

THE OPIOID EPIDEMIC: LEGAL CHALLENGES TO DRUG MANUFACTURERS

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SUMMARY:

- The opioid epidemic is devastating communities across the country, fueling a spike in overdose deaths, and creating a financial strain on all levels of government and among health care providers.
- Essential hospitals continue to play a unique role in preventing and treating opioid addiction and they bear the associated financial burden.
- Federal, state, and local governments, as well as some providers, seek financial restitution for the costs of the opioid epidemic through litigation against opioid manufacturers and distributors.
- There are important, applicable lessons from the tobacco settlements of the 1990s, which resulted in massive settlements, though the uses of that revenue vary greatly between states.

The opioid epidemic continues to challenge communities and government entities at all levels throughout the United States. In 2016, the most recent year for which complete data is available, more than 42,000 individuals died of an overdose involving opioids, more than

a four-fold increase from 2002.¹ This crisis has put a financial strain on state and local governments as they shift resources to health care, social services, education, and criminal justice to combat the epidemic. Given their role in the prevention and treatment of substance use disorders, essential hospitals have borne a significant share of these opioid-related health care costs.

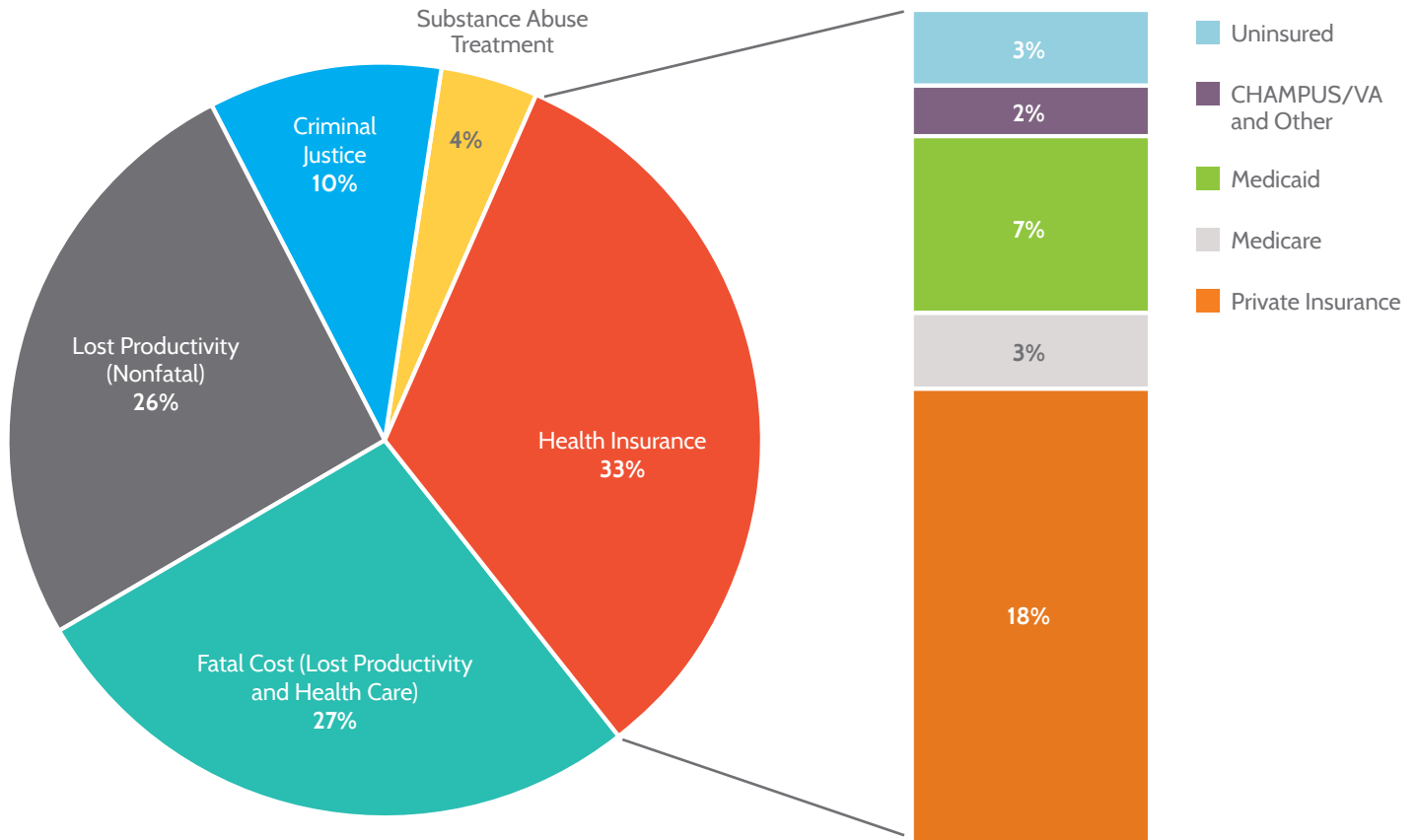
Medicaid covers a disproportionate share of non-elderly adults with opioid addiction, placing many of the associated costs directly on states and the federal government. In 2016, Medicaid beneficiaries with opioid addiction were twice as likely to have received treatment than individuals with an opioid addiction who are covered by private insurance or are uninsured.² Overall, public health insurance programs have funded at least 12 percent of the aggregated costs of the opioid epidemic, according to a study published in the *Journal of Medical Care* using 2013 data (see Figure 1). Of the estimated \$1 trillion spent on the epidemic from 2001 to 2017, approximately \$216 billion were health care costs, largely stemming from emergency department (ED) visits and increased risk of disease or complications following an overdose.³ From 2005 to 2014, the rate of opioid-related inpatient stays increased 64.1

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percent. Over the same period, the number of opioid-related ED visits nearly doubled.⁴

Ongoing litigation against opioid manufacturers and distributors presents a potential opportunity for some financial relief. Funds from successful settlement agreements and judicial decisions can provide support not only to states, but also to essential hospitals to sustain their unique role in caring for patients with opioid use disorders (OUDs). This brief reviews the current state of opioid-related litigation and examines a potentially analogous situation—the tobacco lawsuits of the 1990s. The tobacco lawsuits provide context and examples of how to use litigation as a tool to mitigate a public health crisis by distributing settlement funds in a manner that recognizes the distinct contribution of health care providers in combating the crisis.

FIGURE 1: DISTRIBUTION OF THE ECONOMIC BURDEN OF PRESCRIPTION OPIOID OVERDOSE, MISUSE, AND DEPENDENCE, 2013⁵



Local, state, and federal governments—and in some cases, providers—use the legal system to recover the burdensome costs of combating the opioid epidemic. Settlements can present an opportunity for essential hospitals to access additional funds to fight the epidemic in their communities, even if they are not directly involved in the litigation. If the outcomes of the tobacco litigation of the 1990s are any indication, proactive efforts can ensure that states target opioid-related settlement funds to providers on the front lines, such as essential hospitals, to support prevention and treatment efforts.

ESSENTIAL HOSPITALS ON THE FRONT LINES

Essential hospitals continue to be on the front lines of fighting this devastating epidemic. As leading health care providers in their communities, essential hospitals see firsthand the harm caused by addiction and seek to create innovative programs to educate their patients, treat patients already affected by an OUD, and offer long-term solutions. Essential hospitals are dedicated to prevention, both inside and outside their walls. These hospitals are leaders in implementing innovative programs that provide alternatives to opioids and working with their communities to increase awareness about the dangers

of addiction. When addiction is already present, essential hospitals use evidence-based, integrated approaches to identify and treat OUD, including medication-assisted treatment, peer addiction counseling, and referral to community-based services.

As demonstrated, essential hospitals play a key role in addressing the opioid crisis, despite operating on margins substantially lower than other hospitals—4 percent on average in 2016 compared with 7.8 percent for all hospitals nationwide.⁶ Also in 2016, essential hospitals devoted about 40 percent of their inpatient and outpatient care to Medicaid or uninsured patients.⁷ Across the health care system in 2013, Medicaid paid

for approximately 7 percent of opioid-related costs (a figure that is likely now higher in states that expanded the program); and providers and health systems providing care to uninsured patients accounted for 3 percent (see Figure 1). Given their largely low-income, vulnerable patient populations, essential hospitals are distinctly positioned to make a real and lasting impact on the most disadvantaged, including those living with addiction or in communities where the opioid epidemic is rampant.

CHALLENGING OPIOID MANUFACTURERS AND DISTRIBUTORS IN COURT

For years, individuals, providers, and government entities have sought legal action against opioid manufacturers and distributors in response to perceived negligence and responsibility for the damaging effects of addiction. As the nation continues to grapple with the opioid crisis and its ensuing costs, the trend of pursuing legal action against manufacturers and distributors has intensified. There are several routes a government or other entity can take in seeking to recoup damages from these companies, each with their own unique benefits and challenges.

Examples of State, Local Action Against the Opioid Industry

Several states have sued opioid manufacturers in state or federal court. As mentioned, the lawsuits share claims of fraudulent and deceptive marketing; neglecting to uphold responsibility for monitoring and reporting suspicious opioid purchases; or profiting at the expense of communities.

Legal Underpinnings

Local, state and federal governments turn to the judicial system to hold opioid manufacturers and distributors accountable for their role in the epidemic. To date, states, cities, counties, and Native American tribes have filed hundreds of civil lawsuits in state and federal courts against opioid manufacturers and distributors. While the lawsuits vary in their causes of action, the relief sought by the plaintiffs is consistently grounded in recouping the burdensome costs resulting from combating the crisis and easing the strain on finite public resources.

Fraudulent and Deceptive Marketing

The primary argument (based on state and federal laws) against opioid manufacturers is that the companies involved knew, or should have known, the risks posed by their products and intentionally misled the public about the safety and effectiveness of prescription opioids. In some past settlements, including the *United States of America v. The Purdue Frederick Company Inc. et al.*, manufacturers admitted liability for misleading both providers and patients about the addictiveness of their products (see Table 2). More recent plaintiffs are hopeful that admissions of liability from past settlements, along with government investigations and reporting, will reinforce their claims that manufacturers intentionally ignored the risks associated with their products and continued to heavily market opioids to both providers and consumers⁸;

Failure to Monitor and Report

Some lawsuits charge that manufacturers and distributors violated federal law by not alerting federal authorities of suspicious opioid purchases. The Controlled Substances Act requires distributors to monitor and report suspicious drug orders to the Drug Enforcement Agency (DEA).^{9,10} In West Virginia—the state with the highest rate of opioid-related overdose deaths in 2016—distributors shipped more than 20 million prescription opioid pills over the course of a decade to a town that has a population of fewer than 3,200 residents without raising alarms.^{11,12} More than 30 cities, counties, and municipalities in the state have filed suit against manufacturers and distributors¹³; and

Unjust Enrichment

Many complaints against manufacturers also cite the concept of unjust enrichment, which occurs when one party improperly benefits at the expense of another and is required to pay restitution. Plaintiffs claim opioid manufacturers profited at the expense of federal and state governments by shifting the cost of their business onto public institutions.¹⁴ As manufacturers continued selling excessive amounts of opioids, governments bore the financial consequences of the epidemic through increased health care services, addiction treatment, law enforcement, and other costs linked to opioid misuse. Plaintiffs now seek to recoup these costs through litigation.

Tennessee

In May 2018, the Tennessee attorney general filed a lawsuit in the state's Knox County Circuit Court against Purdue Pharma, alleging the opioid manufacturer violated the state's Consumer Protection Act by making misleading marketing claims about the safety of opioids and its benefits to consumers. The complaint asserts that Purdue also failed to report the illicit use of its products. Additionally, the state claims the manufacturer created a public nuisance by interfering with Tennesseans' health and the state's commercial marketplace.¹⁵

North Carolina

Concurrently, North Carolina filed a lawsuit in the state's Wake County Superior Court against Purdue for reportedly violating the state's Unfair and Deceptive Trade Practices Act. The state claims the manufacturer downplayed concerns regarding opioid addiction, discredited non-opioid pain relievers, claimed that its products did not have maximum dosage limits, and targeted vulnerable patients, such as veterans and seniors.¹⁶

In August 2018, the attorneys general of seven states, led by North Carolina, filed a lawsuit in federal court against Insys Therapeutics for violating the False Claims Act. The complaint alleges that Insys paid providers to prescribe a highly potent fentanyl pain reliever used for cancer patients, Subsys, to patients without cancer and to submit false claims about patient diagnoses to obtain Medicaid reimbursements for Subsys prescriptions. According to the state of North Carolina, its Medicaid program paid more than \$4.8 million for Subsys prescriptions.¹⁷

Examples of Local Action Against the Opioid Industry

In addition to state-level lawsuits, some municipalities have filed lawsuits to ensure their communities receive adequate restitution.

Washington

The City of Tacoma, Washington, filed a lawsuit in federal district court against opioid manufacturers for alleged misleading marketing to physicians regarding the safety and risks of opioids.¹⁸ In its complaint, the city indicates that the opioid crisis has increased its spending for health care, social services, emergency services, and public safety. The city has implemented an additional 0.1 percent sales tax to raise \$10 million per two years to fund opioid response efforts.^{19,20}

California

In California, 30 counties have each filed lawsuits in federal court against opioid manufacturers and distributors for misrepresenting the safety and risks of opioids, and for neglecting to monitor and report suspicious orders leading to the diversion of prescription opioids for illicit purposes.²¹ The California counties are seeking reimbursement for taxpayer dollars that have been spent in response to the opioid crisis, such as emergency response, treatment, monitoring, and prevention.²²

Tennessee

About half of the counties in Tennessee have filed lawsuits at the state's Cumberland County Circuit Court. This is in addition to the state of Tennessee's lawsuit against opioid manufacturers filed in the Knox County Circuit Court.^{23,24} The basis of the plaintiff counties' claims is that the defendants violated the state's Drug Dealer Liability Act. In a letter

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to the Tennessee attorney general, 14 district attorneys indicated that any settlement payments would be used to support local efforts to mitigate the opioid crisis in the represented counties.²⁵ In addition to restitution, the counties seek injunctions to halt the flood of opioids in their communities altogether. The state attorney general challenged the authority of the counties to move forward with separate lawsuits.²⁶ In response, the district attorneys asserted that their lawsuits are necessary to ensure local Tennessee communities receive adequate restitution to support crisis response needs, such as law enforcement, criminal justice, hospitalizations, rehabilitation centers, medical expenses, and educational services for opioid-dependent individuals. The state attorney general retracted his motion to intervene and allowed the separate lawsuits to move forward.²⁷

Consolidation of Federal Cases into Multidistrict Litigation

In December 2017, the Judicial Panel on Multidistrict Litigation (MDL) consolidated more than 600 federal claims filed by government entities, Native American tribes, third-party payers, and individuals from across the nation against opioid manufacturers into MDL to be heard by U.S. District Judge Daniel Polster in the Northern District of Ohio.²⁸ The number of cases has

grown to more than 1,150 since the original filing.²⁹ The Judicial Panel on MDL—created by Congress in 1968 to consolidate 2,000 related antitrust cases nationwide—determines when cases involving common issues and multiple plaintiffs should be heard by a single federal court to speed up the legal process. Consolidation into MDL is meant to promote efficiency and prevent waste of resources by litigating similar cases from different federal courts nationwide. Many of the lawsuits against tobacco manufacturers in the 1990s were settled through MDL.

The lawsuits under the opioid manufacturer MDL, including those brought by the 30 California counties mentioned above, involve common claims of wrongdoing and widespread impact by the same companies.^{30,31} While some parties to the opioid manufacturer MDL argued against consolidation due to the diversity of the claims at issue, the judicial panel concluded that all actions are rooted in common factual questions about the knowledge and conduct of manufacturers and distributors in their marketing practices and/or their failure to report suspicious drug orders. Some plaintiffs also took issue with the consolidation because they strategically selected the federal court in which to file their claim. Ultimately, the panel determined that its decision “will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation.”³²

It is important to note that only federal civil cases are eligible for consolidation into MDL. Therefore, cases filed in state courts or that involved criminal charges against opioid manufacturers must remain as separate entities outside MDL jurisdiction. To add a case to established MDL, participants in

the MDL case or the separate case in question can request inclusion as long as the case meets certain criteria. Additional cases brought against manufacturers are likely to be consolidated into existing MDL if they meet the criteria as federal civil cases. It is unclear what will become of cases filed against manufacturers after a settlement is reached in MDL, and the outcome likely depends on the specific details of such a settlement. For example, the tobacco settlement included payments in perpetuity from certain cigarette manufacturers, eliminating the necessity of further federal suits.

U.S. District Judge Polster has taken an unconventional approach to cases under the opioid manufacturer combined case. While similar MDL has taken years to negotiate, litigate, and ultimately reach a settlement, Polster has set an accelerated schedule, slated to begin in early 2019, for discovery and trials in three of the included cases. Further, Polster insists he will push the parties to reach a settlement that does not “just [move] money around, but should present meaningful solutions to the crisis.”³³

Federal Government Involvement

In February 2018, the U.S. Department of Justice (DOJ) announced it would file a statement of interest in the opioid manufacturer MDL, an action typically reserved for cases strongly connected to the federal government’s interests. The statement details the extensive costs of the epidemic borne by the federal government in the form of federal health program and law enforcement spending. In his announcement, Attorney General Jeff Sessions stated the DOJ will “seek to hold accountable those whose illegality has cost us billions of taxpayer dollars.”³⁴ In April, DOJ filed a motion to

participate in settlement discussions and filed an amicus brief in the opioid MDL, allowing the department to provide legal counsel and expertise without being a formal party to the case.³⁵ In June, Polster ruled to allow DOJ’s participation. The department’s participation emphasizes the federal government’s interest in the case, including any obligations that settlement dollars flow back to the federal treasury.³⁶

In addition to its support in the MDL, DOJ has formed the Prescription Interdiction and Litigation (PIL) Task Force, through which it is “pursuing its own actions against bad actors at every level of the opioid distribution system.”³⁷ DOJ also launched several new initiatives to combat the crisis, including new analytics tools to identify fraud and monitor the distribution of opioids within the United States and opioids imports. In October 2017 and August 2018, DOJ filed charges against Chinese nationals and American-based traffickers for separate conspiracies to distribute fentanyl and other opioids.^{38,39} In 2017, DOJ also reached two settlements with manufacturers, totaling \$185 million in damages. As the MDL and other cases progress, DOJ likely will continue its involvement while also pursuing its own legal actions.

SETTLEMENTS TO DATE

States that settled their opioid-related lawsuits invested the payments into community resources to help mitigate the crisis. Last year, West Virginia’s legislature enacted a law that ordered the expansion of drug treatment facilities across the state funded with \$24 million from a lawsuit settlement with opioid distributors. In 2015, Kentucky received \$12 million from a settlement with Purdue Pharma for misleading opioid marketing. The

TABLE 1 STATE AND LOCAL OPIOID-RELATED LAWSUIT SETTLEMENTS⁴⁰

CASE	SETTLEMENT DATE	CASE DETAILS	SETTLEMENT DETAILS
<i>Commonwealth of Massachusetts v. Insys Therapeutics Inc.</i>	October 5, 2017	Massachusetts sued Insys for engaging in deceptive marketing practices and encouraging off-label use of the opioid Subsys. The state also claimed Insys paid kickbacks to providers.	Insys agreed to pay \$500,000 to help fund the Massachusetts Attorney General's prevention, education, and treatment efforts. Insys also is prohibited from selling the opioid Subsys to most physicians.
<i>The People of the State of Illinois v. Insys Therapeutics Inc.</i>	August 18, 2017	Illinois sued Insys for engaging in unfair and deceptive practices and encouraging off-label use of Subsys to high-volume prescribers. The state also claimed Insys paid kickbacks to high-volume providers.	Insys agreed to pay the state \$4.45 million.
<i>The People of the State of California v. Purdue Pharma L.P. et al.</i>	May 24, 2017*	California sued Purdue Pharma, Teva, Endo Health Solutions, Janssen and Actavis for knowingly misrepresenting the risks and benefits of their opioid products and using deceptive practices to target susceptible prescribers and vulnerable populations.	Teva Pharmaceuticals agreed to pay \$1.6 million to combat the opioid epidemic in Santa Clara and Orange counties. The settlement also bars Teva from deceptive marketing of its products.
<i>State of West Virginia ex rel. Patrick Morrissey v. Cardinal Health Inc.</i>	January 9, 2017	West Virginia sued three distributors—Cardinal Health, Amerisource Bergen, and Miami-Luken—for violating both federal and state law related to monitoring suspicious orders; engaging in unfair or deceptive practices; creating a public nuisance; and unjust enrichment due to state spending on the epidemic.	The distributors agreed to pay a total of \$38.4 million. Some settlement funds were distributed to nine substance use disorder programs to expand residential treatment services in West Virginia.
<i>Commonwealth of Kentucky, ex re. Jack Conway, Attorney General v. Purdue Pharma L.P. et al.</i>	December 23, 2015	Kentucky sued Purdue Pharma for committing Medicaid fraud by misrepresenting the risks and benefits of OxyContin, engaging in false advertising, and reaping unjust enrichment in the form of profits while the state paid for addiction treatment.	Purdue agreed to pay \$24 million over eight years for addiction treatment in Kentucky.
<i>State of Oregon ex rel. Hardy Myers v. Purdue Pharma L.P. et al.</i>	May 8, 2007	Oregon sued Purdue Pharma for falsely claiming that OxyContin was less addictive than other pain medications.	Purdue Pharma paid \$19.5 million to Oregon and pledged not to promote OxyContin for off-label uses.
<i>West Virginia ex rel. McGraw v. Purdue Pharma L.P.</i>	November 5, 2004	West Virginia sued Purdue Pharma for aggressively marketing OxyContin in the state and concealing the extent to which it could cause addiction.	Purdue Pharma paid \$10 million to support drug misuse education and treatment and law-enforcement activities in West Virginia.

* Teva Pharmaceuticals settled on May 24, 2017. Cases against Purdue, Endo Health Solutions, Janssen, and Actavis remain unresolved.

TABLE 2 FEDERAL OPIOID-RELATED LAWSUIT SETTLEMENTS⁴¹

CASE	SETTLEMENT DATE	CASE DETAILS	SETTLEMENT DETAILS
<i>United States of America et al. v. Insys Therapeutics Inc</i>	August 8, 2018	DOJ and 24 states plus the District of Columbia sued Insys for paying doctors kickbacks to prescribe one of its fentanyl-based opioid products	Insys will pay \$150 million over five years to DOJ and other plaintiffs with the possibility of \$75 million in additional payments based on undefined contingent events. ⁴²
<i>United States of America v. Mallinckrodt Inc.</i>	July 11, 2017	DOJ sued Mallinckrodt for failing to put a system in place to detect suspicious orders and, as a result, failing to notify the DEA of such orders.	The company agreed to pay \$35 million to the federal government and allow the DEA to analyze order data.
<i>United States of America v. McKesson Corporation</i>	January 5, 2017	DOJ sued McKesson for failing to maintain controls against diversion and report suspicious activity to the DEA.	McKesson agreed to pay DOJ \$150 million and suspend sales of controlled substances from distribution centers in Colorado, Ohio, Michigan, and Florida for one to three years.
<i>United States of America v. Cardinal Health Inc.; United States of America v. Kinray LLC</i>	December 23, 2016	DOJ sued distributors Cardinal Health and Kinray for violating the Controlled Substance Act by failing to report suspicious orders in Maryland, Florida, and New York.	The distributors will pay DOJ \$44 million.
<i>United States of America v. The Purdue Frederick Company Inc. et al.</i>	June 25, 2007	DOJ sued Purdue Pharma for violating the Federal Food, Drug, and Cosmetic Act. As part of the suit, DOJ also sued three of Purdue's top executives for misleading physicians and patients about the addictiveness of OxyContin and falsely labelling it as abuse-resistant.	Purdue Pharma agreed to pay DOJ \$600 million. The three Purdue executives paid an additional \$34 million cumulatively. All parties admitted fault.
<i>State of Oregon ex rel. Hardy Myers v. Purdue Pharma L.P. et al.</i>	May 8, 2007	Oregon sued Purdue Pharma for falsely claiming that OxyContin was less addictive than other pain medications.	Purdue Pharma paid \$19.5 million to Oregon and pledged not to promote OxyContin for off-label uses.
<i>West Virginia ex rel. McGraw v. Purdue Pharma L.P.</i>	November 5, 2004	West Virginia sued Purdue Pharma for aggressively marketing OxyContin in the state and concealing the extent to which it could cause addiction.	Purdue Pharma paid \$10 million to support drug misuse education and treatment and law-enforcement activities in West Virginia.

state court ordered the money be spent on addiction treatment programs.⁴³ Other settlements to date are detailed in Table 1. Table 2 details past DOJ settlements with opioid manufacturers and distributors, dating back to a historic \$600 million settlement with Purdue Pharma in 2007.⁴⁴

LESSONS LEARNED FROM TOBACCO LAWSUITS

There are clear comparisons between current opioid lawsuits and those filed against tobacco companies in the late 1990s. The volume of opioid lawsuits nationwide is similar to the series of litigation that led to an ultimate settlement with tobacco companies. Many of the opioid lawsuits' plaintiffs include states and municipalities involved in the wave of tobacco lawsuits. Additionally, like the tobacco lawsuits, those related to opioids share common allegations related to deceptive marketing and the consequential toll on public health.

The 1998 Tobacco Master Settlement Agreement (MSA), an accord resulting from numerous private lawsuits and state litigations, ordered tobacco companies to pay an estimated \$206 billion to 46 states over 25 years.^{45,46} In exchange for states foregoing future legal claims based on the conduct at issue in the lawsuits, the tobacco companies agreed to make annual payments, in perpetuity, to states to cover some portion of medical costs for patients with tobacco-related illnesses.^{47,48,49} Additionally, about 40 states filed Medicaid lawsuits against tobacco companies on behalf of taxpayers who had to cover the Medicaid costs for treating such illnesses, and they received \$368.5 billion in a landmark settlement.⁵⁰ To this day, tobacco companies continue to distribute this money annually to states. However, some states no longer receive payments

as they securitized future payments with investors to receive their full settlement payment in advance, which often went directly into the state's general fund.⁵¹

How Did States Use Their Tobacco MSA Money?

States varied in how they allocated their settlement payments from the 1998 Tobacco MSA. To date, most states have designated shares to cover health-related costs, including some for tobacco control.⁵² For example, counties across Texas negotiated with the state to receive approximately \$2.3 billion of the state's tobacco settlement payments—most notably, Harris and Tarrant county hospital districts.⁵³ In 1999, the Texas legislature created the Tobacco Settlement Permanent Trust Account, a permanent endowment to provide local health departments and hospital districts a portion of the state's tobacco settlement payments to offset unreimbursed health care costs for indigent patients.⁵⁴ Other states allocated shares of their tobacco settlement payments to cover unreimbursed hospital expenses. In Pennsylvania's fiscal year (FY) 2019 budget, the state designated 8.2 percent of tobacco settlement payments toward hospitals' uncompensated care or extraordinary expenses.⁵⁵ In FYs 2000 and 2001, 42 of 46 states included in the Tobacco MSA specified the use of payments through new laws or ballot initiatives.⁵⁶ For example, New York implemented a statewide tobacco control program focused on youth with its settlement funds along with revenue from its cigarette tax.

Although the Tobacco MSA funds have been used to support tobacco-related health care costs in important ways, not all funds from the settlement have been used for tobacco control or to care for those

Lessons learned from the tobacco settlements can serve as a guidepost to the federal and state governments as they consider how to allocate funds resulting from opioid-related litigation. Health care stakeholders can begin advocating for targeted, meaningful appropriation of settlement funds to ensure support of necessary services to combat the opioid epidemic.

affected by tobacco use. The MSA did not stipulate how states should spend their settlement dollars, allowing states to appropriate funds as they saw fit. Given competing priorities and budget constraints, states have applied portions of the payments toward budget deficits, capital projects, education, and social welfare. For example, Colorado has spent tens of millions of its settlement money on a literacy program and Kentucky has invested half of its settlement share in agricultural programs. Some states deposit these payments into their respective general fund, leaving designations as part of the appropriations process.⁵⁷

Ultimately, the MSA's lack of guidance on states' use of funds resulted in a variety of efforts from counties, hospital districts, and local providers seeking compensation, with varying success. States' use of the Medicaid portion of the settlement funds was particularly contentious, triggering a great debate in Washington, D.C.

Health Care Stakeholder Advocacy

Much like in the opioid crisis, the Medicaid program played a significant role in combating the adverse health effects stemming from tobacco products. As such, states sought compensation specifically for the Medicaid costs attributable to smoking. The program's federal-state partnership, however, triggered a debate about whether the federal government was entitled to recoup its proportionate share of the related Medicaid settlements. In making its case, the government relied on a provision in the Social Security Act that requires states to share the pro rata share of any Medicaid-related recovery from a third party with the federal government.⁵⁸ States pushed back, arguing that these recovery provisions were intended to cover small claim reimbursements and combat provider fraud—Congress never intended the provisions to apply to immense state-originated settlement negotiations on behalf of the state's entire population. Further, the states claimed that by assuming all the risks and costs of the litigation and related negotiations, they were entitled to the full amount of the funds.

Attempting to address this issue, Congress proposed a bill allowing the federal government to waive its recoupment, allowing the states to retain 100 percent of the funds. Notably, the bill did not require any commitment by the states regarding their use of the funds. This prompted America's Essential Hospitals (then known as the National Association of Public Hospitals and Health Systems) and other health care stakeholders to urge Congress to include more prescriptive language on how states must allocate their settlement funds. Specifically, advocates argued that because the settlement was predominately grounded on the health

care spending related to tobacco products, Congress should ensure that the funds are spent directly on health care services. However, those efforts were unsuccessful as, ultimately, final legislation placed no restrictions on how states could appropriate their settlement funds.⁵⁹

Although the opioid-related MDL is still in its infancy, there are several parallels to the tobacco litigation of the late 1990s. Both used the U.S. court system to find remedy for a public health crisis. Lessons learned from the tobacco settlements can serve as a guidepost to the federal and state governments as they consider how to allocate funds resulting from opioid-related litigation. The opioid epidemic has a direct impact on public health and providers, which states must consider as they receive settlement funds. Health care stakeholders can begin advocating for targeted, meaningful appropriation of settlement funds to ensure support of necessary services to combat the opioid epidemic.

LOOKING AHEAD

The opioid epidemic continues to strain local, state, and federal resources and challenge health care providers on the front lines. Lessons learned from the tobacco settlement can guide essential hospitals as they contemplate their role in future litigation and any subsequent outcomes. A large settlement between opioid manufacturers, distributors, and states in the opioid manufacturer MDL, as well as other ongoing litigation, could provide monetary resources to combat this epidemic. Essential hospitals can play an active role supporting litigation and ensuring any awards are used to fund opioid-related health care services. Essential hospital can get involved through a variety of efforts. Hospitals can actively support and, if appropriate, intervene in lawsuits. Providers also can

have proactive discussions with state and federal legislators and local leaders, where applicable, to explain the opioid epidemic's disproportionate impact on essential hospitals and the desperate need for resources to cover that burden.

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