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**HYPOTHESIZING A SMALL OPIOID MDL SETTLEMENT: AN
ARGUMENT FOR LOCAL PUBLIC HEALTH ACTION AND
LESSONS FROM BIG TOBACCO**

ABSTRACT

*In response to the opioid epidemic, counties and cities across the United States waged *In re: National Prescription Opiate Litigation*, better known as the opioid MDL, against manufacturers and distributors of opioids. The county and city plaintiffs appear to have taken their litigation strategy straight from Big Tobacco playbook of the 1990s. This is to the great disdain of state attorneys general, who fronted Big Tobacco litigation with state-sponsored *parens patriae* litigation.*

The state attorneys general vehemently assert that the MDL claims are the province of state governments rather than local governments. However, the attorney general-led Big Tobacco litigation of the 1990s left much to be desired. While the states were able to procure a \$206 billion tobacco Master Settlement Agreement in 1998, a seemingly enormous win for tobacco victims, the state attorneys general allocated a devastatingly low amount of the proceeds to the intended purposes of smoking cessation programs and public health initiatives. Just like Big Tobacco litigation, a global opioid settlement purported to resolve the MDL claims seems inevitable—and states are eager to undermine local efforts in reaching a settlement.

This Note argues that state attorneys general should not be permitted to overthrow settlement negotiations in the county-and-city-led opioid MDL, positioning that counties and cities are better suited than states to implement evidence-based public health initiatives in their own communities. Spending shortfalls of the Master Settlement Agreement demonstrate precisely why allocating settlement money to the states guarantees little to no spending accountability. This Note further identifies three reasons why, despite many similarities in the litigation tactics between tobacco and opioids, a global opioid settlement agreement will be far smaller than the \$206 billion tobacco Master Settlement Agreement of 1998. Therefore, a smaller settlement would be best utilized by apportioning settlement proceeds directly to the local governments, which are the most impacted by the opioid epidemic.

I. INTRODUCTION

What's happening in our country with the opioid crisis is present and ongoing. I did a little math. Since we're losing more than 50,000 of our citizens every year, about 150 Americans are going to die today, just today, while we're meeting. And in my humble opinion, everyone shares some of the responsibility, and no one has done enough to abate it. That includes the manufacturers . . . the doctors, the federal government and state government, local hospitals, third-party payors, and individuals. . . . So my objective is to do something meaningful to abate the crisis and to do it in 2018.¹

On December 12, 2017, the panel for multidistrict litigation created *In re: National Prescription Opiate Litigation* (the opioid MDL) by transferring sixty-four personal injury cases against opioid manufacturers and distributors to Judge Dan Polster in the United States District Court for the Northern District of Ohio.² These consolidated cases turn on theories that (1) opioid manufacturers, namely Purdue Pharma, the manufacturer of OxyContin, misrepresented the addictive nature of long-term opioid use for persons with chronic pain, and (2) opioid distributors failed to adequately monitor suspicious orders of opioids.³ By September 2019, the opioid MDL had expanded to include over 2,500 individual lawsuits filed by United States counties and cities against manufacturers, distributors, and pharmacies.⁴

Judge Polster's goal is for the parties to reach an effective settlement agreement, and he wanted to do it back in 2018.⁵ As Judge Polster informed all parties in the opioid MDL, "What [going to trial] will accomplish, I don't know. But I'd rather not do that."⁶ "People aren't interested in depositions, and discovery, and trials."⁷ Judge Polster is disinterested in allowing procedural hockey to play out in his chambers, as early case management orders clarified that trial would not be moved because of procedural delay.⁸ Moreover, in all

1. Transcript of Proceedings at 4:1-12, 4:24-25, *In re: National Prescription Opiate Litigation*, No. 1:17-md-02804-DAP (Jan. 9, 2018) (No. 58) [hereinafter MDL No. 2804]. On January 9, 2018, Judge Dan Polster addressed all parties and strongly suggested that with all of these "smart people here and their clients," he was confident the parties could abate the opioid epidemic through effective negotiation tactics. *Id.* at 5:3-6.

2. Transfer Order at 1, 3, MDL No. 2804 (Dec. 12, 2017) (No. 1).

3. See generally, e.g., *MDL 2804: National Prescription Opiate Litigation*, U.S. DISTRICT CT. FOR NORTHERN DISTRICT OHIO, <https://www.ohnd.uscourts.gov/mdl-2804> (last visited Apr. 11, 2020).

4. Memorandum Opinion Certifying Negotiation Class at 1-2, 12, MDL No. 2804 (Sept. 11, 2019) (No. 2590).

5. Transcript of Proceedings, *supra* note 1, at 4:24-25, 6:12-13.

6. *Id.* at 6:9-10.

7. *Id.* at 4:19-20.

8. Case Management Order No. 1 at 17, MDL No. 2804 (Apr. 11, 2018) (No. 232) (stating the granting of an extension of discovery "shall not change the trial date, and the Court does not intend to move the trial date of the Track One case(s).") (emphasis omitted). However, trial was

cases, Judge Polster ordered both plaintiff and defense counsel to select six attorneys to represent their respective clients in negotiations.⁹ The push for settlement reached new heights on September 11, 2019, when Judge Polster certified a first-of-its-kind “Negotiation Class” under Federal Rule of Civil Procedure 23 as a means of encouraging a global settlement between a class of forty-nine plaintiff representatives and thirteen defendants on behalf of every county and city in the United States.¹⁰

The push for settlement appears to be working. On September 15, 2019, just four days after certification of the Negotiation Class, Purdue Pharma announced its proposed settlement agreement in the opioid MDL.¹¹ The terms of the settlement included a filing for Chapter 11 bankruptcy, the Sackler family relinquishing control of the company, and the company agreeing to pay out a minimum of \$3 billion to plaintiffs over the next seven years.¹² Then, on October 20, 2019, the eve of the first trial set in the opioid MDL, four companies—Teva, Cardinal Health, AmerisourceBergen, and McKesson—settled with both Track One bellwether plaintiffs Summit and Cuyahoga Counties in Ohio for \$260 million.¹³ Yet another opioid manufacturer proposed settlement in February 2020, when Mallinckrodt PLC announced it was finalizing a settlement proposal worth at least \$1.6 billion and which included a Chapter 11 bankruptcy filing.¹⁴

Between Judge Polster’s push for global settlement and companies settling along the way, a global settlement purported to resolve all pending cases seems inevitable. The logical comparison may be with Big Tobacco litigation of the 1990s, which culminated with the Master Settlement Agreement of 1998, the

nonetheless postponed to October 21, 2019, and the original three-week trial now stands at eight weeks, with closing arguments set for December 13, 2019. Case Management Order No. 8 at 1–2, MDL No. 2804 (Jan. 29, 2019) (No. 1306); Civil Jury Trial Order at 3, MDL No. 2804 (May 1, 2019) (No. 1598).

9. Minutes of 1/31/18 Settlement Conference & Scheduling Order at 1–2, MDL No. 2804 (Feb. 2, 2018) (No. 111).

10. Order Certifying Negotiation Class & Approving Notice at 3, MDL No. 2804 (Sept. 11, 2019) (No. 2591).

11. *Restructure: Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement*, PURDUE PHARMA (Sept. 15, 2019), <https://www.purduepharma.com/restructure/>.

12. Jan Hoffman & Mary Williams Walsh, *Purdue Pharma, Maker of OxyContin, Files for Bankruptcy*, N.Y. TIMES (Sept. 15, 2019), <https://www.nytimes.com/2019/09/15/health/purdue-pharma-bankruptcy-opioids-settlement.html>.

13. *Opioid MDL Track One Cases Settle on Eve of Openings, Joe Rice Leads Negotiations*, MOTLEY RICE LLC (Oct. 24, 2019), <https://www.motleyrice.com/article/opioid-mdl-track-one-settlement>.

14. Alexander Gladstone et al., *Mallinckrodt Pitches at Least \$1.6 Billion Opioid Settlement, Generics Unit Bankruptcy*, WALL STREET J. (Feb. 24, 2020), <https://www.wsj.com/articles/mallinckrodt-enters-creditor-talks-ahead-of-potential-generics-bankruptcy-11582572100>.

largest civil settlement in United States history that resulted in a \$206 billion award for state attorney general plaintiffs.¹⁵

One striking difference in the opioid MDL, however, is the significant role of county and city plaintiffs. This is to the great disdain of nearly forty state attorneys general, many of whom are pursuing their own state-level claims, who fervently assert the claims of the MDL are the province of the states and not the local governments.¹⁶ Judge Polster has found that if the attorneys general believe they in fact control jurisdiction, then those attorneys general could attempt to foreclose the claims directly.¹⁷ Yet no attorneys general have attempted to shut down the local governments' cases.¹⁸ Judge Polster asserts that until that happens, he cannot "pretend" that the more than 2,000 separate actions filed by counties and cities simply do not exist in his courtroom.¹⁹

This Note argues that state attorneys general should not be permitted to overthrow settlement negotiations in the county-and-city-led opioid MDL, positing that counties and cities are better suited than states to implement evidence-based public health initiatives in their own communities. Spending shortfalls of the Master Settlement Agreement demonstrate precisely why allocating settlement money to the states guarantees little to no accountability. Moreover, this Note identifies three reasons why, despite many similarities in the litigation tactics between tobacco and opioids, a global opioid settlement agreement will be far smaller than the \$206 billion tobacco Master Settlement Agreement of 1998. Therefore, a smaller settlement would be best utilized by apportioning settlement proceeds directly to the local governments, which are the most directly impacted by the opioid epidemic.

Part II discusses the background of tobacco litigation and opioid litigation. Part III identifies three reasons why a global opioid MDL settlement will be far smaller than the \$206 billion tobacco Master Settlement Agreement of 1998. Part IV argues why counties and cities are better suited than states to implement community-based public health initiatives, and it discusses examples of local public health initiatives that have proven successful. Finally, Part V concludes this Note, further reiterating that state attorneys general should not appropriate MDL negotiations.

15. See generally NAT'L ASS'N OF ATTORNEYS GEN., MASTER SETTLEMENT AGREEMENT (1998); Barry Meier, *Cigarette Makers and States Draft a \$206 Billion Deal*, N.Y. TIMES (Nov. 14, 1998), <https://www.nytimes.com/1998/11/14/us/cigarette-makers-and-states-draft-a-206-billion-deal.html>.

16. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 31.

17. *Id.* at 31–32.

18. *Id.*

19. *Id.* at 32.

II. BACKGROUND OF TOBACCO LITIGATION AND OPIOID LITIGATION

A. *History of Tobacco Litigation*

In the early 1990s, the tobacco industry boasted an almost half-century record of having never paid a dime to a single plaintiff who brought suit against it.²⁰ Big Tobacco's litigation strategy was aggressive and straightforward: refuse to settle a single case.²¹ The industry relied largely on its ability to "wear down" plaintiffs in the pretrial process through intimidation and delay.²² The tobacco industry vigorously denied the claim that smoking causes cancer, which required plaintiffs' counsel, generally paid on contingency fee bases, to bear heavy front-loaded costs in retaining experts to rebut the tobacco companies' experts.²³ Big Tobacco teamed up with big law firms to argue endless pretrial motions, take up procedural challenges, and take depositions until most plaintiffs were forced to drop their cases before the claims could even make it to trial.²⁴

That all changed in 1994. That year, Mississippi Attorney General Mike Moore joined with plaintiff's attorneys to file an unprecedented *parens patriae*²⁵ suit on behalf of Mississippi citizens for Medicaid-related expenses arising out of smoking-related illnesses.²⁶ In the following years, forty other state attorneys general followed suit.²⁷ These cases sought equitable relief under claims of

20. See Lynn Mather, *Theorizing About Trial Courts: Lawyers, Policymaking, and Tobacco Litigation*, 23 L. & SOC. INQUIRY 897, 904–05 (1998). From the 1950s to 1995, smokers and their families filed over 700 product liability suits against the tobacco industry. *Id.* Only one case, *Cipollone v. Liggett Group, Inc.*, 693 F. Supp. 208, 210 (D.N.J. 1988), resulted in a jury award for the plaintiffs. *Id.* at 905; On appeal, in *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 583 (3d Cir. 1990), the Third Circuit overturned the \$400,000 jury award, thus preserving the industry's perfect record of having never paid any money to a single plaintiff. *Id.*

21. Robert L. Rabin, *A Sociolegal History of the Tobacco Tort Litigation*, 44 STAN. L. REV. 853, 857–58 (1992).

22. Michael C. Moore & Charles J. Mikhail, *A New Attack on Smoking Using an Old-Time Remedy*, 111 PUB. HEALTH REP. 192, 194 (1996).

23. Rabin, *supra* note 21, at 858.

24. *Id.* at 859.

25. *Parens patriae* literally means "parent of the country." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 600 (1982). To invoke a *parens patriae* suit, a "State must be more than a nominal party," meaning it cannot merely express the interests of particular private parties. *Id.* at 607. A State must express a "quasi-sovereign interest." *Id.* Quasi-sovereign interests fall into two general categories: (1) an "interest in the health and well-being—both physical and economic—of its residents in general;" or (2) an interest in "not being discriminatorily denied its rightful status within the federal system." *Id.* Similarly, in tobacco litigation, states were able to demonstrate their interests in the health and well-being of its residents. *See id.* at 609.

26. Complaint at 1–2, *Moore ex rel. Mississippi v. American Tobacco Co.*, No. 94-1429 (Miss. Ch. Ct. 1994); Michael McCann et al., *Criminalizing Big Tobacco: Legal Mobilization and the Politics of Responsibility for Health Risks in the United States*, 38 L. & SOC. INQUIRY 288, 294 (2013).

27. McCann et al., *supra* note 26, at 294.

restitution, unjust enrichment, and injunction rather than seeking to obtain damages for injuries suffered by the individual smoker.²⁸ Other claims utilized by plaintiffs included conspiracy, fraud or fraudulent misrepresentation, and RICO.²⁹ Underpinning the conspiracy claims were theories that the tobacco industry had manipulated nicotine levels in cigarettes in order to sustain consumer addiction, as well as that the industry knew of the dangers of tobacco use but marketed cigarettes anyway.³⁰ In 1997, four states (Mississippi, Minnesota, Florida, and Texas) were able to settle for \$40 billion with the tobacco industry for costs arising out of Medicaid-related causes of action.³¹ The following year, the remaining forty-six states obtained a \$206 billion Master Settlement Agreement with the tobacco industry, the largest civil settlement in U.S. history, that was to be paid out to the states over the next twenty-five years.³²

B. *Shortfalls of the Master Settlement Agreement*

Such a groundbreaking tobacco settlement, however, left much to be desired. While the tobacco plaintiffs were able to obtain a \$246 billion total award that was supposed to be used for smoking cessation campaigns and public health initiatives, only a small portion of that money has actually been used for its intended purpose.³³ For example, the Government Accountability Office found that between fiscal years 2000 and 2005, when states received a total of \$52.6 billion in tobacco settlement payments, states used only 3.5% of the proceeds for tobacco control and 30% on health care (which included spending for programs like Medicaid and the Children's Health Insurance Program),³⁴ but they used 22.9% for budget shortfalls, 6% on "infrastructure," 7.1% for "general purposes," 7.8% on "other," and 11.9% was unallocated.³⁵ In 2014, New York used \$700,000 of the tobacco funds for a sprinkler system on a public golf course, and regrettably, North Carolina gave \$42 million to tobacco farmers for

28. Moore & Mikhail, *supra* note 22, at 197.

29. Cliff Sherrill, *Tobacco Litigation: Medicaid Third Party Liability and Claims for Restitution*, 19 UALR L.J. 497, 506 (1997).

30. *Id.* at 507.

31. See also TOBACCO CONTROL LEGAL CONSORTIUM, THE MASTER SETTLEMENT AGREEMENT: AN OVERVIEW I (2015); Mather, *supra* note 20, at 898.

32. See generally NAT'L ASSOC. OF ATTORNEYS GEN., MASTER SETTLEMENT AGREEMENT (1998); Meier, *supra* note 15.

33. TOBACCO FREE KIDS, BROKEN PROMISES TO OUR CHILDREN: A STATE-BY-STATE LOOK AT THE 1998 STATE TOBACCO SETTLEMENT 19 YEARS LATER I, 139 (2017).

34. Nicholas Terry & Aila Hoss, *Opioid Litigation Proceeds: Cautionary Tales from the Tobacco Settlement*, HEALTH AFF. (May 23, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180517.992650/full/>.

35. U.S. GOV'T ACCOUNTABILITY OFFICE, TOBACCO SETTLEMENT: STATES' ALLOCATIONS OF PAYMENTS FROM TOBACCO COMPANIES FOR FISCAL YEARS 2000 THROUGH 2005 2, 7 (2007).

“modernization and marketing.”³⁶ In 2018, states were estimated to have spent less than three cents of every dollar in tobacco settlement revenue to actually help prevent tobacco use.³⁷

As of Fiscal Year 2019, total payments to the states from the 1998 Master Settlement Agreement amassed \$156.7 billion.³⁸ During those twenty years since the settlement, states spent just 2.6% of it on tobacco prevention and cessation programs.³⁹ Currently, not a single state uses settlement funds for tobacco prevention programs at the CDC-recommended level.⁴⁰ For Fiscal Year 2019, the CDC-recommended level was a mere \$3.3 billion out of the \$27.3 billion that states received in settlement proceeds and tobacco taxes.⁴¹ Meanwhile, tobacco companies currently spend \$9.1 billion a year—“\$1 million every hour”—on marketing and advertising for their products.⁴²

C. *Today’s Opioid MDL and a Brief History of Opioid Litigation*

Over twenty years after the tobacco Master Settlement Agreement, Mike Moore is at it again, and he’s using litigation tactics straight out of the Big Tobacco playbook.⁴³ Like he did in the 1990s, Moore traveled across the country hoping to recruit state attorneys general and plaintiffs’ firms to his pursuit against the pharmaceutical industry.⁴⁴ That pursuit culminated with the launching of the opioid MDL on December 12, 2017, when the panel for multidistrict litigation consolidated sixty-four opioid personal injury cases and assigned them to Judge Dan Polster in the United States District Court for the Northern District of Ohio.⁴⁵ By August 2018, the opioid MDL had amassed more than 1,000 opioid-related lawsuits from over forty states against pharmaceutical giants such as Purdue Pharma, Mallinckrodt, and Endo

36. 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>.

37. TOBACCO FREE KIDS, BROKEN PROMISES TO OUR CHILDREN: A STATE-BY-STATE LOOK AT THE 1998 STATE TOBACCO SETTLEMENT 20 YEARS LATER I (2018).

38. *Id.*

39. *Id.*

40. *Id.*

41. *See id.*

42. *Broken Promises to Our Children: A State-by-State Look at the 1998 State Tobacco Settlement 21 Years Later*, TOBACCO FREE KIDS (Jan. 16, 2020), <https://www.tobaccofreekids.org/what-we-do/us/statereport>.

43. Esmé E. Deprez & Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, BLOOMBERG BUSINESSWEEK (Oct. 5, 2017), <https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry>.

44. *Id.*

45. Transfer Order, *supra* note 2, at 3.

Pharmaceuticals.⁴⁶ Only a year later, the opioid MDL stood to include well over 2,000 individual lawsuits.⁴⁷

Plaintiffs in the opioid MDL, most of whom are United States counties or cities, allege that (1) the manufacturers of prescription opioids misrepresented to physicians the risks of long-term opioid use for patients with chronic pain, and (2) the distributors failed to adequately monitor, investigate, and detect suspicious orders of prescription opioids, all of which contributed to the current opioid epidemic.⁴⁸ Like in tobacco litigation, causes of action in the opioid MDL include fraudulent concealment, RICO, civil conspiracy, negligence, various criminal acts, and unjust enrichment.⁴⁹

The opioid lawsuits began, however, far before the inception of the opioid MDL. Perhaps taking a lesson from Big Tobacco, early opioid plaintiffs prevailed against pharmaceutical companies in a number of multimillion-dollar settlements, and it is precisely because they initiated their lawsuits with government action. For example, in November 2004, Purdue Pharma, the manufacturer of OxyContin, reached a \$10 million settlement with West Virginia after the state's attorney general accused the company of aggressively marketing OxyContin and causing widespread addiction in the state.⁵⁰ In May 2007, Purdue pled guilty to criminal misbranding and agreed to pay \$600 million in fines, in addition to paying at least \$130 million to help resolve civil suits arising out of addiction claims.⁵¹ In 2015, Kentucky Attorney General Jack Conway settled a lawsuit with Purdue for \$24 million,⁵² and New York Attorney General Eric Schneiderman secured a \$75,000 settlement against the pharmaceutical giant along with the requirement that Purdue modify its

46. Bruce Japsen, *Opioid Lawsuits Look More Like a Tobacco Settlement Every Day*, FORBES (Aug. 25, 2018), <https://www.forbes.com/sites/brucejapsen/2018/08/25/opioid-lawsuits-looking-more-like-tobacco-settlements-every-day/#4035d0ab4f4f>.

47. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 1–2.

48. See Transfer Order, *supra* note 2, at 3.

49. See, e.g., Opinion & Order Adopting Magistrate Judge's Report & Recommendation Denying Defendants' Motions to Dismiss at 3, 6, 20, 31, 36, MDL No. 2804 (Dec. 19, 2018) (No. 1203).

50. Landon Thomas Jr., *Maker of OxyContin Reaches Settlement with West Virginia*, N.Y. TIMES (Nov. 6, 2004), <https://www.nytimes.com/2004/11/06/business/maker-of-oxycontin-reaches-settlement-with-west-virginia.html>.

51. Barry Meier, *U.S. Maker of OxyContin Painkiller to Pay \$600 Million in Guilty Plea*, N.Y. TIMES (May 11, 2007), <https://www.nytimes.com/2007/05/11/business/worldbusiness/11iht-oxy.1.5665287.html>.

52. *Kentucky Settles Lawsuit with OxyContin Maker for \$24 Million*, CBS NEWS (Dec. 23, 2015), <https://www.cbsnews.com/news/kentucky-settles-lawsuit-with-oxycontin-maker-for-24-million/>.

marketing practices.⁵³ These examples demonstrate the sheer power of spearheading health epidemic cases with government action.

D. More Differences than Similarities Between Big Tobacco Litigation and the Opioid MDL

There are, in many ways, logical links between Big Tobacco litigation of the 1990s and today's opioid MDL against Big Pharma. Namely, government plaintiffs initiated both litigation proceedings in response to national public health crises. The causes of action have been nearly identical in both sets of proceedings. Moreover, the end goal of both proceedings has been a largescale, comprehensive "master" or "global" settlement agreement purported to resolve a gamut of cases pending across the country. Key differences in the opioid MDL, however, have transformed the MDL into a truly one-of-a-kind proceeding.

1. County and City Plaintiffs Instead of Attorney General Plaintiffs

Unique to the opioid MDL is that counties and cities, rather than state attorneys general, are the primary government plaintiffs spearheading the litigation.⁵⁴ As of October 2019, the plaintiffs included more than 2,500 cities, counties, tribal communities, and individuals spanning throughout the United States, though the vast majority of the plaintiffs are counties and cities.⁵⁵ This is to the great disdain of state attorneys general, many of whom are keen to enter into a global settlement agreement that would distribute funds to state coffers rather than grant proceeds directly to counties and cities.⁵⁶

2. Early Exits: Track One Settlement and Purdue Pharma's Bankruptcy

Moreover, unlike in the tobacco cases, which did not produce a substantial monetary award for any plaintiff until all the states settled for nearly \$250 billion,⁵⁷ the opioid MDL has already produced an enormous settlement award for two plaintiffs. Compared to the tobacco cases, unique to the opioid MDL is the use of "bellwether" trials, or initial trials meant to set a precedent for how

53. Press Release, New York State Office of the Attorney Gen., A.G. Schneiderman Announces Settlement with Purdue Pharma That Ensures Responsible and Transparent Marketing of Prescription Opioid Drugs by the Manufacturer (Aug. 20, 2015) (on file at the Attorney General press release archives).

54. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 1–2, 31–32.

55. See, e.g., Colin Dwyer, *Your Guide to the Massive (And Massively Complex) Opioid Litigation*, NPR (Oct. 15, 2019), <https://www.npr.org/sections/health-shots/2019/10/15/761537367/your-guide-to-the-massive-and-massively-complex-opioid-litigation>.

56. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 31–32.

57. See Mather, *supra* note 20, at 898.

other similarly-situated categories of MDL cases will proceed.⁵⁸ The first bellwether trial was known as the “Track One” case,⁵⁹ and the two plaintiffs were Cuyahoga County and Summit County in Ohio.⁶⁰ Opening statements were set for Monday, October 21, 2019,⁶¹ with closing arguments and jury instructions to conclude no later than Friday, December 13, 2019.⁶² Then, on October 20, 2019, the eve of trial, four companies—Teva, Cardinal Health, AmerisourceBergen, and McKesson—settled with Summit and Cuyahoga Counties for \$260 million.⁶³ Prior to the tobacco Master Settlement Agreement, no county, city, or other plaintiff had prevailed in such a case against Big Tobacco.⁶⁴

Big Tobacco litigation also did not see the bankruptcies of the biggest defendant-manufacturers named in the proceedings, as the opioid MDL has seen with the bankruptcy of Purdue Pharma. September 15, 2019 marked a momentous day for the opioid MDL and for the history of the pharmaceutical industry: Purdue Pharma, a company whose origins stem back to 1892⁶⁵ and whose aggressive marketing tactics for OxyContin were alleged to have ignited the opioid epidemic,⁶⁶ announced that it would file for Chapter 11 bankruptcy.⁶⁷ As part of the settlement, the notorious Sackler family agreed to relinquish 100% control of the company and pay out a minimum of \$3 billion in cash to plaintiffs over the following seven years.⁶⁸ The family also agreed to restructure the entity

58. See Sarah K. Angelino & Stephen M. Copenhaver, *Why Bellwethers Matter in the Opioid MDL*, SCHIFF HARDIN PUBLICATIONS (June 10, 2019), <https://www.schiffhardin.com/insights/publications/2019/why-bellwethers-matter-in-the-opioid-mdl>.

59. Order Regarding Track One Trial Plaintiffs at 1, MDL No. 2804 (Feb. 25, 2019) (No. 1392).

60. *Id.* Originally, three cases were included as the Track One cases: (1) *The Cty. of Summit, Ohio v. Purdue Pharma L.P.*, No. 18-OP-45090 (N.D. Ohio); (2) *The Cty. of Cuyahoga v. Purdue Pharma L.P.*, No. 17-OP-45004 (N.D. Ohio); and (3) *City of Cleveland v. AmerisourceBergen Drug Corp.*, No. 18-OP-45132 (N.D. Ohio). Case Management Order No. 1, *supra* note 8, at 6. However, the City of Cleveland was removed from the Track One cases and joined with the City of Akron. Together, Cleveland and Akron are known as the “Municipal Plaintiffs” and will receive a trial date after the trial date of the Track Two bellwethers (as defined in Doc. 1218).

61. Civil Jury Trial Order, *supra* note 8, at 3. A three-week trial was originally set for Monday, March 18, 2019. Case Management Order No. 1, *supra* note 8, at 8.

62. Civil Jury Trial Order, *supra* note 8, at 3.

63. *Opioid MDL Track One Cases Settle on Eve of Openings, Joe Rice Leads Negotiations*, *supra* note 13.

64. Mather, *supra* note 20, at 897.

65. Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, ESQUIRE (Oct. 16, 2017), <https://www.esquire.com/news-politics/a12775932/sackler-family-oxy-contin/>.

66. See, e.g., Hoffman & Walsh, *supra* note 12; Thomas, *supra* note 50.

67. *Restructure: Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement*, *supra* note 11.

68. Hoffman & Walsh, *supra* note 12.

into a public benefit trust and sell Mundipharma, their British-based company.⁶⁹ Proceeds from OxyContin and other drugs would also contribute to plaintiffs' claims and further the research and development of addiction and overdose drugs, which would be "donated to the public."⁷⁰ Purdue estimated its settlement to provide over \$10 billion of aid to the opioid epidemic.⁷¹

The company reached the agreement with twenty-four state attorneys general, five territories, and several lead counsels in the opioid MDL.⁷² Paul Hanley Jr., co-lead counsel for the opioid MDL, welcomed the settlement, stating, "A journey of a thousand miles starts with the first step," and he hoped the settlement would forge support for communities across the nation that have suffered from the opioid crisis.⁷³

3. Negotiation Class

Further differing the opioid MDL from any other case in United States history is Judge Polster's unprecedented Negotiation Class that he certified under Federal Rule of Civil Procedure 23 on September 11, 2019.⁷⁴ The Negotiation Class seeks to encourage a global settlement between a class of forty-nine plaintiff representatives and thirteen defendants on behalf of every county and city in the United States,⁷⁵ giving individual class members the option to opt out by November 22, 2019.⁷⁶ While federal courts have conventionally employed Rule 23 to certify "trial class actions" and "settlement class actions," Rule 23 had never been used to certify a "negotiation class action" until the opioid MDL.⁷⁷ The Negotiation Class was a collaborative effort between the Special Master, experts, and parties in the opioid MDL.⁷⁸

The purpose of the Negotiation Class is to require parties to opt out of negotiation "prior to a settlement being reached, as is done in a normal class action geared toward trial."⁷⁹ The result is that class size is fixed prior to negotiations.⁸⁰ This is in contrast to the "standard settlement class action," which

69. *Id.*

70. *Id.*

71. *Restructure: Purdue Pharma Announces Agreement in Principle on Landmark Opioid Litigation Settlement*, *supra* note 11.

72. *Id.*

73. Elizabeth Joseph, *Purdue Pharma Files for Bankruptcy as Part of a \$10 Billion Agreement to Settle Opioid Lawsuits*, CNN (Sept. 16, 2019), <https://www.cnn.com/2019/09/16/us/purdue-pharma-bankruptcy-filing/index.html>.

74. *See generally* Order Certifying Negotiation Class & Approving Notice, *supra* note 10.

75. *See id.* at 1–3.

76. *Id.* at 1.

77. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 7.

78. *Id.* at 2.

79. *Id.* at 3.

80. *See id.*

allows class members to opt out of the class *after* the parties reach a settlement.⁸¹ The Negotiation Class quells defendants' fears that many of the counties and cities would simply opt out of settlement after a global settlement is reached,⁸² which would waste the time and resources spent to reach a global settlement agreement if the parties would still have to entertain a panoply of potentially significant claims.⁸³

The vast majority of attorneys general—including thirty-seven state attorneys general, the attorney general of Washington, D.C., and the attorney general of Guam—vehemently oppose the Negotiation Class.⁸⁴ The attorneys general, who themselves are pursuing state-level opioid litigation and have implied that the claims are the province of the states rather than the cities and counties,⁸⁵ argue that Negotiation Class will impede global settlement rather than promote it.⁸⁶ Judge Polster rejected this argument, reasoning that the Negotiation Class “does not interfere with the States settling their own cases any way they want, and it does not stop parties in the MDL from settling in other ways . . . it does not stop any litigation from continuing and in no way interferes with the upcoming bellwether trials in this MDL. This process simply provides an option – and in the Court’s opinion, it is a powerful, creative, and helpful one.”⁸⁷

The Northern District of Ohio has created a website for the Negotiation Class that includes an interactive Allocation Map based on a “hypothetical \$1 billion gross settlement for Counties and Cities” spanning all fifty states, Washington D.C., and Puerto Rico.⁸⁸ The amount to be allocated to each county or city is based on a metric that takes into account population and the impact of the opioid crisis on that locality. Of that total hypothetical \$1 billion settlement, \$150 million would be reserved for a Special Needs Fund designed to allow Class members to recover litigation costs or obtain additional relief for local impact of the opioid crisis, and \$100 million would be reserved in a Private Attorneys’ Fee Fund.⁸⁹ The website’s hypothetical settlement, after these costs, would leave behind \$750 million for counties and cities.⁹⁰

For all of these reasons, the opioid MDL is truly an unparalleled colossus that cannot be squarely perfectly against Big Tobacco.

81. *Id.* at 2.

82. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 2.

83. *Id.*

84. *Id.* at 5.

85. *Id.* at 31.

86. *Id.* at 3.

87. Memorandum Opinion Certifying Negotiation Class, *supra* note 4, at 3–4.

88. *In Re: National Prescription Opiated Litigation: Allocation Map*, OPIOIDS NEGOT. CLASS, <https://allocationmap.iclaimsonline.com/> (last visited Apr. 12, 2020).

89. *Id.*

90. *Id.*

III. WHY A GLOBAL OPIOID SETTLEMENT WILL BE FAR SMALLER THAN THE TOBACCO MASTER SETTLEMENT AGREEMENT

The stark differences between tobacco and opioid litigation highlight the unique factors underlying the opioid MDL. Three key reasons drive why a global settlement in the opioid MDL will be far smaller than the \$206 billion tobacco Master Settlement Agreement: (1) opioid defendants can shift blame onto a number of other culpable parties, paving the way for causation defenses that were largely unavailable for the tobacco industry; (2) opioids have undeniable health benefits, leading to the medical community's demand for drugs exactly like OxyContin in the years leading up to its FDA approval; and (3) the pharmaceutical industry is less financially viable than it outwardly appears, which is evidenced by a number of recent bankruptcies of opioid manufacturers.

A. *Defenses Unique to Opioids: Shifting Blame onto Other Culpable Parties*

Today, opioid plaintiffs face far more legal barriers than did tobacco plaintiffs.⁹¹ Drug manufacturers, distributors, and pharmacies have a unique advantage of being able to pass blame onto the U.S. Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), doctors, and individual consumers, all of whom have at least partially contributed to the opioid epidemic.⁹² Such arguments were largely unavailable for the tobacco industry, which had complete control over the manufacturing, marketing, and distribution of a single product.⁹³

1. FDA as a Gatekeeper

One of the most significant differences between tobacco products and opioids lies in the FDA. Tobacco was unregulated by the FDA until 2009.⁹⁴ For tobacco plaintiffs in the 1990s and early 2000s, the absence of regulatory oversight meant plaintiffs could place blame directly on tobacco companies for fraudulent marketing schemes.⁹⁵ Additionally, tobacco plaintiffs could use the absence of FDA oversight to advocate for why tobacco products should be

91. Nora Freeman Engstrom & Michelle M. Mello, *Suing the Opioid Companies*, STAN. L. SCH. (Aug. 30, 2018), <https://law.stanford.edu/2018/08/30/q-and-a-with-mello-and-engstrom/>.

92. Brit McCandless Farmer, *The Opioid Epidemic: Who Is to Blame?*, 60 MINUTES (Feb. 24, 2019), <https://www.cbsnews.com/news/the-opioid-epidemic-who-is-to-blame-60-minutes/>.

93. Jan Hoffman, *Payout from a National Opioids Settlement Won't Be as Big as Hoped*, N.Y. TIMES (Feb. 17, 2020), <https://www.nytimes.com/2020/02/17/health/national-opioid-settlement.html>.

94. *See generally* Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 301 (2009); 15 U.S.C. § 1333 (2012).

95. *See generally* U.S. v. Philip Morris, 449 F. Supp. 2d 1, 839, 899–900 (D.D.C. 2006) (holding that substantial evidence established the defendant tobacco companies violated RICO by engaging in a massive fifty-year scheme to defraud the public, including consumers of cigarettes).

regulated by the FDA.⁹⁶ Opioids, however, are subject to rigorous FDA oversight from the initial drug application and approval process all the way through post-approval monitoring.⁹⁷ Congress has empowered the FDA to ensure that new drugs are both “safe” and “effective” before they may be introduced in interstate commerce.⁹⁸

Drug companies have thus been able to successfully argue immunity because of the FDA’s ultimate authority to approve new drugs.⁹⁹ Under *Buckman Co. v. Plaintiffs’ Legal Community*, state law claims alleging that drug companies committed fraud on the FDA are preempted by the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁰⁰ The Court explained this is because the FDCA empowers the FDA alone, not the states, to police and investigate suspected fraud.¹⁰¹ *Buckman*’s reasoning was reaffirmed and extended in *Riegel v. Medtronic, Inc.*, where the Court held that the FDA’s premarket approval process satisfies federal safety requirements and that common law claims of negligence, strict liability, and implied warranty are preempted by the FDCA.¹⁰² Even before *Buckman* and *Riegel*, drug manufacturers were able to prevail on similar arguments. For example, under one Michigan law, drug manufacturers enjoyed an absolute defense from product liability suits (which, in Michigan, include fraud and misleading marketing claims) if: (1) the FDA approved the safety and efficacy of the drug and (2) “the drug and labeling were in compliance with [the FDA’s] approval at the time the drug left the control of the manufacturer.”¹⁰³

96. In *Philip Morris*, 449 F. Supp. 2d at 216, the court referenced in its more than 1,600-page opinion the FDA’s Final Rule that “[a]ll major public health organizations in the United States and abroad” recognized that nicotine in cigarettes and smokeless tobacco was addictive (citing 1996 FDA Jurisdictional Determination, 61 Fed. Reg. 44619 (Aug. 1996) at xv, XVA1242326-3211 at 2572 (US 64323)). Addiction was used by the FDA to argue that nicotine should be considered a drug subject to FDA regulation. *See id.*

97. *See generally*, e.g., 21 U.S.C. §§ 355-360 (2018).

98. *Id.*

99. *See generally* *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 345 (2008).

100. *Buckman*, 531 U.S. at 353.

101. *Buckman*, 531 U.S. at 348.

102. *Riegel*, 552 U.S. at 323–30. While *Buckman* and *Riegel* involved medical devices rather than prescription drugs, courts have applied the same reasoning to suits against drug manufacturers. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965–66 (6th Cir. 2004) (holding that preemption under *Buckman* applies not only to medical device claims, but to drug claims as well).

103. *Garcia*, 385 F.3d at 963–64; Mich. Comp. Laws § 600.2946 (1996). In *Garcia*, the Sixth Circuit held that the Michigan statute was wholly preempted under the Supreme Court’s ruling in *Buckman*. *Garcia*, 385 F.3d at 965–67. The *Buckman* preemption had the effect of preventing claims arising under the Michigan statute from being brought at all in Michigan state court. This was to the vast benefit of drug companies—drug companies went from being granted immunity under state law, to then being granted federal preemption.

Perhaps even more simply, drug manufacturers can argue FDA approval means there is a gatekeeper to blame when drugs with adverse effects reach the public. The FDA itself touts, “American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world. The main consumer watchdog in this system is FDA’s Center for Drug Evaluation and Research (CDER).”¹⁰⁴ When a drug manufacturer develops a new drug, the drug must undergo preclinical animal testing;¹⁰⁵ followed by an “investigational new drug” application;¹⁰⁶ followed by three phases of human clinical trials;¹⁰⁷ followed finally by an “NDA,” or new drug application, which, if approved by the FDA, ensures that the drug’s health “benefits exceed the risks.”¹⁰⁸ During the three phases of human clinical trials, approximately seventy percent of drugs qualify to pass from Phase I to Phase II, and only about thirty-three percent of those remaining drugs are able to move from Phase II to Phase III.¹⁰⁹ After undergoing such a strenuous approval process, it is difficult to convince a jury that an FDA-approved drug is defective.¹¹⁰ In 2016, Purdue Pharma was able to cite over twenty years of scientific research, including over a dozen controlled clinical studies, supporting the FDA’s approval of its twelve-hour dosing for OxyContin extended-release tablets.¹¹¹ Purdue stated its warning label was updated more than thirty times and that “at no point did FDA request a change to [OxyContin’s] dosing frequency.”¹¹² Such statements only lend further credence to pharmaceutical companies’ ability to use the FDA as a shield to liability.

2. DEA as a Sleeping Watchdog

In addition to FDA approval of opioids is DEA oversight of them. The Controlled Substances Act of 1970 required drug manufacturers and distributors to report their controlled substance transactions directly to the U.S. Attorney General, and in turn, the Attorney General delegates that authority to the DEA (an arm of the U.S. Department of Justice).¹¹³ The database by which drug companies report that information is known as the Automation of Reports and

104. *Development & Approval Process (Drugs)*, FDA (June 13, 2018), <https://www.fda.gov/drugs/developmentapprovalprocess/default.htm>.

105. 21 C.F.R. § 312.23(a)(5) (2018).

106. *Id.* § 312.20(a).

107. *Id.* § 312.21(a)-(c).

108. *Id.* § 314.50.

109. *Step 3: Clinical Research*, FDA (Jan. 4, 2018), <https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm>.

110. Engstrom & Mello, *supra* note 91.

111. *E.g.*, Harriet Ryan, *Purdue Pharma Issues Statement on Oxycontin Report*; *L.A. Times Responds*, L.A. TIMES (May 6, 2016), <https://www.latimes.com/projects/purdue-response/>.

112. *Id.*

113. *Automation of Reports and Consolidated Orders System (ARCOS)*, DEA, <https://www.dea.diversion.usdoj.gov/arcos/index.html> (last visited Apr. 11, 2020).

Consolidated Order System (ARCOS).¹¹⁴ “ACROS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to the point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions.”¹¹⁵ ACROS accumulates these transactions and summarizes them into reports that give federal and state government agencies information necessary “to identify the diversion of controlled substances into illicit channels of distribution.”¹¹⁶ Such information can then be used by U.S. Attorneys and the DEA to prosecute drug crimes.¹¹⁷

In July 2019, undisclosed ARCOS data were brought to light that revealed the DEA knew America’s largest drug distributors had released seventy-six billion oxycodone and hydrocodone pills throughout the United States between the years 2006 and 2012.¹¹⁸ During that period, ARCOS had tracked the “path of every single pain pill sold in the United States—from manufacturers and distributors to pharmacies in every town and city.”¹¹⁹ The ARCOS data revealed a number of red flags suggesting that high volumes of pills violated federal law, and patterns indicated that the opioids were being diverted to the black market.¹²⁰ The three states with the highest concentrations of opioid pills per person were West Virginia with 66.5 pills per person, Kentucky with 63.3 pills per person, and South Carolina with 58 pills per person—numbers that far exceeded reasonable use.¹²¹ The DEA had sole access to this data for years and failed to act on it or release it.¹²²

Six distributors were responsible for the distribution of seventy-five percent of the pills: McKesson Corp., Walgreens, Cardinal Health, AmerisourceBergen,

114. *Id.*

115. *Id.*

116. *Id.*

117. *Id.*

118. Scott Higham et al., *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html. Discovery during the opioid MDL revealed the possibility that the ARCOS data would be key to litigation. In June 2019, the Sixth Circuit Court of Appeals agreed to make the ARCOS data public after a push from media, primarily from *The Washington Post*. See, e.g., Joseph F. Rice, *Sixth Circuit Ruling Regarding ARCOS Data in the Opioid Litigation Is Welcome*, MOTLEY RICE LLC (June 20, 2019), <https://www.motleyrice.com/blogpost/arcos-data-opioid-litigation-sixth-circuit>; *Opioid Litigation*, MOTLEY RICE LLC, <https://www.motleyrice.com/public-client/opioid-litigation> (last visited Apr. 12, 2020).

119. Higham et al., *supra* note 118.

120. *Id.*

121. *Id.*

122. *Id.*

CVS, and Walmart.¹²³ Three manufacturers, SpecGx, a subsidiary of Mallinckrodt; Actavis Pharma; and Par Pharmaceutical, a subsidiary of Endo Pharmaceuticals, manufactured eighty-eight percent of the pills.¹²⁴

After the release of the ARCOS data, drug distributors were readily prepared to condemn the government for failing to do more to address the crisis. McKesson spokeswoman Kristen Chasen responded, “For decades, DEA has had exclusive access to this data, which can identify the total volumes of controlled substances being ordered, pharmacy-by-pharmacy, across the country.”¹²⁵ The DEA, as the overseer of drug manufacture and distribution, sets the quota for how many opioids manufacturers can produce and tracks where they can go.¹²⁶ Via ARCOS, the DEA had therefore not only approved drug manufacturers’ production of exorbitant numbers of opioid pills, but the DEA also blessed distribution of those pills to pharmacies all across the country.¹²⁷

3. Physician Behavior and the Learned Intermediary Doctrine

Aside from government oversight, further removing manufacturers and distributors from the opioid crisis is physician autonomy. The FDA is primarily a consumer protection agency that does not regulate physicians’ behavior.¹²⁸ Therefore, while the FDA approves drug labels and recommends certain uses for approved drugs,¹²⁹ physicians are generally free to use their own medical judgment to prescribe drugs for whatever medical purposes they see fit, a practice known as “off-label” prescribing.¹³⁰ FDA drug approval also means the causal link between drug manufacturers’ alleged failure to warn and physicians’ prescribing practices is broken under the learned intermediary doctrine.¹³¹

123. *Id.*

124. Higham et al., *supra* note 118.

125. *Id.*

126. Zachary Siegel, *The Opioid Crisis Is About More than Corporate Greed*, NEW REPUBLIC (July 30, 2019), <https://newrepublic.com/article/154560/opioid-crisis-corporate-greed>.

127. *Id.*

128. 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, 28 (2016).

129. *Understanding Unapproved Use of Approved Drugs “Off Label,”* FDA (Feb. 5, 2018), <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>.

130. *Id.*

131. *See, e.g.,* Timmons v. Purdue Pharma Co., No. 8:04-CV-1479-T-26MAP, 2006 WL 263602, at *4 (M.D. Fl. Feb. 2, 2006) (reasoning that even if OxyContin’s warning label was insufficient, all physicians were able to testify that they independently knew the risks of OxyContin addiction, and there was therefore insufficient evidence to show that the physicians were deceived by the defendants’ marketing. Moreover, “. . .the learned intermediary doctrine precluded a finding of causation between Purdue’s misrepresentations and/or failure to warn regarding the addictiveness of OxyContin. . .”).

Generally, under the learned intermediary doctrine, “once a manufacturer warns a doctor about a drug’s inherent dangers, [the manufacturer] has fulfilled its legal duty to provide a warning.”¹³² The manufacturer’s duty to warn the prescribing physician displaces the manufacturer’s duty to warn patients directly of the drug’s inherent dangers.¹³³ “The reasoning behind this rule is that the doctor acts as a learned intermediary between the patient and the prescription drug manufacturer by assessing the medical risks in light of the patient’s needs.”¹³⁴ Under the learned intermediary doctrine, a plaintiff generally must demonstrate that: (1) the manufacturer failed to provide an adequate warning to the prescribing physician of the dangers inherent in the use of the product, and (2) the omission was the proximate cause of injury.¹³⁵

However, even if a plaintiff succeeds in proving the elements of the learned intermediary doctrine, the doctrine further shields a manufacturer if the physician otherwise acquired independent knowledge of the risks associated with a prescription drug.¹³⁶ Where the physician’s independent knowledge is “substantially the same” as that which an adequate warning label would have communicated, the causal link between the plaintiff’s injury and the manufacturer’s alleged failure to warn is broken, and the plaintiff cannot establish proximate cause.¹³⁷ Further, even where the FDA recommends more rigorous warnings from a manufacturer, the doctrine may bar a plaintiff’s recovery so long as the manufacturer warned of inherent risks associated with a drug.¹³⁸ Every federal Circuit Court that has taken up a learned intermediary appeal has affirmed summary judgment or dismissal in favor of drug manufacturers.¹³⁹ No federal case has reversed in favor of plaintiffs.

132. Wright *ex rel.* Trust Co. of Kansas v. Abbott Labs., Inc., 259 F.3d 1226, 1233 (10th Cir. 2001); Eck v. Parke, Davis & Co., 256 F.3d 1013, 1017 (10th Cir. 2001) (noting the exception to the manufacturer’s duty to warn under the learned intermediary doctrine. “[W]here a product is properly prepared and marketed and proper warning is given to the prescribing physicians, the manufacturer is shielded from liability.”).

133. Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 706 (E.D. Ky. 2003).

134. Eck, 256 F.3d at 1017.

135. See Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995).

136. *Id.* at 1192.

137. *Id.*

138. See Wright *ex rel.* Trust Co. of Kansas v. Abbott Labs., Inc., 259 F.3d 1226, 1233–35 (10th Cir. 2001) (affirming summary judgment for the manufacturer when the manufacturer had already warned the hospital of a drug’s inherent risks through the package slip, but the FDA recommended further warnings); *but cf.* Edwards v. Basel Pharmaceuticals, 933 P.2d 298, 299 (Okla. 1997) (holding that a manufacturer’s “compliance with FDA warning requirements does not necessarily satisfy the manufacturer’s common law duty to warn the consumer”).

139. Dean v. Eli Lilly & Co., 387 F. App’x 28, 30 (2d Cir. 2010); *In re Avandia Marketing, Sales Practices and Prods. Liability Litigation*, 746 F. App’x 122, 124 (3d Cir. 2018); Talley v. Danek Medical, Inc., 179 F.3d 154, 164 (4th Cir. 1999); Ackermann v. Wyeth Pharmaceuticals, 526 F.3d 203, 214 (5th Cir. 2008); Meridia Products Liability Litigation v. Abbott Labs., 447 F.3d 861, 869 (6th Cir. 2006); Ziliak v. AstraZeneca LP, 324 F.3d 518, 521 (7th Cir. 2003); Elhis v.

In addition to barring failure to warn claims, the learned intermediary doctrine may be used to bar plaintiffs' false advertising claims as well. For example, in *Dean v. Eli Lilly & Co.*, the Second Circuit employed the learned intermediary doctrine to reject the plaintiff's argument that "overpromotion of a product negates any warnings."¹⁴⁰ Although the plaintiff was able to point to the defendant's vigorous sales campaign for the drug that was aimed at the doctor, there was no evidence that the manufacturer's salespeople either misled the doctor about the link between the drug and the injury, or that the salespeople caused the doctor to prescribe the drug to the plaintiff.¹⁴¹ Instead, the evidence showed that the doctor's prescription of the drug was based on the patient's prior success with the drug and an assessment of the patient's needs.¹⁴²

Few learned intermediary cases have been used against opioid manufacturers. However, in the ones that have, manufacturers have emerged undefeated. For example, in *Bodie v. Purdue Pharma L.P.*, the plaintiff's claims were barred because the prescribing physician had independent knowledge of the risks of OxyContin addiction.¹⁴³ Similarly, in *Foister v. Purdue Pharma, L.P.*, a Kentucky court adopted, for the first time, the learned intermediary doctrine when it barred an individual opioid addict plaintiff's failure to warn claim when the warning label clearly stated that the drugs should not be chewed or snorted.¹⁴⁴

The expectation of physician responsibility has extended to criminal proceedings as well. In June 2018, when the Department of Justice announced the largest health care fraud takedown in U.S. history, 162 health care providers were charged for their roles in illegally prescribing and distributing opioids and other narcotics.¹⁴⁵ Doctors who run "pill mills," such as Dr. Jacqueline Cleggett,¹⁴⁶ give doctors an increasingly bad reputation for contributing to the

Shire Richwood, Inc., 367 F.3d 1013, 1019 (8th Cir. 2004); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1024 (10th Cir. 2001); *Dietz v. Smithkline Beechman Corp.*, 598 F.3d 812, 816 (11th Cir. 2010).

140. *Dean*, 387 F. App'x. at 29.

141. *Id.*

142. *Id. Cf.* *Tyree v. Boston Scientific Corp.*, 56 F. Supp. 3d 826, 833 (S.D.W.V. 2014) (holding that the learned intermediary doctrine would not have protected the manufacturer if it had advertised directly to patients, but the doctrine was controlling because the manufacturer did not advertise to patients).

143. *Bodie v. Purdue Pharma L.P.*, 236 Fed. App'x. 511, 516, 521 (11th Cir. 2007).

144. *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 696 (E.D. Ky. 2003).

145. DEP'T OF JUSTICE, *National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over \$2 Billion in Fraud Losses* (June 28, 2018), <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over>.

146. Mahita Gajanan, *Netflix's The Pharmacist Depicts the True Story of Grieving Father's Fight Against the Opioid Epidemic*, TIME (Feb. 6, 2020), <https://time.com/5778759/the-pharmacist-netflix/>. Cleggett was made notable in the Netflix docuseries, *The Pharmacist*, for running a pain

opioid epidemic. They also give drug manufacturers further credence under the learned intermediary doctrine for why doctors should know better than to irresponsibly—or even illegally—prescribe dangerous narcotics.

4. Consumer Behavior

Aside from the FDA and physicians, other issues of causation arise with individuals' addiction, abuse, and criminal behavior. In 2017, West Virginia had the highest rate of opioid-related overdose deaths in the United States, with a rate of 49.6 deaths per 100,000 persons—more than three times that of the national rate of 14.6 deaths per 100,000.¹⁴⁷ While doctors were partially to blame,¹⁴⁸ the majority of those deaths were attributable to synthetic opioids and heroin,¹⁴⁹ which are not created by drug manufacturers. Similar to individual tobacco plaintiffs, to whom courts have been largely unsympathetic,¹⁵⁰ courts today take issue with awarding damages to individual drug addicts. For example, in *Foister v. Purdue Pharma*, a Kentucky court rejected the plaintiffs' "victimization" mentality when they had engaged in crushing, snorting, and injecting OxyContin and had histories of abusing prescription medications.¹⁵¹ In *Ashley County v. Pfizer*, twenty individual counties in Arkansas pursued equitable relief against the manufacturer of an over-the-counter cold medicine for not taking adequate steps to prevent the cold medicine from being converted into methamphetamine.¹⁵² The Eighth Circuit dismissed the case, reasoning:

Proximate cause is bottomed on public policy as a limitation on how far society is willing to extend liability for a defendant's actions. As a federal court construing state law, we are very reluctant to open Pandora's box to the avalanche of actions that would follow if we found this case to state a cause of action under Arkansas law. We could easily predict that the next lawsuit would be against farmers' cooperatives for not telling their farmer customers to sufficiently safeguard their anhydrous ammonia . . . tanks from theft by methamphetamine cooks. And what of the liability of manufacturers in other

management clinic in New Orleans, which was a hub of the opioid epidemic. *Id.* Cleggett had a habit of prescribing individuals who did not show signs of chronic pain or illness 40 mg or more of OxyContin, often in combination with medications like Xanax and Soma, for a deadly combination known as the "holy trinity." *Id.* Cleggett lost her license and pleaded guilty in 2009 to illegally dispensing controlled substances. *Id.*

147. *West Virginia Opioid Summary*, NAT'L INST. ON DRUG ABUSE (Mar. 2019), <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/west-virginia-opioid-summary>.

148. *See id.* In 2013, West Virginia doctors were writing around 125 opioid prescriptions per 100 persons. In 2017, they were writing 81.3 opioid prescriptions per every 100 persons, compared to the average U.S. rate of 58.7 prescriptions. *Id.*

149. *Id.*

150. Sherrill, *supra* note 29, at 497.

151. *Foister v. Purdue Pharma*, L.P., 295 F. Supp. 2d 693, 695–701 (E.D. Ky. 2003).

152. *Ashley County v. Pfizer*, 552 F.3d 659, 662–63, 673 (8th Cir. 2009).

industries that, if stretched far enough, can be linked to other societal problems?¹⁵³

This logic is extended to cases barring plaintiffs' recovery because of their own contributory negligence and wrongful conduct.¹⁵⁴ Individual West Virginia plaintiffs have been unable to recover damages against drug manufacturers because their own behavior precludes a finding of proximate cause.¹⁵⁵

Taken together, all of these actors allow opioid defendants to mitigate their liability by breaking the causal chain of liability. This simply was not the case for Big Tobacco. "[F]our cigarette companies produced a single product—one whose dangers were undisputed."¹⁵⁶ Cigarettes were everywhere, and their impact insidious, but there was no else to blame but tobacco companies.

B. *The Relationship Between Opioids and Doctors: It's Complicated*

Lingering behind all of this is perhaps the biggest difference: there is no health benefit in smoking,¹⁵⁷ but there are undeniable health benefits to opioid therapy.¹⁵⁸ As such, the medical community has a complex, longstanding history with opioids that came in waves of rejection and support for opioid therapy.¹⁵⁹

Complicating the opioid epidemic is the medical community's position on opioids in the years leading up to OxyContin's approval: that opioids were non-addictive. In 1980, Jane Porter and Hershel Jick published a letter in the *New England Journal of Medicine* that became the basis of the medical community's widespread understanding that opioid use rarely resulted in addiction.¹⁶⁰ A 1986 retrospective analysis of thirty-eight patients taking opioids for chronic pain concluded that only two of the patients misused or abused the drugs, and it

153. *Id.* at 671.

154. *E.g.*, *McCauley v. Purdue Pharma LP*, 331 F. Supp. 2d 449, 452 (W.D. Va. 2004); *Orzel by Orzel v. Scott Drug Co.*, 537 N.W.2d 208, 210–11 (Mich. 1995).

155. *McCauley*, 331 F. Supp. 2d at 462.

156. Hoffman, *supra* note 93.

157. *See generally* *Smoking & Tobacco Use: Tobacco-Related Mortality*, CDC, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/tobacco_related_mortality/ (last visited Apr. 11, 2020).

158. *See generally* Brief for Center for Public Health Law Research at Temple University et al. as Amici Curiae Supporting Settlement with Favorable Public Health Outcomes at 15–16, MDL No. 2804 (discussing that opioid treatment is vital in three areas: "1. Short-term treatment of severe acute pain; 2. Sustained treatment of cancer-related pain and end-of-life care; and 3. Sustained treatment of opioid use disorder (OUD) with opioid maintenance medications, including methadone and buprenorphine.").

159. *See generally, e.g.*, Mark R. Jones et al., *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN THERAPY 13 (2018).

160. Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 N. ENG. J. MED. 123, 123 (1980); Jones et al., *supra* note 159, at 15.

maintained that both patients had a prior history of drug abuse.¹⁶¹ That same year, the World Health Organization shed light on the under-treatment of cancer pain and suggested that opioid analgesics were an avenue by which to alleviate pain.¹⁶² Ronald Melzack pondered “the tragedy of needless pain” in 1990 and suggested that morphine should be available for patients with chronic pain rather than remain limited to cancer patients.¹⁶³

Thus, when the FDA first approved OxyContin (“oxycodone controlled-release”) in 1995,¹⁶⁴ it was in response to the medical community’s demand for drugs exactly like OxyContin. This accordingly allows drug manufacturers to use the theory behind the learned intermediary doctrine as a basis for why it created the drugs in the first place: doctors had concluded that opioids were safe, doctors wanted to prescribe opioids to their patients, and doctors are better suited than drug companies to decide what is best for patients. Pharmaceutical companies like Purdue can therefore argue, in a sense, that necessity bred innovation.

Immediately following the FDA’s approval of OxyContin, the American Pain Society launched its campaign for “pain as the fifth vital sign,” which the Veteran’s Health Administration adopted in its policies.¹⁶⁵ In 1997, the Federation of State Medical Boards released statements acknowledging that it would lessen its control over physicians’ prescriptions of opioids, which the U.S. Drug Enforcement Agency fully endorsed.¹⁶⁶ In 2000, The Joint Commission (TJC) published strict standards for pain management in hospitals that recommended physicians rely on patients’ self-reported pain score, and those standards required an “acceptable” pain score before a patient could be discharged from post-anesthesia care units.¹⁶⁷ In response, physicians aggressively prescribed opioids out of fear that failure to meet TJC standards would result in withholding of federal funds for their hospitals.¹⁶⁸ Through enforcing TJC standards, hospitals all but forced the overprescription of opioids

161. Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-malignant Pain: Report of 38 Cases*, 25 PAIN 171, 173, 177 (1986); Jones et al., *supra* note 159, at 15.

162. WHO, CANCER PAIN RELIEF 7–8 (1986); Jones et al., *supra* note 159, at 15.

163. Ronald Melzack, *The Tragedy of Needless Pain*, 262 SCI. AM. 27, 27 (1990); Jones et al., *supra* note 159, at 15.

164. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, FDA (May 30, 2019), <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm>.

165. Jones et al., *supra* note 159, at 15.

166. David E. Joranson et al., *Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change*, 23 J. PAIN & SYMPTOM MGMT. 138, 142–43 (2002); Jones et al., *supra* note 159, at 16.

167. David W. Baker, *History of The Joint Commission’s Pain Standards: Lessons for Today’s Prescription Opioid Epidemic*, 317 JAMA 1117, 1117 (2017).

168. Jones et al., *supra* note 159, at 16.

in efforts to remain compliant with TJC and boost patient satisfaction scores.¹⁶⁹ This was particularly dangerous when hospitals tied their physicians' compensation to patient satisfaction scores.¹⁷⁰

With the institutionalized dogma of what constituted best medical practices for pain management, an entire generation of doctors had fostered a deep-seated habit of aggressive opioid prescription. Then, as soon as the medical consensus changed and doctors concluded that opioids were addictive, drug manufacturers were readily able to argue under the learned intermediary doctrine that doctors should have known better than to irresponsibly prescribe opioids.

C. *Big Pharma: A Different Financial Ball Game than Big Tobacco*

Another glaring factor drives why a global opioid settlement will be far smaller than the tobacco Master Settlement Agreement: Big Pharma simply has less money than many think it does. In 2016, U.S. tobacco sales totaled \$94.4 billion, while prescription opioid sales only totaled \$8.5 billion.¹⁷¹ Meanwhile, in 2016, Big Tobacco generated nearly \$20 billion in net *profits* (emphasis in original).¹⁷² Annual prescription opioid sales amount to even less than the \$9.1 billion that Big Tobacco spends each year just on marketing and advertising alone.¹⁷³

Experts estimate that if all national distributors paid an amount proportional to the quantity of opioids they distribute to their own pharmacies (the determination of how distributors are generally sued), the amount would be about \$13.8 Billion total.¹⁷⁴ Three drug distributors (AmerisourceBergen, Cardinal Health, and McKesson Corporation) and two manufacturers (Johnson & Johnson and Teva) have tentatively proposed a \$48 Billion settlement, much of it to be paid out over eighteen years.¹⁷⁵ However, about half of that amount is an assessment of the value of addiction treatment and services that the companies vow to provide in the future.¹⁷⁶

Manufacturers similarly do not have the assets to produce a tobacco-like settlement, and they perhaps have even fewer assets than distributors. When

169. *Id.*

170. See Joshua J. Fenton et al., *The Cost of Satisfaction: A National Study of Patient Satisfaction, Health Care Utilization, Expenditures, and Mortality*, 172 ARCH INTERNAL MED. 405, 405 (2012).

171. Terry & Hoss, *supra* note 34.

172. Michelle L. Richards, *Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation*, 54 U. RICH. L. REV. 405, 451 (2020).

173. *Broken Promises to Our Children: A State-by-State Look at the 1998 State Tobacco Settlement 21 Years Later*, *supra* note 42.

174. Hoffman, *supra* note 93.

175. Tom Hals & Nate Raymond, *Several States Wary of \$48 billion Opioid Settlement Proposal*, REUTERS (Oct. 24, 2019), <https://www.reuters.com/article/us-usa-opioid-lawsuits/several-states-wary-of-48-billion-opioid-settlement-proposal-idUSKBN1X315P>.

176. *Id.*; Hoffman, *supra* note 93.

Purdue Pharma filed for bankruptcy and agreed to pay out a minimum of \$3 billion in cash over the next seven years, several states, including Pennsylvania, Massachusetts, and New York, vehemently opposed the settlement.¹⁷⁷ These states sought to hold the Sackler family personally liable, alleging that the family used Purdue to transfer billions of dollars to shell corporations and private accounts.¹⁷⁸ Pennsylvania Attorney General Josh Shapiro said the settlement was a “slap in the face to everyone who has had to bury a loved one due to this family’s destruction and greed” and that it “allow[ed] the Sackler family to walk away billionaires and admit no wrongdoing.”¹⁷⁹

From the outset, the Sackler family does appear enormously wealthy. There is a Sackler Wing at New York’s Metropolitan Museum of Art; other Sackler wings at the Louvre and the Royal Academy; Sackler museums at Harvard and Peking Universities; a Sackler Center at the Guggenheim; even a species of pink rose and an asteroid are named after the Sacklers.¹⁸⁰ Forbes named the Sackler family the nineteenth richest family in America in 2016, estimating a net worth of \$13 billion.¹⁸¹ However, this merely demonstrates that all of the Sackler family’s personal wealth and Purdue’s assets combined would still fail to even approach the \$206 billion tobacco Master Settlement Agreement. Purdue’s bankruptcy thus reflects the simple reality that opioid manufacturers lack the financial ability to resolve the estimated \$2.5-trillion cost of the opioid epidemic.¹⁸²

Purdue’s bankruptcy and agreement to pay out just \$3 billion also created a strategic defense for other companies: settle early, file for bankruptcy if necessary, and do it for less than \$3 billion. Simply put, when Purdue Pharma—the center of much discovery, litigation, and negative publicity¹⁸³—settles for only \$3 billion, it stands to reason that the remaining defendants will argue that they should pay less than the company that developed and manufactured OxyContin. This is exactly what Mallinckrodt PLC did when it settled and filed bankruptcy for \$1.6 billion in February 2020.¹⁸⁴

Bankrupting pharmaceutical companies also has negative public health and societal implications. Pharmaceutical companies are sources of life-saving

177. See Joseph, *supra* note 73; Hoffman & Walsh, *supra* note 12.

178. Hoffman & Walsh, *supra* note 12.

179. Joseph, *supra* note 73.

180. Glazek, *supra* note 65.

181. *America’s Richest Families 2016*, FORBES (June 29, 2016), <https://www.forbes.com/profile/sackler/?list=families#61bf7b7e5d63>.

182. See Hoffman, *supra* note 93.

183. See generally Sari Horwitz et al., ‘SELL BABY SELL!’: *Unsealed Documents in Opioids Lawsuit Reveal Inner Workings on Industry’s Marketing Machine*, WASH. POST (Dec. 6, 2019), <https://www.washingtonpost.com/graphics/2019/investigations/opioid-marketing/>.

184. Gladstone et al., *supra* note 14.

vaccines, drugs, and medical devices.¹⁸⁵ In the twentieth century alone, pharmaceutical companies developed therapies for a number of previously untreatable diseases, including drugs for heart disease, arthritis, high blood pressure, bacterial infections, anxiety, asthma, cancer, and AIDS, in addition to developing the first prescription contraceptives.¹⁸⁶ When the United States faced frequent polio epidemics in the early 1950s, Dr. Jonas Salk and others sought the help of pharmaceutical companies to ensure adequate public administration of the polio vaccine.¹⁸⁷ It similarly stands to reason that when new epidemics and pandemics inevitably devastate future populations, the world will look to researchers and the pharmaceutical industry as first responders. Bankrupting Big Pharma would disproportionately harm more people worldwide than it would help victims of the opioid epidemic—particularly when pharmaceutical companies create the very medications that help to treat opioid addiction.

IV. SOLUTION: AVOIDING ANOTHER BIG TOBACCO BLUNDER THROUGH LOCAL PUBLIC HEALTH ACTION

All of these factors demonstrate that a global opioid settlement arising out of the opioid MDL is inevitable, and it will likely be dwarfed by the \$246 billion total award that the tobacco plaintiffs were able to obtain in 1998. A smaller global settlement, however, even as small as \$50 billion, could still be enormously successful if the proceeds are channeled directly into evidence-based public health initiatives at the local level.

The opioid crisis is a uniquely local problem that impacts rural counties and urban cities alike.¹⁸⁸ It is counties and cities that bear the brunt of not only financial costs of addiction, but also human costs of lives lost in their communities.¹⁸⁹ Counties and cities view themselves as being entrusted to serve the health, safety, and vitality of their communities.¹⁹⁰ They are eager to join the

185. See Stewart Lyman, *Pharma's Tarnished Reputation Helps Fuel the Anti-Vaccine Movement*, STAT (Feb. 26, 2019), <https://www.statnews.com/2019/02/26/anti-vaccine-movement-pharma-tarnished-reputation/>.

186. *Id.*

187. See *id.* See also Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, HEALTH AFF. (May/June 2005), <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.24.3.622> (discussing the role of pharmaceutical companies such as Eli Lilly, Parke Davis, Pitman-Moore, Wyeth Laboratories, and Cutter Laboratories in the testing, production, and distribution of Jonas Salk's polio vaccine).

188. See generally NAT'L LEAGUE OF CITIES & NAT'L ASS'N OF CTYS., *A PRESCRIPTION FOR ACTION: LOCAL LEADERSHIP IN ENDING THE OPIOID CRISIS* 3 (2016).

189. See *id.* at 17.

190. See *id.* at 3.

MDL fight, in part because of state laws that limit local governments' ability to recover under the types of causes of action brought in the opioid MDL.¹⁹¹

The answer to better use of settlement funds therefore rests with counties and cities, rather than states, directly addressing the opioid crisis by enacting evidence-based public health initiatives in their own communities. If counties and cities lack the infrastructure to act alone, then similarly situated counties should their pool settlement proceeds from a global MDL settlement to implement solutions that would best suit addressing the opioid epidemic in their particular localities. State attorneys general should not be permitted to thwart the negotiations of county and city plaintiffs in the opioid MDL, nor should they be permitted to usurp the proceeds of a global MDL settlement.

A. *Lessons from Big Tobacco: Settlement Proceeds Going to State Coffers Means Little to No Spending Accountability*

The goal of a comprehensive opioid settlement must be a plan that tangibly addresses the opioid epidemic, not just a settlement agreement that procures the largest monetary award for plaintiffs and state attorneys general. This is a lesson that comes directly from the tobacco Master Settlement Agreement. Today, over twenty years after the tobacco settlement, state attorneys general have allocated a devastatingly low proportion to the intended purpose of funding public health measures and smoking cessation programs. There is already some reason to fear the same result would ensue if attorneys general take over opioid MDL negotiations.

For example, West Virginia, the state with the worst overdose rate in the nation,¹⁹² used funds from a 2004 opioid settlement with Purdue Pharma to remodel its state's police academy by building a brand-new fitness center.¹⁹³ When Oklahoma opted out of the opioid MDL and pursued opioid defendants in state court, the state obtained a \$270 million settlement from Purdue Pharma in March 2019.¹⁹⁴ A measly \$12.5 million of the proceeds went to counties and municipalities in Oklahoma; \$60 million went to legal fees.¹⁹⁵ In August 2019, Oklahoma obtained a \$572 million damages award from Johnson & Johnson

191. See Elizabeth Weeks & Paula Sanford, *Financial Impact of the Opioid Crisis on Local Government: Qualifying Costs for Litigation and Policymaking*, 67 U. KAN. L. REV. 1061, 1073–74 (2019).

192. *West Virginia Opioid Summary*, *supra* note 147.

193. Terry & Hoss, *supra* note 34.

194. Martha Bebinger, *Purdue Pharma Agrees to \$270 Million Opioid Settlement with Oklahoma*, NPR (Mar. 26, 2019), <https://www.npr.org/sections/health-shots/2019/03/26/706848006/purdue-pharma-agrees-to-270-million-opioid-settlement-with-oklahoma>.

195. Jackie Fortiér, *Here's What Happened to \$829 Million Oklahoma Was Awarded to Treat Opioid Addiction*, KGOU (Jan. 16, 2020), <https://www.kgou.org/post/here-s-what-happened-829-million-oklahoma-was-awarded-treat-opioid-addiction>.

(which was later reduced to \$465 million due to the judge's math error).¹⁹⁶ The state of Oklahoma is presently entitled to receive \$829 million from four different settlements with opioid manufacturers.¹⁹⁷ So far, Oklahoma has spent none of it on addiction treatment.¹⁹⁸ Despite this, Oklahoma's Attorney General has since initiated a pursuit against opioid distributors as well.¹⁹⁹

Local communities, on the other hand, have already implemented on-the-ground solutions to addressing the opioid epidemic.

B. Evidence-Based Public Health Solutions Already Exist at the Local Level

In response to the opioid epidemic, local leaders throughout the U.S. have already implemented effective solutions to fighting opioid addiction, overdose, and death.²⁰⁰ In 2018, the City of Chicago invested \$225,000 in hiring and training community members who experienced opioid addiction to serve as "peer workers" and bring evidence-based treatment to the south and west sides.²⁰¹ Chicago used an evidence-based research model that allowed these peer workers to disseminate overdose prevention information, distribute naloxone (an overdose reversal drug), and further connect members of the community with resources for treatment.²⁰² As early as 2013, San Diego County created safe opioid prescribing guidelines for physicians.²⁰³ Boston has implemented drug take-back kiosks for the confidential and free disposal of unused or expired medications.²⁰⁴ Moreover, Philadelphia launched its "Don't Take the Risk" campaign that discouraged people from taking opioids in the first place.²⁰⁵ These are just a few examples of local leaders taking initiative to combat the opioid crisis.

The National Association of Counties and the National League of Cities created an action plan calling for local leaders to lead the way in the fight against

196. *Id.*

197. *See id.*

198. *Id.*

199. *See* Nathaniel Weixel, *Oklahoma Sues Three Major Opioid Distributors*, HILL (Jan. 13, 2020), <https://thehill.com/policy/healthcare/478067-oklahoma-sues-three-major-opioid-distributors>.

200. *E.g.*, *Combating the Opioid Crisis*, BIG CITIES HEALTH COALITION, <https://www.bigcitieshealth.org/combating-opioids> (last visited March 29, 2020).

201. *Mayor Emanuel, Chicago Department of Public Health Increase Community Investment to Fight Opioids*, CHI. (Mar. 8, 2018), https://www.chicago.gov/city/en/depts/mayor/press_room/press_releases/2018/February/FightingOpioids.html.

202. *Id.*

203. *See generally* PRESCRIPTION DRUG ABUSE TASK FORCE, SAFE PAIN MEDICATION PRESCRIBING GUIDELINES (2013).

204. *Drug Take-Back Kiosks*, CITY BOSTON, <https://www.boston.gov/departments/recovery-services/drug-take-back-kiosks> (last visited Apr. 11, 2020).

205. *Don't Take the Risk*, PHILA. DEP'T PUB. HEALTH, <https://www.donttaketherisk.org/en> (last visited Apr. 11, 2020).

the opioid crisis.²⁰⁶ Specific actions included convening community leaders, educating community members about the effects of the opioid crisis, expanding treatment options, and fostering relationships with neighboring communities.²⁰⁷

Moreover, the Centers for Disease Control and Prevention (CDC) has published a report outlining evidence-based strategies for preventing opioid overdose as a resource for leaders who are spearheading the prevention of opioid abuse in their own communities.²⁰⁸ In that report, the CDC pointed to examples of community trailblazers that successfully implemented various programs.²⁰⁹ The following discussion outlines some of those local initiatives that worked.

1. Medication-Assisted Treatment in Jails

Medication-assisted treatment (MAT) is repeatedly considered the “gold standard” for individuals suffering from opioid use disorder.²¹⁰ The FDA has approved three medications for use with MAT: methadone, buprenorphine, and naltrexone.²¹¹ Respectively, these medications are agonists, partial agonists, and antagonists that drastically reduce the risk of withdrawal and overdose.²¹² Methadone and buprenorphine prevent the agonizing withdrawal symptoms of opioids “without causing euphoria,” while naltrexone entirely blocks the effects of opioids.²¹³ Decades of research have supported the efficacy of methadone and buprenorphine in preventing overdose.²¹⁴ Early research also supports the effectiveness of naltrexone, though naltrexone may be less effective at treating some patients than opioid agonists (i.e., methadone and buprenorphine).²¹⁵

One of the biggest problems facing MAT, however, is social stigma. Opioid agonists are themselves opioids, and some fear that MAT is just “replacing one

206. See generally NAT’L LEAGUE OF CITIES & NAT’L ASS’N OF CTYS., *supra* note 188.

207. *Id.*

208. See generally JENNIFER J. CARROLL ET AL., CDC, EVIDENCE-BASED STRATEGIES FOR PREVENTING OPIOID OVERDOSE: WHAT’S WORKING IN THE UNITED STATES (2018).

209. *Id.* at 9 *passim*.

210. E.g., ST. LOUIS CTY., ACTION PLAN: ADDRESSING OPIOID ADDICTION AND OVERDOSE 19 (2017).

211. *Information about Medication-Assisted Treatment (MAT)*, FDA (Feb. 14, 2019), <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>.

212. See *Medication-Assisted Treatment (MAT)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., <https://www.samhsa.gov/medication-assisted-treatment> (last visited Mar. 9, 2020). Methadone is a full agonist that prevents withdrawal, but it does not block the effects of other narcotics (i.e., the feelings of euphoria) when administered. Buprenorphine is a partial agonist that blocks the effects of other narcotics when administered while still reducing risk of withdrawal. Naltrexone is an antagonist that blocks the effects of narcotics while also preventing withdrawal.

Id.

213. CARROLL ET AL., *supra* note 208, at 10.

214. *Id.*

215. *Id.*

addiction with another.”²¹⁶ Admittedly, that fear is not entirely unfounded: It is possible to overdose on methadone and other opioid agonists, and opioid agonists can become addictive.²¹⁷ However, the research emphatically shows that MAT is not a substitute to heroin or opioids.²¹⁸ In contrast to heroin, which produces a “cycle of euphoria, crash, and craving,” methadone and buprenorphine produce stable levels of opioids in the brain, resulting in patients failing to experience a “rush” and significantly reducing their desire to take opioids.²¹⁹ MAT accordingly allows individuals suffering from opioid dependence to gradually wean off opioids and achieve long-term recovery.

The stigma of MAT decreases, however, as MAT programs are implemented in communities by community leaders, and specifically, by local law enforcement officials. Despite jail administrators and sheriffs historically not providing treatment for substance use disorders, the National Sheriffs’ Association and the National Commission on Correctional Health Care have encouraged jails to take the lead in implementing jail-based MAT and working with community leaders to provide MAT upon release.²²⁰ This is an enormous step in decreasing stigma for MAT from the very group that gatekeeps the detention of these individuals.

Jails²²¹ are perhaps one of the most important places to implement MAT. “More than 10 million individuals pass through jails around the country annually, with at least half of those individuals having substance use disorders, half of whom are opioid abusers.”²²² Jails are uniquely positioned to not only oversee individuals as they are suffering withdrawal, but also to initiate treatment in a safe and controlled environment.²²³

216. See NAT’L INST. ON DRUG ABUSE, PRINCIPLES OF DRUG ADDICTION TREATMENT: A RESEARCH-BASED GUIDE 27 (3d ed. 2018). See also German Lopez, *There’s a Highly Successful Treatment for Opioid Addiction. But Stigma Is Holding It Back*, VOX (Nov. 15, 2017), <https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone> (discussing why MAT is not “just replacing one drug with another.”); *Information about Medication-Assisted Treatment (MAT)*, *supra* note 211.

217. See WHO/UNODC/UNAIDS, SUBSTITUTION MAINTENANCE THERAPY IN THE MANAGEMENT OF OPIOID DEPENDENCE AND HIV/AIDS PREVENTION 19 (2004).

218. NAT’L INST. ON DRUG ABUSE, *supra* note 216, at 27–28.

219. *Id.* at 27.

220. NAT’L SHERIFFS’ ASS’N & NAT’L COMM’N ON CORR. HEALTH CARE, JAIL-BASED MEDICATION-ASSISTED TREATMENT: PROMISING PRACTICES, GUIDELINES, AND RESOURCES FOR THE FIELD 2–3 (2018).

221. In contrast to prisons, which are operated by federal or state systems, jails are run by local government agencies. See *Terms & Definitions: State and Federal Prisoners and Prison Facilities*, OFF. JUST. PROGRAMS, <https://www.bjs.gov/index.cfm?ty=tdtp&tid=13> (last visited March 30, 2020).

222. NAT’L SHERIFFS’ ASS’N & NAT’L COMM’N ON CORR. HEALTH CARE, *supra* note 220, at 2.

223. *Id.*

While MAT is offered in few jails throughout the county, the impetus appears to be growing. For example, at New York City's jail, Rikers Island Correctional Facility, treatment for opioid-dependent inmates includes both methadone and buprenorphine.²²⁴ In 2011, Washington County jail in Maryland became the first jail to administer MAT for nonpregnant women and for men.²²⁵ In 2016, Rhode Island, which operates a combined jail/prison, became the first state to administer methadone, buprenorphine, and naltrexone to all inmates who experience substance use disorders.²²⁶ St. Louis County Jail in Missouri followed suit in July 2019, initiating its three-phase MAT program that includes the administration of methadone, buprenorphine, and naltrexone.²²⁷ Additionally, Cuyahoga County in Ohio, one of the Track One bellwether plaintiffs that settled in October 2019, outlined a \$900,000 plan to implement a MAT treatment program with methadone and buprenorphine in its jail.²²⁸

MAT implementation in jails serves as a springboard for law enforcement to treat opioid addiction as a public health issue rather than a criminal issue. For example, when Cuyahoga County planned to allocate \$900,000 to a MAT treatment program in its jail, it also planned to allocate more than twice that amount—\$2.5 million—in a diversion program that kept low-level drug offenders out of jail in the first place.²²⁹

2. Targeted Naloxone Distribution

Another option is for counties and cities to distribute naloxone, an opioid antagonist that acts as an immediate overdose reversal drug.²³⁰ Naloxone “carries no risk of abuse and has no effect on individuals who do not already have opioids in their system,” it fosters no physical dependency, and it “produces no neurological or psychological effects of euphoria.”²³¹ The CDC reports that naloxone distribution is most effective when it is administered to those who are at a high risk of experiencing or are in a position to react to overdose.²³² Naloxone is also particularly useful for rural communities, where those in the

224. CARROLL ET AL., *supra* note 208, at 23.

225. NAT'L SHERIFFS' ASS'N & NAT'L COMM'N ON CORR. HEALTH CARE, *supra* note 220, at 6.

226. CARROLL ET AL., *supra* note 208, at 23.

227. *See generally* POLICY AND PROCEDURE NO. 1323: MEDICATION-ASSISTED TREATMENT – BUPRENORPHINE/METHADONE DOSING, ST. LOUIS CTY. JUSTICE CTR. (2019), <https://www.stlouisco.com/portals/8/docs/document%20Library/justice%20services/PolicyAndProcedures/policy1323.pdf>.

228. Courtney Astolfi, *Cuyahoga County Outlines Plan for \$23M in Opioid Settlement Money*, CLEVELAND.COM (Oct. 10, 2019), <https://www.cleveland.com/news/2019/10/cuyahoga-county-outlines-plan-for-23m-in-opioid-settlement-money.html>.

229. *Id.*

230. CARROLL ET AL., *supra* note 208, at 8.

231. *Id.*

232. *Id.*

midst of an overdose may face longer wait times for Emergency Medical Services (more commonly known as EMS).²³³

A 2012 Morbidity and Mortality Weekly Report (MMWR) collected data from 188 local opioid prevention programs that distributed naloxone from 1996 to 2010.²³⁴ The MMWR revealed that after these programs distributed naloxone to and trained 53,032 persons, the programs achieved 10,171 overdose reversals.²³⁵ Naloxone education and distribution thus materially helps to reduce opioid overdose mortality.²³⁶

3. Syringe Services Programs

Implementation of syringe services programs, sometimes known as “needle exchange” programs, also serves as another option for local implementation. When the Cabell-Huntington Health Department in West Virginia opened its syringe service program, the program helped to reduce client needle-sharing from above 25% to below 10% between September 2015 and March 2016 alone.²³⁷ One Seattle study found that compared to those who did not use syringe exchange programs, syringe services program participants were five times more likely to initiate drug treatment and 3.5 times more likely to cease injection altogether.²³⁸ By 2014, syringe services programs operated in nearly 200 U.S. cities.²³⁹

4. Academic Detailing

Another compelling alternative is for community leaders to use the same marketing tactics that pharmaceutical companies use to market their products, but for evidence-based best practices for opioid prescribing. This is a tactic known as “academic detailing.”

“Detailing” is “a structured educational strategy developed by commercial manufacturers of medical and pharmaceutical technologies to market these products to prescribers and pharmacists.”²⁴⁰ “Academic detailing,” on the other hand, “consists of structured visits to healthcare providers by trained

233. Howard K. Mell et al., *Emergency Medical Services Response Times in Rural, Suburban, and Urban Areas*, 152 JAMA 983, 984 (2017). See generally Mark Faul et al., *Disparity in Naloxone Distribution Administration by Emergency Medical Service Providers and the Burden of Drug Overdose in US Rural Communities*, 105 AM. J. PUB. HEALTH e26, e26–e32 (Supp. 2015).

234. Eliza Wheeler et al., *Community-Based Opioid Overdose Prevention Programs Providing Naloxone – United States, 2010*, 61 MMWR 101, 101 (2012).

235. *Id.*

236. *See id.*

237. CARROLL ET AL., *supra* note 208, at 26, 28.

238. See Holly Hagan et al., *Reduced Injection Frequency and Increased Entry and Retention in Drug Treatment Associated with Needle-Exchange Participation in Seattle Drug Injectors*, 19 J. SUBSTANCE ABUSE TREATMENT 247, 249–50 (2000).

239. CARROLL ET AL., *supra* note 208, at 28.

240. *Id.* at 12.

professionals who can provide tailored training and technical assistance, helping healthcare providers use best practices.”²⁴¹ Commercial detailing overpowers traditional academic information sources primarily because researchers and others seeking to disseminate scientific medical knowledge are “rarely trained in effective communication strategies.”²⁴² Academic detailing corrects the communication disparity by “marketing” science to clinicians in a clear and compelling manner.²⁴³

Local leaders have achieved empirical success with academic detailing efforts. When Staten Island launched a multifaceted public health strategy that largely involved academic detailing in 2011, the borough saw a 29% decline in opioid-related overdose deaths from 2011–2013, while the overdose death rate remained unchanged in the four other New York City boroughs that lacked academic detailing initiatives.²⁴⁴ Two years later, in 2013, when New York City carried out a two-month-long academic detailing program on Staten Island for overdose prevention, the intervention resulted in a 12.4% decrease in high-dose prescribing rates.²⁴⁵ Moreover, after physicians in San Francisco received just a half-hour-long academic detailing session for naloxone, their rate of naloxone prescription increased eleven-fold.²⁴⁶

Academic detailing serves as an option for both urban and rural areas. Since 2013, the New York City Department of Health and Mental Hygiene has collaborated with the CDC to implement two academic detailing campaigns: one to support buprenorphine-based MAT with providers, and one to offer training and support to clinic staff to adopt safe opioid prescription practices.²⁴⁷ Moreover, the San Francisco Department of Public Health sponsored California’s statewide academic detailing intervention program study, which supports rural counties for developing and implementing best practices for prescription, overdose, and buprenorphine-based MAT.²⁴⁸

Taken together, all of these local actions show that communities are highly capable of implementing on-the-ground action in their localities.

241. *Id.*

242. *Id.*

243. See Jerry Avorn, *Academic Detailing: “Marketing” the Best Evidence to Clinicians*, 317 JAMA 361, 361–62 (2017).

244. Denise Paone et al., *Decrease in Rate of Opioid Analgesic Overdose Deaths – Staten Island, New York City, 2011–2013*, 64 MMWR 491, 491 (2015).

245. Jessica A. Kattan et al., *Public Health Detailing—A Successful Strategy to Promote Judicious Opioid Analgesic Prescribing*, 106 AJPH 1430, 1430, 1435 (2016).

246. CARROLL ET AL., *supra* note 208, at 13. See also Emily Behar et al., *Academic Detailing Pilot for Naloxone Prescribing Among Primary Care Providers in San Francisco*, 49 FAM. MED. 122, 125 (2017).

247. CARROLL ET AL., *supra* note 208, at 13.

248. *Id.*

C. *The Spirit of the Opioid MDL Was to Include Counties and Cities, Not States*

It was by no accident that the opioid MDL amassed over 2,500 plaintiffs, most of which were counties and cities across the U.S. This litigation strategy appears to have been a deliberate effort to address the very spending shortfalls associated with the attorney general plaintiffs of Big Tobacco litigation. As such, counties and cities, rather than states, should be the parties responsible for obtaining a global settlement and for spending the money as they see fit in their communities.

This is not to say that counties and cities are immune to corrupt or otherwise inappropriate spending of settlement proceeds. Precisely because of the known spending shortfalls of the tobacco Master Settlement Agreement, plaintiffs in the opioid MDL have a responsibility not merely to achieve the largest possible settlement for their clients, but rather to pave the way for effective use of litigation proceeds. Any global opioid MDL settlement must be transparent, there must be spending accountability, and the money must go toward legitimate efforts aimed at abating the opioid epidemic.

Nonetheless, counties and cities have been the most directly impacted by opioid addiction, withdrawal, and overdose, and they are best equipped to devise on-the-ground solutions. Cities and counties deploy first responders to overdose. Local hospitals and treatment facilities provide medical assistance to victims of opioid dependence. When individuals die of overdose, they are viewed as lost members of communities, not of states. Local law enforcement officials arrest and prosecute those who distribute opioids, are opioid dependent, or both. Settlement funds would thus best be served by directing proceeds directly to counties and cities, many of which already have opioid programs in place, rather than to the far-removed state level.

As Judge Polster reflected, the solution to addressing the opioid epidemic “is not just moving money around, because this is an ongoing crisis.”²⁴⁹ “Moving money around” would seem to be the precise outcome of an MDL settlement if state attorneys general overthrow MDL settlement negotiations. Early examples of this are West Virginia, which used opioid settlement funds to remodel its states police academy, and Oklahoma, which still has yet to allocate any of its \$800 million in opioid settlement proceeds to any meaningful public health action on opioids. This is juxtaposed against Cuyahoga County in Ohio, which immediately had an allocation plan for a settlement the same month that it settled the Track One case in October 2019.²⁵⁰ Prioritizing county and city plaintiffs during the opioid MDL does not mean eliminating states entirely from the opioid conversation, but it does mean ensuring that counties and cities are heard during negotiations and that they actually receive the money they deserve.

249. Transcript of Proceedings, *supra* note 1, at 9:9-11.

250. Astolfi, *supra* note 228.

Judge Polster further contemplated, “ideally, [solving the opioid epidemic] should be handled by the legislative and executive branches, our federal government, and our state governments.”²⁵¹ “The federal court is probably the least likely branch of government to try and tackle this, but candidly, the other branches of government, federal and state, have punted. So it’s here.”²⁵² Maybe Judge Polster is right. Maybe this should have been handled by other branches of government. However, where the other branches and the states failed to act, either by legislation or by litigation, local governments stepped up to the plate. It would be an insult to proactive counties and cities to usurp them of their opportunity to achieve a global MDL settlement simply because state attorneys general—who have already demonstrated they are incapable of appropriately distributing such proceeds—commandeered the very litigation efforts that they failed to initiate.

V. CONCLUSION

The lesson from Big Tobacco litigation is that procuring enormous settlement awards, while imposing no spending accountability, is a sheer waste of resources that insults the victims of a deadly public health crisis. Counties and cities spearheaded the opioid MDL precisely to avoid the shortfalls of attorney general plaintiffs involved in Big Tobacco litigation. For state attorneys general to sabotage opioid MDL settlement negotiations at the eleventh hour would be to effectively strip local governments of the opportunity to launch meaningful solutions that would best suit their communities and save lives.

The opioid MDL is a truly unique opportunity to gather brilliant minds and influential stakeholders in one place to create meaningful answers to this public health crisis. We owe it to the local governments trying to solve the crisis—and all those who have been affected by opioid addiction—to grant proceeds directly to those parties capable of implementing on-the-ground solutions to the opioid epidemic. Public health is a public responsibility. Aren’t local governments also “the public”?

ASHTON K. DIETRICH*

251. Transcript of Proceedings, *supra* note 1, at 9:25-10:1-3.

252. *Id.* at 4:13-16.

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