No. 1:17-MD-2804

United States District Court
Northern District of Ohio

In Re: National Prescription Opiate Litigation

Brief of Amici Curiae in Support of Settlement with Favorable Public Health Outcomes

Brief of Amici Curiae

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Public Health Law Watch

May 3, 2019

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BRIEF OF *AMICI CURIAE*
PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF SETTLEMENT WITH FAVORABLE PUBLIC HEALTH OUTCOMES

Amici Curiae appear in this proceeding as genuine friends of the court. The parties to this brief have no stake in any of the arguments presented herein, nor do they take a position on any pending motions in bellwether cases. Rather, we come before the Court in support of its expressed wish that any settlement in this litigation includes measures to "do something meaningful to abate this crisis" and reduce its adverse public health impact rather than simply "moving money around." Transcript of Record at 416, In Re: National Prescription Opiate Litigation, MDL No. 2804, No. 1:17-CV-2804 N. Dist. Ohio (Jan. 9, 2018)[1]

The *amici* are nonprofit public health organizations or university-affiliated institutes dedicated to protecting and improving the public's health, and are profoundly concerned about the acute and likely chronic public health crisis attributable to opioid

[1] Jan Hoffman, *Can This Judge Solve the Opioid Crisis?*, N.Y. TIMES, Mar. 5, 2018, https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html.

addiction. It is our wish to discuss possible approaches the Court may consider that are informed by our experiences as researchers and practitioners.

Interests of Amici Curiae

The Center for Public Health Law Research at Temple University conducts and provides technical assistance for research that evaluates the implementation and impact of health laws. Staff has many years' experience mapping and analyzing state opioids policies.

ChangeLab Solutions works across the nation to advance equitable laws and policies that ensure healthy lives for all. We prioritize communities whose residents are at highest risk for poor health. Our interdisciplinary team of lawyers, planners, policy analysts, and more, works with neighborhoods, cities, and states to create thriving communities.

Health in Justice Action Lab is an interdisciplinary think tank based at Northeastern University. The Lab's portfolio focuses on advancing data-driven solutions to address today's overdose crisis. The statements expressed in this brief do not necessarily represent the views of any individuals or organizations affiliated with Health in Justice.

The **Network for Public Health Law** provides legal technical assistance along with resources and training to public health officials, practitioners, advocates and attorneys to enable them to make full use of the law as a tool to improve health outcomes. While organizations and individuals committed to improving public health can join the Network, the views expressed in this brief are solely those of Network staff and may not represent those of any affiliated individuals or institutions.

Through teaching, research, and engagement with key decision makers, **Northeastern University's Center for Health Policy and Law** promotes innovative solutions to public health challenges at home and around the globe. The Center advances law and policy reforms to strengthen population health, reduce health disparities, nourish public health programs, and enhance access to affordable, high-quality health care. Housed in the School of Law and firmly rooted in the University's nine academic colleges and its international network, the Center brings together Northeastern faculty, students, and experts across disciplines to share knowledge; conduct and disseminate research; and influence the formulation and implementation of health policy and law. This brief has been joined by the Center for Health Policy and Law at Northeastern University School of Law, but does not present the view of the law school, University, or individual members of the faculty affiliated with the Center.

The Public Health Advocacy Institute ("PHAI") is a nonprofit organization incorporated in Massachusetts in 1979 and based in Boston, Massachusetts. PHAI is a legal research and advocacy center focused on public health issues. It is committed to research in public health law, public health policy development, legal technical assistance, and collaborative work at the intersection of law and public health, including litigation. The present case is of great interest to PHAI because failure to properly remediate the opioid epidemic will have devastating public health consequences. PHAI was actively involved in supporting the cost recovery actions of states against cigarette manufactures that resulted in the Tobacco Master Settlement Agreement ("MSA") in 1998 and has evaluated the public health impact of that settlement.[2]

[2] *See*, *e.g.*, Richard Daynard, Wendy Parmet, Graham Kelder & Patricia Davidson, *Implications For Tobacco Control Of The Multistate Tobacco Settlement*, 91(12) AM. J. PUB. HEALTH 1967 (2001); Richard

The **Public Health Law Watch ("PHLW")** is a project of the George Consortium, a nationwide network of over sixty public health law scholars, academics, experts, and practitioners who are dedicated to advancing public health through law. PHLW's goal is to increase visibility and understanding of public health law issues and changes, identify ways to engage on these issues, and provide legal analysis and commentary. The statements expressed in this brief do not necessarily represent the views of any individuals or institutions affiliated with PHLW.

Daynard, *Why Tobacco Litigation? Just How Important Is Litigation In Achieving The Goals Of The Tobacco Control Community?* 12(1) TOBACCO CONTROL 1 (2003); Michele Bloch, Richard A. Daynard & Ruth Roemer, *A Year of Living Dangerously: The Tobacco Control Community Meets the Global Settlement*, 113(6) PUB. HEALTH REP. 488 (1998).

Argument Presented

Invariably, when scholars have examined the opioid crisis and how to effectively address it, they have compared it with the tobacco epidemic and the remedies applied in that context.[3] The implementation of the 1998 Master Settlement Agreement ("MSA") between states and cigarette manufacturers offers valuable lessons into how an MDL settlement can be structured to ensure it has a meaningful restorative impact on the opioid crisis. Although the legal and public health issues raised by the MSA and the MDL are not identical, there is significant overlap, including the number of claims, the role of addiction, the magnitude of the injuries, the involvement of profitable product industries, and the complexity of resolving the health harms. There are also notable differences that must be taken into account when structuring the MDL settlement.

This brief will first provide an overview of the MSA and identify three central lessons learned from its implementation. Next, it will detail key differences between tobacco and opioids that must be considered when drafting MDL settlement provisions. The brief will then describe four key elements of a remedial response that must be addressed in order to plan a truly constructive response to the crisis. Finally, the brief will propose the creation of a nonprofit foundation to (a) monitor implementation of the settlement; (b) participate in implementing programmatic initiatives; and (c) administer a funding mechanism to encourage the best use of resources for treatment and prevention at the community level.

[3] *See* Derek Carr, Corey S. Davis & Lainie Rutkow, *Reducing Harm Through Litigation Against Opioid Manufacturers? Lessons From The Tobacco Wars*, 133(2) PUB. HEALTH REP. 207 (2018); Abbe R. Gluck, Ashley Hall & Gregory Curfman, *Civil Litigation and the Opioid Epidemic: The Role of Courts In A National Health Crisis*, 46(2) J. OF LAW, MED. & ETHICS 351 (2018); Edgar Aliferov, *The Role of Direct Injury Government Entity Lawsuits in the Opioid Litigation*, 87 FORDHAM L. REV. 1141, 1181-1183 (2018); Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J MED. 2301 (2017); Nicolas P. Terry, *The Opioid Litigation Unicorn,* 70 S.C. L. REV. 637 (2019).

I. Master Settlement Agreement with Cigarette Manufacturers: An Overview, and Lessons Learned

The MSA derived from litigation brought by the states against cigarette manufacturers in the 1990s. When the first state claim was filed, no cigarette manufacturer had ever lost a lawsuit. Ultimately, 46 states (and 5 territories) participated in a Master Settlement Agreement ("MSA"),[4] which was executed on November 23, 1998 with the major cigarette companies and subsequently with numerous smaller manufacturers (collectively known as "Participating Manufacturers" or "PMs"). The settlement resulted in over $125 billion of actual payments from cigarette manufacturers to the states from 1999 to 2018.[5]

Now, after twenty years of MSA payments, researchers have a clear understanding of the MSA's efficacy, including which provisions were beneficial to public health, and which proved ineffective.[6] Most notably, the payment structure, which paid settlement money to the states, failed to adequately address public health issues, as states used only a small fraction of the payments for public health purposes.[7] However, the creation of an

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[4] 1998 Master Settlement Agreement, https://www.publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf. Mississippi, Florida, Texas, and Minnesota, having settled earlier, did not participate.

[5] *Payments To States Inception Through July 19, 2018*, National Association of Attorneys General Tobacco Project, http://www.naag.org/assets/redesign/files/Tabacco/2018-07-25__Payments_to_States_Inception_through_July_19_2018.pdf.

[6] *See* Walter J. Jones & Gerard A. Silvestri, *The Master Settlement Agreement and Its Impact on Tobacco Use 10 Years Later: Lessons for Physicians About Health Policy Making*, 137(3) CHEST 692 (2010); Monique E. Muggli, Howard M. Crystal, & Kim Klausner, *Transparency as a remedy against racketeering: preventing and restraining fraud by exposing Big Tobacco's dirty secrets,* 24(5) TOBACCO CONTROL 514 (2015). *See also* CARR, *supra* note 3.

[7] JONES AND SILVESTRI, *supra* note 6; TERRY, *supra* note 3 at 648. Although there were no explicit statements in the MSA directing the funds to be used for a particular purpose, the language of the MSA recitals suggested the intention was to use the funds for public health.

> WHEREAS, the Settling States and the Participating Manufacturers wish to avoid the further expense, delay, inconvenience, burden and uncertainty of continued litigation (including appeals from any verdicts), and, therefore, have agreed to settle their respective lawsuits and potential claims pursuant to terms which will achieve for the Settling States and their citizens significant funding for the advancement of public health, the implementation of important tobacco-related

independent foundation and the implementation of transparency rules conferred concrete benefits to public health.[8] The MSA was not nearly as effective of an approach to public health as many had hoped, but the lessons learned during the past two decades can facilitate the drafting and implementation of a successful MDL settlement agreement.

a. States Did Not Utilize Payments to Address Public Health Issues

The MSA experience showed that simply moving money from the defendants to the plaintiffs in this type of third-party addictive product recovery action has a negligible impact on public health. Generally, the states utilized little of their settlement payments to address the underlying public health issues caused by the defendants' products.[9] Perversely, a recent study showed that higher MSA payments were actually associated with *weaker* tobacco control measures; because a state's share of MSA funds was dependent on the number of smokers in the state and its estimated tobacco-related Medicaid expenditures, the MSA did not necessarily discourage diversion of funds to other purposes.[10]

A fundamental reason that MSA funds were not funneled into public health improvements is that funds paid from a settlement to a political entity, whether a state, county, or municipality, are received as general revenue. Appropriations are almost always at the sole discretion of the governmental body that is responsible for budgeting (e.g. the

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> public health measures, including the enforcement of the mandates and restrictions related to such measures, as well as funding for a national Foundation dedicated to significantly reducing the use of Tobacco Products by Youth.

Master Settlement Agreement, *supra* note 4. *See also* Stephen A. Schroeder, *Tobacco Control in the Wake of the 1998 Master Settlement Agreement*, 350(3) N. ENG. J. MED. 293, 295 (2004) ("According to [the late Senator John] McCain, at the time of the settlement there was general agreement that the money would be used 'for tobacco education and treatment of smoking-related illnesses.'").

[8] CARR, *supra* note 3 at 209.

[9] TERRY, *supra* note 3 at 648; JONES AND SILVESTRI, *supra* note 6 at 695-96.

[10] Jayani Jayawardhana, W. David Bradford, Walter Jones, Paul J. Nietert & Gerard Silvestri, *Master Settlement Agreement (MSA) Spending and Tobacco Control Efforts*, 9(12) PLOS ONE 1, 13 (2014).

legislature) and in most instances, there is no simple way to earmark payments for a specific purpose. Moreover, the states and local governments that received the funds are constantly faced with a large number of competing budgetary priorities.[11]

As a result, MSA settlement funds were largely used to address budget gaps instead of funding tobacco control programs.[12] For instance, the state of New York used $700,000 of its settlement money to buy golf carts and irrigation sprinklers for a public golf course.[13] In North Carolina, 75% of MSA revenue was directed to tobacco farmers and tobacco-dependent communities, including money for modernization and marketing: surely, these payments did not reflect the original intent of the attorneys general who negotiated the settlement and the public health advocates who supported it.[14] Several states securitized some or all of their MSA payments, resulting in bond issues for capital projects or debt reduction.[15]

Currently, no state funds tobacco-control programs at CDC-recommended levels.[16] California and Alaska come closest, providing 70% of the recommended funding, while 28 states spend less than 20% of the recommended funds.[17] The Campaign for Tobacco-

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[11] JONES AND SILVESTRI, *supra* note 6 at 695.
[12] Frank A. Sloan, Jennifer S. Allsbrook, Leanne K. Madre, Leah E. Masselink & Carrie A. Mathews, *States' Allocations Of Funds From The Tobacco Master Settlement Agreement*, 24(1) HEALTH AFFAIRS 220 (2005).
[13] Howard Markel, *Burning Money*, N.Y. TIMES, Aug. 22, 2005, https://www.nytimes.com/2005/08/22/opinion/burning-money.html.
[14] INSTITUTE OF MEDICINE, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION, 180 (Richard J. Bonnie, Kathleen Stratton, & Robert B. Wallace, eds., 2007); Jim Estes, *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.
[15] U.S. GOVERNMENT ACCOUNTABILITY OFFICE, STATES' USE OF MASTER SETTLEMENT AGREEMENT PAYMENTS, GAO-01-851 (June 2001), https://www.gao.gov/assets/240/231942.pdf. *See also* Jonathan H. Adler et. al., *Baptists, Bootleggers & Electronic Cigarettes*, 33 YALE J. ON REG. 313, 354 (2016).
[16] Campaign for Tobacco-Free Kids, American Heart Association, American Cancer Society Cancer Action Network, American Lung Association, Robert Wood Johnson Foundation, Americans for Nonsmokers' Rights & Truth Initiative, *Broken Promises to Our Children: A State-by-State Look at the 1998 Tobacco Settlement 20 Years Later*, Dec. 14, 2018, https://www.tobaccofreekids.org/what-we-do/us/statereport.
[17] *Id.*

Free Kids, along with other organizations, has recently noted that in fiscal year 2019, the states will collect over $27 billion from MSA proceeds and tobacco taxes but allocate only 2.4% of that income ($655 million) to tobacco prevention and related public health efforts.[18] In comparison to this $655 million invested in tobacco control efforts, the tobacco companies will spend nearly $10 billion in marketing campaigns and promotions.[19] This unbalanced spending is a truly unacceptable (and avoidable) outcome in the eyes of public health professionals, and is especially egregious given the extremely high return of investment yielded by funding tobacco control, as reflected by dramatically reduced healthcare expenditures.[20]

As demonstrated, the Court's concerns about a settlement that mostly moves money around are well-placed. Key public health gains from the MSA derived not from the payments to the states, but from a) price increases necessitated by the manufacturers' ongoing payment obligations, which led in turn to decreased consumption; b) the establishment of a nonprofit entity to achieve specific public health goals and c) the transparency provided by the availability of internal industry corporate documents.[21] Although as noted below in Section II(c), price increases would be ineffective in the context of opioids, the other two measures would be impactful. The establishment of a nonprofit entity to perform a range of functions precisely tailored to alleviate the opioid

[18] *Id.*
[19] *Id.*
[20] James Lightwood & Stanton A. Glantz, *The Effect of the California Tobacco Control Program on Smoking Prevalence, Cigarette Consumption, and Healthcare Costs: 1989-2008,* 8(2) PLOS ONE 1 (2013); Julia A. Dilley, Jeffrey R. Harris, Michael J. Boysun & Terry R. Reid, *Program, Policy, and Price Interventions for Tobacco Control: Quantifying the Return on Investment of a State Tobacco Control Program*, 102 AM. J. PUB. HEALTH e22, e27 (2012) (finding that over 10 years, the return on investment for Washington State's tobacco program was more than $5 for each $1 spent).
[21] *See* CARR, *supra* note 3 at 209.

crisis would be a powerful way to accomplish public health goals and avoid a settlement that succeeds only in "moving money around."

In an uncertain economy where government budget shortfalls may occur, the temptation to tap into potential liquidity by filling budget gaps or securitizing settlement proceeds can overshadow efforts to address the underlying public health issue. As shown by the history of the MSA, giving settlement money to the plaintiffs provides no guarantee that the funds will be used to minimize the devastating effects of the opioid crisis.

b. MSA Marketing Provisions had Limited Effect

The MSA also contained several marketing restrictions meant to improve public health outcomes. The MSA:

a) Banned the use of cartoons in the advertising, promotion, packaging or labeling of cigarettes;

b) Prohibited targeting youth in advertising, promotions, or marketing as well as actions aimed at initiating, maintaining or increasing youth smoking;

c) Banned most outdoor advertising, including: billboards, signs and placards in arenas, stadiums, shopping malls, and video game arcades as well as transit advertising;

d) Banned the distribution and sale of apparel and merchandise with brand-name logos (e.g., caps, T-shirts, backpacks, etc.); and

e) Banned payments to promote tobacco products in movies, television shows, theater productions or live performances, live or recorded music performances, videos and

video games as well as brand name sponsorship of events with a significant youth audience or team sports (football, basketball, baseball, hockey or soccer).[22]

While the marketing restrictions may have produced some benefits to public health, these benefits were likely not fully realized, as the restrictions were neither followed to the letter nor in spirit. Public health advocates and attorneys general have repeatedly had to bring costly litigation and enforcement actions against the MSA settling defendants for violations of these provisions.[23]

Additionally, many provisions contained loopholes[24] that, for example, allowed settling defendants to simply shift marketing expenditures from billboards to point-of-purchase advertising.[25] Even when the defendants have observed the letter of the MSA, they have often violated its spirit of protecting children from taking up smoking, particularly through their advertising campaigns targeting youth[26] and point-of-sale marketing tailored to attract underage purchasers.[27] The judge in the federal civil

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[22] Master Settlement Agreement, *supra* note 4. *See also* PUBLIC HEALTH LAW CENTER, THE MASTER SETTLEMENT AGREEMENT: AN OVERVIEW (2018), https://publichealthlawcenter.org/sites/default/files/resources/MSA-Overview-2018.pdf.

[23] *See, e.g.*, *Washington v. R.J. Tobacco Company*, 211 P.3d 448 (Wash. Ct. App. 2009) (finding R.J. Reynolds liable for using cartoons and brand-name merchandise to market Camel cigarettes in violation of MSA in suit brought by Washington and seven other states); *Vermont v. R.J. Reynolds Tobacco Co.*, 2013 Vt. Super. LEXIS 15 (ordering RJR to pay more than $8.3 million in civil penalties for violating the Vermont consumer fraud act, the MSA and a related consent decree for deceptive advertising of its Eclipse cigarette brand in a suit similar to one filed by four other states); *People ex rel. Lockyer v. R.J. Reynolds Tobacco Co.*, 11 Cal. Rptr. 3d 317 (Cal. Ct. App. 2004) (upholding trial court award of $14.8 million fine against R.J. Reynolds for distributing free samples of cigarettes to minors at six outdoor events in 1999).

[24] DAYNARD, *supra* note 2 at 1969.

[25] Melanie A. Wakefield, Yvonne M. Terry-McElrath, Frank J. Chaloupka, Dianne C. Barker, Sandy J. Slater, Pamela I. Clark & Gary A. Giovino, *Tobacco Industry Marketing at Point of Purchase After the 1998 MSA Billboard Advertising Ban,* 92(6) AM J. PUB. HEALTH 937 (2002).

[26] John Pierce, Karen Messer, Lisa Vera, Martha M. White, Sheila Kealey, Donna M. Vallone & Cheryl G. Healton, *Camel No. 9 Cigarette-Marketing Campaign Targeted Young Teenage Girls*, 125(4) PEDIATRICS 619 (2010).

[27] Cheryl Bettigole & Thomas A. Farley, *Retail Stores and the Fight Against Tobacco—Following the Money*, 176(10) JAMA INTERN. MED. 1520 (2016); Ellen Feighery, Kurt M. Ribisl, Nina Schleicher, Rebecca Lee & Sonia Halvorson, *Cigarette Advertising and Promotional Strategies In Retail Outlets: Results Of A Statewide Survey In California*, 10(2) TOBACCO CONTROL 184, 187 (2001).

racketeering lawsuit brought against the MSA defendants by the Department of Justice found pervasive and continuing violations of the agreement amounting to a continuing fraudulent enterprise perpetrated upon their customers, and ordered new equitable remedies against the tobacco defendants.[28] The goals of the MSA marketing provisions were not fully achieved, but this brief does not suggest marketing provisions would be ineffective in the MDL; rather, it cautions against relying too heavily upon marketing provisions and encourages examination of potential loopholes.

c. MSA Independent Foundation and Transparency Provisions were Effective

Although the marketing regulations were not as effective as many public health advocates would have hoped, several of the MSA's provisions clearly had a positive effect on tobacco control. The establishment of an independent foundation and the implementation of transparency provisions are regarded as public health successes.[29]

First, and most notably, the MSA required industry funding of $1.7 billion for an independent foundation to carry out a nationwide sustained advertising, research, and education program to discourage youth tobacco use and educate consumers about tobacco-related diseases.[30] These funds established the Truth Initiative (formerly "American

[28] *U.S. v. Philip Morris USA Inc. et al.*, 449 F. Supp. 2d 1 (D. D.C. 2006). *See also* SARA GUARDINO, CHRISTOPHER BANTHIN & RICHARD DAYNARD, THE PUBLIC HEALTH ADVOCACY INSTITUTE, POTENTIAL MASTER SETTLEMENT AGREEMENT VIOLATIONS EVIDENCED IN JUDGE KESSLER'S FINDINGS IN USA V. PHILIP MORRIS USA, INC., ET AL. (2007).

[29] Matthew C. Farrelly, James Nonnemaker, Kevin C. Davis, & Altijani Hussin, *The Influence of the National truth® Campaign on Smoking Initiation,* 36(5) AM. J. PREV. MED. 379 (2009); W. Douglas Evans, Simani Price & Steven Blahut, *Evaluating the truth® brand,* 10(2) JOURNAL OF HEALTH COMMUNICATION 181 (2006); David F. Sly, Richard S. Hopkins, Edward Trapido & Sarah Ray, *Influence of a Counteradvertising Media Campaign on Initiation of Smoking: The Florida "Truth" Campaign,* 91(2) AM. J. PUB. HEALTH 233 (2001); CARR, *supra* note 3 at 209.

[30] U.S. Gen. Accounting Office, *supra* note 15.

Legacy Foundation") and its "Truth" counter-marketing campaign.[31] From 2000 to 2016, tobacco use among teenagers dropped from 23% to 6%.[32] Researchers have concluded the counter-marketing campaign created by the Truth Initiative accounted for a significant percentage of this decline in youth smoking prevalence in the years following the MSA.[33] The Surgeon General has observed that the Truth Initiative "has been a leader in using national mass media to help increase anti-tobacco-related knowledge, attitudes, beliefs, and behaviors among youth and adults."[34]

Second, the MSA required tobacco companies to open, at their expense, a website which includes all documents produced in state and other smoking and health related lawsuits, maintain it for 12 years, and add all documents produced in future civil actions involving smoking and health cases.[35] These documents have been cited to in Congressional hearings on tobacco regulation and in rulemaking, and created the dataset for a significant bibliography of scholarship, including nearly 800 journal articles and 29 full books, which has influenced public health policy for tobacco prevention and beyond.[36] This information has also been used in numerous campaigns for the Truth Initiative;[37]

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[31] CARR, *supra* note 3 at 209.
[32] Business of Giving Podcast, Interview with Robin Koval, President and CEO of the Truth Initiative, https://www.philanthropy.com/resources/audio/podcast-using-tobacco-money-t/6319/.
[33] Matthew C. Farrelly, Kevin C. Davis, M. Lyndon Haviland, Peter Messeri, & Cheryl Healton, *Evidence of a Dose-Response Relationship Between "truth" Antismoking Ads and Youth Smoking Prevalence*, 95(3) AM. J. PUB. HEALTH 425 (2005).
[34] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL, 800 (2014).
[35] This did not include documents as to which defendants made successful claim of privilege, trade-secret protection, confidential or proprietary business information, or inappropriateness for public disclosure to due personal privacy interests or contractual rights of third parties. Master Settlement Agreement, *supra* note 4 Section IV.
[36] Lisa Bero, *Implications Of The Tobacco Industry Documents For Public Health And Policy*, 24 ANN. REV PUB. HEALTH 267 (2003); Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 21 C.F.R. § 1130 (2018); Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018). *See also* Univ. of Cal. San Francisco Library, *Bibliography - Publications based on Truth Tobacco Industry Documents*, https://www.industrydocumentslibrary.ucsf.edu/tobacco/biblio (listing 994 citations Dec. 28, 2018).
[37] *See* Truth, "The Facts," https://www.thetruth.com/the-facts.

Truth's national television advertisements have used this information to expose tobacco companies' predatory targeting of minority communities,[38] people with mental health issues,[39] and the LGBT community,[40] among other revelations.

These important provisions of the MSA may not have been obtainable as the result of equitable relief through the trial courts absent the settlement and its resulting consent decrees. This shows how the crafting of a settlement and related consent decrees has the potential to contribute to public health in a way that litigating to judgment may not. While many individuals and organizations have been disappointed in the outcome of the MSA, especially as it relates to state spending, the settlement certainly demonstrates that important public health gains are achievable, if not always achieved, through settlement of cases of this nature.[41]

II. Key Differences between Tobacco and Opioids

There are important differences to consider between the public health problems attributable to tobacco and those attributable to opioid pain medications. These distinctions demonstrate the necessity for an even more nuanced response to opioid control, as poorly calibrated responses that have slashed access to prescription opioids

[38] "Making Menthol Black," *available at* https://www.youtube.com/watch?v=2LBMriiWiZ8, "Who thinks blacks have low self-esteem?" *available at* https://www.youtube.com/watch?v=sSOAelxtoI0.
[39] "Business or Exploitation? Mental Health," *available at* https://www.youtube.com/watch?v=PiQVg1cFPlE.
[40] "Who thinks gay people are scum?" *available at* https://www.youtube.com/watch?v=hBSM9Bpn31U.
[41] Cheryl Healton, *The Tobacco Master Settlement Agreement – Strategic Lessons For Addressing Public Health Problems*, 379(11) N. ENG. J. MED. 997 (2018); Dearell Niemeyer, Kathleen R. Miner, Lisa M. Carlson, Katie Baer, & Lawrence Shorty, *The 1998 Master Settlement Agreement: A Public Health Opportunity Realized—Or Lost?*, 5(3 Suppl) HEALTH PROMOTION PRACTICE 21S (2004); Bronwyn M. Sinclair-White, Virginia Pressler, Tonya Lowery St. John, Janice Okubo, Katie Richards & Lola H. Irvin, *The Tobacco Settlement Special Fund: How Investments in Prevention Save Lives and Dollars*, 74(4) HAW. J. MED. & PUB. HEALTH 154 (2015).

have in some cases exacerbated the problem they were attempting to fix.[42] The most striking differences are that (a) cigarette use is always harmful, while opioid use constitutes an important (though not risk-free) health care tool; (b) the harms from cigarettes were nearly exclusively caused by the defendants' own products, while the harms from opioids have resulted from both defendant's products and illicitly-manufactured drugs, or combinations of pharmaceutical and black market products; and (c) price increases in cigarettes directly increased costs to individual users, thereby reducing consumption, while price increases in opioids would likely increase costs to insurance companies, as well as the plaintiffs and federal government.

a. Opioids Have Important Therapeutic Benefits

The first key difference between tobacco and opioids is that smoking cigarettes is always harmful, while proper opioid use has therapeutic benefits.[43] While cigarettes are harmful when used as intended, opioid pharmaceutical products are an essential health care tool.[44] Opioids are especially vital in three areas: 1. Short-term treatment of severe acute pain;[45] 2. Sustained treatment of cancer-related pain and end-of-life care[46] and 3.

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[42] Mark A. Rothstein, *The Opioid Crisis and the Need for Compassion in Pain Management,* 107(8) AJPH 1253 (2017). For an analysis of increased opioid purchasing through online illicit marketplaces, *see* James Martin, Jack Cunliffe, David Décary-Hétu, & Judith Aldridge, *Effect of restricting the legal supply of prescription opioids on buying through online illicit marketplaces: interrupted time series analysis*, 361:k2270 BMJ (2018). One study projected that lowering the incidence of prescription opioid misuse alone would decrease overdose deaths by only 3.0% to 5.3%, and concluded a more multifaceted approach is necessary to combat the opioid crisis. Qiushi Chen, Marc R. Larochelle, Davis T. Weaver, et al, *Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States,* 2(2) JAMA NETWORK OPEN (2019). *See also* Allison L. Pitt, Keith Humphreys, Margaret L. Brandeau, *Modeling Health Benefits and Harms of Public Policy Responses to the US Opioid Epidemic,* 108(10) AJPH 1394 (2018).

[43] CARR, *supra* note 3 at 210.

[44] ROTHSTEIN, *supra* note 42.

[45] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 53 (The National Academies Press, 2017).

[46] *Id* at 62; Phillip J. Wiffen, Bee Wee, Sheena Derry, Rae F. Bell & R. Andrew Moore, *Opioids for cancer pain – an overview of Cochrane reviews,* COCHRANE DATABASE OF SYSTEMATIC REVIEWS (2018). *See*

Sustained treatment of opioid use disorder (OUD) with opioid maintenance medications, including methadone and buprenorphine.[47] Because of this crucial difference between opioids and smoking tobacco products, marketing and supply-reduction measures must be carefully calibrated to restrict inappropriate access while maintaining appropriate level of needed access.[48] Aside from possibly causing unnecessary suffering, if patients are unable to legitimately obtain prescription opioids for pain or OUD management, they may turn to nonprescription black market opioids, vastly increasing their risk of overdose morbidity and mortality.[49]

b. Large Market for Illicit Opioids

The second key difference between tobacco and opioids is the existence of a large black market for opioid products not produced by defendants.[50] There is no comparable black market for tobacco products. While an individual's opioid addiction may have originated with use, misuse, or diversion of defendants' opioid pain medications, addiction may be maintained or overdoses may be triggered by a range of opioid products including Schedule I opioids sold on the street such as heroin and illicit fentanyl.[51] At this time in our nation's overdose crisis, only about one third of overdoses involve an opioid including

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World Health Organization, "WHO's cancer pain ladder for adults," https://www.who.int/cancer/palliative/painladder/en/.

[47] Substance Abuse and Mental Health Services Administration, "Medication and Counseling Treatment," https://www.samhsa.gov/medication-assisted-treatment/treatment; Marc A. Schuckit, *Treatment of Opioid-Use Disorders,* 375 N. ENG. J. MED. 357, 360 (2016); Joycelyn Sue Woods & Herman Joseph, *From Narcotic to Normalizer: The Misperception of Methadone Treatment and the Persistence of Prejudice and Bias,* 53:2 SUBSTANCE USE AND MISUSE 323 (2017).

[48] ROTHSTEIN, *supra* note 42.

[49] ROTHSTEIN, *supra* note 42; Theodore J. Cicero, Matthew S. Ellis & Zachary A. Kasper, *Increased use of heroin as an initiating opioid of abuse,* 74 ADDICTIVE BEHAVIORS 63 (2017). *See* CHEN, *supra* note 42.

[50] U.S. DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION, 2018 NATIONAL DRUG THREAT ASSESSMENT, https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20final%20low%20resolution.pdf.

[51] Stefan G. Kertesz, *Turning the tide or riptide? The changing opioid epidemic*, 38(1) SUBST. ABUSE 3, 5 (2016); ROTHSTEIN, *supra* note 42.

prescription opioids.[52] As stated in the above Section II(a), extremely strict prescribing rules would likely be ineffective, as patients unable to access prescription opioids for their pain may turn to high-risk illicit street drugs instead, for which there is a thriving, widely-accessible market.[53] Additionally, it is important to note marketing restrictions akin to those in the MSA would be unlikely to have a meaningful impact on the illicit market that now drives much of the crisis' continuing impact on public health.[54]

c. Opioid Price is Distorted by Insurance Market

The third key difference between tobacco and opioids is that the insurance market distorts the price of opioids. There is no similar market distortion for the price of tobacco. Goals of the MSA included reducing demand for cigarettes by increasing product prices through defendants passing settlement costs to consumers in a manner similar to an excise tax.[55] However, an increase in the price of prescription opioids would likely result in higher costs to insurance companies, with a far smaller increase passed along to consumers. Additionally, even to the extent that opioid costs *do* affect the prices for individual consumers, this could increase the number of consumers seeking pain relief through illicit street opioids, as detailed in the preceding paragraph.[56]

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[52] Lawrence Scholl, Puja Seth, Mbabazi Kariisa, Nana Wilson & Grant Baldwin, *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017,* 67(5152) CDC MORBIDITY AND MORTALITY WEEKLY REPORT 1419 (2019), https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w.

[53] KERTESZ, supra note 51 at 7; CICERO, *supra* note 49. For a detailed analysis of the market for illicit opioids, *see* 2018 NATIONAL DRUG THREAT ASSESSMENT, *supra* note 50, 11-37.

[54] *See* CHEN, *supra* note 42.

[55] Frank A. Sloan & Justin G. Trogdon, *The Impact of the Master Settlement Agreement on Cigarette Consumption*, 23(4) J. POL'Y ANALYSIS & MGMT. 843, 844 (2004).

[56] PITT, *supra* note 42; Austin Frakt, *The Opioid Dilemma: Saving Lives in the Long Run Can Take Lives in the Short Run,* N.Y. TIMES, March 4, 2019. *See also* KERTESZ, supra note 51 at 7.

The relationship between the crisis and the pharmaceutical products at issue is complex, and there is a high risk of unintended consequences[57] that was not present in the context of the MSA. These significant distinctions from the facts underlying the MSA suggest the importance of a nuanced approach that considers the complexities raised by an enormous and independent illicit opioid market. Poorly-calibrated interventions that simply slash access to prescription opioids are not helpful, and are likely harmful. Proper controls are necessary, but the proper controls for opioids will be distinct from and far more surgical than the tobacco controls deployed by the MSA. A nonprofit foundation with public health expertise, specifically opioid expertise, would be best positioned to navigate these problems and effectively implement the nuanced approach necessary for actual harm reduction.

III. Key Elements of a Remedial Response to the Opioid Crisis

The CDC reported that in 2017, 70,237 Americans died from drug overdose, and of those, 47,000 from opioids.[58] The report also stated 11.1 million people reported misusing prescription opioids, and 2.1 million people suffered from opioid use disorder that year.[59]

Expanded availability and aggressive marketing of prescription opioids helped to ignite the overdose crisis, but the crisis has evolved such that an exclusive focus on suppressing medication supply would be misguided and ineffective.[60] In order to

[57] *See* KERTESZ, *supra* note 51.
[58] U.S. Dept. of Health and Human Services, "Naloxone: The Opioid Reversal Drug that Saves Lives," https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf
[59] *Id.*
[60] Nabarun Dasgupta, Leo Beletsky, & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108(2) AM. J. PUB. HEALTH 182 (2018).

remediate the crisis, any approach must factor in four issues. First, it must improve access to evidence-based addiction and overdose treatment, including medication-assisted treatment and overdose reversal drugs. Second, it must improve access to effective pain management. Third, it must address the root causes of substance use and overdose, and refer back to them when constructing and implementing its plan. Finally, it should publicize defendants' internal documents. The approach should allow for adaptability as further evidence on approach efficacy accumulates.

a. Improve Access to Addiction Treatment and Overdose Reversal Drugs

Access to addiction treatment is lacking and urgently needs expansion. Although medication-assisted treatment and overdose-reversal drugs are proven lifesavers, there exists a significant gap between need and availability.

Because opioid use disorder (OUD) and addiction is driving the overdose epidemic, improving access to proven addiction treatments is an obvious necessity for any plan to confront the crisis.[61] Opioid medications methadone and buprenorphine have been proven effective in treating OUD.[62] Studies have shown that maintenance care with these medications reduces mortality in people suffering from OUD by 50-80%.[63] However, access to medication-assisted treatment remains limited, in substantial part as a result of

[61] Nora D. Volkow, Thomas R. Frieden, Pamela S. Hyde & Stephen S. Cha, *Medication-Assisted Therapies – Tackling the Opioid-Overdose Epidemic*, 370 N. ENGL. J. MED. 2063 (2014). *See also* KERTESZ, *supra* note 51.

[62] Richard P. Mattick, Courtney Breen, Jo Kimber, & Marina Davoli, *Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence,* 3 COCHRANE DATABASE OF SYST. REV. (2009) (finding "[m]ethadone appeared statistically significantly more effective than non-pharmacological approaches in retaining patients in treatment and in the suppression of heroin use").

[63] Amy Gibson, Louisa Degenhardt, Richard P. Mattick, Robert Ali, Jason White, & Susannah O'Brien, *Exposure to opioid maintenance treatment reduces long-term mortality,* 103(3) ADDICTION 462 (2008).

legal barriers both at the federal and state level.[64] Policy and regulatory obstacles, combined with and partially due to misinformation and stigma surrounding medication-assisted treatment, have caused access to remain at an unacceptably low level.[65] For instance, sixteen states, including West Virginia and Kentucky, prohibit Medicaid coverage of methadone maintenance, and privately insured patients can also experience difficulty getting coverage due to preauthorization decisions.[66]

Paradoxically, some of the same aggressive marketing techniques that helped to spark the overdose crisis are now being used by other pharmaceutical companies to profit from it. There are concerns about the aggressive marketing and high cost of the addiction treatment drug Vivitrol, which is both less effective and less cost-effective than the other medication options.[67] Naloxone, the opioid overdose antidote, is another crucial part of opioid response. However, pharmaceutical companies seem to be taking advantage of the opioid overdose crisis, as naloxone prices have skyrocketed. From 2006 to 2017, the price of naloxone has raised precipitously, from 244% to 3797% depending on the specific product.[68] A CBS 60 Minutes investigation showed that Kaleo's Evzio injector contained only a few cents worth of naloxone.[69] Initially, the injector was priced at $575 but the manufacturer later raised the price to $4,000.[70] However, the public bears the brunt of the

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[64] *See* Rebecca L. Haffajee, Amy S.B. Bohnert & Pooja A. Lagisetty, *Policy Pathways to Address Workforce Barriers to Buprenorphine Treatment*, 54(6) AMER. J. PREV. MED. S3280 (2018). *See also* KERTESZ, *supra* note 51.
[65] VOLKOW, *supra* note 61 at 2064-65.
[66] DASGUPTA, *supra* note 60 at 184-85.
[67] Abby Goodnough & Kate Zernike, *Seizing on Opioid Crisis, a Drug Maker Lobbies Hard for its Product,* N.Y. TIMES, June 11, 2017.
[68] Matthew Rosenberg, Grace Chai, Shekhar Mehta, & Andreas Schick, *Trends and economic drivers for United States naloxone pricing*, *January 2006 to February 2017*, 86 ADDICTIVE BEHAVIORS 86 (2018).
[69] Lesley Stahl, *Evzio: The Overdose-Reversal Drug with a $4000+ Price Tag*, CBS NEWS, https://www.cbsnews.com/news/evzio-the-opioid-overdose-reversal-drug-naloxone-with-a-4000-price-tag-60-minutes/.
[70] *Id.*

cost: the majority of revenue from Evzio comes from Medicare, which has paid out more than $142 million for the drug in the last four years.[71]

In addition to being overpriced, naloxone is also underprescribed. Patients who are prescribed opioids and have a high risk of addiction or overdose would lessen their risk of overdose by being prescribed naloxone simultaneously with the opioids.[72] According to the Department of Health and Human Services, less than 1% of at-risk patients receive a prescription for naloxone.[73]

b. Improve the Regulation of Pain Management

Although poorly tailored restrictions on opioid prescription practices may be counterproductive, driving more patients to illicit drugs while leaving other patients with inadequate pain control, more hands-on involvement by physicians prescribing opioids could stem prescription opioid abuse and overdose.[74] For example, more patient counseling regarding opioid risks and safety measures could be included as part of doctors' typical standard of care.

The exploration of additional options for pain management would also be beneficial. Although a multidisciplinary approach to chronic pain reduction can be highly effective in relieving pain, only 200,000 people are enrolled in such a program, as only large medical centers provide the service and third-party payers find them too expensive.[75] Additionally, many patients are never informed of non-pharmacologic pain management

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[71] *Id. See also* U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, MAJORITY AND MINORITY STAFF REPORT - COMBATTING THE OPIOID CRISIS: THE PRICE INCREASE OF AN OPIOID OVERDOSE REVERSAL DRUG AND THE COST TO THE U.S. HEALTH CARE SYSTEM (2018).
[72] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *supra* note 58.
[73] *Id.*
[74] Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106(8) AM. J. PUB. HEALTH 1365, 1366 (2016). *See also* KERTESZ, *supra* note 51 at 6 (urging "[i]ndividualized, patient-centered decision-making").
[75] MELDRUM, *supra* note 74 at 1365.

options like transcutaneous electrical nerve stimulation (TENS) units, which have been found effective for relieving both chronic and acute pain.[76]

Finally, the development of a national counter-detailing program to provide healthcare providers with education and training surrounding opioid risks and benefits, best prescribing practices, alternative pain management treatments, and addiction care, would be an important element of a remedial response. Detailing refers to the activities of pharmaceutical sales representatives promoting prescription drugs to healthcare providers, including gift-giving and in-office educational visits. A successful counter-detailing program would provide clinicians with data-driven information in a non-commercial environment, and would balance the information given by drug detailers.[77]

c. Address Root Causes of Problematic Substance Use and Overdose

In order to fully address the opioid crisis, a holistic approach that takes into account social and structural drivers of the crisis must be utilized.[78] For many people with opioid use disorder, opioids are used to numb "physical and psychological trauma, concentrated disadvantage, isolation, and hopelessness."[79]

Social and structural drivers include:

- Occupational injuries: People in poorer communities tend to work in jobs with higher physical hazards, leading to more chronic pain conditions.[80]

[76] Josimari M. DSantana, Deirdre M. Walsh, Carol Vance, Barbara A. Rakel, & Kathleen A. Sluka, *Effectiveness of Transcutaneous Electrical Nerve Stimulation for Treatment of Hyperalgesia and Pain,* 10(6) CURR. RHEUMATOL REP. 492 (2008).
[77] Jerry Avorn*, Academic Detailing: "Marketing" the Best Evidence to Clinicians*, 317(4) JAMA 361 (2017).
[78] DASGUPTA, *supra* note 60.
[79] *Id* at 182.
[80] *Id* at 183.

- Criminal records: Having a drug-related criminal record further limits employment opportunities, further increasing stress and hopelessness.[81]
- Childhood trauma: Researchers have discovered strong links between childhood trauma and increased opioid misuse in adulthood.[82]

Additionally, much research remains to be done regarding the connections between opioid misuse and potentially related illness such as obesity and depression.[83]

Introduced in July 2018, Chicago's Narcotics Arrest Diversion Pilot Program is an example of a program that addresses these social and structural issues. Under the program, people arrested for narcotic possession can enter department-approved addiction treatment in lieu of receiving criminal charges.[84] Although it is too soon to comment on the program's efficacy, research has shown that similar programs, like drug courts, which also substitute social services for criminal charges, result in lower rates of substance abuse.[85]

d. Make Defendants' Internal Documents Public

Publicizing defendants' internal documents would be another important component of a remedial settlement. As stated above in Section I(c), the implementation of transparency provisions requiring tobacco companies to publicize their internal discovery documents was crucial to future policymaking, as the documents have been

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[81] *Id.*
[82] *Id* at 184. (citing Kelly Quinn, Lauren Boone, Joy D. Scheidell, Pedrom Mateu-Gelabert, Susan P. McGorray, Nisha Beharie, Linda B. Cottler & Maria R. Khan, *The Relationships of Childhood Trauma and Adulthood Prescription Pain Reliever Misuse and Injection Drug Use*, 169 DRUG ALCOHOL DEPENDence 190 (2016)).
[83] *Id* at 183.
[84] Chicago Police Department, Narcotics Arrest Diversion Pilot Program – 011th District, http://directives.chicagopolice.org/directives/data/a7a57b85-16413ac9-60716-413a-de8a6daa0ab16a25.html?hl=true&fbclid=IwAR0Rt8BDVJ4JBwUGaa4HxXaHLCI0IPaQ7XDCD6pcL0hapnePNjBa3cEGMDo.
[85] Roger H. Peters & Mary R. Murrin, *Effectiveness of Treatment-Based Drug Courts in Reducing Criminal Recidivism,* 52 MENTAL HEALTH LAW & POLICY FACULTY PUBLICATIONS (2000).

cited to in both rulemaking and Congressional hearings; additionally, the documents created the dataset for a significant bibliography of influential scholarship.[86] In the present case, the publication of documents produced by defendants in the MDL would, in addition to influencing policy directly, both facilitate the creation of more addiction-related research and assist with counter-detailing efforts.

As shown in Sections II and III, the opioid crisis is more complex than can be addressed by a "quick fix" solution. A foundation with specialized knowledge of the opioid crisis would be best able to examine the research on addiction treatment and pain reduction through the lens of social and structural drivers, and to develop effective programming in response.

IV. A Proposed Initiative

Amici suggest an approach that establishes and employs a public health-focused nonprofit foundation to coordinate and implement a range of activities to reduce the public health impact of the opioid crisis. The entity would receive funding for its services, research, and other initiatives from the MDL settlement. This approach does not leave plaintiffs with the primary responsibility of fixing the underlying structural problems of the opioid crisis, and is consistent with the lessons learned through twenty years of MSA history, where MSA payments have played little role in reducing or redressing the harms caused by tobacco.

[86] BERO, *supra* note 36.

a. Form of Initiative

One way this entity could be effectively formed is by utilizing the structure of the foundation incorporated into the MSA, the Truth Initiative. Regardless of how it is structured, the proposed remedy will be referred to herein as the "Foundation." Section VI of the MSA describes:

> a charitable foundation, trust or similar organization (the "Foundation") and/or to a program to be operated within the Foundation (the "National Public Education Fund"). The purposes of the Foundation will be to support (1) the study of and programs to reduce Youth Tobacco Product usage and Youth substance abuse in the States, and (2) the study of and educational programs to prevent diseases associated with the use of Tobacco Products in the States.[87]

Because the Truth Initiative was created and chartered for the sole purpose of addressing youth tobacco use, there has not been a high risk of fund diversion. It would be similarly critical for the Foundation to have a clear, limited, and legally binding purpose.

It might be expected that plaintiffs would prefer to use some of the settlement proceeds to conduct their own prevention activities, rather than have those proceeds directed to a third party. The Foundation, unlike plaintiffs, would not be subject to budgetary pressures that could result in a diversion of such funds and would be in a strong position to address the underlying problems that give rise to plaintiffs' claims. To alleviate plaintiffs' concerns, the settlement could require that some percentage of the Foundation's money be directed to plaintiffs' local prevention and treatment programs,[88] or give special consideration to applicants for treatment and prevention program funding that originate from plaintiffs' communities and institutions.

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[87] *See* MSA, *supra* note 4. The "Foundation" ultimately became the American Legacy Foundation, later known as The Truth Initiative.

[88] Micah L. Berman, *Using Opioid Settlement Proceeds for Public Health: Lessons from the Tobacco Experience* 22 (Ohio State Public Law, Working Paper No. 474, 2019).

b. Functions of the Foundation

The recent settlement between Purdue Pharma and the state of Oklahoma was encouraging in that it earmarks part of the settlement to the establishment of a foundation for addiction treatment and research (38%), treatment drugs (7%) and localities (4%). However, *Amici* encourage the creation of a foundation with functions specified in greater detail, and that carries a great assurance that a substantial amount of settlement money goes to direct services and community interventions and support.

The Foundation could serve six distinct functions to advance its mission:

1. Serve as a fiscally-neutral watchdog over the pain management and addiction treatment sector of the U.S. pharmaceutical industry by tracking and reporting on emerging trends in marketing, distribution, adverse events, and other phenomena within the sector that bear on population health. Such research and its dissemination would raise awareness of these trends among the public, policymakers, and other stakeholders.
2. Develop and administer a national evidence-based "counter-detailing" (also known as "academic detailing") program to provide clinicians with medical educational modules or other training where opioid pain medication benefits and risks, alternative pain treatments, addiction care, and other data-driven content is discussed in a non-commercial environment to facilitate adoption or maintenance of best prescribing practices.[89]
3. Support, through funding and education, state-of-the-art programs that seek to (a) provide treatment, (b) deliver support to current users to encourage treatment and

[89] Avorn, *supra* note 77.

reduce risk of overdose, and (c) focus on specific addiction prevention strategies. Such support, provided after careful review and targeting based on need, might include innovative demand and harm reduction efforts, including providing overdose reversal medications, addiction treatment medications and support, recovery assistance, and community educational and organizational prevention programs.

4. Develop, support, and evaluate innovative but yet unproven programs that show promise for reducing the public health toll associated with problematic substance use and overdose and advancing the state of the art in prevention and harm reduction.
5. Educate the public and policymakers at the local, state, and federal levels about data-driven solutions to address the problematic use of opioids and other substances, while assuring access to essential medications for overdose reversal, addiction treatment, and pain care.
6. Support timely evaluation research to assess the implementation and impact of program initiatives, and promote better use of resources based on results.

The Foundation would require a well-defined and transparent structure and method of governance to ensure that resources allocated are carefully and wisely distributed to most effectively address the public health toll of the opioid crisis.

c. Funding Requirements

The Foundation, as envisioned herein, would require substantial resources for operations as well as funding for grant-making to successful local applicants. In envisioning a possible settlement to these cases, we assume that at least some of the

defendants are liable to some of the plaintiffs on the theory that such liable defendants' misconduct and/or defective products were a substantial contributing cause of the expenses and losses plaintiffs have incurred in responding to the opioid epidemic. Alternatively, we allow for the possibility that a settlement structured on terms consistent with such liability might be negotiated without any admission of wrongdoing. Under either assumption, based on the current estimates of plaintiffs' financial injuries, it is likely that the financial aspects of a settlement will be very consequential, reaching into the tens of billions of dollars as a lump sum or perhaps, as in a settlement modeled after the MSA, significant payments in perpetuity.

The economic toll of the opioid crisis in the U.S. ranges from $100 to $500 billion per year by some estimates.[90] The public sector shoulders around 25% of these costs, including treatment, law enforcement, and Medicaid, among other expenses.[91] There are numerous governmental entities and others such as insurers with injuries that are not parties to this MDL seeking damages in other actions not before this court. The annual revenue from sales of prescription opioid medications in the U.S. is, perhaps, about $9 billion/year.[92] Since $100 billion is more than 10 times larger than the $9 billion in sales revenue, it seems unlikely that all current and potential plaintiffs could realize the full value of their claims.

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[90] *Economic Toll Of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, ALTARUM (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001 (estimating opioid crisis has cost an average of $100 billion per year); THE COUNCIL OF ECONOMIC ADVISORS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS (Nov. 2017) (estimating economic cost of opioid crisis was $504.0 billion, or 2.8 percent of GDP in 2015).

[91] Harold A. Pollack, *So Prescription Opioid Disorders are a $78.5 Billion Problem*, 54(1) MED. CARE 899 (2016).

[92] David Crow, *US Seeks A Fix For Its Opioid Addiction*, FINANCIAL TIMES, Sept. 11, 2017, https://www.ft.com/content/4bc03acc-915e-11e7-a9e6-11d2f0ebb7f0.

Despite this inevitable shortfall, *Amici* believe that defendants' revenue is certainly sufficient to fund an initiative that could have a meaningful impact in terms of mitigating future harm related to the opioid crisis and reducing its public health impact, while leaving significant funds to provide some direct compensation to the injured parties to the actions herein. Indeed, a settlement in this MDL may encourage those with substantial claims, whether or not currently in litigation elsewhere, to join in an MDL-led settlement, including its provisions for establishing and funding the initiative described here.

The rough estimates herein are loosely based on federal tax filings for the Truth Initiative, the foundation resulting from the MSA.[93] Likely expenses would include:

1. Sufficient administrative staffing to carry out basic institutional responsibilities. This may require funding leadership positions such as CEO, CFO, and COO.
2. Scientific staff, to ensure that funded programs represent and/or advance the state of the art. This may include development of an external peer review protocol, as appropriate. Scientific and Initiative leadership must be well-qualified to create and disseminate reporting of its findings and summaries of the funded research.
3. Regulatory specialists and policy analysts to gather and analyze data and develop recommendations to enhance regulatory oversight of opioid pain medication ("OPM") manufacturers.
4. Programmatic requirements may very well include:

[93] *See* 2010 990 filing of Truth Initiative (formerly American Legacy Foundation) at: https://truthinitiative.org/sites/default/files/annual_reports/990/LEG-2009-990.pdf (last visited January 8, 2019).

a. Grants for evidence-based programs;

b. Grants for pilot or demonstration programs; and

c. Development and deployment of Continuing Medical Education or other counter-detailing programs.

5. Facilities for operations such as office space, infrastructure, and data access.

Although costs may vary, particularly during initial years of operation, it appears, based on rough estimates, that the proposed Foundation would be adequately funded at a rate of approximately $750 million - $1.25 billion per year.

The goal of a Foundation of this type is to put itself out of business within a decade by contributing toward arresting the opioid crisis and thereby becoming obsolete. The ideal way to phase out the initiative is to set meaningful and transparent public health benchmarks for success, such as lowered rates of overdose and addiction among targeted subpopulations. Tying funding levels to meaningful statistical measures and with a sunset provision for termination of the Initiative when certain benchmarks are reached might be a reasonable approach to know when the Foundation's work is complete.

Conclusion

The public health impact of the injuries alleged in these actions by localities and local institutions continue to radiate to their communities. Any settlement of the claims must actually address this continuing damage to public health.

An independent non-profit entity ("Foundation") should be sufficiently funded through the settlement to:

a. Monitor the pain management and addiction treatment industry and raise awareness of industry trends;

b. Create and conduct a national counter-detailing program to disseminate best practices to clinicians;

c. Fund local evidence-based addiction treatment and overdose prevention programs;

d. Fund pilot programs that show promise and innovation to prevent addiction, treat addiction, and reverse overdoses; and

e. Educate the public and policymakers at the local, state, and federal levels while assuring access to essential medications for overdose reversal, addiction treatment, and pain care.

f. Evaluate the efficacy of program initiatives.

Although opioid addiction will not go away, a better regulatory system, clinical training, and understanding of how to reduce overdose and treat and prevent opioid addiction will result in a vastly improved public health outcome, less injury to the plaintiffs in this MDL and, consequently, less potential liability for the defendants moving forward. Therefore, a significant and meaningful public health commitment is urgently needed and should be a core principle of any settlement to the pending litigation.

Respectfully submitted,

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