

# Opioid Litigation: Insurance and Risk Management Considerations



The United States is confronting an opioid epidemic that is taking thousands of lives annually and causing billions of dollars in economic losses (see Figure 1). While many individuals and constituencies are working to address the health effects of the crisis, there is also a drive by plaintiffs' attorneys to litigate and seek monetary damages against various parties.

City, state, and county governments across the US have filed lawsuits against organizations associated with the manufacturing, distribution, and/or sale of opioids. Litigation targets — including pharmaceutical manufacturers, distributors, pharmacies, prescribing physicians, and pharmacy benefit managers (PBMs) — must develop a comprehensive approach and practice to address and defend against opioid-related claims, as well as maximize any potential insurance coverage.

FIGURE 1: THE OPIOID EPIDEMIC'S ECONOMIC AND HUMAN COSTS



**115**

Average number of deaths per day from opioid overdoses.



**42,249**

Opioid-related (prescription and illicit) overdose deaths in 2016.



**400%**

Annual increase in deaths from prescription opioids since 1999.



**\$504 billion**

Estimated US economic cost of the opioid crisis in 2015, including:

- Health care spending.
- Criminal justice costs.
- Lost productivity due to addiction and incarceration.
- Losses from fatalities based on standard value of a statistical life (VSL) analysis.

Sources: Centers for Disease Control and Prevention, Council of Economic Advisers

## LITIGATION TRENDS

Cities, states, counties, Native American tribes, trade unions, and others have filed hundreds of lawsuits, ostensibly in an effort to partially recover the costs associated with treating addiction and resulting overdoses, while 41 state attorneys general have formed a coalition to investigate opioid makers and distributors.

The suits typically allege, among other things, that the defendants have:

- Oversaturated the prescription drug market while failing to implement proper safeguards against misuse, addiction, and diversion.
- Engaged in deceptive business practices, making false representations about their products' addictiveness and effectiveness.
- Failed to monitor suspicious orders in accordance with the federal Controlled Substances Act (CSA).

Many of the complaints of which there are currently more than 400 – have been consolidated in a multi-district litigation known as *In re: National Prescription Opiate Litigation*, pending before Judge Dan A. Polster in the federal district court for the Northern District of Ohio. The judge recently set a March 2019 trial date for three of the representative cases. These cases will be considered “bellwethers” to help assess liability and potential damages and determine how an overall settlement might proceed.

## SETTLEMENT AND TRIAL OBSTACLES

Some, including Judge Polster, have suggested that the parties negotiate a global settlement similar to the one negotiated in 1998 between four major US tobacco companies and the attorneys general of 46 states. Under that agreement, the tobacco companies agreed to contribute \$206 billion over 25 years to fund educational and enforcement efforts and to recover tobacco-related health care costs.

There are several major hurdles to a global settlement, including:

- Unlike cigarettes, opioid pain medications have been shown to benefit many people who suffer from severe and/or chronic pain, — such as cancer patients.
- Prescription opioid medications are closely regulated by the Food and Drug Administration (FDA) for their safety and efficacy. Other agencies, such as the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS), seek to enforce federal law, including the CSA, and ensure the protection of public health and safety.
- Prescriptions for opioids are written by physicians, a fact which can enable manufacturers to invoke the “learned intermediary doctrine,” which holds that a manufacturer can discharge its duty to warn consumers by informing a “learned intermediary” — such as a prescribing physician — of risks associated with its product.
- The defendants in litigation to date are not homogenous; they represent several different parts of the opioid supply chain and, in many cases, do not have direct interaction with patients. Thus, the defendants may not view themselves as equally responsible — if at all — for the crisis.

Nevertheless, litigation remains an avenue for government entities to address demands that they “do something” and potentially secure financial damages through settlements and/or verdicts. Plaintiffs’ attorneys also play a significant role, since they could see a windfall like the estimated \$30 billion in fees that attorneys earned in tobacco litigation. Attorneys representing governments in these actions generally do so on a contingency basis, meaning the governments’ investment risk is minimal. Defendants, on the other hand, face significant legal expenses and may suffer additional reputational damage.

## TARGETS OF LITIGATION AND REGULATORY SCRUTINY

Government lawsuits filed to date have primarily targeted opioid manufacturers, wholesale drug distributors, retail pharmacy chains, and PBMs, as well as clinics and individual physicians alleged to have operated so-called pill mills.

In addition to allegations of fraud and misrepresentation, deceptive marketing, negligence in supervision of distribution practices, and creating a “public nuisance,” some recent suits have accused companies of violating the Racketeer Influenced and Corrupt Organizations (RICO) Act, a federal law created to aid in the prosecution of organized crime. In some cases, follow-on litigation has targeted directors and officers of defendants.



In addition to civil lawsuits, drug manufacturers and distributors have been targeted by regulators for alleged violations of the CSA, including misbranding, failure to report suspicious orders, and filling of incomplete prescriptions. According to public records, companies have agreed to at least 11 settlements with federal and state regulators since 2006 to resolve these charges, ranging in value from \$11.75 million to more than \$600 million (see Figure 2).

## INSURANCE COVERAGE ISSUES

Organizations that are named in lawsuits will naturally look to their insurance coverage for possible protection from financial damage. Several forms of coverage could apply, depending on the specific allegations and targets in a case. The following are some examples, but these should be noted as illustrative only as coverage details will depend on specific policy wording and other issues:

- Manufacturers of opioids, one of plaintiffs' primary targets, could have coverage under product liability policies if the complaints are read to seek damages because of bodily injury sustained by addicts and abusers. This is because the damages sought include, at least in part, costs to treat opioid addiction and overdoses. Other coverage challenges are likely to be confronted, including whether the injuries were expected or intended.
- Distributors of opioids have been targeted frequently, particularly for alleged negligence and failure to follow Drug Enforcement Administration (DEA) regulations and guidelines. For example, suits filed by Kentucky's attorney general in March 2018 accused such companies of excessively distributing opioids within the state and failing to report suspicious drug orders to state and federal authorities. As with manufacturers, distributors could have coverage under product liability policies, but are likely to encounter some of the same coverage questions faced by manufacturers.
- Retail pharmacy chains and major retailers with pharmacy operations have been named in a number of opioid-related lawsuits, including one filed in April 2017 in Oklahoma by the Cherokee Nation against two large pharmacy chains and a major retailer. The allegation against retailers is that they have filled prescriptions despite "red flags" indicating that prescribed opioids may not be used for legitimate medical purposes. Such claims may be covered under policies issued to pharmacies providing coverage for druggist liability.

FIGURE 2: REGULATORY SETTLEMENTS IN OPIOID CASES

Year	Company Type	Regulator(s)	Settlement Value
2017	Prescription drug distributor**	US Department of Justice	\$150 million
2017	Drug manufacturer	US Department of Justice	\$35 million
2017	Prescription drug distributor*	State of West Virginia	\$20 million
2017	Prescription drug distributor	State of West Virginia	\$16 million
2017	Retailer	US Department of Justice	\$11.75 million
2016	Prescription drug distributor*	US Department of Justice	\$44 million
2015	Prescription drug maker***	Commonwealth of Kentucky	\$24 million
2015	Prescription drug maker	Commonwealth of Kentucky	\$15.5 million
2008	Prescription drug distributor*	US Department of Justice	\$34 million
2008	Prescription drug distributor**	US Department of Justice	\$13.25 million
2006	Prescription drug distributor***	US Department of Justice	\$634.5 million

\*Same company.

\*\*Same company.

\*\*\*Same company.

Note: The above list is drawn from numerous public records and is not necessarily all-inclusive.

- Pharmacy benefit managers, which have been named in several recent suits alleging that they have played a role in the opioid supply chain, may have coverage under errors and omissions policies, which provide coverage for professional services provided to third parties, as well as general liability policies.
- Directors and officers of opioid manufacturers and distributors have been less prominent litigation targets, although they have been named in some securities class action lawsuits when there have been stock price drops and allegations of misrepresentation or of distributing misleading information to investors. They would typically look for coverage for such claims under directors and officers liability policies.

As a result of claims filed by manufacturers, distributors, pharmacies, and others, insurers have raised various coverage defenses and sought to impose exclusions for certain types of claims arising out of opioids and other controlled substances. To date, only a few court decisions have addressed the applicability of insurance coverage for opioid-related claims, with mixed outcomes. For example, in 2016, a federal circuit court of appeals held that the claims were potentially covered as governmental entities sought damages because of bodily injury.<sup>1</sup> Yet, in 2014, a lower federal district court held that an opioid suit did not seek damages because of bodily injury.<sup>2</sup> Similarly, a federal circuit court recently held<sup>3</sup> that an opioid suit alleged a potentially covered occurrence given allegations of “accidental injury,” while a federal district court<sup>4</sup> reached a contrary result.

## ACTION STEPS FOR LITIGATION TARGETS

It is unclear what course the consolidated litigation will ultimately take. Regardless, more lawsuits are likely to be filed, not only by governmental bodies but by other entities seeking to recover unreimbursed costs for treating addicts and overdoses. More companies in the opioid supply chain may also become litigation targets.

Companies with a connection to the manufacture, distribution, or sale of opioids should undertake an immediate review of potentially applicable insurance coverage. Risk professionals should also prepare to address exclusions that insurers might seek to add at renewal.

Organizations should also:

- **Optimize recovery.** Organizations should engage insurance recovery experts to help maximize potential insurance coverage for opioid lawsuits.
- **Report claims properly.** Organizations should submit notice to insurers, pursue them for acknowledgment of claims, and scrutinize coverage positions. Insurance buyers should also maintain an electronic archive of all communications with insurers.
- **Report potential future claims.** Some insureds have the ability under current claims-made policies to give notification of circumstances that could lead to future claims. Such companies should consider exercising this right, especially if underwriters seek to impose new exclusions on future policies.



<sup>1</sup> *Cincinnati Ins. Co. v. H.D. Smith, L.L.C.*, 829 F.3d 771 (5th Cir. 2016).

<sup>2</sup> *Cincinnati Ins. Co. v. Richie Enterprises, LLC*, 2014 WL 3513211 (N.D. Ky. 2014).

<sup>3</sup> *Liberty Mutual Fire Ins. Co. v. JM Smith Corp.*, 602 Fed.Appx. 115 (4th Cir. 2015).

<sup>4</sup> *The Travelers Prop. Cas. Co. of America v. ANDA*, 90 F.Supp. 3d 1308 (S.D. Fla. 2015), *aff'd on other grounds*, 658 Fed.Appx. 955 (11th Cir. 2016).

- **Coordinate information.** Companies involved in litigation should provide insurers with regular updates on its progress — for example, by organizing regular calls with insurers — while taking care to preserve privileged information.
- **Initiate discussions on renewals.** Litigation related to opioids has been ongoing since the early 2000s, but the flood of government suits is a relatively new phenomenon and may not be reflected in current policies. Insureds should be attentive to insurers' efforts to impose exclusions and ensure that they are not broader than necessary.

Most, if not all, companies in the opioid manufacturing, distribution, and sales chain have taken steps to prevent the diversion of opioids, curb sales to suspicious entities, and improve monitoring and reporting of sales. Litigation often targets past events and practices, but adopting best practices may deter future lawsuits and improve how an organization is viewed by insurers at renewal.

The opioid epidemic is an extraordinarily complex problem with no clear solutions. As governments and other entities seek alleged damages for the costs emanating from addiction, treatment, and other effects of opioid abuse, conflicts among insurers and insureds will be unavoidable. Pharmaceutical manufacturers and distributors, retailers, PBMs, and others should carefully review existing policies, pursue coverage under applicable insurance policies, communicate clearly and frequently with insurers, and negotiate the broadest scope of coverage possible going forward.

## ABOUT THIS BRIEFING

This briefing was prepared by Marsh's Casualty Practice with contributions from:

- Marsh Risk Consulting.
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