

# Reducing Harm Through Litigation Against Opioid Manufacturers? Lessons From the Tobacco Wars

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"It's déjà vu all over again."

—Yogi Berra

The opioid epidemic in the United States continues unabated. After increasing every year since 2002, opioid overdose deaths surpassed 33 000 in 2015.<sup>1</sup> Heroin and fentanyl account for an increasing percentage of these deaths, but a substantial number involve prescription opioid pain relievers (OPRs), and many people became addicted to OPRs before transitioning to illicit opioids.<sup>1-4</sup> In addition to these human costs, the estimated economic burden of OPR disorders exceeded \$78 billion in 2013.<sup>5</sup>

OPR prescriptions increased by more than 350% from 1999 to 2015, driven predominantly by attempts to reduce the burden of chronic noncancer pain.<sup>6</sup> Although accompanied by a sharp rise in opioid-related morbidity and mortality, increased OPR prescriptions—annual sales of which increased from \$1 billion in 1992 to nearly \$10 billion in 2015—do not appear to have decreased the population-level prevalence of pain.<sup>1,7-9</sup> As the opioid epidemic's human and economic costs and industry profits accumulate, public scrutiny has turned toward the misleading and, at times, arguably illegal practices of some companies that make and market OPRs.

Dozens of state, local, and tribal governments have sued OPR manufacturers for their alleged role in fueling the opioid overdose epidemic, and 41 state attorneys general are investigating potential unlawful sales and marketing practices by OPR manufacturers.<sup>10,11</sup> The trajectory of these investigations and lawsuits appears similar to those against the tobacco industry during the 1990s, when nearly every state sued tobacco manufacturers over predatory and deceptive practices that led to the death and disability of millions of people. Those lawsuits ended when 46 states and the 4 largest cigarette manufacturers entered into the Master Settlement Agreement (MSA), which provided billions of dollars to state and local governments but did little to foster future reductions in tobacco-related harm.<sup>12,13</sup>

Despite similarities between lawsuits against OPR manufacturers and those leading to the MSA, OPRs and cigarettes differ in important ways. Chief among these differences is that unlike tobacco, which provides no medicinal value and is often deadly when used as intended, OPRs can be used safely and are indispensable for palliative care and treating some cancers, human immunodeficiency virus, and acute pain.<sup>14</sup> The regulatory environment for OPRs and cigarettes also differs in important ways. Nevertheless, the history of tobacco litigation offers important lessons for addressing the role of OPR manufacturers in the opioid overdose epidemic. We examine ongoing litigation against OPR manufacturers within this context, highlighting parallels between lawsuits filed against OPR manufacturers and lawsuits that resulted in the MSA, and discuss why a similar agreement in the OPR context would be unlikely to substantially reduce opioid-related morbidity and mortality absent contemporaneous comprehensive regulatory reform.

## Litigation Against the Tobacco Industry

Individual smokers sued tobacco companies as early as 1954, arguing that the companies negligently failed to disclose tobacco products' harmful nature or were strictly liable for marketing a dangerous product.<sup>15</sup> None of the more than 800 cases filed from 1954 through 1994 succeeded.<sup>15-17</sup> Beginning in 1983, concerted efforts by plaintiffs' attorneys and public health advocates to develop and advance new legal theories fueled a second wave of litigation against the

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tobacco industry.<sup>15</sup> Although tobacco companies avoided paying any financial judgments during this second wave, they suffered a substantial blow from the landmark 1992 Supreme Court decision *Cipollone v Liggett*.<sup>18</sup>

Rose Cipollone, a lifetime smoker, initiated the litigation before her death from lung cancer. The case eventually reached the Supreme Court, which held that federally mandated health warnings on cigarette packaging preempted (ie, prohibited) most lawsuits based on cigarette advertisements' failure to include sufficient health warnings. However, the court also breathed new life into lawsuits against tobacco companies by holding that federal law did not prohibit lawsuits based on tobacco companies' efforts to mislead the public about the dangers of smoking.<sup>18</sup> Furthermore, *Cipollone* and other litigation forced tobacco companies to turn over thousands of internal documents. These documents made clear that the companies knew about the danger of cigarettes and systematically concealed this information by creating and disseminating favorable research while suppressing research that linked smoking with health harms.<sup>15,19</sup>

Buoyed by the *Cipollone* decision and mounting evidence of the tobacco industry's widespread misconduct, a more successful wave of litigation began in 1994, during which several individual and class-action lawsuits resulted in verdicts against or settlements with tobacco companies.<sup>13,20</sup> These victories, although important, paled in comparison to what would become the high-water mark of tobacco litigation: medical care cost recovery lawsuits brought by state attorneys general.<sup>13</sup>

In May 1994, Mississippi Attorney General Michael Moore filed the first state lawsuit against the tobacco industry. The state's legal complaint detailed the industry's decades-long effort to mislead the public about the harms of smoking cigarettes and argued that tobacco companies, rather than taxpayers, should be responsible for Medicaid and other health care expenditures incurred by the state in treating tobacco-related disease.<sup>21</sup> Within months, Minnesota and West Virginia filed similar lawsuits; Florida and Massachusetts followed the next year.<sup>22</sup> By 1998, 43 states and numerous local jurisdictions had filed suit against tobacco companies.<sup>23,24</sup>

Faced with an increasing number of lawsuits and continued public release of damaging internal documents, tobacco companies began settlement discussions.<sup>22</sup> Five states settled with the Liggett Corporation in March 1996, and 4 states reached settlement agreements with other tobacco companies between July 1997 and May 1998.<sup>13,22</sup> In November 1998, the remaining states, the District of Columbia, and 5 US territories (settling states) entered into the MSA with the 4 largest cigarette manufacturers.<sup>12</sup>

Under the MSA, which remains the largest civil settlement in US history, the 4 largest cigarette manufacturers agreed to pay the settling states \$206 billion during 25 years and up to \$9 billion annually in perpetuity thereafter, based largely on the volume of cigarettes sold each year.<sup>12,25</sup> In addition, the MSA provided initial funding for a national

foundation and advertising campaign to reduce tobacco-related disease and youth tobacco use, required the public release of additional internal tobacco industry documents, and imposed restrictions on tobacco companies' advertising and marketing practices.<sup>12,25,26</sup> The tobacco companies also agreed to disband industry research entities and front groups. In exchange, the settling states released the tobacco companies from all current and future medical care cost reimbursement claims.<sup>12</sup> The MSA did not affect lawsuits brought by individuals or entities other than the settling states.<sup>12,27</sup>

### State and Federal Litigation Against OPR Manufacturers

The earliest major lawsuit against an OPR manufacturer was brought in 2001, when West Virginia sued Purdue Pharma for its alleged illegal marketing of OxyContin.<sup>28</sup> A class-action lawsuit filed by 26 states and the District of Columbia made similar allegations, including that Purdue made misleading claims about OxyContin's addiction risks.<sup>29</sup> Purdue settled both lawsuits, agreeing to pay modest financial penalties and modify some marketing and business practices.<sup>30</sup>

In 2007, a federal criminal investigation into Purdue ended with 3 executives and the company itself pleading guilty to illegally marketing OxyContin and agreeing to pay \$635 million in fines. Purdue admitted to telling "health care providers that OxyContin did not cause a 'buzz' or euphoria... had less addiction [and] abuse potential, [and] was less likely to be diverted than immediate-release opioids."<sup>31</sup> The following year, the drug maker Cephalon pled guilty in federal court to illegally marketing 3 drugs, including 1 product, Actiq, which contained the powerful opioid fentanyl, and paid \$425 million in fines.<sup>32</sup>

Despite these legal consequences, some OPR manufacturers allegedly continued to use misleading and illegal practices. In 2015, Purdue settled lawsuits brought by New York and Kentucky alleging improper marketing of OxyContin—nearly the same allegations to which the company had pled guilty in federal court 8 years before.<sup>33,34</sup> Insys, manufacturer of the oral fentanyl spray Subsys, paid millions to settle lawsuits brought by Illinois and Oregon, and the federal government brought criminal charges against 6 Insys executives for bribing physicians to prescribe the powerful opioid.<sup>35-37</sup> Other OPR manufacturers, including Mallinckrodt and Endo Pharmaceuticals, have also faced civil and criminal charges.<sup>38,39</sup>

These initial efforts against the opioid industry involved individual OPR manufacturers and company executives. However, increased public scrutiny of industry practices prompted several states to take action to hold OPR manufacturers collectively accountable for their role in the opioid epidemic. In December 2015, the Mississippi attorney general's office—the same office that sparked widespread state litigation against the tobacco industry—sued Purdue, Cephalon, Teva, Janssen, Johnson & Johnson, Endo, and Allergan, alleging violations of many of the same state laws used to

pursue the tobacco industry. These allegations included engaging in Medicaid fraud and in unfair and deceptive trade practices in violation of state consumer protection laws.<sup>40</sup>

From May through September 2017, 4 other states—Missouri, New Mexico, Ohio, and Oklahoma—filed similar lawsuits against some or all of these OPR manufacturers.<sup>41–44</sup> Furthermore, a coalition of 41 state attorneys general is investigating potentially unlawful sales and marketing practices by OPR manufacturers; in September 2017, they served several companies with investigative subpoenas.<sup>45,46</sup>

The states' civil complaints detailed how the OPR industry allegedly used many of the same practices used by the tobacco industry to systematically increase the prescription and use of OPRs, including paying front groups, physicians, and other key opinion leaders to make promotional activities appear independent and avoiding regulatory restrictions through unbranded marketing campaigns. The states also alleged that OPR manufacturers disseminated misleading direct-to-consumer advertising; facilitated the creation and dissemination of scientifically suspect research, medical education, and treatment guidelines that promoted increased OPR use while misrepresenting the risks and benefits of their products and alternative treatments; and targeted certain practitioners to foster new high-volume OPR prescribers.<sup>40–44</sup>

### *The MSA: A Missed Opportunity*

State litigation against tobacco manufacturers represented an unprecedented opportunity to hold the industry legally accountable for the morbidity and mortality associated with smoking, but the MSA produced mixed results. The MSA did accomplish several important objectives, some that may have been difficult or impossible to achieve via regulation alone. For example, the MSA provided initial funding for the Truth Initiative, which oversaw one of the more successful public health advertising and social-norm change campaigns in recent history.<sup>47,48</sup> Internal tobacco industry documents released under the MSA and subsequent court decisions have helped to improve tobacco control policy, and tobacco billboards disappeared due to MSA-imposed advertising restrictions that would otherwise not have been constitutionally permissible.<sup>49–51</sup>

These achievements, however, must be viewed alongside the MSA's shortcomings. The MSA's effect on reducing smoking rates—its ostensible public health goal—is unclear. Smoking rates declined after the MSA, primarily due to increased cigarette prices, but these declines began before the agreement and were likely influenced by contemporaneous tobacco prevention and control efforts.<sup>13,26,52,53</sup> Moreover, although the MSA virtually eliminated outdoor tobacco advertisements and substantially reduced tobacco industry sponsorships and branded merchandise, tobacco industry marketing expenditures more than doubled from 1996 through 2005 as companies shifted to avenues left

unrestricted by the settlement, such as point-of-sale advertising and pricing promotions.<sup>54,55</sup>

Central to the MSA's shortcomings was its failure to include any requirements or limitations on how states could spend the billions of dollars received from the tobacco industry. Although MSA funding was a welcome benefit to settling states and a handful opted to use those funds to make substantial investments in tobacco control and public health, most states treated them as general revenue to cover budget shortfalls, subsidize tax cuts, and support general government services.<sup>56</sup> Moreover, by calculating payment amounts based on domestic cigarette sales, the MSA actually created a perverse incentive for states to protect the sale of cigarettes.<sup>57</sup> Many states have already spent future settlement funds by issuing bonds against future tobacco payments and are, therefore, dependent on those payments to avoid defaulting on those bonds.<sup>58,59</sup> In one instance, state attorneys general helped Phillip Morris fight a court judgment with the potential to bankrupt the company in part to ensure that the MSA payments would continue.<sup>57</sup>

### *Implications of the Tobacco Settlement for Opioid Litigation*

Courts have yet to address the merits of the lawsuits against OPR manufacturers, but, largely because of the facial similarities between the tobacco and opioid litigation, speculation has already emerged that states and OPR manufacturers will pursue a settlement agreement (opioid MSA) modeled on the tobacco MSA.<sup>60</sup> An opioid MSA appears possible considering the growing number of lawsuits against OPR manufacturers and with state attorneys general (and outsourced law firms hired by those attorneys general) likely weighing protracted litigation against the benefits of settling. Indeed, Purdue has reportedly proposed an MSA-style settlement agreement to state attorneys general.<sup>11</sup> An opioid MSA might benefit all parties to the litigation: OPR manufacturers get clarity about certain types of potential liability, states get needed funding, and state attorneys general get a legal and political victory against an unpopular industry. However, the MSA experience suggests that such an agreement would likely not be the most effective solution for reducing future harm to the states' citizens.

As a preliminary manner, key differences between tobacco and OPRs may negatively affect lawsuits against OPR manufacturers. At the time of states' lawsuits against the tobacco industry, the only direct federal regulation of tobacco products concerned health warnings on cigarette packaging, prohibition of cigarette advertising on radio and television, and prohibition of smoking on domestic flights and interstate buses.<sup>15</sup> This regulatory vacuum allowed for the introduction, marketing, and sale of tobacco products largely without federal oversight and permitted state lawsuits against the tobacco industry to proceed without a complicated interplay between state and federal law. In contrast, federal laws such as the Food, Drug, and Cosmetic Act

regulate nearly every aspect of the prescription drug market, and the Controlled Substances Act subjects certain drugs, including OPRs, to even stricter regulation.<sup>61,62</sup> Moreover, although cigarettes have no recognized medical value, OPRs are beneficial for some patients with certain conditions.<sup>14</sup>

These differences will not necessarily determine the outcome of lawsuits against OPR manufacturers. States generally maintain authority to supplement federal regulation of prescription drugs and controlled substances, including, for example, via aspects of consumer protection laws.<sup>63</sup> Federal courts have held that the Food, Drug, and Cosmetic Act does not preempt certain state tort law claims against prescription drug manufacturers and that a drug's US Food and Drug Administration (FDA) approval does not provide its manufacturer(s) blanket protection from liability under state law.<sup>64</sup>

Nevertheless, OPR manufacturers are already exploiting opportunities not available in the tobacco context to combat lawsuits against them. For example, the expansive federal regulation of OPRs often allows OPR manufacturers to argue that courts should stay proceedings against them while the FDA completes a review of the issues presented by the lawsuits. Indeed, a California state judge halted a case brought by 2 California counties on those grounds, and OPR manufacturers asked the court hearing the case brought against them by the Ohio attorney general to do the same.<sup>65,66</sup> The uncertain timeline for the FDA to complete evaluations on the risks and benefits of OPRs and the constant stream of new research mean that such stays may give OPR manufacturers an indefinite reprieve from states' lawsuits.

The process leading to the MSA and the settlement itself offers valuable lessons for the ongoing lawsuits against OPR manufacturers. In many ways, the MSA reflected limitations inherent to government-led civil litigation and corresponding settlement agreements. These lawsuits and settlement agreements can bring attention to industry misdeeds, exact substantial financial concessions, and impose binding obligations on the corporations that were sued.<sup>16</sup> However, from a public health standpoint, they do not necessarily accomplish more than could be achieved through legislation or regulation and often take far longer.

Even with the collective resources and leverage of every state attorney general, billion-dollar industries often have a decisive advantage in settlement negotiations. Indeed, the continued existence and profitability of a tobacco industry dedicated to the sale of deadly products occurred by design, not happenstance—both the tobacco companies and the state attorneys general entered into an agreement that permitted the continued sale and marketing of a product known to cause nearly 500 000 deaths annually.<sup>13,26,67</sup> An opioid MSA may fare better considering the more modest goals of state litigation against OPR manufacturers, where states seek to be compensated for costs they incurred in addressing opioid-related harm and potentially to modify the practices used by OPR manufacturers, not to eliminate the OPR industry entirely. However, given the long delays and uncertain

outcomes of litigation, regulation may be a more promising option for reducing opioid-related morbidity and mortality.

The MSA's most direct and substantial effect on reduced smoking rates and per-capita cigarette consumption resulted from increased cigarette prices, as tobacco companies sought to offset their payments to states.<sup>13,25,53</sup> These price increases essentially operated as an excise tax on cigarette sales, a widely used regulatory strategy with unquestioned efficacy in reducing tobacco use.<sup>15,25,68</sup> However, even if litigation against OPR manufacturers causes OPR prices to increase, such a result is unlikely to substantially affect opioid-related morbidity and mortality because health insurers, not consumers, pay most prescription drug costs. In contrast, a comprehensive, sustained regulatory and policy strategy has proven effective in reducing overdose morbidity and mortality.<sup>69</sup> Similar evidence on the efficacy of other public health regulations, such as clean indoor air laws, is so widespread as to need no further elaboration.<sup>70,71</sup>

## Conclusion

The opioid overdose epidemic continues to cut short the lives of tens of thousands of Americans each year. Urgent action is needed to rapidly and dramatically reduce this preventable harm. Much of the rise in opioid-related morbidity and mortality was allegedly driven by the misleading and, at times, illegal practices used by OPR manufacturers—all without substantial reduction in overall pain prevalence. As with litigation against the tobacco industry, state litigation against OPR manufacturers can play a critical role in uncovering questionable industry practices, holding accountable entities that violate state or federal law, and galvanizing support for reform.

The tobacco MSA has provided billions of dollars to state and local governments but fallen short in fostering future reductions in tobacco-related harm. Few reasons exist to believe a similarly styled opioid MSA would produce better results. States should be mindful of these lessons and use litigation against OPR manufacturers in conjunction with the robust regulatory solutions needed to meaningfully reduce opioid-related harm.

## Authors' Note

The views expressed in this article are solely those of the authors and do not necessarily represent those of any individuals or organizations with whom the authors are affiliated.

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