BIG PHARMA FACING BIG LOSSES TIED TO OPIOID EPIDEMIC FALLOUT

By Sean Donnelly

BACKGROUND

In 2017, a total of 70,237 people in the United States died from a drug overdose. A staggering 67.8% of those deaths involved the use of opioids, a startling escalation that has been classified as a national epidemic. Deaths attributed to synthetic opioids have become increasingly prevalent, accounting for 59.8% of all opioid overdose deaths.

Every day, an average of 46 people in the United States die from overdoses specifically involving *prescription* opioids. The highest prescription opioid-involved death rates in 2017 were in West Virginia, Maryland, Kentucky and Utah[1]. According to the National Institute on Drug Abuse, drug overdose deaths involving opioids that were prescribed rose from 3,442 in 1999 to 17,029 in 2017[2].

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In particular, oxycodone (such as OxyContin®), hydrocodone (such as Vicodin®), methadone, and fentanyl have been identified as the most common drugs associated with prescription opioid overdose deaths[3].

Fentanyl, a synthetic opioid used to treat severe pain, is one of the chief agents being linked to the recent rash of drug overdose deaths. In 2011, Fentanyl was identified as being the cause of 1,663 deaths; in 2016, that figure surged to 18,335 deaths[4].

Natural and semi-synthetic opioids, a category that includes oxycodone and hydrocodone, accounted for 14,495 deaths in the United States in 2017[5]. On a molecular level, oxycodone is nearly identical to heroin[6].

STATES FIGHT BACK

Massachusetts

In the last decade, more than 11,000 people died from opioid-related overdoses in Massachusetts alone[7]. Massachusetts patients who were prescribed opioids for more than one year were 51 times more likely to die of an opioid-related overdose[8].

The Attorney General for Massachusetts, Maura Healey, alleged in a recent lawsuit[9] against Purdue Pharma that the pharmaceutical giant possessed actual knowledge that its prescription opioid OxyContin was leading to overdose deaths. Since 2009, in Massachusetts alone, 671 people who filled prescriptions for opioids manufactured by Purdue ultimately died from an opioid-related overdose[10].

Yet, Healey claims that the company turned a blind eye towards the evidence of OxyContin's addictive qualities and instead engaged in a large-scale sales blitz in Massachusetts to push sales of the prescription drug while deceiving doctors and patients. Pleadings filed by Healey assert that Purdue's OxyContin offensive included threatening to fire sales reps whose physician targets failed to write sufficient opioid prescriptions, advocating that the powerful drug be used to treat elderly patients with arthritis, and obscuring the risk of addiction in its marketing materials.

Healey's case focuses on Purdue's deceptive practices, which allegedly included making misleading claims in order to push more patients onto its opioids at higher doses and for longer amounts of time, while simultaneously diverting patients away from safer alternatives[11].

Additional counts charge Purdue with creating a public nuisance of addiction, illness, and death and interfering with the public health by engaging in deceptive marketing practices that fostered a dangerous epidemic of opioid addiction in the state[12].

Further, Healey contends that Purdue acted negligently and recklessly with regard to the known risks of its drugs[13], including by intentionally targeting high-prescribing doctors and rewarding them with gifts and money in exchange for them prescribing more Purdue opioids[14], even when Purdue knew that its opioids were being misused and harming patients.

In one instance, Purdue's governing board had allegedly been warned by staff that two Massachusetts doctors had prescribed opioids inappropriately, but it failed to notify medical licensing officials. Purdue made more than $823,000 off those two doctors alone in just two years[i].

In March, Purdue's attorneys filed a second motion to dismiss the case that labeled Healey's allegations as "oversimplified scapegoating," countering that the company neither created nor caused the opioid epidemic in Massachusetts[15].

Instead, Purdue made the case that unlawful opioids like heroin and illicitly-produced fentanyl were the root cause of the great majority of opioid-related overdose deaths in Massachusetts[16]. Accordingly, Purdue claimed that its FDA-approved OxyContin could not, as a matter of law, be considered the proximate or but-for "cause" of the state's opioid crisis[17]. The Massachusetts Attorney General's Office is currently opposing Purdue's motion.

Oklahoma

Oklahoma ranked as the leading state in the nation in terms of amount of opioids distributed per adult resident in 2016[18]. In 2018, nearly fifty percent of drug overdose deaths in Oklahoma were caused by pharmaceutical drugs. In that same year, of the more than 3,000 Oklahoma residents who were admitted to a hospital for a non-fatal overdose, eighty percent of those overdoses were due to prescription opioid medications[19].

At the epicenter of this epidemic, Purdue Pharma was again in the crosshairs of a state lawsuit centered on opioid addiction.

The case brought by Oklahoma, originally filed in June 2017 by the Oklahoma Attorney General's Office, named opioid manufacturers Purdue Pharma, Johnson

& Johnson, and Teva Pharmaceuticals as defendants. Rather than face a televised trial, Purdue in this instance elected to settle with the state to the tune of $270 million.

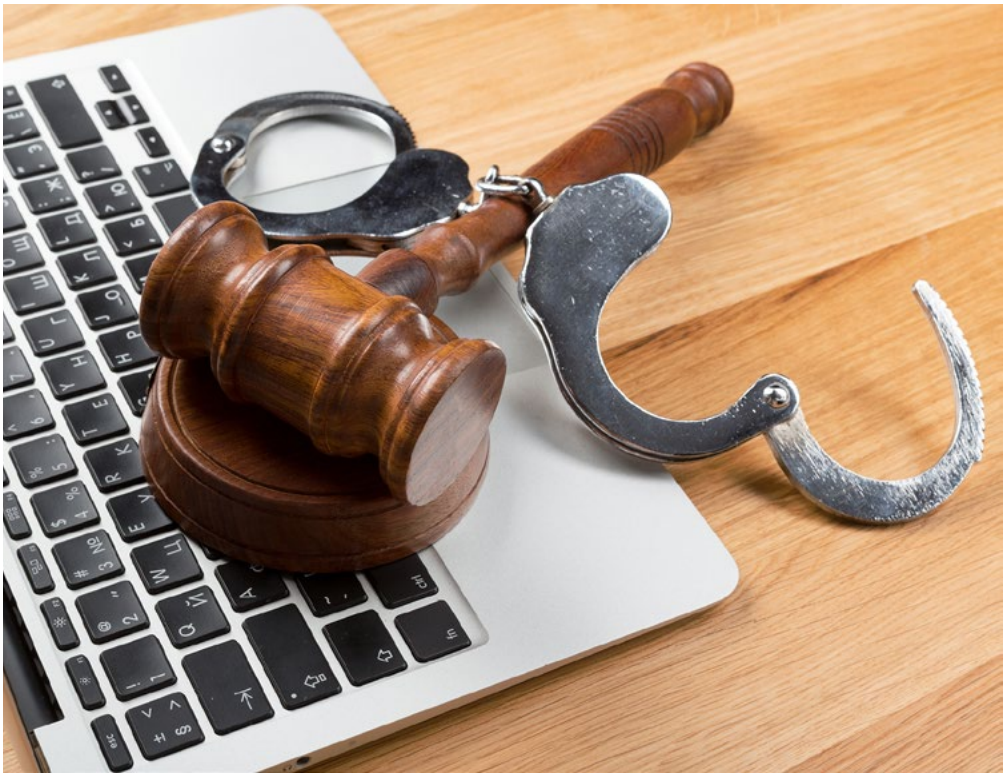
The settlement funds will be used to establish an almost $200 million endowment at the Oklahoma State University's Center for Wellness and Recovery for the purpose of addiction treatment and research.

More than $100 million of the settlement proceeds will be used to fund a new addiction treatment and research center at Oklahoma State University. $20 million of that amount will be earmarked for addiction treatment medicines.

Another $12.5 million in settlement funds will be dedicated to use by cities and counties to help fight the opioid epidemic.

In late May, Teva Pharmaceuticals reached its own $85 million settlement with the state. The case against the remaining defendant, Johnson & Johnson, is moving forward with a bench trial that began on May 28th.

The complaint filed by the Oklahoma Attorney General[20], Mike Hunter, revealed that Purdue's OxyContin sales skyrocketed from $48 million in 1996 to $3 billion in 2009[21].



Hunter alleged that Purdue misrepresented the risks of opioid addition in its marketing materials and promoted unproven benefits in an effort to boost sales. According to the complaint, Purdue caused "catastrophic damage" in Oklahoma by engaging in a false and deceptive marketing campaign that deluded both doctors and patients into thinking Purdue's opioids were actually less harmful than had originally been warned by the medical community[22].

Specifically, Hunter claims that Purdue falsely downplayed the risk of addiction associated with OxyContin and erroneously maintained that scientific studies had supported the prescription drug's low risk of addiction[23].

One Purdue sales manager is quoted in the complaint as being trained to say that OxyContain was "non-habit forming," going so far as to admit he was instructed "to say things like [OxyContin] is 'virtually' non-addicting…It's not right, but that's what they told us to say."[24]

The complaint also alleged that Purdue misrepresented the benefits of its opioids, including by falsely promoting that OxyContin had been studied for use with arthritis and recommending that it was effective in treating chronic non-cancer related pain[25].

Abbe Gluck, a professor at Yale Law School, theorized that Purdue's decision to settle the case was largely driven by its apprehension that these allegations by the state would be "publically aired against it during a televised trial," thereby risking "exposure to what could have been an astronomical jury verdict."[26]

New York

For the first time since the onset of the opioid crisis, criminal charges have been levied against the individual executives running a drug distribution company.

The United States Attorney's Office for the Southern District of New York (USAO), in cooperation with the New York Division of the U.S. Drug Enforcement Administration (DEA), announced in late April that criminal charges were filed against two executives of Rochester Drug Co-Operative, Inc.

Rochester, which is one of the largest wholesale pharmaceutical distributors in the United States, was accused of unlawfully distributing both oxycodone and fentanyl and conspiring to defraud the DEA.

Most notably, the company's former chief executive officer and former chief compliance officer were both individually charged with the illegal distribution of controlled substances, a felony offense.

For its part, Rochester admitted culpability for the unlawful distribution and agreed to pay a $20 million fine and allow for future oversight of it operations by an independent monitor.

If Rochester adheres to the government's terms over the next five years, the USAO has agreed to dismiss the charges against the company.

The press release from the USAO underscored that the unprecedented charges "should send shock waves throughout the pharmaceutical industry reminding them of their role as gatekeepers of prescription medication."[27]

With respect to the individual executives, the USAO alleged that they conspired to distribute oxycodone and fentanyl outside of the scope of professional practice and not for a legitimate medical purpose[28].

The indictment alleges that they willfully failed to report suspicious orders of controlled substances to the DEA and likewise failed to advise the DEA that Rochester's customers were diverting the controlled substances for illegitimate use[29].

In particular, over an approximately five-year period, Rochester received 412 orders of fentanyl and 2,530 orders of oxycodone from its pharmacy customers that the company designated as "suspicious."[30]

Of those almost 3,000 orders that Rochester's internal compliance team red-flagged, the former executives only reported four total orders to the DEA at the direction of Rochester's former CEO[31].

One member of Rochester's compliance team explicitly warned the CEO and other executives that this practice could place the company in the DEA's "cross-hairs… because of [its] willful blindness and deliberate ignorance."[32]

The former executives were also cited with having lied to the DEA about conducting due diligence on new pharmacy customers when no proper review was ever performed[33].

These customers were ultimately supplied with opioids from Rochester despite the company and its executives allegedly knowing that the drugs were in turn being sold and used illicitly[34].

Laurence Doud, the former CEO, was charged with one count of conspiracy to distribute controlled substances, which carries a maximum sentence of life in prison and a mandatory minimum sentence of 10 years, and one count of conspiracy to defraud the United States, which carries a maximum term of 5 years.

William Pietruszewski, the former Chief Compliance Officer, pled guilty in April to charges of conspiracy to distribute controlled substances, conspiracy to defraud the United States, and failing to file suspicious order reports with the DEA.

PROACTIVE OPTIONS FOR SELF-FUNDED PLANS

Plan participants that misuse or intentionally abuse prescription opioids are more likely to incur high-dollar medical charges, whether in the form of emergency room visits, lengthy inpatient hospital stays, or recurrent physician visits.

Statistics provided by the Centers for Disease Control and Prevention indicate that over 1,000 people per day receive emergency medical services as a result of misusing prescription opioids[35].

In 2014, there were over 1.27 million emergency room visits and hospital inpatient stays for opioid-related issues, which represented a 99% increase for emergency room treatment and 64% increase for inpatient care from just 2005[36].

These increased emergency room visits, extended hospitalizations, and even a rise in workers' compensation claims stemming from opioid addiction are putting a considerable financial strain on employers and the plans they sponsor.

Opioid abuse can cost an employer-sponsored plan an additional $10,000 to $20,000 in annual excess costs per patient[37].

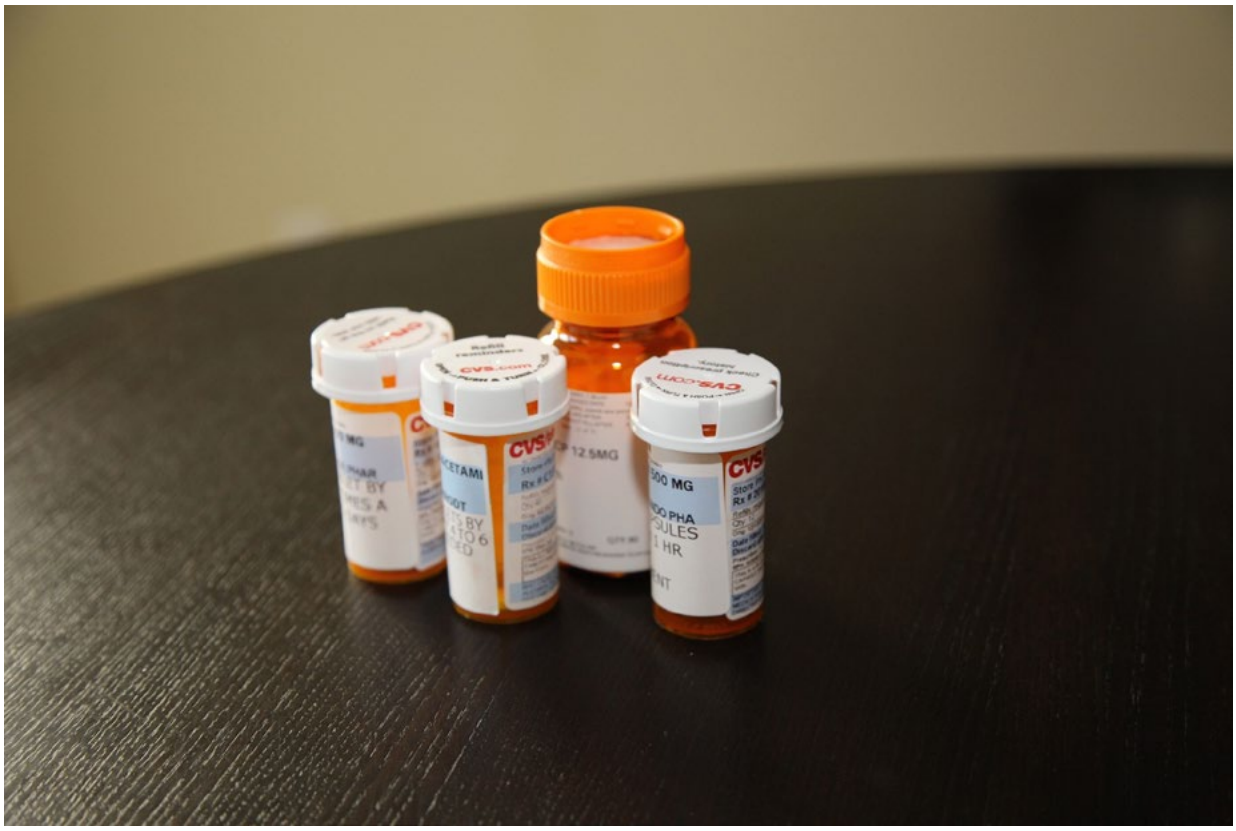
Almost one-third of prescription painkillers covered by employer-sponsored plans are abused[38].

Fortunately, there are a number of options available to self-funded plans to combat the epidemic and mitigate the rising costs associated with opioid abuse:

(1) Plan Design – Employers can customize their plans to discourage opioid abuse and instead incentivize participants to utilize pain management alternatives, such as acupuncture, chiropractic care, physical and behavioral therapy and heat-focused massage.

(2) Insist on Compliance with CDC and FDA Guidelines – Employer-sponsored plans should confirm whether the providers in their networks are properly following opioid prescription guidelines established by the Centers for Disease Control and Prevention (CDC). The CDC guidelines were established as a baseline for providers to follow to better ensure that opioids are prescribed safely and appropriately in order to minimize the chances of abuse or misuse. Additionally, plans should take steps to make sure their participants are aware of, and diligently follow, the Food and Drug Administration's (FDA) guidelines that instruct patients on how to properly discard surplus opioids before they can be accessed by other household members who do not have a prescription.

(3) Establish a Limit – CDC studies have revealed that the likelihood of a patient becoming addicted to opioids spikes on day four of use. Consequently, Plans may want to consider placing a three-day limit on the use of opioid prescriptions for initial pain treatment39. Plans should work directly with their utilization



management vendor and pharmacy benefit manager to establish strict dosage caps and dispensation/refill limits.

(4) Plan Participant Education – Employers need to take proactive steps to ensure that their employees are fully-informed of the dangers of opioid addiction and misuse. Group discussions and annual meetings are useful forums for discussing the dangers of opioid side effects, recognizing the symptoms of painkiller abuse, and identifying helpful resources available to employees such as substance abuse hotlines.

(5) Identify Vulnerable Participants – Plans should analyze their prescription drug data to identify plan participants with a history of excessive prescription drug use who may be more prone to abusing opioids. Plans should then work with their vendors and administrators to preemptively reach out to providers and pharmacists in order to steer susceptible participants towards pain management alternatives, establish prescription limitations, and make such participants aware of assistance networks and other resources at their disposal to help them through substance abuse issues. ■

Sean Donnelly joined The Phia Group, LLC in 2013 and currently serves as Associate General Counsel. In his role as Associate General Counsel, Sean is primarily responsible for handling the drafting, negotiation and enforcement of The Phia Group's contracts and agreements. He also serves as a key advisor to The Phia Group's management on legal and regulatory compliance issues, business governance issues and internal policies and procedures. Sean earned his B.A. in Political Science with Distinction from the University of Michigan and his J.D. from Boston College Law School.

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