



The Opioid Epidemic

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I. History and Background

A. Opioids

Opioids are a powerful class of painkillers derived from opium, which comes from the poppy plant. They act on opioid receptors in the body and brain to provide pain relief. Opioids include: (a) prescription drugs such as oxycodone (OxyContin), hydrocodone (Vicodin), codeine and morphine, which are controlled substances regulated by the FDA; (b) synthetic drugs such as fentanyl; and (c) illegal drugs like heroin.

The pain relieving properties of opioids have been known for centuries. Properly prescribed, opioids are recognized as an effective treatment for short term, acute pain, such as post-surgical relief or end of life care. The long-term use of opioids for chronic pain is far more controversial, and it is what principally drives the current flood of litigation against opioid manufacturers, distributors and retail pharmacies.

In general terms, plaintiffs allege that opioid manufacturers could mass produce opioids cheaply, but lacked a sufficient market for their drugs, because: (a) there were no studies indicating that opioids were effective for long-term use; and (b) opioids were considered highly addictive if used over a long period of time. Nonetheless, in order to achieve “blockbuster” profits, the manufacturers are alleged to have engaged in a coordinated scheme to convince doctors and the public that opioids not only were safe and effective for long-term use, but that effective treatment of chronic pain *required* opioids. As a result of their efforts, the market for opioids exploded, and so did the attendant costs. The distributors and retail pharmacies are alleged to have contributed to the expanded use and abuse of opioids, described more fully below.

B. Statistics

Opioid abuse is a health epidemic of enormous scope. According to recent statistics, every day over 100 people die from opioid overdoses in the U.S. In 2016, according to the CDC, more than 42,000 people died from opioids (including prescription opioids, heroin and fentanyl).¹ Unfortunately, the number of opioid deaths in 2016 is not anomalous, but rather is part of a longer-term trend. From 2000 to 2016, the prescription opioid epidemic killed almost 200,000 people.² Some estimate that over the next decade, the epidemic could kill another 500,000 people.³

Many individuals who do not overdose still may suffer greatly from opioid addiction. In 2015, it is estimated that about two million Americans were addicted to opioids -- a

¹ <https://www.cdc.gov/drugoverdose/index.html> (last visited Jan. 17, 2018).

² ‘DEA agents say a huge opioid case ended in a whimper’, Washington Post, Dec. 17, 2017.

³ Rebecca L. Haffajee, Michelle M. Mello, *Drug Companies’ Liability for the Opioid Epidemic*, New England Journal of Medicine (Dec. 20, 2017).

significant increase compared to the number of opioid addicts just five years earlier.⁴ The estimated economic cost of opioid abuse is staggering. According to the U.S. Department of Health and Human Services, in 2016, the opioid epidemic cost \$504 billion.⁵ This estimate of economic costs is drastically higher than earlier estimates, which themselves were strikingly high. For example, a study in the October 2016 issue of *Medical Care*, which relied on data from 2013, estimated aggregate costs for prescription opioid overdose, abuse and dependence at \$78.5 billion.⁶ That study broke down those costs by category, estimating that:

- Spending for health care and substance abuse exceeded \$28 billion;
- Costs for lost productivity were over \$20 billion;
- Fatal overdoses, including health care and lost productivity, cost \$21.5 billion; and
- Criminal justice-related costs were \$7.7 billion.

C. Statutes & Regulations

States have enacted policies that aim to address this epidemic while also ensuring access to pain management. The first of these statutes was enacted by the Massachusetts legislature in early 2016. The act, among other provisions, sets a seven-day supply limit for initial (first-time) opioid prescriptions. Prior to Massachusetts' act, some states had passed bills targeting the prescribing of opioids. For example, Washington's legislature directed five professional boards and commissions to adopt rules related to chronic, non-cancer pain management.

By the end of 2016, seven states had passed legislation limiting opioid prescriptions. More than thirty states considered at least 130 bills related to opioid prescribing in 2016 and 2017. By December 2017, twenty-four states had enacted legislation with some type of limit, guidance, or requirement related to opioid prescribing.

Most legislation limits first-time opioid prescriptions to a certain number of days' supply. A few states also set dosage limits. Nearly half the states with limits specify that they apply to treating acute pain, and many states have exceptions for chronic pain treatment, cancer and palliative care, treatment of substance use disorder, medication-assisted treatment, or for the professional judgment of the provider prescribing the opioid.

⁴ See CNN, *Opioid addiction rates continue to skyrocket*, June 29, 2017 ("An analysis from Blue Cross Blue Shield of its members found that from 2010 to 2016, the number of people diagnosed with an addiction to opioids ... climbed 493%).

⁵ <https://www.hhs.gov/opioids/about-the-epidemic/index.html> (citing *Mortality in the United States*, 2016 NCHS Data Brief No. 293, Dec. 2017).

⁶ *Florence, et al.*, *Economic Burden of Prescription Opioid Overdose*, *supra*.

A few states, including Alaska, Connecticut, Indiana, Louisiana, Massachusetts and Pennsylvania, set limits specifically for minors.

Other states direct/authorize other entities (i.e., department of health/state health official, or provider regulatory boards) to set limits (i.e., New Hampshire, Ohio, Oregon, Vermont, Virginia, Washington, Wisconsin, and Arizona's executive order).

Some states like Maryland and Utah provide guidance on opioid prescribing.

States have also enacted laws related to prescription drug monitoring programs, access to naloxone, pain clinic regulation, and provider education and training.

D. Public Policy

Insurers and policyholders have and will continue to offer competing public policy arguments with respect to coverage for opioid-related liability. Insurers claim holding them responsible to pay for public services costs will transform private party liability insurance into "social insurance" covering public health epidemics. This will, according to carriers, increase the cost of liability insurance, burden insurers because they have not accounted for this risk when setting premiums, and shift costs away from those best suited to address the issue (opioid suppliers).

Policyholders maintain that: (a) insurance law allows parties to freely contract to cover risks; and (b) carriers must pay for any risks they agree to cover -- including risks not foreseen at the time of policy drafting -- and may not engage in post-claim underwriting. Courts interpret insurance policies according to their plain language and construe any ambiguous language against carriers. Some jurisdictions construe policy language in favor of insureds' reasonable expectations of coverage. In addition, policyholders claim liability insurance is a form of risk management, and deterrence and compensation functions of insurance are important to the social functioning and ordering of society.⁷

II. Underlying Claims

In light of the public health risks and significant economic costs, entities have pursued lawsuits against opioid manufacturers and distributors. In 2012, the State of West Virginia filed a lawsuit against opioid distributors alleging that the defendants overstated the benefits of opioids and understated the risks of addiction (the "West Virginia Action"). West Virginia alleged that the defendants were responsible for creating "pill mills" which led to an addiction epidemic. The State sought to recoup the cost of public services (including medical and law enforcement costs) associated with opioid abuse.

⁷ See, e.g., J.W. Stempel, *The Insurance Policy as Social Instrument and Social Institution*, 51 William & Mary L. Rev. 1489 (2010).

In 2017, the press reported a total of approximately \$47 million in settlements in the West Virginia Action. Given the amount sought by the State, these settlements did not necessarily signal admissions by makers and distributors or an easy path for following plaintiffs. The result of that suit appears to have nonetheless spawned an acceleration of opioid lawsuits, which continue to grow by the day.

Plaintiffs. Most opioid lawsuits have been brought by government entities -- states, counties, and municipalities -- that seek to recoup economic damages incurred in addressing the opioid epidemic in their jurisdictions. Like West Virginia, these plaintiffs seek damages including costs for providing public services (*e.g.*, law enforcement, health care, social services) and costs incurred in the governments' role as an employer (*e.g.*, health insurance for employees, lost productivity). Over the last year, other types of entities -- including hospitals, pension funds, third-party administrators of health care benefits, and unions -- have begun to file similar suits. To date, relatively few suits have been brought by or on behalf of individual opioid users. Recently, the Department of Justice indicated an intention to pursue damages incurred by the federal government in addressing opioid addiction.

Defendants. The opioid lawsuits have principally targeted two categories of defendants. The first category is prescription opioid manufacturers, including doctors and clinics that are alleged to have worked with and aided the manufacturers. The complaints against the manufacturer defendants typically allege that the manufacturers, along with doctors funded by the pharmaceutical industry (referred to as "key opinion leaders") intentionally misrepresented the benefits and risks of long-term opioid use, in order to expand the market for opioids and achieve blockbuster profits.

The second category of defendants is prescription opioid distributors. The complaints against the distributor defendants typically allege that those defendants intentionally or negligently failed to detect, investigate, or report excessive and suspicious orders of prescription opioids. Some of the complaints also allege that the distributor defendants -- like the manufacturer defendants -- misrepresented the addictiveness of opioids. A meaningful portion of the suits against the distributor defendants allege violations of the Controlled Substances Act, similar state laws, and state laws prohibiting unfair trade practices and racketeering. The group of distributor defendants has expanded over time. Initially, complaints generally targeted wholesale distributors (*e.g.*, ABC, McKesson, Cardinal Health). Increasingly, claims are also being made against consumer-facing distributors (*i.e.*, retail pharmacies, such as CVS, Wal-Mart and Costco).

MDL. In December 2017, the United States Judicial Panel on Multidistrict Litigation ordered at least 64 opioid lawsuits to be transferred to the Northern District of Ohio (Eastern Division), for pre-trial proceedings.⁸ The number of lawsuits involved in this multi-district litigation ("Opioid MDL") has grown rapidly. As of March 1, 2018, over 300 lawsuits were pending or had been conditionally transferred to the Opioid MDL. More federal lawsuits will be added, as more existing cases are formally transferred to the Opioid MDL and as new

⁸ Transfer Order, *In Re: National Prescription Opiate Litigation*, MDL No. 2804 (Dec. 5, 2017).

cases are filed. Although the Opioid MDL is dominating opioid litigation in federal courts, a significant number of opioid cases are also pending in state courts.

Judge Polster aggressively pursued a global settlement in the early stages of the Opioid MDL, creating settlement committees comprised of selected plaintiffs and defendants. He also invited the state attorney generals to the process, and indicated that he intended to coordinate with the judges presiding over the state court actions, if possible. Although those efforts are ongoing, Judge Polster recognized, at a hearing on March 6, 2018, that settlement discussions had reached an impasse. He therefore ordered the parties to engage in targeted litigation, including limited discovery, motion practice and bellwether trials.

Government Investigations. In addition to civil litigation, opioid manufacturers and distributors have been the targets of government investigations, which could lead to civil enforcement actions and/or criminal prosecutions. For example:

- In January 2017, McKesson agreed to pay \$150 million and suspend sales from four distribution centers, in order to resolve a federal investigation.
- In December 2016, Cardinal Health agreed to pay \$44 million to resolve investigations in four states involving allegations that it had violated the Controlled Substances Act.
- In 2016 and 2017, CVS entered into a series of settlements, totaling over \$15 million, to resolve federal investigations in three states.
- As of last fall, Purdue Pharma was under investigation by federal prosecutors in Connecticut, in connection with its representations about OxyContin.
- At least 40 state attorneys general are conducting an investigation into opioid distribution practices, including the practices of ABC, Cardinal Health, and McKesson.

These government investigations create additional pressures and potential liability for the opioid manufacturers and distributors. Further, if information from the investigations is made public, that information will be used by plaintiffs in the opioid lawsuits.

III. Coverage

A. Policies

Insureds have sought coverage for opioid-related defense costs and settlements, judgments, and/or verdicts under several types of insurance policies.

B. Coverage Issues – CGL Policies

The opioid lawsuits have created a growing body of insurance coverage litigation. These cases -- which principally have involved the duty to defend -- have focused primarily on three coverage issues with respect to commercial general liability (“CGL”) policies: (a) whether the allegations in the underlying lawsuits constitute an “occurrence”; (b) whether the lawsuits seek amounts that the insured is legally obligated to pay as damages “because of” or “for” “bodily injury”; and (c) whether a products exclusion excludes coverage.

(1) Occurrence

In certain cases, primary insurers have denied a duty to defend on the ground that the underlying opioid complaint did not contain allegations sufficient to qualify as an “occurrence”. The insurers argued that the complaint contained allegations that the defendants engaged in *intentional* conduct for profit, which did not qualify as accidental conduct sufficient to constitute an “occurrence” under a CGL insurance policy.

This argument has faced mixed results. One set of declaratory judgment cases arose from the West Virginia Action, which involved only distributor defendants. Three federal courts -- applying South Carolina, Kentucky and Illinois law, respectively -- concluded that certain allegations in the underlying complaint sounded in negligence, including allegations that the defendants failed to implement sufficient controls to identify suspicious prescription drug orders. These courts ruled that the complaints’ allegations were sufficient to qualify as an “occurrence” for duty to defend purposes.⁹

By contrast, the Court of Appeals of California rejected a pharmaceutical manufacturer’s claim for coverage in connection with underlying cases brought by several California counties and the City of Chicago alleging deceptive marketing and sales practices.¹⁰ The Court held that the allegations in the underlying complaint did not constitute an “accident” or “occurrence” under California law, because the policyholder was accused of a deliberate course of conduct designed to increase sales of its opioids by intentionally misleading doctors and the public. The Court emphasized that under California law, the fact that a policyholder engaged in allegedly intentional misconduct that resulted in unintended consequences -- such as opioid or heroin abuse -- does not transform the alleged misconduct into an “accident” giving rise to a duty to defend. The California Supreme Court recently accepted certiorari in connection with the *Actavis* case.

In short, in assessing the “occurrence” issue in the context of opioid litigation, courts have principally focused on: (a) the nature of the allegations (negligent oversight vs. intentional scheme); and (b) the governing law (focus on conduct v. focus on harm).

⁹ See *Liberty Mut. Ins. Co. v. J M Smith Corp.*, 602 F. App’x 115 (4th Cir. 2015); *Cincinnati Ins. Co. v. Richie Enterprises LLC*, 2014 U.S. Dist. LEXIS 27306 (W.D. Ken. March 4, 2014) (Richie I); *Cincinnati Ins. Co. v. H.D. Smith Wholesale Drug Co.*, 2015 U.S. Dist. LEXIS 100823 (C.D. Ill. Aug. 3, 2015).

¹⁰ See *Trav. Prop. Cas. Co. of Am. v. Actavis, Inc.*, 2017 Cal. App. LEXIS 976, G053749 (Cal. Ct. App. Nov. 6, 2017).

(2) Bodily Injury

Some insurers have denied coverage for underlying opioid lawsuits on the ground that the underlying complaints did not allege covered damages “because of” or “for” “bodily injury”, as required under a CGL policy. When litigated, this coverage defense again has led to mixed results.

In 2016, the Seventh Circuit Court of Appeals -- applying Illinois law -- concluded that a duty to defend was triggered, because the underlying complaint in the West Virginia Action alleged damages “because of” bodily injury.¹¹ The Court reasoned that the “because of bodily injury” language in the operative insurance policies created wider coverage than the “for bodily injury” wording sometimes used in CGL policies. The Court also concluded that language in the policies that provided coverage for “damages claimed by any person or organization for care ... resulting ... from bodily injury” supported a duty to defend, because West Virginia had alleged, at least in part, that it incurred excessive costs relating to the care of its citizens suffering opioid addiction.

By contrast, two federal district courts concluded that there was no duty to defend government entity complaints, because those complaints did not allege covered bodily injury.¹² Instead, the courts concluded that the State of West Virginia sought damages only for its own economic loss, and the State did not assert claims on behalf of its individual citizens for the physical harm they personally sustained.

(3) Products Exclusion

In some cases, insurers have denied coverage related to underlying opioid lawsuits on the ground that a products exclusion contained in the policy barred coverage for “bodily injury” either “arising out of” or “resulting from” products manufactured, sold, handled, or distributed by the policyholder. The U.S. Court of Appeals for the 11th Circuit and the Court of Appeals of California have both relied on a products exclusion to conclude that insurers have no duty to defend opioid lawsuits against pharmaceutical policyholders.¹³ The courts concluded, in sum, that because “bodily injury” (if any) related to opioid addiction “arising out of” opioid products, the products exclusions were triggered. To date, no case has reached a contrary conclusion in the context of opioid litigation. The impact of this exclusion may be dependent on its wording – “arising out of,” “because of” and “resulting from” could auger differing results.

¹¹ *Cincinnati Ins. Co. v. H.D. Smith, LLC*, 2016 U.S. App. LEXIS 13175 (7th Cir. July 19, 2016).

¹² *Travelers Prop. Cas. Co. of Am. v. Anda, Inc.*, 2015 U.S. Dist. LEXIS 31450 (S.D. Fla. Mar. 9, 2015) (applying California law) *affirmed on other grounds* 2016 U.S. App. LEXIS 15760 (11th Cir. Aug. 26, 2016); *Cincinnati Ins. Co. v. Richie Enterprises LLC*, 2014 U.S. Dist. LEXIS 96510, at *15 (W.D. Ken. July 16, 2014) (applying Kentucky law).

¹³ *Travelers Prop. Cas. Co. of Am. v. Anda, Inc.*, 2016 U.S. App. LEXIS 15760 (11th Cir. Aug. 26, 2016); *Trav. Prop. Cas. Co. of Am. v. Actavis, Inc.*, 2017 Cal. App. LEXIS 976, G053749 (Cal. Ct. App. Nov. 6, 2017). Choate Hall was counsel for Travelers in both cases.

C. Coverage Issues – Products Liability Policies

Insureds, such as those operating in the pharmaceutical industry, have also sought coverage under products liability policies. These policies typically cover sums the insured becomes legally obligated to pay as damages because of bodily injury included within the products-completed operations hazard. They cover all bodily injury occurring away from premises owned or rented by the policyholder and arising out of the insured's "product."

- (1) The "Expected or Intended" Exception to the Definition of "Occurrence"

Insurers have denied coverage under products liability policies on the basis that policyholders expected the injury and loss. This is a variant on the "no occurrence" defense asserted under CGL policies. As noted above, this argument has spawned mixed results.

- (2) Exclusions for "Unfair Competition," Criminal Violations, and Intentional Acts of Non-Compliance with FDA Rules/Regulations

Insurers also cite exclusions for "unfair competition," criminal violations, and/or intentional acts of non-compliance with FDA rules or regulations. These exclusions are typically found in policies issued to companies involved in the opioid distribution chain.

One federal district court found an unfair competition exclusion precluded coverage for an opioid-related complaint.¹⁴ The exclusion provided as follows: "[i]n the event a claim is made or suit is brought...alleging...any loss" "in any way related to any actual or alleged...[u]nfair competition...and...[a]ny other loss; then this exclusion shall apply to preclude coverage for the entire claim or suit...or a duty to defend..." The court ruled that the count titled "Violations of the West Virginia Consumer Credit and Protection Act (WVCCPA) – Unfair Methods of Competition or Unfair or Deceptive Acts or Practices" alleged unfair competition by the insured and the exclusion thus precluded coverage for the complaint.

D. Coverage Issues – D&O Policies

In recent months, shareholders have filed lawsuits against opioid manufacturers and distributors, as well as their directors and officers. Some allege that directors and officers of opioid distributors failed to monitor the size and frequency of shipments and report aberrations to the Drug Enforcement Administration, resulting in civil fines or other liabilities. Other suits allege the defendant companies, and certain directors and officers, made materially false public statements regarding the companies' opioid practices, resulting in drops in share price when misstatements were corrected or drugs were withdrawn from the

¹⁴ *Travelers Prop. Cas. Co. of Am. v. Anda, Inc.*, 2015 U.S. Dist. LEXIS 31450 (S.D. Fla. Mar. 9, 2015).

market in response to FDA pressure. These suits potentially implicate another kind of insurance policy: directors' and officers' ("D&O") policies.

D&O policies typically afford coverage for loss arising from claims first made during the policy period against insured persons for "wrongful acts," commonly defined to include any "actual or alleged act, error, misstatement, misleading statement, neglect, omission or breach of duty." Private company D&O insurance policies cover wrongful acts of the company and individuals; public company D&O insurance policies usually cover loss to the company arising from securities claims brought against the company on behalf of shareholders, and derivative actions brought to enforce a right of the company, for wrongful acts.

To date, there are no published cases addressing coverage for opioid-related liability under D&O policies.

(1) Definition of "Loss"

Insurers may deny coverage for opioid-related liability based on D&O policies' definition of "Loss", which commonly excludes fines, penalties or matters deemed uninsurable under applicable law.

(2) Conduct Exclusions

Carriers may also cite exclusions for claims arising out of: (1) the gaining by any insured of any profit or advantage to which such insured was not legally entitled; or (2) the commission by any insured of any criminal or deliberately fraudulent or dishonest act.

IV. Predictions and Trends

The development of the Opioid MDL may go a long way toward setting the stage for the nature and resolution of coverage issues between policyholders and insurers. If Judge Polster is successful in fashioning a global settlement, a number of important questions could affect the availability of insurance coverage (if any), including: (a) how is the settlement amount calculated; (b) what remedies are included as part of the settlement; (c) how are the settlement dollars allocated among the defendants; (d) what "damages" are encompassed by the settlement, and in what time period(s) were those amounts incurred; and (e) what role, if any, will insurers play in the settlement discussions. Certainly, coverage counsel for policyholders and insurers will be keeping a close eye on the Opioid MDL.

Also, because the case law to date has focused principally on the duty to defend, indemnity issues -- which are likely to be exceedingly more complicated -- have yet to play out. For example, courts have yet to address questions such as: (a) whether there is coverage for indemnity; and (b) if so, (i) what trigger of coverage will apply, (ii) how will that trigger apply to the facts underlying opioid addiction claims, (iii) which categories of damages sought by plaintiffs are covered and not covered (*i.e.* addiction treatment; lost productivity;

additional police and court personal; etc.), (iv) when did any covered damages occur, and (iv) how will doctrines such as known loss and late notice apply, if at all. In short, the parties have just scratched the surface of the coverage issues.

More generally, any attorney who has tilled the coverage fields of environmental coverage litigation and the welter of product-liability and mass-tort litigation knows well what is afoot: who is to bear the social cost of a growing population with an equally burgeoning taste for laying blame – typically on someone who can pay the bill. Addiction is not new – AA itself was founded more than 80 years ago – and the number of substances which claim bodies and lives has increased exponentially as natural addictions now vie with laboratory inventions far more addictive than natural counterparts.

We can safely predict that it will get worse, and the social cost in real dollars will only increase. As a result, litigation over who should pay will surely increase, including the ancillary coverage litigation. And, since insurance coverage is a state-specific issue, as we have already seen, schisms in decisional authority will develop fueling careful study of conflict of laws, venue choices and insurance product types. Blame will certainly travel upstream to the executive suite, triggering D&O policy issues – the dollars are simply too large not to attract the attention of venture capital and other investors (and lawyers who ply that trade). Accordingly, we are likely at the front end of a long, challenging and expensive process.