of dollars nears, the mistakes made when creating the tobacco litigation should be at the forefront of the settlement drafters' minds. One of the greatest criticisms of the MSA is that the spending obligations outlined in the agreement or, more appropriately, the lack thereof, made it nearly impossible to hold states accountable for ensuring tobacco control policy was enacted.[193]

Recognizing that states may have different immediate needs related to the opioid crisis and that the opioid litigation differs in key ways to the tobacco litigation, the impending opioid settlement, much like the MSA, should be designed to allow for some flexibility.[194] However, a

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[191] *See* COUNCIL OF THE INSPECTORS GEN. ON INTEGRITY & EFFICIENCY, COMBATTING THE OPIOID CRISIS: ROLE OF THE INSPECTOR GENERAL COMMUNITY 3 (2009) (featuring an infographic which details the chain of opioid use and abuse).

[192] *See id.*

[193] *Fifteen Years Later, Where Did All the Cigarette Money Go?*, NPR (Oct. 13, 2013), https://www.npr.org/2013/10/13/233449505/15-years-later-where-did-all-the-cigarette-money-go; *see also* Jones & Silvestri, *supra* note 114, at 697 (concluding that "the MSA has not resulted in a clear and straightforward intensification of state tobacco control efforts . . . .").

[194] Although the MSA imposed many restrictions on tobacco manufacturers themselves including restrictions on advertising and direct targeting of youth and was generally designed to cater to states' needs, the MSA is arguably too flexible. *See e.g.*, TOBACCO CONTROL LEGAL CONSORTIUM, *supra* note 102, at 5 (discussing how, "[a]s a result of decisions by state legislatures, which are responsible for deciding how the [tobacco] money is spent, state coffers lined with this money . . . have not been used for tobacco control and prevention programs.").

comprehensive public-health approach[195] and requirements to spend settlement money in specific ways should be outlined directly in the settlement agreement, either in its provisions or through the use of an appendix.

The MDL presents a unique opportunity for the court to effectuate change in a massive opioid crisis. The tobacco litigation is a prime example of how litigation efforts can fail if mandated spending requirements are not imposed directly through a settlement agreement.[196] As discussed below, a settlement agreement which specifies state-mandated spending requirements could raise constitutional law questions. However, judges also have the power to creatively solve litigation, fee, and settlement concerns.[197]

In this matter, Judge Polster has made it clear that the goal of the litigation is to reduce the problem of opioid addiction and abuse, claiming that "[t]he federal court is probably the least likely branch of government to try to tackle this, but candidly, the other branches of government, federal and state, have punted. So, it's here."[198] When the government branches tasked with developing solutions to a public health crisis fail, another branch must pick up the slack. Therefore, to avoid potential settlement money from funding state deficits, the settlement agreement should determine how participating states spend the money as they have in the past.

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[195] For an example on one public health approach to the opioid crisis, see James G. Hodge, Jr. et al., *Exploring Legal and Policy Responses to Opioids: America's Worst Public Health Emergency*, 70 S.C. L. REV. 481, 505 (2019) (discussing policy approaches to the opioid crisis and suggesting that "[m]ore aggressive and expansive approaches are needed to reduce real-time morbidity and mortality.").

[196] *See supra* Section III.A.

[197] *See* Thomas Sekula, *Selective Settlement and the Integrity of the Bellwether Process*, 97 TEX. L. REV. 859, 868–70 (2019) (discussing the concept of "inherent judicial authority" and the various tools which can be employed by an MDL judge).

[198] Transcript of Proceedings at 411, *In re* Nat'l Prescription Opiate Litig., MDL No. 2804, No. 1:17-CV-2804 (N.D. Ohio Jan. 9, 2018).

Arguably, the complex legal battle and diversity of the plaintiffs may make it difficult to impose strict spending requirements. However, the settlement agreement should clearly determine the specific amount to be distributed to each plaintiff at minimum. The agreement should also mandate states use the funds for specific public health purposes based on the states' needs and health infrastructure. Critics of a mandated spending approach believe controlling revenue is a legislative function, and to create mandated spending in a settlement agreement raises a separation of powers issue.[199] However, whether a settlement agreement, in its terms, can require funds to be used for specific purposes is up for debate.

Certainly, allowing a state attorney general to force a state legislature to spend the opioid settlement a specific way, or even to allow a state attorney general the authority to sign off on a strict spending agreement could raise a state constitutional law issue. An important legislative function is the power to tax and spend, and otherwise control public money.[200] When courts step in to "police" the spending of money, some argue the court upsets the separation of powers.[201] While it is not clear whether including state-mandated spending requirements in a settlement would violate a state's separation of powers doctrine, some argue that the changing and unique

[199] Allison Torres Burtka, *'98 Settlement Agreement*, AM. MUSEUM OF TORT L. (Apr. 13, 2016), https://www.tortmuseum.org/98-tobacco-settlement/. The author discusses an in-depth interview with Joe Rice, lead private counsel for the tobacco litigation. When asked whether the settlement could "have gone further to ensure that more of the revenue went to tobacco control programs[,] Rice said, 'If we'd gone much further, we could have had a separation of powers disagreement and may have needed legislative approval of the settlement'—which would have complicated the process further." *Id.*

[200] *See generally Power of the Purse*, HIST., ART & ARCHIVES, https://history.house.gov/Institution/Origins-Development/Power-of-the-Purse/ (last visited Nov. 11, 2019).

[201] *See* Burtka, *supra* note 197 ("Some [attorneys general] were actively involved with their governors to ensure that some of the funds were directed to tobacco control programs and public health, and 'others felt it was a legislative function to appropriate all the money and did not support directing the funds,' . . . .").

landscape of mass tort litigation and MDL litigation might not raise such a concern if the separation of powers doctrine is not read so expansively.[202]

Yet, there are options for the settlement agreement to be broad enough to limit the attorney general's power while being narrow enough to effectuate change. One suggestion proposes to divide the settlement money so that a portion diverts to a national non-profit foundation dedicated to opioid treatment, care, and education.[203] The remaining amount is then split among the states through a general fund with an outline or proposal plan for state legislatures to implement as they see fit for their communities.[204]

However, while this proposal is worth exploration, the lack of state requirements would arguably lead to a similar outcome, as seen in the MSA. Additionally, the amount going to states is likely be far smaller than the MSA. Thus, if the money is split between federal and state programs, most participating states might feel it is not worth the time and effort to begin new public health programs. Therefore, an effective opioid settlement must impose requirements on states, regardless of the possibility of a future separation of powers claim.

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[202] *See e.g.*, Benjamin Ewing & Douglas A. Kysar, *Prods and Pleas: Limited Government in an Era of Unlimited Harm*, 121 YALE L.J. 350, 410–12 (2011) (discussing how the separation of powers is not practical, and suggesting that the doctrine of separation of powers should not preclude courts from aiding other branches when they have failed to take action); *but see* Donald G. Gifford, *The Constitutional Bounding of Adjudication: A Fuller(ian) Explanation for the Supreme Court's Mass Tort Jurisprudence*, 44 ARIZ. ST. L.J. 1109, 1154–56 (2012) (suggesting that generalized harms (specifically climate change) should be handled by legislatures and administrative agencies and not courts).

[203] *See* Berman, *supra* note 122, at 1054–55 (2019) (discussing the MSA's model which allocates part of the settlement money to the Truth Initiative which allowed for widely available treatment options and nationwide educational campaigns. The author also discusses Mississippi's settlement plan model, which directed the settlement money directly to a state non-profit entity. However, this model would be extremely difficult to implement and enforce in a complex national settlement such as the opioid settlement because it would involve state politics and likely much competition from non-profits within each state).

[204] *Id.*

At minimum, the settlement plan could outline several general, relevant categories of public health actions and mandate that the states choose from the list of action plans based on their needs. This approach of having the judiciary tell states how they should spend money has been seen in local opioid cases, including the Johnson & Johnson trial in Oklahoma. In the case, Judge Balkman made it clear that states must use the money for education and treatment for addiction.[205] However, imposing requirements on a state following a localized trial is arguably easier than imposing requirements through a global settlement agreement.

Yet, requiring states to spend settlement money for a certain purpose directly through a settlement agreement is not unheard of. For example, Wells Fargo recently went under fire after allegations surfaced that the bank violated consumer protection laws when it opened millions of unauthorized accounts for customers, without their knowledge, to improve their banking enrollment numbers.[206] In the Wells Fargo Multistate Settlement Agreement under the heading "Monetary Payment to the States," the agreement reads:

> Wells Fargo shall pay an aggregate amount of $575 million related to the Covered Conduct to the signatory Attorneys General. Wells Fargo shall pay to each signatory Attorney General the specific amount set forth in Appendix A . . . The payments to the signatory Attorneys General shall be used for the purposes specified and according to the general instructions of each signatory Attorney General as set forth in Appendix B.[207]

Appendix B provides the procedure for fund allocation and allowable spending purposes. For example, the Wells Fargo Settlement Agreement required Arkansas to deposit the settlement

[205] *See* State of Oklahoma v. Purdue Pharma L.P., No. CJ-2017-816, 2019 WL 4019929, at *20 (Okla. Dist. Ct. Aug. 26, 2019) (concluding that the abatement of the nuisance and costs of services including treatment services, treatment resources, public programs, and personnel costs, among other program costs is expected to total $572,102,028).
[206] Settlement Agreement, Att'ys Gen.-Wells Fargo, 1–2 (Dec. 28, 2018), https://www.attorneygeneral.gov/wp-content/uploads/2018/12/Wells-Fargo-Multistate-Settlement-Agreement-12-28-18.pdf (stemming, in part, from employees needing to meet unobtainable quotas set by management).
[207] *Id.* at ¶ 37.

funding into the states' "Consumer Education and Enforcement Fund to be used in accordance with Act 763 of 2013, or for other uses permitted by state law."[208] In contrast, Indiana may use the settlement payment "for any purpose allowable under Indiana law."[209]

The amounts listed in Appendix A of the Agreement include both payments to the Attorneys General for the costs of investigation and are to be used "for the purposes specified and according to the general instructions of each Investigating Attorney General . . . ."[210] This Agreement language suggests that a States' Attorney General can specify instructions for their state to use accordingly.

The Wells Fargo Multistate Agreement does a better job of laying out specific state's requirements than the Tobacco MSA. However, even the Wells Fargo Multistate Agreement does not impose strict spending requirements on states, and largely leaves it to the state's discretion.[211] Yet, the model created by the Wells Fargo Agreement suggests that outlining spending requirements is possible, and an agreement can mandate, depending on the state, that a state put the funds toward a stated purpose. Of course, it would be challenging to get each state to approve of such strict requirements. Such a model could lead to many states dropping out of a multistate agreement and instead opt to go to trial or form agreements directly with drug manufacturers outside of the MDL.

Additionally, while the word "mandate" again raises concerns about whether a multistate settlement plan could, through its terms, force states to spend money a certain way, there is one

[208] *Id.* at B1 (noting the Fund to be used in accordance with the state of Arkansas' consumer protection law, Act 763 of 2013).
[209] *Id.* at B3.
[210] *Id.* at ¶ 38.
[211] *See id.*

simple work-around for this issue. The settlement could directly require the state to pass legislation to receive funding, effectively creating an outline to reduce opioid abuse.[212] The possible action plans laid out in the settlement plan could then serve as a guide for possible language to use so that states can begin implementation as soon as possible. If states refuse to take legislative action, they could alternatively submit a proposed plan for funding or opt-out of the multistate settlement agreement entirely.

The question of whether a settlement plan, through its terms, can mandate how a state spends its settlement money in a certain way is a question that has not been tested. However, the opioid settlement provides an opportunity to test the theory through state-mandated spending provisions.

Notably, while the settlement money will provide an immediate boost to states, the most important consideration for any program is a dedication to the plan despite ongoing or rising costs. A public health-centered opioid program must not have an end date and must have a minimum of a five-year funding allowance to get traction. Creating programs to dissolve them within two or three years was the downfall for many states when it came to MSA spending. Also, the lack of commitment or structure to a plan could mean states risk spending huge down payments without a return on investment. Additionally, funding treatment programs can bring hope to individuals and communities, and the dissolution of such programs could cause the public to lose all trust in public officials.

[212] *See infra* Section IV.B.1. (discussing Minnesota's legislative efforts to create a plan for spending the opioid settlement money).

B. Sample Statewide Programs

States involved in the litigation expect a global settlement agreement from the opioid bellwether trials to bring a significant sum of money. As argued above, because the opioid crisis involves the collaboration of numerous agencies and decision-makers, the settlement must impose minimum obligations on the states to effectuate change. States must also establish a public health-driven approach to spending the money to see progress in the opioid epidemic and to avoid repeating mistakes from the MSA.

Additionally, if the settlement money is not directly, through its terms, used for public health purposes, states must have a fallback plan and should dedicate a significant portion of the settlement funds to address the current crisis until certain reduction targets are met. As a result, states need an established multi-step spending plan, and the plans must include perspectives from doctors, patients, and addicts, alike. Further, states must be transparent in their spending and be open to public feedback. As the death toll rises, the consequences of not doing so are too high. While not perfect, the following programs and policies provide examples for states to consider when implementing new legislations or creating public-health programs to resolve the opioid crisis in local communities.

1. Minnesota's Opioid Epidemic Response Law

In 2019, Minnesota's governor Tim Walz signed a landmark piece of legislation, effectively securing a source of funding for the state to tackle the opioid epidemic within the state's boundaries.[213] H.F. No. 400, now titled "Opiate Epidemic Response" bill, requires drug companies to pay $20 million annually through taxes and fees from prescribers, manufacturers,

[213] *See* Opiate Epidemic Response, ch. 63, H.F. 400 (2019).

and distributors, which will go into a separate state revenue fund to provide funding to address the impact of the opioid crisis.[214]

Essentially, the state created this legislation to fund sustainable treatment and opioid services statewide.[215] While Minnesota's policy and program efforts require joint collaboration across several state agencies, the newly created Opioid Epidemic Response Advisory Council oversees the funding.[216] The law provides an option to roll back fees for drug manufacturers depending on the amount of potential settlement money the state of Minnesota could receive.[217] The new law represents the state's strong legislative effort to ensure that the potential opioid settlement will be funneled through a separate state account and will be spent directly on tackling the crisis.

The Opiate Epidemic Response law is not the first action Minnesota has taken to combat the states' opioid crisis. In 2015, the Minnesota Legislature established the Opioid Prescribing Improvement Program (OPIP) to reduce opioid addiction and dependency by Minnesotans.[218] The state recognized that writing a prescription can change a patient's life forever. As it stands, the current proposal states that Minnesota will accomplish a reduction in opioid dependency by

> developing statewide guidelines on appropriate opioid prescribing for acute pain, post-acute pain and chronic pain; developing educational resources for providers for communicating to patients about pain; and implementing a clinical quality improvement program among Minnesota Health Care Program (MHCP)-enrolled

[214] Torey Van Oot, *Minnesota Launches Landmark Opioid Response Law*, STAR TRIB. (July 1, 2019), http://www.startribune.com/minnesota-launches-landmark-opioid-response-law/512088472/.
[215] *Opioid Epidemic Response Advisory Council*, MINN. DEP'T HUM. SERVS., https://mn.gov/dhs/opioids/oer-advisory-council.jsp (last visited Nov. 11, 2019).
[216] *Id.*
[217] *Id.*
[218] MINN. DEP'T HUM. SERVS., LEGIS. REP., OPIOID PRESCRIBING IMPROVEMENT PROGRAM (2020).

providers whose prescribing behaviors are found to be outside of community standards.[219]

To follow through on the OPIP, the Minnesota Department of Human Services and the Department of Health created the Opioid Prescribing Work Group (OPWG) to formulate prescribing protocols and pain prescribing guidelines.[220]

2. Florida's Opioid Response Project

Since the year 2000, Florida's opioid overdose rate tripled, causing state officials to better understand the need for change in prescribing habits and understand the public health implications of the opioid epidemic.[221] In 2019, Florida Governor DeSantis received $26 million in federal funding for Florida's State Opioid Response Project (SOR)—a program administered through Florida's Office of Substance Abuse and Mental Health to provide comprehensive opioid abuse prevention.[222] This program is "designed to address the opioid crisis and reduce opioid-related deaths by providing a comprehensive array of evidence-based prevention, medication-assisted treatment (MAT), and recovery support services."[223]

In the proposal for grant funding, Florida outlined plans for how the state would use the funding.[224] The plans included hiring a full-time project director to oversee the Opioid Response Project, education for middle and high school students in rural areas,

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[219] *Id.* at 4.
[220] *Id.* at 9.
[221] *Florida Drug Overdose Surveillance and Epidemiology (FL-DOSE)*, FLA. DEP'T HEALTH, http://www.floridahealth.gov/statistics-and-data/fl-dose/index.html (last visited Nov. 11, 2019).
[222] *Florida's State Opioid Response Project*, FLA. DEP'T CHILD. & FAMILIES, https://www.myflfamilies.com/service-programs/samh/opioidSTRP.shtml (last visited Nov. 11, 2019).
[223] *Id.*
[224] *See Florida's Opioid State Targeted Response Project*, FLA. DEP'T CHILD. & FAMILIES, https://www.myflfamilies.com/service-programs/samh/docs/opioid/Florida%20STR%20Project%20Narrative.pdf.

and data analysis and research.[225] However, the majority of spending will be used for methadone maintenance to help those already addicted to overcome their addiction and to reduce opioid-related deaths.[226]

Though similar programs focused on opioid prescription management, Florida has seen great success in opioid-related mortality. Through targeted efforts on preventing excessive prescribing by physicians, Florida witnessed a fifty percent decrease in oxycodone overdose deaths.[227] Of course, as argued above, opioids do have a public health benefit, and prescription management can be a difficult measure of success because many individuals suffering from chronic pain need to maintain access to prescription opioids.[228] Some have argued that Florida's program, among other prescription reduction programs, is too strict, leaving chronic pain and cancer patients without necessary pain medications.[229] Thus, reducing access to opioids is perhaps not always the best solution.

While the Florida' State Opioid Response Project does not include language about how potential settlement may impact funding, the plan shows, for the first time in many years, a progressive effort by the state's policy makers to combat the opioid crisis that has long impacted their state. Therefore, a potential opioid settlement could positively impact

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[225] *Id.* at 1.
[226] *Id.*
[227] *State Successes*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/policy/successes.html (last visited Nov. 10, 2019).
[228] *See* discussion *supra* Section III.C.
[229] *See* 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, 12 (2016) (describing how negligent prescribing habits by some physicians have left others nervous to prescribe opioids to treat pain despite the fact that "[p]hysicians have an obligation to treat pain, and opioids remain one of the most broadly effective medications for many types of pain . . . .").

current efforts by providing the necessary ongoing funding that state opioid programs need. Given the states' recent efforts, it is likely that the state would be supportive of strict settlement language that could funnel massive amounts of funding directly to the state's opioid response fund.[230]

V. CONCLUSION

As with most public health issues, the current opioid epidemic did not happen overnight. What we see today is the progression of a severe health crisis—fueled and funded by drug manufacturers and physicians—from a "supposedly harmless" painkiller to a substance known as black tar heroin which is an opiate drug made by processing morphine from plants.[231] However, addiction to the legal painkiller or the illegal street drug, the outcome in many opioid addiction cases is death from an overdose.

Over the last thirty years, the opioid issue has appeared in three waves, from overprescribing legal OxyContin® to street manufactured fentanyl overdoses we see today.[232] The shifting landscape of the opioid crisis often came from drastic government responses to the issue, such as immediate prohibitions or restrictions on pain medications.[233] While there are no easy answers or solutions to this crisis, nor is there one party to blame for the widespread

[230] Florida's State Opioid Response Project is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). *See Florida's Opioid State Targeted Response Project*, *supra* note 222. Because SAMHSA is a federal agency within the U.S. Department of Health and Human Services, the funding would likely be directed to Florida's general fund. However, as argued in Section IV.A, even funding sent directly to a state general fund could include mandated spending requirements. Alternatively, Florida policy makers could consider enacting legislation effectively creating a separate fund for opioid settlement money.
[231] *See* DRUG ENFORCEMENT AGENCY, HEROIN, HTTPS://WWW.DEA.GOV/TAXONOMY/TERM/441.
[232] *Supra* Section II.
[233] *See supra* Section II.A.

substance use disorder of opioids in the United States, the current opioid litigation and potential settlement creates an opportunity for states to implement necessary policy changes.

Although large scale litigation in response to public health crises is not a new phenomenon, the government's response has historically neglected to implement strategies to combat the crisis. For example, lack of uniformity and requirements in the tobacco MSA of 1998 resulted in states spending large sums of settlement money with no strings attached.[234] The MSA presented an opportunity for the states to fund tobacco control efforts, but states mostly failed to take advantage of the outcome.

The current opioid litigation shares many similarities to the tobacco litigation of the 1990s. First, the legal theories and foundation for the range of claims are based on a nearly identical argument: the government is spending billions to address a problem that is caused, in part, by the defendants.[235] Additionally, the parties for both the tobacco litigation and the multistate opioid lawsuit are comprised of similar governmental entities.[236]Like the MSA, the potential opioid settlement could also bring a large influx of secured funding to states and create an opportunity for a public health response to the opioid crisis and allow for an immediate surge of funding for such programs.

However, there are crucial differences between the MSA and the opioid litigation. Perhaps most importantly, opioids serve a purpose in the health care system. Chronic pain and cancer pain are terrible things to endure, and the effects of such pain on a person cannot be

[234] *See supra* Section III.A.
[235] *See supra* Section II.C; *see also supra* Section III.A.
[236] Private attorneys also pursue the claims on a contingency fee basis. For a full list of named defendants, see *In re* Nat'l Prescription Opiate Litig., 290 F. Supp. 3d 1375, 1380–82 (J.P.M.L. 2017).

understated. Prescription opioids can help a person suffering from such pain, and thus, should not be eliminated from a physician's arsenal of possible prescription medications for patients.[237]

While alternative pain medications and awareness campaigns could help prevent addiction in new and existing patients, the reality is that opioids are here to stay. Therefore, the best option is direct spending toward a multifaceted public health approach to help those already addicted, prevent future opioid addiction, and to eliminate the stigma surrounding addiction, among other needs.

The MSA set the groundwork for how a multistate settlement effort could be created. Yet, mistakes were certainly made. Because the MSA did not mandate state spending, states did not spend the settlement primarily on tobacco control efforts. This opioid litigation presents a chance to learn from those mistakes. To break the cycle of opioid addiction and truly create change in communities, states must do better this time around.

[237] *See supra* Section III.C.