

# The Role of Tort Litigation in Shaping Opioid Marketing and Regulation

Margaret Wilson

## Abstract

In light of the staggering economic toll of the opioid crisis, local governments, including state Attorney Generals, have made recent headlines by increasingly turning to litigation as a means of seeking funding to combat the ongoing opioid crisis and mitigate its financial burden. Thousands of lawsuits have been filed over the course of the last few years, most notably by local governments. Plaintiffs hope that litigation may lead to big payoffs, like those resulting from “Big Tobacco” litigation, but with greater local reach and although suits thus far have had relatively low settlement payouts. This piece will trace the trajectory and effects of the two major waves of opioid litigation since the early 2000s, shortly after FDA approval of OxyContin in 1996, and analyze current litigation and its potential outcomes, including the Ohio Multidistrict Litigation. I argue that tort litigation against pharmaceutical companies builds on the history of the “Big Tobacco” suits and the host of legal arguments surrounding corporate liability and responsibility that were developed in the context of major tobacco tort litigation. Throughout this piece, I will gesture to parallel concepts and effects that opioid litigation shares with other historical torts, like tobacco. Ultimately, I argue, the effects of litigation on opioid marketing and regulation are cumulative and often indirect, as the tide of public opinion turns against opioid companies, court decisions build on prior opioid suits, and litigation continues to facilitate the investigation and release of documents detailing industry practices.

## Biography

Margaret Wilson is a recent graduate of Harvard College, where she majored in History and Science with a Secondary Field in Global Health and Health Policy.

## Citing This Work

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*“Litigation is a blunt instrument; it’s not a surgical tool. But it provokes interest quicker than anything I’ve ever seen.” - Mike Moore, former Attorney General of Mississippi<sup>1</sup>*

## **Introduction**

The CDC estimates that prescription opioid misuse alone costs the U.S. \$78.5 billion per year.<sup>2</sup> \$28.9 billion is due to increased health care and substance abuse treatment expenditures, and over \$19.6 billion is borne by the public sector and due to increased use and costs of health care, substance abuse treatment, and criminal justice services.<sup>3</sup> According to a recent study by the U.S. Department of Health and Human Services, each opioid overdose requires approximately \$4.35 million in healthcare costs alone. Such costs are overwhelmingly shouldered by local governments, particularly cities and counties. These costs include, but are not limited to, emergency room admissions, costs of first responders and other emergency response services and equipment, emergency overdose medication (e.g. Narcan), substance abuse treatment centers, additional local health clinics, care of infants affected by prenatal opioid exposure, law enforcement costs, prison services, additional hiring of public employees (in health services and law enforcement), and indirect effects of the epidemic, such as economic instability or effects on local tax bases.<sup>4</sup> While the federal government has provided some financial assistance to states on

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<sup>1</sup> Esmé E. Deprez and Paul Barrett, "The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry," *Bloomberg*, October 5, 2017, accessed September 25, 2018, <https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry>.

<sup>2</sup> *This figure includes the costs of lost productivity.*

NIH National Institute on Drug Abuse, "Opioid Overdose Crisis," *drugabuse.gov*, March 2018, accessed 26 Nov. 2018, <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>.

<sup>3</sup> C.S. Florence, C. Zhou, F. Luo, L. Xu, "The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013," *Med Care*, 2016 Oct;54(10):901-6, *PubMed.gov*, accessed 26 Nov. 2018, doi: 10.1097/MLR.0000000000000625, <https://www.ncbi.nlm.nih.gov/pubmed/27623005>.

<sup>4</sup> Andrew Erteschik and J.M. Durnovich, "Local Governments vs. Big Pharma - A New Wave of Litigation Alleges Liability for the Opioid Epidemic," *Mondaq*, November 2, 2017, <https://advance-lexis-com.ezp-prod1.hul.harvard.edu/api/document?collection=news&id=urn:contentItem:5PW0-YWN1-JCMN-Y42M-00000-00&context=1516831>.

the front lines of the opioid crisis, legislatures and administrative agencies are struggling to adequately address the opioid epidemic in a timely manner,<sup>5</sup> and the massive costs associated with the opioid epidemic continue to mount.

Local governments, including state Attorney Generals, are increasingly turning to litigation as a means of seeking funding to combat the ongoing opioid crisis and mitigate its financial burden, with thousands of opioid-related suits filed since the mid- to late-2000s.<sup>6</sup> Plaintiffs hope that litigation may lead to big payoffs, like those resulting from “Big Tobacco” litigation, although suits thus far have had relatively low settlement payouts. Claims have been made against pharmaceutical companies (manufacturers and distributors), pharmacies, individual doctors and practices, and hospitals, among other defendants. Affected individuals and families, primarily alleging prescription practices that constitute malpractice and/or criminal negligence, have also brought substantial numbers of opioid-related suits, often against individual doctors, pharmacies, or hospitals. While a range of types of opioid-related lawsuits exist, in this analysis, I will focus primarily on suits against pharmaceutical manufacturers and distributors due to their high-profile nature and their potential to most substantially affect high-level regulatory change, particularly when those suits are brought by governmental bodies. Suits against large pharmaceutical companies brought by governmental bodies also have the greatest potential to result in a large-scale, multi-state settlement like the tobacco Master Settlement Agreement (MSA).

While plaintiffs and attorneys involved in opioid litigation hope for big payouts, and perhaps changes in industry practices to stem the ongoing crisis, the effects of tort litigation surrounding the

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<sup>5</sup> Michael J. Purcell, “Article: Settling High: A Common Law Public Nuisance Response to the Opioid Epidemic,” *Columbia Journal of Law and Social Problems*, 52, 135 (Fall, 2018), [https://advance-lexis-com.ezp-prod1.hul.harvard.edu/api/document?collection=analytical-materials&id=urn:contentItem:5TMN-4WF0-00CV-B1DB-00000-00&context=1516831](https://advance.lexis-com.ezp-prod1.hul.harvard.edu/api/document?collection=analytical-materials&id=urn:contentItem:5TMN-4WF0-00CV-B1DB-00000-00&context=1516831).

<sup>6</sup> Curtis Weyant, “Opioid Lawsuits,” *ConsumerSafety.org*, accessed September 25, 2018, <https://www.consumersafety.org/legal/opioid-lawsuits/>.

opioid epidemic are varied and often indirect. Suits that have seen success in court have been filed largely by state or local governments, and thus far, payoffs have been in the low millions to low-hundreds of millions, barely making a dent in the multibillion-dollar pharmaceutical industry.<sup>7</sup> I argue that litigation has tightened restrictions on opioid marketing, challenging a wide range of pharmaceutical promotional activities in court, and successfully uncovering and achieving the abandonment of illegal marketing tactics. Legal scrutiny of aggressive marketing tactics and snowballing litigation have arguably led to decisions like Purdue's recently announced end to direct-to-doctor opioid marketing.<sup>8</sup> However, I also suggest that the direct outcomes of the individual cases and settlements have mattered much less than the wide public attention brought to the abuses of the opioid industry by such litigation, as OxyContin sales continue to plunge (from \$2.8 billion in 2012 to \$1.8 billion in 2017) and the tide of public sentiment turns against major pharmaceutical companies implicated in snowballing litigation.<sup>9</sup> Lastly, due to the ongoing nature of much of the opioid litigation, the full scope of the direct effects of litigation on industry regulation remains to be seen, in particular due to the Northern Ohio-based Multidistrict Litigation in progress and its potential for a large-scale settlement like the tobacco Master Settlement Agreement (MSA).

In *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*, Allan M. Brandt asserts that "[t]he historical development of American tort law is predicated on the theory that it leads to greater safety of consumer goods."<sup>10</sup> Under this premise,

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<sup>7</sup> Rebecca L. Haffajee and Michelle M. Mello, "Drug Companies' Liability for the Opioid Epidemic," *New England Journal of Medicine* 377, no. 24 (2017), accessed September 25, 2018, doi:10.1056/nejmp1710756.

<sup>8</sup> German Lopez, "The Maker of OxyContin Will Finally Stop Marketing the Addictive Opioid to Doctors," *Vox*, February 12, 2018, accessed September 25, 2018, <https://www.vox.com/science-and-health/2018/2/12/16998122/opioid-crisis-oxycontin-purdue-advertising>.

<sup>9</sup> *Ibid.*

<sup>10</sup> Allan M. Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*, New York: Perseus, 2007.

manufacturers have a strong incentive to safeguard against possible harms of their products and, if harms become evident, modify their products. If manufacturers do not modify their products, “companies are responsible for the excess social costs that ensue.”<sup>11</sup> Strict liability torts, a specific type of tort claim that emerged following World War II, further expanded companies’ potential liability for harmful products, as a company’s actions no longer needed to be deemed “negligent” for a company to be responsible for its products’ harms. In other words, strict liability was “unburdened by fault.”<sup>12</sup> Brandt writes, “Tort law became a tool for indirect regulatory policy; the full costs of the product would be borne by a company with appropriate incentives for safety and risk reduction.”<sup>13</sup> “Public tort” litigation is one of the more recent developments in product liability. Legal scholar Richard C. Ausness, in “Public Tort Litigation: Public Benefit or Public Nuisance,” defines public tort litigation as government-sponsored suits by “federal, state, or local government entities to recover the cost of public services provided to persons who have been injured as the result of a defendant’s alleged misconduct.”<sup>14</sup> Ausness notes that the ‘Big Tobacco’ litigation of the 1990s, “in which more than forty states brought suit against the leading tobacco companies to recoup the cost of providing health care services to indigent smokers,”<sup>15</sup> is the most well-known example of public tort litigation and that subsequent public tort suits brought by municipalities against handgun manufacturers and paint companies (due to lead-based paint) were largely encouraged by the results of the states’ cases against tobacco companies.<sup>16</sup> I argue that tort litigation against pharmaceutical companies builds on the history of the “Big Tobacco” suits and the host of legal arguments surrounding corporate liability and responsibility that were developed

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<sup>11</sup> Ibid.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

<sup>14</sup> Richard C. Ausness, *Public Tort Litigation: Public Benefit or Public Nuisance*, 77 *Temp. L. Review* 2004, *HeinOnline*, pp. 826-827,

[https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law\\_facpub](https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law_facpub).

<sup>15</sup> Ibid., p. 827.

<sup>16</sup> Ibid.

in the context of major tobacco tort litigation. Throughout this piece, I will gesture to parallel concepts and effects that opioid litigation shares with other historical torts, like tobacco.

## Literature Review

Particularly in the past few years, much has been written about the history and progression of the current opioid crisis in both academic and public media, including the corporate and regulatory failures that arguably contributed to the current crisis.<sup>17</sup> Much of this writing is composed of news articles, investigative journalism, and popular media due to the contemporaneity of the opioid crisis and its surrounding litigation. The academic literature is also substantially situated in law reviews due to the complex legal questions and arguments raised by the current wave of opioid litigation. A great deal of relevant secondary source material also exists on the tobacco litigation of the '90s, particularly *The Cigarette Century* by Allan Brandt.<sup>18</sup> I will use the aforementioned sources for background to historicize the opioid epidemic and to attempt to understand the policy and regulatory outcomes of major tort litigation in the public health sphere. In addition to drawing from a specific source base on the opioid crisis and the tobacco litigation of the '90s, I plan to bring into dialogue with the opioid and tobacco literature additional literature on other regulated substances and associated lawsuits that have drawn on tobacco litigation strategies for inspiration (particularly lead paint and handgun litigation<sup>19</sup>). In addition to my use of news articles and investigative journalistic sources, my additional source material will largely

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<sup>17</sup> D. W. Graeme, *The Opioid Epidemic of America: What You Need Know about the Opiate and Opioid Crisis ... and How We Can Heal from It*, 2017

Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, Baltimore: Johns Hopkins University Press, 2016

Barry Meier, *Pain Killer: An Empire of Deceit and the Origin of America's Opioid Epidemic*, New York: Random House, 2018.

<sup>18</sup> Allan M. Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*, New York: Perseus, 2007.

<sup>19</sup> "Public Tort Litigation: Public Benefit or Public Nuisance?" Temple University Law Review, Vol. 77, pp. 826-827, 2004. *HeinOnline*. [https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law\\_facpub](https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law_facpub).

consist of court documents from a number of notable lawsuits, available in public records online. I plan to draw on a specific set of literature and bring different literatures - on the opioid crisis, associated litigation, and other similar litigation like that against Big Tobacco - into dialogue with each other.

News articles and pieces in popular media covering the opioid epidemic, abuses of the pharmaceutical industry, and related litigation have become too numerous to count, as new municipalities and other plaintiffs continue to file suit as the opioid crisis continues. In addition to pieces in a range of small-scale and local news outlets, major publications like *The New York Times* have followed the legal and regulatory developments of the opioid crisis as they emerge.<sup>20</sup> Investigative reporting has shed light on industry practices relevant to pharmaceutical industry liability and current legal claims. Most notably, the *Los Angeles Times* pursued an investigation of the trajectory of Purdue Pharma's claims about OxyContin, through which previously-unreleased industry documents and communications were obtained and published.<sup>21</sup>

Academic writing on the specifics of opioid litigation, its historical precedents, and legal questions surrounding opioid promotion is primarily situated in legal journals and law reviews. In "Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing" in *Boston University Law Review*, Mark A. Ford details liability around "off-label" use and marketing, which is use or marketing of a drug for a purpose not approved by the Food and Drug Administration (FDA). "Misbranding" of a drug, a catch-all phrase that includes off-label marketing, is prohibited. However, doctors are permitted to prescribe a drug for off-label use, or

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<sup>20</sup> Katie Benner, "Snaring Doctors and Drug Dealers, Justice Dept. Intensifies Opioid Fight," *The New York Times*, 22 Aug. 2018, <https://www.nytimes.com/2018/08/22/us/politics/opioids-crackdown-sessions.html>.

<sup>21</sup> Harriet Ryan, Lisa Girion, and Scott Glover, "'You Want a Description of Hell?' OxyContin's 12-Hour Problem: A Times Investigation," *Los Angeles Times*, 5 May 2016, <https://www.latimes.com/projects/oxycontin-part1/>.

uses not approved by the FDA. Misbranding and off-label marketing claims comprise a notable portion of the marketing-related claims against pharmaceutical manufacturers,<sup>22</sup> and the doctor-industry relationship, particularly in the context of permissible marketing, is the cornerstone of much of the litigation against pharmaceutical companies like Purdue. Additionally, Ford ultimately argues that “the deterrent effects of potential tort liability alone does not [sic] adequately protect healthcare consumers.”<sup>23</sup> There is substantially more legal scholarship on tobacco litigation than opioid litigation, based on its ongoing nature. One notable article that attempted to make projections about the successes of lead paint litigation based on the precedents set by tobacco and asbestos mass tort litigation is “Turning Lead into Asbestos and Tobacco: Litigation Alchemy Gone Wrong,” by Scott A. Smith (*Defense Counsel Journal*). Smith writes, “In 1999, some prominent members of the mass tort plaintiffs’ bar, fresh off conquests of the tobacco and asbestos industries and with war chests in the hundreds of millions of dollars, set their sights on a new target - the former manufacturers of lead paint and lead pigment and their successors-in-interest....To the top plaintiffs’ lawyers, the perceived parallels among asbestos, tobacco and lead were irresistible.”<sup>24</sup> Smith notes that “nearly five years after the plaintiffs’ lawyers’ assaults began in earnest and despite their predictions, as well as those of some legal commentators, lead paint and pigment defendants’ winning record remains intact” in 2004.<sup>25</sup> Some victories against the paint industry have occurred since the publication of Smith’s piece - for example, in late 2018, after 25 years and a series of cases, three paint manufacturers were ultimately deemed responsible for lead

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<sup>22</sup> Mark A. Ford, “Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing,” *Boston University Law Review*, Vol. 83, 2003, p. 432, <https://heinonline.org/HOL/LandingPage?handle=hein.journals/bulr83&div=18&id=&page=>.

<sup>23</sup> *Ibid.*, p. 430.

<sup>24</sup> Scott A. Smith, “Turning Lead into Asbestos and Tobacco: Litigation Alchemy Gone Wrong,” *Defense Counsel Journal*, Vol. 71, 2004, pp. 119-130, <https://www.questia.com/library/journal/1P3-639957051/turning-lead-into-asbestos-and-tobacco-litigation>.

<sup>25</sup> *Ibid.*

contamination in thousands of California houses, but the case was an unexpected victory.<sup>26</sup>

However, Smith's analysis of important differences between industries involved in tort litigation provides valuable historical insight on outcomes of mass tort litigation in the public health sphere and, specifically, projections for opioid litigation.<sup>27</sup>

Richard C. Ausness has published a number of relevant pieces of scholarship on tort litigation relevant to current opioid suits, including: "Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing Products Liability" (South Carolina Law Review, 2001-2002), analyzing the soundness of the doctrine of "negligent marketing"<sup>28</sup>; "Public Tort Litigation: Public Benefit or Public Nuisance" (Temple Law Review, 2004), analyzing the history of public tort litigation against tobacco, handgun, and paint manufacturers (and foreshadowing the potential for future cases against alcohol, fast food, and prescription drug companies), controversy over the value and legitimacy of public tort litigation, and theories of and defenses to liability in public tort litigation;<sup>29</sup> and, most recently, "The Role of Litigation in the Fight Against Prescription Drug Abuse" (West Virginia Law Review, 2013), detailing the liability theories employed in opioid-related litigation, defenses and other limitations on liability, various types of cases being pursued, criminal prosecutions of pharmaceutical

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<sup>26</sup> Columbia Mailman School of Public Health, "A Surprise Environmental Health Victory at the U.S. Supreme Court," *Public Health Now: News*, 22 Oct. 2018, <https://www.mailman.columbia.edu/public-health-now/news/surprise-environmental-health-victory-us-supreme-court>.

<sup>27</sup> Scott A. Smith, "Turning Lead into Asbestos and Tobacco: Litigation Alchemy Gone Wrong," *Defense Counsel Journal*, Vol. 71, 2004, pp. 119-130, <https://www.questia.com/library/journal/1P3-639957051/turning-lead-into-asbestos-and-tobacco-litigation>.

<sup>28</sup> Richard C. Ausness, "Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing Products Liability," *South Carolina Law Review* Vol. 53, pp. 907-966, 2001-2002, [https://uknowledge.uky.edu/law\\_facpub/404/](https://uknowledge.uky.edu/law_facpub/404/).

<sup>29</sup> Richard C. Ausness, "Public Tort Litigation: Public Benefit or Public Nuisance," *Temple Law Review* Vol. 77, Issue 825, 2004, [https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law\\_facpub](https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law_facpub).

companies, prescribing physicians, and pharmacists, and downsides of and alternatives to litigation.<sup>30</sup>

Other notable legal scholarship on opioid litigation includes: “Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation” by Abby Cunningham (Northern Illinois University Law Review, 2017);<sup>31</sup> “Opioid Addiction Litigation and the Wrongful Conduct Rule” by Samuel Fresher (University of Colorado Law Review, 2018);<sup>32</sup> and “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis” by Abbe R. Gluck, Ashley Hall, and Gregory Curfman (Journal of Law, Medicine, & Ethics, 2018).<sup>33</sup>

Cunningham broadly traces the trajectory of opioid litigation, but focuses on the highly specific legal concept of “primary jurisdiction doctrine,” which aims to reconcile courts’ and agency rulings.<sup>34</sup> Fresher analyzes obstacles for plaintiffs in opioid addiction litigation against healthcare institutions and practitioners, “argues that defenses based on plaintiffs’ wrongful conduct, which deny plaintiffs access to civil remedies due to their immoral or illegal conduct, should be eliminated or avoided in suits arising out of addiction,” and advocates that “our civil courts and legislatures should encourage a broad-reaching settlement agreement between governments and healthcare industry actors as a means of ameliorating the disastrous impacts of the opioid crisis on

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<sup>30</sup> Richard C. Ausness, “The Role of Litigation in the Fight Against Prescription Drug Abuse,” West Virginia Law Review Vol. 116, 2014, [https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1341&context=law\\_facpub](https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1341&context=law_facpub).

<sup>31</sup> Abby Cunningham, “Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation,” The Northern Illinois University Law Review, Vol. 9 No. 1, Fall 2017, <https://commons.lib.niu.edu/handle/10843/17903>.

<sup>32</sup> Samuel Fresher, “Opioid Addiction Litigation and the Wrongful Conduct Rule,” University of Colorado Law Review Vol. 89, 2018, pp. 1312-1320, <http://lawreview.colorado.edu/wp-content/uploads/2018/07/89.4-Fresher.pdf>.

<sup>33</sup> Abbe R. Gluck, Ashley Hall, and Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *The Journal of Law, Medicine, and Ethics*, 17 July 2018, <https://doi.org/10.1177%2F1073110518782945>.

<sup>34</sup> Abby Cunningham, “Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation,” The Northern Illinois University Law Review, Vol. 9 No. 1, Fall 2017, <https://commons.lib.niu.edu/handle/10843/17903>.

American society.”<sup>35</sup> Gluck, et. al, focuses on the “second wave” of opioid litigation, primarily on civil cases, and provides a “snapshot of the current state of the opioid litigation, with the caveat that the terrain is constantly shifting,” analyzing legal claims and successes thus far.<sup>36</sup>

Additionally, relevant scholarship in public health and medicine-related source bases includes: “Drug Companies’ Liability for the Opioid Epidemic” by Rebecca L. Haffajee and Michelle M. Mello (*New England Journal of Medicine*, 2017);<sup>37</sup> “Transparency Needed in Opioid Marketing, Litigation Shows” by Alison Knopf (*Alcoholism & Drug Abuse Weekly*, 2018),<sup>38</sup> and “Reducing Harm Through Litigation Against Opioid Manufacturers? Lessons From the Tobacco Wars” by Derek Carr, Corey S. Davis, and Lainie Rutkow (*Public Health Reports*, 2018).<sup>39</sup> The extremely recent publication of most of this relevant scholarship points to the current and ongoing nature of opioid litigation and the fact that much of the litigation’s direct impact remains to be seen.

### **The Context of the Current U.S. Opioid Crisis**

The human toll of the current opioid epidemic in the U.S. presents a staggering picture of a crisis needing urgent remedy. According to the Centers for Disease Control and Prevention (CDC),

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<sup>35</sup> Samuel Fresher, “Opioid Addiction Litigation and the Wrongful Conduct Rule,” *University of Colorado Law Review* Vol. 89, 2018, pp. 1312-1320, <http://lawreview.colorado.edu/wp-content/uploads/2018/07/89.4-Fresher.pdf>.

<sup>36</sup> Abbe R. Gluck, Ashley Hall, and Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *The Journal of Law, Medicine, and Ethics*, 17 July 2018, <https://doi.org/10.1177%2F1073110518782945>.

<sup>37</sup> Rebecca Haffajee, Michelle M. Mello, “Drug Companies’ Liability for the Opioid Epidemic,” *New England Journal of Medicine* Vol. 377, 2017, pp. 2301-2305, <https://www.nejm.org/doi/10.1056/NEJMp1710756>.

<sup>38</sup> Alison Knopf, “Transparency Needed in Opioid Marketing, Litigation Shows,” *Alcoholism & Drug Abuse Weekly*, Vol. 30, Issue 23, 8 June 2018, <https://onlinelibrary.wiley.com/doi/abs/10.1002/adaw.31995>.

<sup>39</sup> Derek Carr, Corey S. David, Lainie Rutkow, “Reducing Harm Through Litigation Against Opioid Manufacturers? Lessons from the Tobacco Wars,” *Public Health Reports* Vol. 133, Issue 2, pp. 207-213, 2018, <https://doi.org/10.1177/0033354917751131>.

an average of 115 people die each day in the United States due to opioid overdoses.<sup>40</sup> For every person in the U.S. lost to gun violence, three people will die due to an opioid overdose,<sup>41</sup> and opioid addiction is now the leading cause of death for persons under the age of 50.<sup>42</sup> Since the beginnings of the epidemic in 1999 until 2016, the number of opioid-related overdose deaths - including those related to prescription opioids and illegal opioids like heroin and fentanyl - increased fivefold. Over that 17-year time span, over 350,000 people died from an opioid overdose. As the epidemic has run its course, its magnitude has continued to grow rather than slowing down, buoyed by spikes in heroin and fentanyl deaths<sup>43</sup>: from 2010 to 2015 alone, annual deaths in the U.S. due to opioid overdoses increased by almost 57%.<sup>44</sup> In 2014, more than 28,000 deaths were due to opioid overdoses - over 14,000 of them due to prescription overdoses<sup>45</sup> - and of the 42,000 people killed by opioid overdoses in 2016, 40% were due to prescription opioids. These figures do not account for the deaths of drug users who began using prescription opioids and moved to deadlier alternatives.<sup>46</sup> While causes of the epidemic are multiple and contested,

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<sup>40</sup> Centers for Disease Control and Prevention, "Opioid Overdose - Understanding the Epidemic," *Centers for Disease Control and Prevention*, August 31, 2017, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>41</sup> "Former DOJ Litigator Jonathan Novak Joins Dallas Law Firm Fears Nachawati; Attorney Brings Significant Opioid Expertise to Mass Tort Litigation," *PR Newswire*, 29 Oct. 2018, accessed Nov. 22, 2018, <https://www.prnewswire.com/news-releases/former-doj-litigator-jonathan-novak-joins-dallas-law-firm-fears-nachawati-300739560.html>.

<sup>42</sup> Curtis Weyant, "Opioid Lawsuits," *ConsumerSafety.org*, accessed September 25, 2018, <https://www.consumersafety.org/legal/opioid-lawsuits/>.

<sup>43</sup> Centers for Disease Control and Prevention, "Opioid Overdose - Understanding the Epidemic," *Centers for Disease Control and Prevention*, August 31, 2017, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>44</sup> CDC National Center for Injury Prevention and Control, "Prescription Behavior Surveillance System (PBSS): Issue Brief," July 2017, *Cdc.gov*, accessed Nov. 26, 2018, <https://www.cdc.gov/drugoverdose/pdf/pbss/PBSS-Report-072017.pdf>.

<sup>45</sup> Dina Gusovsky, "Americans Consume Vast Majority of the World's Opioids," *CNBC*, 27 April 2016, accessed 26 Nov. 2018, <https://www.cnbc.com/2016/04/27/americans-consume-almost-all-of-the-global-opioid-supply.html>.

<sup>46</sup> Centers for Disease Control and Prevention, "Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants - United States, 2015-2016," 30 March 2018, 67(12);349-358, accessed 26 Nov. 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm>.

and have been extensively analyzed, the literature supports the notion that major pharmaceutical companies' highly aggressive, multi-stage marketing tactics (particularly of OxyContin), often with unsubstantiated or false claims, and insufficient monitoring of massive shipments of prescriptions opioids certainly exacerbated, if not helped initiate, the unprecedented current crisis the U.S. faces today.

The CDC has described the current opioid epidemic as composed of three distinct waves. The first wave began in the 1990s: this decade marked a dramatic increase in opioid prescriptions that has continued to this day,<sup>47</sup> resulting in increasing prescription opioid-related deaths since 1999. The second wave, according to the CDC, began in 2010 with a sharp increase in documented heroin overdose deaths. Heroin overdose deaths increased by over 500% between 2010 and 2016. The third wave, starting in 2013, consists of a staggering increase in overdose deaths due to synthetic opioids, particularly illicitly-manufactured fentanyl (IMF), which is found in combination with counterfeit prescription pills, in addition to heroin and cocaine.<sup>48</sup> IMF-related overdoses have dramatically spiked in recent years. Rates of synthetic opioid-related deaths in the U.S. increased 73% from 2014 to 2015 and 264% from 2012 to 2015.<sup>49</sup> The quantity of opioid prescriptions dispensed by U.S. retail pharmacies jumped from 76 million prescriptions in 1991 to a peak of 219 million prescriptions in 2011, a nearly 300% increase.<sup>50</sup> Additionally, extreme

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<sup>47</sup> A brief decrease in opioid prescribing occurred from 2011 to 2013, after which time opioid prescriptions continued increasing again.

<sup>48</sup> Centers for Disease Control and Prevention, "Opioid Overdose - Understanding the Epidemic," *Centers for Disease Control and Prevention*, August 31, 2017, <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

<sup>49</sup> CDC National Center for Injury Prevention and Control, "Prescription Behavior Surveillance System (PBSS): Issue Brief," July 2017, *Cdc.gov*, accessed Nov. 26, 2018, <https://www.cdc.gov/drugoverdose/pdf/pbss/PBSS-Report-072017.pdf>.

<sup>50</sup> NIH National Institute on Drug Abuse, "Senate Caucus on International Narcotics Control Hearing - America's Addiction to Opioids: Heroin and Prescription Drug Abuse," 14 May 2014, accessed 26 Nov. 2018, <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

variation exists in rates of opioid prescribing across states.<sup>51</sup> According to a 2014 study, 82.5 prescriptions for opioid pain relievers (OPR) were dispensed per 100 persons in the U.S. in 2012. However, OPR prescription rates varied up to 2.7 fold between states,<sup>52</sup> for example, between Alabama (142.9 prescriptions per 100 persons) and Hawaii (52.0 prescriptions per 100 persons).<sup>53</sup> Prescription rates per 100 persons varied substantially more dramatically between states when analyzing only high-dose and long-acting/extended release (LA/ER) opioid pain relievers - rates of 4.6-fold (Delaware and Texas) and 5.3-fold (Maine and Texas) respectively.<sup>54</sup> Since 2011, prescription rates have begun to slowly decrease, in the face of growing concerns over irresponsible prescribing practices and increased public attention on opioid-related drug abuse and mortality. In 2017, over 191 million opioid prescriptions were dispensed to patients in the U.S.,<sup>55</sup> down from the 219 million prescriptions peak in 2011.<sup>56</sup> Many states have adopted policies to change prescribing practices using data from prescription drug monitoring programs (PDMPs), particularly targeting patients using multiple prescribers and the most egregious prescribers, which have been met with success in some states.<sup>57</sup>

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<sup>51</sup> Centers for Disease Control and Prevention, "Prescription Opioids," *Opioid Overdose*, 29 August 2017, accessed 26 Nov. 2018, <https://www.cdc.gov/drugoverdose/opioids/prescribed.html>.

<sup>52</sup> Centers for Disease Control and Prevention, "Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines - United States, 2012," *Morbidity and Mortality Weekly Report (MMWR)*, 4 July 2014, 63(26);563-568, accessed 26 Nov. 2018, [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s\\_cid=mm6326a2\\_w#Tab](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w#Tab).

<sup>53</sup> *Ibid.*

<sup>54</sup> *Ibid.*

<sup>55</sup> Centers for Disease Control and Prevention, "Prescription Opioids," *Opioid Overdose*, 29 August 2017, accessed 26 Nov. 2018, <https://www.cdc.gov/drugoverdose/opioids/prescribed.html>.

<sup>56</sup> NIH National Institute on Drug Abuse, "Senate Caucus on International Narcotics Control Hearing - America's Addiction to Opioids: Heroin and Prescription Drug Abuse," 14 May 2014, accessed 26 Nov. 2018, <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

<sup>57</sup> Centers for Disease Control and Prevention, "Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines - United States, 2012," *Morbidity and Mortality Weekly Report (MMWR)*, 4 July 2014, 63(26);563-568, accessed 26 Nov. 2018, [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s\\_cid=mm6326a2\\_w#Tab](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2_w#Tab).

## The Emergence and Trajectory of Opioid Litigation

Like the current opioid epidemic itself, opioid litigation has occurred in distinct “waves.” Since the beginnings of the rise in opioid painkiller prescriptions in the late 1990s, there have been two major waves of litigation.<sup>58</sup> The first wave took place in the early 2000s, shortly after OxyContin was released to market by Purdue Pharma in 1996.<sup>59</sup> (Between its introduction in 1996 and 2000, Oxycontin sales skyrocketed from \$48 million to \$1.1 billion.<sup>60</sup>) This first wave of litigation largely targeted pharmaceutical companies, particularly Purdue, as well as some individual doctors, and was composed of individual suits, class action suits, and suits by state attorneys general, alleging that pharmaceutical manufacturers broke the law by fraudulently and negligently marketing drugs like OxyContin by claiming they were significantly less addictive than other opioid painkillers, despite indications to the contrary.<sup>61</sup> Claims alleged included violations of state consumer protection statutes, conspiracy, breach of implied warranty, violation of strict product products liability, fraud, and various forms of negligence, largely targeting opioid manufacturers’ marketing practices,<sup>62</sup> including claims that Purdue overstated OxyContin’s duration.<sup>63</sup> Hundreds of suits filed by individuals who used OxyContin (as well as by their families) were dismissed.<sup>64</sup> Purdue, among other pharmaceutical companies, avoided liability “by placing blame on the individual plaintiffs who brought suit; by arguing that class actions largely ignored the individual medical records of patients who used their products; and by focusing on the

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<sup>58</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 6, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>59</sup> *Ibid.*, p.3.

<sup>60</sup> *Ibid.*

<sup>61</sup> *Ibid.*, p.4.

<sup>62</sup> *Ibid.*

<sup>63</sup> Harriet Ryan, Lisa Girion, and Scott Glover, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem: A Times Investigation,” *Los Angeles Times*, 5 May 2016, <https://www.latimes.com/projects/oxycontin-part1/>.

<sup>64</sup> *Ibid.*

physicians who 'know the risks...yet decided to prescribe [the medication] anyway.'"<sup>65</sup> Courts that dismissed these cases usually determined that "'intervening conduct' by patients and physicians broke any chain of causation from drug manufacturers to harm."<sup>66</sup> This 'intervening conduct' by patients was key to drug manufacturers' defense because of stigma against addiction, which was arguably more pervasive 10-20 years ago and was reflected in the courtroom. "Individual plaintiffs suffering from addiction to prescription opioids were perceived to have made the choice to abuse their prescriptions."<sup>67</sup> An emphasis was placed on the "illegal conduct" of those suffering from prescription opioid addiction by misusing those drug, and as a public policy matter, courts argued, that illegal conduct "should bar legal recovery."<sup>68</sup> In an early case against Purdue, the Supreme Court of Mississippi asserted, "'This Court will not lend aid to a party whose cause of action directly results from an immoral or an illegal act committed by that party.'"<sup>69</sup> The Mississippi Supreme Court's language echoes that of other courts that dismissed opioid addiction suits at the time.<sup>70</sup> Similar defenses have been used in litigation against handgun manufacturers and distributors. While an appellate court in Illinois rejected "defendants' assertion that they could not be held liable for harm caused by the criminal misuse of its products"<sup>71</sup> in a case brought by the City of Chicago, the Illinois Supreme Court overturned that court's decision and declared in a

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<sup>65</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, "Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis," *Journal of Law, Medicine, & Ethics*, p. 4, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>66</sup> *Ibid.*

<sup>67</sup> *Ibid.*

<sup>68</sup> *Ibid.*

<sup>69</sup> *Ibid.*

<sup>70</sup> *Ibid.*

<sup>71</sup> Richard C. Ausness, Public Tort Litigation: Public Benefit or Public Nuisance, 77 *Temp. L. Review* 2004, *HeinOnline*, p.842, [https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law\\_facpub](https://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1391&context=law_facpub).

unanimous opinion that “there is no public right to be free from the threat of illegal conduct by others.”<sup>72</sup>

Additionally, opioid addiction class action suits were dismissed due to the uniqueness of each individual’s medical history, different prescriptions between patients, and even the fact that patients had different doctors. Courts deemed opioid addiction cases as insufficiently based on a lack of “common issues of law and fact”<sup>73</sup> that are required among claimants in a class action. The indirect “chain of causation” argument was also compelling to many courts, due to the role of the doctor as an intermediary between a drug manufacturer and a plaintiff. One federal court claimed, “[The] existence of individual Learned Intermediaries trumps any common marketing issues.”<sup>74</sup> However, physicians and pharmacists were heavily sued during this first wave of litigation. The DEA soon launched its “OxyContin Action Plan” in “an effort to target doctors and pharmacists who engaged in improper opioid prescription practices.”<sup>75</sup> Arguably, DEA efforts were primarily intended to target “pill mills,” in which prescriptions are distributed for money, often in mass quantities,<sup>76</sup> but controversy existed over unclear standards of pain treatment and doctors’ potential liability for both ‘underprescribing’ and ‘overprescribing.’<sup>77</sup> Notably, throughout most of this first wave of litigation, Purdue successfully petitioned courts to seal evidence, which included millions of pages of industry documents. While those materials technically still remain sealed,

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<sup>72</sup> Ibid.

<sup>73</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, pp. 4-5, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>74</sup> Ibid., p.5.

<sup>75</sup> Ibid., p.6.

<sup>76</sup> Ibid.

<sup>77</sup> Ibid.

investigative journalists have reviewed thousands of them and have been able to release many of them to the public, ranging from internal company memos to communications with the FDA.<sup>78</sup>

Ultimately, the first wave of litigation, throughout which Purdue maintained a ‘no settlement’ policy,<sup>79</sup> came to a halt in 2007.<sup>80</sup> Purdue agreed to pay approximately \$600 million in fines to settle a variety of criminal and civil charges and pleaded guilty to making false claims about its opioid painkillers.<sup>81</sup> Purdue’s top lawyer, former chief medical officer, and former president also pleaded guilty to “misbranding” the drug, receiving three years of probation and 400 mandated hours of community service.<sup>82</sup> By introducing a “misbranded drug” into interstate commerce, the Purdue executives were found to have violated the Federal Food, Drug, and Cosmetic Act (FDCA). 26 states and the District of Columbia received payouts totaling \$20 million in that settlement, while the \$600 million in fines went to the federal government. However, it is unclear how each state used the relatively small amount of settlement money received and whether anti-addiction programs were even benefitted. For example, Connecticut, which received \$719,000, directed the vast majority of the money to the state’s general fund or to attorneys’ fees, and \$100,000 went towards state prescription monitoring programs.<sup>83</sup> Rather than settle in this 26-state agreement, Kentucky, hit particularly hard by the opioid epidemic, filed suit in 2007 against

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<sup>78</sup> Harriet Ryan, Lisa Girion, and Scott Glover, “‘You Want a Description of Hell?’ OxyContin’s 12-Hour Problem: A Times Investigation,” *Los Angeles Times*, 5 May 2016, <https://www.latimes.com/projects/oxycontin-part1/>.

<sup>79</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 4, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>80</sup> *Ibid.*, p.5.

<sup>81</sup> Barry Meier, “In Guilty Plea, OxyContin Maker to Pay \$600 Million,” *The New York Times*, 10 May 2007, accessed 26 Nov. 2018, <https://www.nytimes.com/2007/05/10/business/11drug-web.html>.

<sup>82</sup> Phil McCausland and Tracy Connor, “OxyContin Maker Perdue to Stop Promoting Opioids in Light of Epidemic,” *NBC News*, 10 Nov. 2018, <https://www.nbcnews.com/storyline/americas-heroin-epidemic/oxycontin-maker-purdue-stop-promoting-opioids-light-epidemic-n846726>.

<sup>83</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 5, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

Purdue over marketing of OxyContin as nonaddictive. In late 2015, Kentucky finally settled with Purdue for \$24 million, to be paid over eight years, after turning down a \$500,000 settlement offer in 2007.<sup>84</sup> The Kentucky's case's settlement states, "The settlement resolves allegations that Purdue Pharma illegally misrepresented and/or concealed the highly addictive nature of OxyContin and encouraged doctors who weren't trained in pain management to overprescribe the opioid pain reliever to Kentucky patients."<sup>85</sup> Notably, the court ordered the state to spend the \$24 million from the settlement on addiction treatment programs. While the Kentucky case was arguably a victory for obtaining funds to combat the opioid crisis, the settlement amount was far lower than initially hoped, as the former Kentucky Attorney General who filed the lawsuit argued that the case could be worth \$1 billion if it went in front of a jury. Additionally, unlike in the \$600 million federal settlement,<sup>86</sup> Purdue did not admit to any wrongdoing as part of the Kentucky settlement agreement.<sup>87</sup>

The next major suits brought by governmental bodies started in 2014, as Mississippi, Orange County (CA), Santa Clara County (CA), and Chicago filed suit against Purdue.<sup>88</sup> (It is notable that Mississippi was the first state to file suit in the second-wave of litigation due to its involvement in Big Tobacco litigation, as Mississippi's former Attorney General Mike Moore is known for having negotiated the Master Settlement Agreement and is now heavily involved in opioid litigation.<sup>89</sup>)

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<sup>84</sup> CBS News, "Kentucky Settles Lawsuit with OxyContin Maker for \$24 Million," *Associated Press*, 23 Dec. 2015, <https://www.cbsnews.com/news/kentucky-settles-lawsuit-with-oxycotin-maker-for-24-million/>.

<sup>85</sup> *Ibid.*, pp. 31-32.

<sup>86</sup> Barry Meier, "In Guilty Plea, OxyContin Maker to Pay \$600 Million," *The New York Times*, 10 May 2007, accessed 26 Nov. 2018, <https://www.nytimes.com/2007/05/10/business/11drug-web.html>.

<sup>87</sup> CBS News, "Kentucky Settles Lawsuit with OxyContin Maker for \$24 Million," *Associated Press*, 23 Dec. 2015, <https://www.cbsnews.com/news/kentucky-settles-lawsuit-with-oxycotin-maker-for-24-million/>.

<sup>88</sup> Abby Cunningham, "Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation," *Northern Illinois University Law Review*, Vol. 9 No. 1, Fall 2017, p. 32, accessed 26 Nov. 2018, <https://commons.lib.niu.edu/handle/10843/17903>.

<sup>89</sup> Esmé E. Deprez and Paul Barrett, "The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry," *Bloomberg.com*, October 5, 2017, accessed September 25, 2018,

Additionally, California and Chicago cases were filed with assistance from the same outside counsel, with nearly identical arguments, often sharing exact wording of arguments or entire paragraphs.<sup>90</sup> Even the first sentence of each complaint is word-for-word identical: “A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers.”<sup>91</sup>

The major difference between the first and second waves of litigation is the targets of such lawsuits. First, rather than only targeting major pharmaceutical manufacturers and individual doctors, the current litigation is increasingly focused on “deep pockets,”<sup>92</sup> “as plaintiffs have looked for entities with the ability to pay the multi-billion-dollars price tag associated with efforts to address the [opioid] crisis.”<sup>93</sup> Additionally, “second-wave” suits have increasingly been brought by state and local governments, including sovereign Native American tribes. These suits have arguably received the most media attention, as new counties and cities continue to file. One example of a “typical” local filing is a suit brought by Summit County, Ohio, alleging that the county “has spent \$66 million since 2012 on ramifications of the opioid crisis and is seeking to recoup that large monetary loss to address the ongoing opioid crisis in the County.”<sup>94</sup> The DEA has also increasingly brought criminal prosecutions, a stark shift from the difficulties faced in court by plaintiffs in first-wave opioid litigation.<sup>95</sup>

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<https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry>.

<sup>90</sup> Abby Cunningham, “Purpose, Prudence, and Path: Reevaluating the Primary Jurisdiction Doctrine in the Context of Opioid Litigation,” *Northern Illinois University Law Review*, Vol. 9 No. 1, Fall 2017, p. 32, accessed 26 Nov. 2018, <https://commons.lib.niu.edu/handle/10843/17903>.

<sup>91</sup> *Ibid.*, p.34.

<sup>92</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 6, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>93</sup> *Ibid.*

<sup>94</sup> *Ibid.*, p.7.

<sup>95</sup> *Ibid.*

Finally, a major shift in strategy from the first wave to the second wave litigation is claims against opioid distributors, including major distributors like McKesson<sup>96</sup> and pharmacies like Walmart.<sup>97</sup> The “Big Three” opioid distributors are Cardinal Health, AmerisourceBergen, and McKesson Corporation, which, combined, distribute 85% of all prescription drugs in the U.S. For reference, McKesson alone makes approximately \$4 billion profit annually solely from prescription opioid sales.<sup>98</sup> The legal tactics against both major distributors and pharmacies are quite novel and largely stem from distributors’ obligation to “monitor, detect, investigate, refuse and report suspicious orders of prescription opioids” under federal and state law.<sup>99</sup> When reporting duties are ignored, “opioid diversion,” or the diversion of opioids from legal channels of distribution into the black market, is facilitated. Statistics on staggeringly disproportionate quantities of prescription opioids shipped to municipalities with comparatively small populations provide ample support for distributors’ failure to fulfill reporting duties. One example of a typical piece of evidence in claims against distributors comes from the West Virginia County of Cabell, which despite its population of only 96,000 (including infants and children), was shipped almost 40 million opioid pills over a five year period. 780 million opioid pills were shipped to the state of West Virginia overall over a five-year period. Despite requirements on distributors to report any suspicious orders, not a single suspicious order was reported between 2007 and 2012 in Cabell County, as the opioid epidemic picked up strength and increases in addiction were documented.<sup>100</sup> However, distributors argue that “criminal activity by others necessarily breaks any causal chain”<sup>101</sup> and that “the intervening

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<sup>96</sup> Ibid., p.9.

<sup>97</sup> Ibid., p.10.

<sup>98</sup> Ibid.

<sup>99</sup> Ibid., p.9.

<sup>100</sup> Ibid., p.10.

<sup>101</sup> Ibid., p.12.

actions of physicians and other criminal conduct break the causal link and therefore absolve manufacturers from liability.”<sup>102</sup>

Claims against pharmacies take much of the same line of argument - derived from the duties of pharmacies under the Consumer Protection Act, which state practitioners’ “responsibility for the proper prescribing and dispensing of controlled substances” and pharmacists’ “corresponding responsibility.”<sup>103</sup> Federal settlements have already provided jumping-off points for litigation against pharmacies, as in 2013 Walgreens paid \$80 million to resolve claims from the DEA of “record-keeping and dispensing violations” and in 2016 CVS<sup>104</sup> paid \$8 million in a settlement over federal claims that it issued opioid prescriptions not for a “legitimate medical purpose.”<sup>105</sup>

Claims against distributors have the potential to be less successful than many of the claims involving manufacturer marketing. At least one federal court has argued that the Consumer Protection Act “does not likely create a private cause of action — that is, that while the distributors may have rights owing to the government, only the government, not individuals, can enforce those rights.”<sup>106</sup> If that ruling is adopted by other courts, many claims against distributors will be delegitimized.<sup>107</sup> However, on a federal level, the DEA has increasingly pursued federal enforcement of DEA regulations against distributors, particularly successfully against McKesson,<sup>108</sup> suggesting that even if private litigants’ claims fail, distributors may still be held liable by federal agencies, and regulatory enforcement may be improved. Ultimately, two of the major complicating factors in opioid litigation are the multi-step chain of delivery to opioid users and opioids’ approval as safe and effective by the FDA - both of which are unique to opioid litigation

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<sup>102</sup> Ibid.

<sup>103</sup> Ibid.

<sup>104</sup> Ibid.

<sup>105</sup> Ibid., p.11.

<sup>106</sup> Ibid.

<sup>107</sup> Ibid.

<sup>108</sup> Ibid., p.10.

in contrast to tobacco litigation,<sup>109</sup> necessitate the casting of a wide net of defendants, and are likely to have substantial implications for where liability may be enforced. A spokeswoman for Janssen Pharmaceuticals (owned by Johnson & Johnson), which is being sued in many of the government-backed cases, told a Missouri reporter that Janssen had “acted appropriately, responsibly and in the best interests of patients regarding our opioid pain medications, which are FDA-approved and carry FDA-mandated warnings about the known risks of the medications on every product label,”<sup>110</sup> both doubling down on FDA approval as a shield from liability and hearkening back to tobacco companies’ arguments that product labels and warnings about known risks should protect manufacturers from liability.

In potentially the most significant development in the ongoing litigation, over 1,400 opioid lawsuits filed by county, municipal, and tribal governments, primarily against large pharmaceutical companies,<sup>111</sup> have been consolidated into Multidistrict Litigation (MDL) suit MDL 2804 in the United States District Court for the Northern District of Ohio,<sup>112</sup> the largest current opioid suit, under the purview of Judge Dan Aaron Polster.<sup>113</sup> Multidistrict courts were created under federal law and facilitate the consolidation of cases that are pursuing the same or similar claims against the same defendant(s)<sup>114</sup> - “civil actions involving one or more common questions

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<sup>109</sup> Ibid., p.14.

<sup>110</sup> Katie Mettler, “In Lawsuit, Missouri Says Big Pharma Caused Opioid Crisis with ‘Campaign of Fraud and Deception,’” *The Washington Post*, 22 June 2017, [https://www.washingtonpost.com/news/morning-mix/wp/2017/06/22/in-lawsuit-missouri-says-big-pharma-caused-opioid-crisis-with-campaign-of-fraud-and-deception/?noredirect=on&utm\\_term=.9878a2b0f7de](https://www.washingtonpost.com/news/morning-mix/wp/2017/06/22/in-lawsuit-missouri-says-big-pharma-caused-opioid-crisis-with-campaign-of-fraud-and-deception/?noredirect=on&utm_term=.9878a2b0f7de).

<sup>111</sup> Curtis Weyant, “Opioid Lawsuits,” *Consumer Safety*, Accessed November 20, 2018, <https://www.consumersafety.org/legal/opioid-lawsuits/>.

<sup>112</sup> Ibid.

<sup>113</sup> Daniel Fisher, “Time Running Out for Lawyers Suing Opioid Industry to Show Specific Proof,” *Forbes*, October 19, 2018, <https://www.forbes.com/sites/legalnewslive/2018/10/19/time-running-out-for-lawyers-suing-opioid-industry-to-show-specific-proof/#53d5546c2a86>

<sup>114</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 15, July 17, 2018, <https://doi.org/10.1177/1073110518782945>.

of fact” - despite those cases being filed in different districts.<sup>115</sup> An MDL can then be brought before a single judge, maximizing efficiency, among other benefits.<sup>116</sup> Plaintiffs involved in the Ohio MDL are suing under claims including public nuisance, racketeering and corruption, fraud, and federal and state laws governing controlled substances.<sup>117</sup> The Ohio-based MDL has gained substantial attention of the media and legal scholars, in large part due to Judge Polster’s extremely bold statements<sup>118</sup> indicating that he intends to push the case towards settlement discussions as quickly as possible due to the urgency of mitigating the effects of the opioid epidemic, rather than spend a great deal of time on discovery or venture into litigation.<sup>119</sup> The MDL is extraordinarily unique in its grouping together of a wide range of defendants - including manufacturers, distributors, retailers, and individual physicians<sup>120</sup> - taking an unprecedented approach and showing the potential for a “legislative approach more than a litigation approach.”<sup>121</sup>

I argue that this snowballing litigation - thousands of cases alleging largely overlapping improprieties, although with locally-specific effects - has led to increasingly restricted opioid marketing, most notably Purdue’s ceasing of direct-to-doctor opioid marketing, once the crown jewel of its sales program. While there was (and continues to be) substantial recruitment of municipalities into lawsuits by private firms already involved in litigation in other districts, local

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<sup>115</sup> 28 U.S. Code § 1407, accessed 26 Nov. 2018, <https://www.law.cornell.edu/uscode/text/28/1407>.

<sup>116</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 15, July 17, 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>117</sup> Jan Hoffman, “Can This Judge Solve the Opioid Crisis?” *The New York Times*, March 5, 2018, <https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html>.

<sup>118</sup> *Ibid.*

<sup>119</sup> United States District Court Northern District of Ohio Eastern Division, In Re: National Prescription Opiate Litigation, MDL No. 2804, “Transcript of Proceedings,” 9 January 2018, accessed 26 Nov. 2018, <https://assets.documentcloud.org/documents/4345753/MDL-1-9-18.pdf>.

<sup>120</sup> *Ibid.*, p.17.

<sup>121</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 17, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

governments have been particularly motivated to file individually due to concerns that, as with the financial payouts of the tobacco MSA, financial damages awarded in a potential settlement with states may not reach local communities or may be used for purposes other than those related to the litigation complaints, such as opioid addiction treatment programs.<sup>122</sup> However, municipalities have also stated that motivations for suing include the need for changes in industry behavior and regulation, such as curtailing fraudulent marketing and irresponsible distribution monitoring. Fulton County, part of the Atlanta metropolitan area, has had the highest number of opioid deaths of any county in Georgia and is suing manufacturers, distributors, and doctors for their role in the opioid epidemic, due to which Fulton “has been forced to spend exorbitant amounts of money[,]...including Medicaid costs, law enforcement, judicial, foster care, Narcan costs, loss of productivity and various other costs directly caused by the actions of the defendants,” a combined “millions of dollars each year in its efforts to combat the public nuisance created by Defendants’ deceptive marketing campaign.”<sup>123</sup> The Fulton County manager, Dick Anderson, has argued that the suit “would help with the ‘mounting pressure’ needed to get drug companies to curtail their practices.”<sup>124</sup> However, he argues that if the county does receive money via this litigation, it can be used to assist in residents’ addiction recovery. Shayna Sacks, an attorney involved in the Fulton County case and whose firm is involved in many suits nationwide, argued, ““The only way you can affect change is their wallet.”<sup>125</sup>”

In a particularly unique development, in light of the City of Chicago’s suits against five major pharmaceutical manufacturers, Pfizer (which only markets one prescription opioid) reached an

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<sup>122</sup> Ibid., p.8.

<sup>123</sup> Arielle Kass, “Fulton County Files Suit Against Opioid Manufacturers, Distributors,” *The Atlanta-Journal Constitution*, 23 Oct. 2017, accessed 11 Dec. 2018, <https://www.ajc.com/news/local-govt--politics/fulton-county-files-suit-against-opioid-manufacturers-distributors/HBBwDZy7uJpO9WBDka0htO/>.

<sup>124</sup> Ibid.

<sup>125</sup> Ibid.

agreement with the City of Chicago committing to certain codes of conducts for opioid marketing. A headline from news outlet STAT read: “Pfizer agrees to opioid marketing deal to escape a lawsuit by Chicago.”<sup>126</sup> The statement emphasized that “[t]he City has made no findings that Pfizer has violated any law or ordinance; and Pfizer’s cooperation should not be seen in any way as an admission of any liability or wrongdoing. Pfizer, in fact, denies any liability and denies that it has engaged in any wrongdoing.”<sup>127</sup> In essence, Pfizer agreed to cooperate with the city “by providing city officials with documents and other evidence useful to the lawsuit.”<sup>128</sup> Industry officials note that the requirements of the code of conduct to which Pfizer agreed are already mandated by law - such as disclosing risk of addiction in all promotional materials, emphasizing the lack of sufficient research on the efficacy of long-term opioid use, and refraining from off-label marketing. However, this agreement has made headlines for its particularly unique legal maneuver and officials’ hope that such codes of conduct can be expanded to other pharmaceutical companies to become standard practice.<sup>129</sup>

The State of New Jersey’s case against Purdue, originally filed in October 2017 (the complaint was later revised), is an illustrative example of many government-backed suits targeting illegal marketing practices by Purdue. New Jersey’s case is unique in that it is solely targeting Purdue, but allows for specific analysis of marketing-focused claims. The complaint lays out the range of allegations pursued against Purdue, including, but not limited to:

*“A. From the Late 1990s to 2007, Purdue Engaged in a Campaign of Deception to Create and Sustain a Market for Its Opioids:*

*1. Purdue Used the Medical Community’s Increased Focus on Pain as a Springboard for Its Deceptive Marketing*

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<sup>126</sup> Ed Silverman, “Pfizer Agrees to Opioid Marketing Deal to Escape a Lawsuit by Chicago,” *STAT*, 6 July 2016, accessed 11 Dec. 2018, <https://www.statnews.com/pharmalot/2016/07/06/pfizer-opioids-chicago-painkiller/>.

<sup>127</sup> “Separate Agreement Pursuant to Release Agreement,” Pfizer Inc and the City of Chicago, 30 June 2016, accessed 11 Dec. 2018, <http://freepdfhosting.com/98647a7475.pdf>.

<sup>128</sup> Ed Silverman, “Pfizer Agrees to Opioid Marketing Deal to Escape a Lawsuit by Chicago,” *STAT*, 6 July 2016, <https://www.statnews.com/pharmalot/2016/07/06/pfizer-opioids-chicago-painkiller/>.

<sup>129</sup> *Ibid.*

2. *Purdue Seeded the Science Regarding the Efficacy and Risks of Opioids with Flawed and Biased Research*
3. *Purdue Worked with Professional Associations to Create Treatment Guidelines that Overstated the Benefits and Understated the Risks of Opioids*

...

*B. From 2007 to the Present Day, Purdue’s Marketing in New Jersey Has Continued to Misrepresent the Risks and Benefits of Opioids.*

1. *Purdue Has Falsely Minimized or Failed to Disclose the Known, Serious Risk of Addiction*
  - a. *Omitting, trivializing, and mischaracterizing addiction risk*
  - b. *Overstating the efficacy of screening tools*
  - c. *Failing to disclose increased risk of higher doses*
  - d. *Overstating the efficacy of “abuse-deterrent” properties*
2. *Purdue Has Grossly Overstated the Benefits of Chronic Opioid Therapy While Failing to Disclose the Lack of Evidence Supporting Long-term Use*
3. *Purdue Has Misleadingly Promoted OxyContin as Supplying 12 Hours of Pain Relief*

*C. Purdue Targeted the Elderly and Opioid-Naive Patients to Expand Market Share and Profits*

*D. Purdue Has Caused Significant Harm to Public Health, Welfare, and Safety in New Jersey”<sup>130</sup>*

The New Jersey complaint is an excellent reflection of the primary marketing-focused claims against Purdue across current litigation.<sup>131</sup> Its claim that Purdue “worked with Professional Associations to Create Treatment Guidelines that Overstated the Benefits and Understated the Risks of Opioids”<sup>132</sup> refers to one of the newest suits, filed on November 2, 2017, against the Joint Commission On Accreditation of Health Care Organizations (“The Joint Commission”), which is a non-profit organization that certifies most major hospitals nationwide and a total of over 20,000 healthcare organizations. The Joint Commission released a now-infamous 2001 report on new standards for pain management, now often known as “pain as the fifth vital sign.”<sup>133</sup> Shortly before

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<sup>130</sup> Complaint for Violation of the New Jersey False Claims Act, N.J.S.A., 2A:32C-1, ET SEQ., As Well As Other Claims, Christopher S. Porrino, Attorney General of the State of New Jersey, and Sharon M. Joyce, Acting Director of the New Jersey Division of Consumer Affairs, Plaintiffs, v. Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company; and XYZ Corporations 1-20, Defendants, accessed 11 Dec. 2018.

<sup>131</sup> *Ibid.*

<sup>132</sup> *Ibid.*

<sup>133</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p.11, July 17, 2018, accessed 26 Nov. 2018, <https://doi.org/10.1177/1073110518782945>.

that class action was filed in West Virginia federal district court,<sup>134</sup> The Joint Commission released new standards and has since released a further updated set of standards to be enacted January 1, 2019,<sup>135</sup> acknowledging that knowledge of pain management practices and precautions has developed since the release of the 2001 report.

As evident by the mass amounts of news articles and popular media outlets covering developments in the opioid crisis and associated litigation, the publicity around opioid-related pharmaceutical companies and lawsuits has exploded into public view in the a very short timeframe. As public tort litigation continued to take hold across the country in areas affected by the opioid crisis, in a legal onslaught of unseen proportions for the opioid industry throughout 2017, Purdue announced in February of 2018 its decision to end its now-infamous direct-to-doctor marketing. In a news article by Vox, German Lopez writes: "Purdue's decision to stop marketing OxyContin comes at a convenient time for the company. Purdue, along with other opioid companies, has over the past several years faced an increasing number of lawsuits from cities, counties, and states blaming the drug manufacturers for irresponsibly fostering the current overdose crisis."<sup>136</sup> While causation is highly difficult to prescribe, the immense public media scrutiny on Purdue, including a number of protests, has dramatically changed public opinion of opioid companies as the epidemic continues. Public pressure for behavior change, in tandem with thousands of lawsuits, arguably played a major role in Purdue's ending of the marketing program that made it famous.

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<sup>134</sup> Ibid.

<sup>135</sup> The Joint Commission, "Prepublication Standards - Revisions for Pain Assessment and Management," *The Joint Commission*, Topic Details, 25 June 2018, accessed 11 Dec. 2018, [https://www.jointcommission.org/prepublication\\_standards\\_-\\_revisions\\_for\\_pain\\_assessment\\_and\\_management/](https://www.jointcommission.org/prepublication_standards_-_revisions_for_pain_assessment_and_management/).

<sup>136</sup> German Lopez, "The Maker of OxyContin Will Finally Stop Marketing the Addictive Opioid to Doctors," Vox, February 12, 2018, accessed September 25, 2018, <https://www.vox.com/science-and-health/2018/2/12/16998122/opioid-crisis-oxycontin-purdue-advertising>.

Another major function of litigation, in conjunction with resulting media and publicity, is its investigatory function and potential for release of damning documents, one of the hallmarks of the Big Tobacco litigation.<sup>137</sup> Purdue is currently embroiled into a multi-year fight with the state of Kentucky over sealed documents from its 2015 settlement. After documents were ordered released by a local Kentucky judge, Purdue appealed, and the decision is still pending, resulting in no unsealing of the documents up to this point. However, in August 2018, House lawmakers at the federal level have requested one of the most sought-after documents in the Kentucky material - a deposition of Dr. Richard Sackler, former Purdue president.<sup>138</sup> While arguably the settlement led to the negative effect of the sealing of documents that could benefit current litigation and payouts, the litigation itself provided immense benefit by facilitating the obtaining and creation of millions of pages of documents that will likely become increasingly relevant to federal investigations. While like in the tobacco cases, effective discovery in litigation by no means guarantees a clear victory, sufficient payouts, or effective regulatory reform, evidence from internal pharmaceutical documents has the potential to be the “smoking gun” many prosecutors have been looking for in opioid litigation.

Ultimately, while change appears to be coming to the opioid industry as it continues to face mounting public pressure and litigation, the full outcomes of litigation remain to be seen due to the Ohio MDL, due to its extraordinary uniqueness among other tort litigation. Judge Polster, in statements in court, argued that he, along with all of the plaintiffs and defendants assembled in his courtroom, has an obligation to address the opioid epidemic and stem the continuation of deaths continuing to occur, even citing the number of deaths from opioids likely to occur just while

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<sup>137</sup> Allan M. Brandt, *The Cigarette Century: The Rise, Fall, and Deadly Persistence of the Product That Defined America*, New York: Perseus, 2007.

<sup>138</sup> Andrew Joseph, “Congress Requests Sackler Deposition That Purdue Pharma Is Fighting to Keep Sealed,” *STAT*, 6 Aug. 2018, accessed 11 Dec. 2018, <https://www.statnews.com/2018/08/06/congress-purdue-pharma-richard-sackler-deposition/>.

sitting in the courtroom that day. Polster went so far as to say in court: “[I]n my humble opinion, everyone shares some of the responsibility, and no one has done enough to abate it. That includes the manufacturers, the distributors, the pharmacies, local governments, hospitals, third-party payors [sic], and individuals. Just about everyone we’ve got on both sides of the equation in this case.”<sup>139</sup>

Polster went on to state:

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. I don’t think anyone in the country is interested in a whole lot of finger-pointing at this point, and I’m not either. People aren’t interested in depositions, and discovery, and trials. People aren’t interested in depositions, and discovery, and trials. People aren’t interested in figuring out the answer to interesting legal questions like preemption and learned intermediary, or unravelling complicated conspiracy theories. So my objective is to do something meaningful to abate the crisis and to do it in 2018. And we have here — we’ve got all the lawyers. I can get the parties, and I can involve the states. So we’ll have everyone who is in a position to do it. And with all of these smart people here and their clients, I’m confident we can do something to dramatically reduce the number of opioids that are being disseminated, manufactured, and distributed....So that’s really what I want to talk to everyone today, and if we can get some agreement on both sides that that’s what we ought to do and that’s how we should spend—I mean, look around this room; an incredible amount of talent. I doubt if any judge has ever assembled this kind of talent ever....I think we have an opportunity to do it, and it would be an abject abdication of our responsibility not to try it. And if we can’t, then we’ve got to do the other way. And if we can get some general agreement that we should try it, then we’ll figure out today, how do we organize that effort, who is not here that we need to get involved, and we’ll get about doing it and what help I’ll need.<sup>140</sup>

This approach - which has earned Judge Polster a fair amount of ridicule and disdain from peers, in addition to praise - <sup>141</sup> seems optimistic and unprecedented among other historical examples of mass tort litigation. However, the urgency of the opioid crisis and its death toll - which appears to be motivating Judge Polster to find and implement policy-style solutions rather than spending years

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<sup>139</sup> United States District Court Northern District of Ohio Eastern Division, In Re: National Prescription Opiate Litigation, MDL No. 2804, “Transcript of Proceedings,” 9 January 2018, accessed 26 Nov. 2018, <https://assets.documentcloud.org/documents/4345753/MDL-1-9-18.pdf>.

<sup>140</sup> *Ibid.*

<sup>141</sup> Jan Hoffman, “Can This Judge Solve the Opioid Crisis?” *The New York Times*, March 5, 2018, <https://www.nytimes.com/2018/03/05/health/opioid-crisis-judge-lawsuits.html>.

in court or focusing on document discovery - will dramatically shape how the MDL plays out. as litigation continues to pile on as the opioid crisis continues, along with the push for a comprehensive multi-state settlement, the potential of litigation to affect opioid companies in the ways in which litigation affected “Big Tobacco” companies in the ‘90s become a more distinct possibility, with the hope that financial payments will be more effectively distributed and utilized than through the Master Settlement Agreement (MSA), in order to address the highly localized effects of the opioid crisis. Some scholars have argued that governments have been particularly motivated to file individually due to concerns that, as with the financial payouts of the tobacco MSA, financial damages awarded in a potential settlement with states may not reach local communities or may be used for purposes other than those related to the litigation complaints, such as opioid addiction treatment programs.<sup>142</sup> Litigation may prove to have the benefit of effecting regulatory change that has thus been impossible on the state and federal level due to the influence of pharmaceutical lobbyists, much like automotive manufacturer litigation led to regulation that was previously politically unattainable due to industry lobbyists.<sup>143</sup> The influence of opioid litigation on industry marketing and regulation only continues to grow, as increased publicity and legal scrutiny converge, and the federal government builds on the history of previous opioid litigation in its investigations. Now, the question remains as to how to best shape the effects of future and ongoing litigation to comprehensively address the opioid crisis, rather than solely providing a payday for plaintiffs’ lawyers and general state funds.

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<sup>142</sup> Abbe R. Gluck, Ashley Hall, Gregory Curfman, “Civil Litigation and the Opioid Epidemic: The Role of Courts in a National Health Crisis,” *Journal of Law, Medicine, & Ethics*, p. 8, July 17, 2018, <https://doi.org/10.1177/1073110518782945>.

<sup>143</sup> *Ibid.*, p.21.

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