

DOJ'S AGGRESSIVE EFFORT TO COMBAT OPIOID CRISIS PLACES EVERYONE IN THE CROSSHAIRS

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By: Christopher L. Nasson, Joshua I. Skora, Elma Delic

INTRODUCTION

A wave of recent indictments unsealed against opioid distributors and their executives signifies that the U.S. Department of Justice ("DOJ") has embarked on a criminal crackdown after years of civil enforcement efforts failed to staunch America's opioid epidemic. In particular, the DOJ appears to have broadened its investigatory and enforcement activity to encompass not just customary bad actors, such as "pill mills," drug trafficking organizations, and rogue prescribers, but also companies involved in the drug supply and distribution chain. Such companies include manufacturers, wholesale distributors, and retail pharmacies. In addition, the DOJ is increasingly pursuing criminal charges against senior executives at companies allegedly responsible for the overutilization or diversion of opioids. Recent victories in the DOJ opioid crackdown, such as the convictions of five top executives at Insys Therapeutics, Inc. ("Insys"), an opioid manufacturer, for racketeering conspiracy, as well as a related settlement by Insys with the federal government to resolve, in part, criminal investigations into the company's marketing practices, likely will encourage and embolden federal prosecutors.

The increase in enforcement actions taken against these companies and their senior executives follows from the Trump administration's public commitment to end the improper diversion and distribution of addictive opioids and deter similar malfeasance in the future. In October 2017, the Trump administration officially declared the opioid crisis a public health emergency.^[1] Alex Azar II, Secretary of the U.S. Department of Health and Human Services, most recently renewed the public health emergency declaration on July 17, 2019.^[2] As a result, the Trump administration has prioritized enhanced regulatory enforcement, including the investigation and prosecution of high-impact individuals and companies, as a tool to fight the opioid epidemic. For example, in February 2018, the DOJ announced the creation of a new task force, the Prescription Interdiction & Litigation Task Force, charged with "aggressively deploy[ing] and coordinat[ing] all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors."^[3] More recently, on August 8, 2019, the DOJ announced the immediate suspension of the Certificate of Registration issued by the U.S. Drug Enforcement Administration ("DEA") to Oak Hill Hometown Pharmacy ("Oak Hill"), a West Virginia pharmacy alleged to have improperly filled large volumes of an addictive controlled narcotic, on grounds that the pharmacy posed an "imminent danger to the public health or safety."^[4]

Furthermore, according to the DEA's Automation of Reports and Consolidated Orders System, which tracks all opioid purchases in the United States, 15 percent of pharmacies handled almost half of opioids that were distributed — a total of 35 billion opioids.^[5] These pharmacies, largely comprised of small independent

pharmacies in rural areas, "had annual double-digit growth in pain pills and bought far more opioids than competitors in the same counties." [6] Although some of the pharmacies were previously subject to disciplinary actions or warnings from regulators, it is not clear whether all high-volume pharmacies were similarly sanctioned. [7] The pharmacies, some of which now operate under new ownership, are located in Kentucky, Idaho, Kansas, Illinois, Tennessee, West Virginia, Nevada, Utah, Oregon, Michigan, and Oklahoma. Government agencies are increasingly relying on data analytics in order to target so-called "bad actors" for further investigations. Accordingly, pharmacies that dispense opioids or other controlled substances in volumes or patterns that are aberrant to those of similarly situated pharmacies are at increased risk of government inquiries into their internal business operations and practices. A similar example of the current government focus on facilities or actors believed to be large contributors to the crisis involves Purdue Pharma, which is reportedly offering \$10–\$12 billion to settle all of the cases and a recent raid in which the DOJ charged 41 people for allegedly running a "pill mill" in Texas. [8]

In response to this increased government scrutiny, companies conducting business at any stage of the supply and distribution chain in the opioid space and investment firms that own portfolio companies in the industry should carefully evaluate corporate compliance programs, particularly with respect to marketing strategies, utilization review, and communications with health care prescribers, to determine whether they are effectively implemented or mere "paper programs."

THE PAST

In the past, the DOJ's enforcement efforts primarily involved civil settlements that included substantial fines. For example, in 2008, McKesson Corporation ("McKesson"), a distributor of pharmaceutical drugs, agreed to pay a civil penalty of \$13,250,000 in order to settle alleged violations of the Controlled Substances Act. [9] The DOJ alleged that McKesson failed to properly report to the DEA suspicious purchases of controlled substances by pharmacies and clinics. In 2017, the DOJ alleged that McKesson again violated federal reporting requirements pertaining to suspicious orders for controlled substances it received from third parties. As a result, McKesson entered into another settlement agreement with the DOJ whereby the distributor agreed to a \$150 million civil penalty and the suspension of controlled substances sales from certain noncompliant distribution centers, as well as adherence to an enhanced compliance program. [10] While this civil penalty constituted the largest settlement amount at that time, no criminal charges were filed against McKesson's executives in either settlement.

The DOJ's prior reliance on civil penalties to ensure compliance with drug control laws was not limited to McKesson. For example, in 2017, the DOJ announced a settlement with Mallinckrodt LLC ("Mallinckrodt"), one of the largest manufacturers of generic oxycodone, to resolve allegations that Mallinckrodt did not appropriately detect and report orders for controlled substances that were suspicious due to their frequency, size, or other factors. In announcing the settlement, then-Attorney General Jeff Sessions stated:

... as a result of today's settlement, we are sending a clear message to drug companies: this Department of Justice will hold you accountable for your legal obligations and we will enforce our laws. I believe that will prevent drug abuse, prevent new addictions from starting, and ultimately save lives. [11]

While past settlements have signaled the DOJ's willingness to resolve opioid cases with a company "cutting a check," those days appear to be long gone. The recent wave of criminal prosecutions shows that the DOJ is developing a playbook to charge companies and executives involved in over-prescribing and over-distributing opioids.

RECENT AND ONGOING CASES REFLECT DOJ'S NEW GAME PLAN

Several ongoing cases demonstrate federal prosecutors' aggressive new approach. Earlier this year, the DOJ pursued for the first time felony criminal charges against a pharmaceutical distributor.[12] In *United States v. Rochester Drug Co. Operative, Inc.*, prosecutors brought drug-trafficking charges against two former executives and Rochester Drug Co. Operative, Inc. ("RDC"), one of the largest pharmaceutical distributors in the United States, alleging that RDC shipped millions of oxycodone pills, fentanyl, and other opioids to pharmacies that its executives knew were distributing the drugs illegally.[13] In particular, the DOJ charged RDC with conspiring to distribute drugs, conspiracy to defraud the United States, and failing to file suspicious order reports.[14] The company paid \$20 million in penalties and entered into a deferred prosecution agreement.[15] During a press conference discussing the case, U.S. Attorney for the Southern District of New York Geoffrey Berman noted, "[t]his country is in the midst of a prescription drug abuse epidemic . . . [t]his epidemic has been driven by greed." [16] The former CEO of RDC faces related charges and is scheduled for trial in May 2020.[17] The former chief compliance officer has pled guilty and is cooperating with prosecutors.[18]

Shortly after announcing charges against RDC and its executives, the DOJ pursued a criminal case against Miami-Luken, Inc. ("Miami-Luken"), an Ohio-based distributor, its former executives, and two pharmacists for an alleged scheme that resulted in the distribution of millions of opioids throughout various states.[19] Specifically, the DOJ alleged that Miami-Luken and its executives distributed "more than 2.3 million oxycodone pills and 2.6 [million] hydrocode pills" to a single pharmacy located in a town with a population of approximately 1,394.[20] According to the DOJ, "[the two executives] and Miami-Luken sought to enrich themselves by distributing millions of painkillers to doctors and pharmacies in rural Appalachia, where the opioid epidemic was at its peak." [21] The indictment further alleged that the two executives and Miami-Luken "ignored obvious signs of abuse and diversion" [22] In connection with its investigation, the DOJ similarly charged two West Virginia pharmacists whose pharmacies had received significant amounts of opioids from Miami-Luken; the pharmacists now face 20 years in prison.

The two cases have striking similarities. First, both cases involve criminal charges against the compliance officers of opioid distributors. Second, both cases involve companies that serviced pharmacies that were previously terminated by other distributors or wholesalers. Third, both cases involved allegations that the distributor shipped opioids to pharmacies that were under investigation by the DEA. Finally, in both cases, the facts indicate that the compliance officer or other executives had knowledge of the opioids being provided illicitly or otherwise were aware of red flags.

In addition to the imposition of criminal charges, the government also is relying on administrative enforcement mechanisms to crack down on the opioid epidemic. This is most clearly demonstrated in the DOJ's suspension of Oak Hill's DEA registration due to allegations of improper dispensing activities dating back to December 2016. According to the DOJ, Oak Hill continued to fill 2,000 prescriptions of Subutex, a Schedule III controlled substance, despite multiple prescription abuse and diversion indicators.[23] In particular, the DOJ noted the

frequency of prescriptions written by out-of-state physicians, cash payments, and long travel distances made by patients, as well as multiple prescriptions written on the same date. In its press release, the DOJ discussed pharmacies' obligations and role in combating the prescription drug abuse by stating:

Every pharmacy that fills prescriptions of scheduled narcotics has a corresponding responsibility to assure that those prescriptions do not include unresolvable red flags and are for a legitimate medical purpose. It is the proper role of law enforcement and the Drug Enforcement Administration to ensure public safety with respect to the dispensing of controlled substances by pharmacists and providers. We take this responsibility seriously.[24]

The DOJ's recent use of criminal as well as administrative actions against individuals and companies reflects that multiple factors and industry stakeholders contributed, and continue to contribute, to the opioid crisis. The DOJ approach further reflects the government's view that various mechanisms and strategies are necessary to punish and deter future harm.

MASSACHUSETTS AT THE FOREFRONT

The aggressive prosecution of key actors in the opioid industry may be most evident in Massachusetts. As noted, the U.S. Attorney's Office for the District of Massachusetts brought criminal and civil charges against Insys, which agreed in June 2019 to a \$224 million settlement in connection with various civil and criminal investigations into the company's promotion of its drugs.[25] To resolve the criminal investigation, Insys agreed in part to enter into a deferred prosecution agreement and pay \$30 million in criminal penalties. A subsidiary of Insys also agreed to plead guilty to mail fraud. The government alleged that Insys violated the federal Anti-Kickback Statute, among other allegations, by utilizing a "sham speaker program" as a mechanism to bribe physicians and other health care practitioners into prescribing opioids.[26] Through these speaker programs, prescribers received kickbacks for generating new prescriptions for and increasing dosages of Subsyst, a highly addictive opioid painkiller.[27] The DOJ settlement with Insys comes after a jury convicted five former Insys executives, including the company's founder, of racketeering conspiracy charges.[28] In its press release regarding the convictions of the Insys executives, the government reiterated its focus on this new enforcement strategy. In particular, U.S. Attorney Andrew Lelling stated:

Just as we would street-level drug dealers, we will hold pharmaceutical executives responsible for fueling the opioid epidemic by recklessly and illegally distributing these drugs, especially while conspiring to commit racketeering along the way . . . This is a landmark prosecution that vindicated the public's interest in staunching the flow of opioids into our homes and streets.[29]

Massachusetts also provides an example of how state agencies are getting involved in the opioid crackdown. In one of the first cases of its kind, the Massachusetts Attorney General brought charges against eight members of

the Sackler family and Purdue Pharma ("Purdue") for misleading doctors and patients about OxyContin. The complaint alleges that Purdue is responsible for 671 deaths in Massachusetts due to opioids manufactured and marketed by Purdue.[30] Specifically, the complaint states, "Purdue promoted its opioids to Massachusetts patients with marketing that was designed to obscure the risk of addiction and even the fact that[?] Purdue was behind the campaign." [31] The case is currently pending, after a recent motion-to-dismiss hearing where the judge took the defendant's motion under advisement.[32]

CONCLUSION

As the government ramps up enforcement efforts against business entities alleged to have contributed to the opioid crisis, all industry stakeholders are impacted. Continued success by the DOJ or state agencies in these areas undoubtedly will result in increased investigations of key pharmaceutical companies, not just "bad actors" that directly interact with patients. Businesses involved in the controlled substances supply chain, particularly relative to opioids, would be wise to thoroughly review existing compliance programs to ensure that appropriate and robust safeguards are in place to prevent the improper diversion and distribution of such drugs.

[1] U.S. Dep't of Health & Human Servs., *Determination that a Public Health Emergency Exists*, (Oct. 26, 2017), <https://www.whitehouse.gov/opioids/>.

[2] U.S. Dep't of Health & Human Servs., *Renewal of Determination that a Public Health Emergency Exists*, (July 17, 2019), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

[3] U.S. Dep't of Justice, *Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force*, (Feb. 27, 2018), <https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force>.

[4] U.S. Dep't of Justice, *Statement of United States Attorney Mike Stuart Regarding Oak Hill Hometown Pharmacy*, (Aug. 8, 2019), <https://www.justice.gov/usao-sdvv/pr/statement-united-states-attorney-mike-stuart-regarding-oak-hill-hometown-pharmacy>.

[5] Jenn Abelson, Andrew Ba Tran, Beth Reinhard & Aaron C. Davis, *As overdoses soared, nearly 35 billion opioids — half of distributed pills — handled by 15 percent of pharmacies*, WASH. POST (Aug. 12, 2019) https://www.washingtonpost.com/investigations/the-opioid-crisis-15-percent-of-the-pharmacies-handled-nearly-half-of-the-pills/2019/08/12/b24bd4ee-b3c7-11e9-8f6c-7828e68cb15f_story.html?noredirect=on.

[6] *Id.*

[7] *Id.*

[8] Melanie Schuman, Jean Casarez & Taylor Romine, *Opioid maker Purdue Pharma is in talks to settle thousands of suits that claim it fed a deadly national drug epidemic*, CNN, (Aug. 28, 2019) <https://www.cnn.com/2019/08/27/us/purdue-settlement-ohio/index.html>; Marina Pitofsky, *Dozens charged in opioid network accused of distributing 23 million pills*, THE HILL, (Aug. 29, 2019), <https://thehill.com/blogs/blog-briefing-room/news/459375-justice-department-charges-dozens-in-opioid-network-with>.

[9] U.S. Dep't of Justice, *McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription Medications*, (May 2, 2008), <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

[10] U.S. Dep't of Justice, *McKesson Agrees to Pay Record \$150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs*, (January 17, 2017), <https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

[11] U.S. Dep't of Justice, *Mallinckrodt Agrees to Pay Record \$25 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations*, (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders>.

[12] U.S. Dep't of Justice, *Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances*, (Apr. 23, 2019), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and>.

[13] *Id.*

[14] *Id.*

[15] Jonathan Stempel & Nate Raymond, *U.S. brings first criminal case against major drug distributor over opioids*, REUTERS (Apr. 23, 2019), <https://www.reuters.com/article/us-usa-opioids-rochester/u-s-brings-first-criminal-case-against-major-drug-distributor-over-opioids-idUSKCN1RZ1RV>.

[16] *Id.* (internal quotations omitted).

[17] Stewart Bishop, *Drug Distributor's Ex-CEO Faces May Trial Over Opioid Sales*, LAW360 (July 31, 2019), https://www.law360.com/whitecollar/articles/1184045/drug-distributor-s-ex-ceo-faces-may-trial-over-opioid-sales?nl_pk=bb564918-13cc-4713-ac90-8faaebbc2ead&utm_source=newsletter&utm_medium=email&utm_campaign=whitecollar&read_more=1.

[18] *Id.*

[19] U.S. Dep't of Justice, *Pharmaceutical Distributor & Executives, Pharmacists Charged With Unlawfully Distributing Painkillers*, (July 18, 2019), <https://www.justice.gov/usao-sdoh/pr/pharmaceutical-distributor-executives-pharmacists-charged-unlawfully-distributing>.

[20] *Id.*

[21] *Id.*

[22] United States v. Rattini, No. 1:19-cr-00081 (S.D. Ohio July 17, 2019).

[23] U.S. Dep't of Justice, *Statement of United States Attorney Mike Stuart Regarding Oak Hill Hometown Pharmacy*, (Aug. 8, 2019), <https://www.justice.gov/usao-sdvw/pr/statement-united-states-attorney-mike-stuart-regarding-oak-hill-hometown-pharmacy>.

[24] *Id.*

[25] U.S. Dep't of Justice, *Insys Therapeutics Agrees to Enter into \$225 Million Global Resolution of Criminal Civil Investigations*, (June 5, 2019), <https://www.justice.gov/usao-ma/pr/insys-therapeutics-agrees-enter-225-million-global-resolution-criminal-and-civil>.

[26] *Id.*

[27] *Id.*

[28] U.S. Dep't of Justice, *Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy*, (May 2, 2019), <https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy>.

[29] *Id.*

[30] *Massachusetts v. Purdue Pharma L.P.*, No. 1884-CV-01808 (Mass. 2018).

[31] *Id.* at ¶ 31.

[32] Deborah Becker, *What To Know About A Major Hearing In AG Healey's Lawsuit Against Purdue Pharma*, WBUR (Aug. 2, 2019), <https://www.wbur.org/commonhealth/2019/08/02/sackler-massachusetts-healey-oxycotin-purdue>.

KEY CONTACTS



CHRISTOPHER L. NASSON
PARTNER

BOSTON, NEW YORK
+1.617.261.3135
CHRISTOPHER.NASSON@KLGATES.COM



JOSHUA I. SKORA
PARTNER

DALLAS
+1.214.939.6235
JOSHUA.SKORA@KLGATES.COM

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