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From: HarrisMartin's Drugs & Medical Devices Publication
Date: July 17, 2018
www.harrismartin.com

'Opioids and Legal Enforcement—A Primer'

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I. Introduction

The opioid crisis in America is now well known, affecting a staggering number of people directly or indirectly and occupying a regular place in media reports and political discussions. In addition to potential public health and legislative approaches, various government enforcement strategies have been considered. At the federal level, the U.S. Department of Justice (DOJ) and its related law enforcement agencies have taken a renewed focus on combatting opioid-related issues through civil, criminal and regulatory means. Similar efforts have been undertaken at the state level by state authorities, and an array of private legal actions have likewise been brought by various plaintiffs. Below we provide an overview of these and other efforts in opioid-related enforcement and highlight several likely trends.

II. Overview of the opioid supply chain

In many ways, lawfully prescribed opioids follow a similar path to market as do other pharmaceuticals. At the beginning of the supply chain are manufacturers—typically large pharmaceutical companies—that manufacture and package the pills. Next, the manufacturers transfer the pills to distribution companies. Three distribution companies account for the vast majority of distribution in the United States: McKesson Corporation, Cardinal Health, Inc. and AmerisourceBergen. Those companies supply the opioids to pharmacies and other healthcare providers that, in turn, dispense the medications to consumers.

Several other entities, while not part of the actual supply chain, play important roles. Most obviously,

prescribing physicians are involved because they provide the prescription that enables opioids, like any prescription medications, to be dispensed to the end consumer. Pharmacy benefit managers (PBMs) interface with manufacturers during negotiations for placement on the PBM's formulary and may negotiate with pharmacies to determine reimbursement levels for drugs dispensed by the pharmacy. Health plans likewise play a role, providing insurance coverage to consumer-beneficiaries and contracting with PBMs to manage the plan's drug benefit. Finally, two government agencies, the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), provide regulatory oversight at different points in the supply chain related to suspicious orders, potentially counterfeit or adulterated drugs, and diversion issues among others.

III. Potential types of enforcement

A. Private civil litigation

The opioid crisis has spawned countless private lawsuits asserting varying causes of action against a host of different categories of defendants. The primary national vehicle for such suits now is In re Nat'l Prescription Opiate Litig., 1:17-md-2804, the federal multi-district litigation (MDL) pending in the Northern District of Ohio before U.S. District Judge Dan Polster. MDLs are an unorthodox procedural tool that allows consolidation of massive numbers of cases that could not be combined in a more traditional class action under Federal Rule of Civil Procedure 23. Although permitted under federal law since the late 1960s, see 28 U.S.C. § 1407, MDLs have become more common in recent years in enormous cases that would be procedurally intractable under the typical rules of civil procedure. Other notable MDLs include cases involving the BP oil spill and concussions suffered by NFL players.

In general, plaintiffs in the cases now comprised by the opioid MDL allege that manufacturers of prescription opioids overstated those medications' benefits and understated their risks when aggressively marketing the drugs to physicians. In addition, the plaintiffs allege that distributors failed to monitor, detect, and investigate suspicious orders of opiates. In transferring the cases to the Northern District of Ohio and forming the federal MDL, the court found the cases shared common issues of fact such as the manufacturers' and distributors' knowledge of alleged diversion of the opiates and the manufacturers' alleged improper marketing. See JPML Transfer Order (Doc. #1), In re Nat'l Prescription Opiate Litig., No. 2804 (N.D. Ohio, Dec. 5, 2017). Among the types of claims by various plaintiffs are violations of different states' consumer protection laws, racketeering statutes, controlled substance laws, and various common law actions such as public nuisance, negligence, negligent misrepresentation, fraud, and unjust enrichment. The Northern District of Ohio was chosen as the transferee district based on Ohio's strong factual connection to the litigation given its significant number of opioid overdoses, its geographic centrality, and Judge Polster's experience with opioid litigation. Id.

While the federal MDL includes hundreds of cases in federal court, other cases in state court still are pending in jurisdictions across the country. Many state cases were removed to federal court—a procedural mechanism that allows a party to seek to transfer a state case to federal court on various grounds—and then made part of the federal MDL. Some plaintiffs, including states and municipalities, have resisted being included in the federal MDL for fear of losing leverage amid such a large number of cases and a potential global settlement. See, e.g., "Attorneys for CT Cities Pledge Fight Against Move to Opioid MDL," Connecticut Law Tribune, Jan. 24, 2018. In most circumstances, large defendants prefer consolidation so there is a single legal battlefield, and they are not subject to the vagaries of state-court juries across the country. Individual states also have their own multi-district litigation mechanisms that could be used to consolidated large numbers of cases in a single state that

are not in the federal MDL. For example, in Texas, Purdue Pharma, McKesson Corp. and other manufacturers and distributors moved to consolidate 16 cases in different Texas counties into a single state MDL. On June 14, 2018, a Texas judicial panel on multi-district litigation granted the motion and consolidated the cases. See In re Texas Opioid Litig., MDL No. 18-0358 (Tex. 2018).

B. Criminal prosecution

Not surprisingly, intentional and egregious opioid-related misconduct often results in criminal charges.

"Pill mill" prosecutions remain the most common criminal enforcement tool in the opioid arena. Indicators of pill mill operations include an abnormally high volume of patients, patients who have traveled from a different state, multiple patients from same family, a high volume of prescriptions in general and for opioid "cocktails" in particular, little or no medical examinations during patient visits, insistence on cash payment, odd office hours, and the presence of security guards. Undercover law enforcement officers commonly pose as opioid-seeking patients during the investigation of suspected pill mills.

The primary charging tool used in pill mill cases is the Controlled Substances Act (CSA), 21 U.S.C. § 801 et seq., which criminalizes prescriptions that are not for a legitimate medical purpose or that are outside the usual course of professional practice. Examples of illegitimate prescribing purposes and acting outside the usual course of professional practice include prescribing inappropriate combinations of opioids, engaging in unprofessional conduct with patients, and failing to assess an individual's medical history and/or risk of abuse of a controlled substance.

Pill mill investigations have led to charges against doctors, nurse practitioners, nurses, staff members, and pharmacists. For example, in October 2017, two pharmacists in Georgia were convicted of CSA and money laundering charges and sentenced to 19 and 20 years in prison, respectively, for using their pharmacy to supply controlled substances to patients of a known pill mill. In addition, they were ordered to pay a total of $5 million in community restitution to Georgia state agencies responsible for substance abuse treatment and victims' assistance. See https://www.justice.gov/usao-ndga/pr/two-pharmacists-sentenced-19-and-20-years-prison-and-ordered-pay-5-million-restitution.

Pill mill cases often also include healthcare fraud allegations if the provider submits suspicious claims to any healthcare benefits programs, especially government health plans. See, e.g. 18 USC § 1347 (general healthcare fraud statute). Pill mill fraud schemes can include the familiar patterns charged in conventional healthcare fraud cases–medically unnecessary testing, upcoding, double billing, and kickbacks, among others. Depending on the facts underlying a particular case, charges for obstruction of justice, false statements, wire fraud, mail fraud, money laundering, or identity-theft offenses may also be brought in conjunction with such cases.

In May 2018, five Pennsylvania physicians who contracted with Redirections Treatment Advocates, LLC, an opioid addiction treatment practice, were charged with unlawfully dispensing opioids and causing fraudulent claims to be submitted to Medicare or Medicaid to cover the costs of the unlawfully prescribed drugs. See https://www.justice.gov/opa/pr/five-pennsylvania-physicians-charged-unlawfully-distributing-buprenorphine-and-defrauding.

Similarly, four doctors and the CEO of Tri-County Wellness, a healthcare company that owns and operates numerous pain clinics, laboratories, and other providers in Michigan and Ohio, were charged in June with

healthcare fraud, kickbacks, money laundering, and wire-fraud conspiracy. The charges relate to the alleged distribution of over 4.2 million medically unnecessary dosage units of controlled substances including oxycodone, hydrocodone, and oxymorphone, some of which ended up on the street for resale, and medically unnecessary injections given to Medicare beneficiaries to increase revenue. Five additional defendants have previously entered guilty pleas related to this investigation. See https://www.justice.gov/opa/pr/health-care-ceo-and-four-physicians-charged-superseding-indictment-connection-200-million.

Though less common than pill mill cases, the government has focused more resources on pursuing criminal charges involving pharma companies and distributors for opioid related offenses. Cases involving misbranding, off-label promotion, bribery, and kickbacks have all been prosecuted recently as part of the government's opioid enforcement efforts.

C. Government civil enforcement

In addition to criminal prosecutions, the federal government has certain civil-enforcement tools at its disposal, none more important than the False Claims Act (FCA).

The FCA is the government's primary civil enforcement statute. Codified at 31 U.S.C § 3729, et seq., the FCA imposes up to treble damages and significant per-claim penalties for anyone who knowingly submits or causes the submission of a false or fraudulent claim payable by the U.S. government or related entities. By its terms, the FCA focuses on claims for payment. As such, it does not cover every garden-variety fraud or torts and it is not the vehicle to police minor compliance issue. Without a claim for payment to the government (or a failure to repay an overpayment from the government), there can be no FCA action.

To state a claim under the FCA, the government generally must show (1) the existence of a claim actionable under the FCA; (2) that the claim was false, either factually or legally; (3) that the falsity was material to the payment of the claim; and (4) that the defendant acted with knowledge of the falsity. See 31 U.S.C. § 3731(d).

Among the other notable features of the FCA is that it includes a whistleblower provision. Procedurally, a private individual, known as a "relator," can bring a whistleblower (a/k/a, a qui tam) action and enforce the FCA on the government's behalf. 31 U.S.C. § 3730(b). The relator may be anyone with knowledge of the allegations—such as a current or former employee, a competitor, a customer, or a consultant. When brought by a relator, a complaint is filed under seal and remains unserved on the defendant until the presiding federal court orders otherwise. 31 U.S.C. § 3730(b)(2). While the complaint is under seal, the government can investigate the relator's claims and decide whether it will intervene and take responsibility for litigating the action or decline to intervene, leaving the relator to litigate his or her complaint. 31 U.S.C. § 3730(b)(4). The FCA incentivizes private relators to bring claims by providing them with a share of any damages awarded—15 to 25 percent if the government intervenes and 25 to 30 percent if the government does not intervene. 31 U.S.C. § 3730(d).

The FCA is a powerful enforcement tool for the government—in fiscal year 2017, the government recovered over $3.7 billion in FCA settlements and judgments. And it surely will play some role in the government's effort to combat the opioid crisis. Attorney General Jeff Sessions stated as much when announcing, in February 2018, the formation of the Prescription Interdiction and Litigation (PIL) tax force, noting that the FCA and other tools would be used to address pain clinics, drug-testing centers, and physicians who over-prescribe opioids. The government has, in fact, brought FCA lawsuits involving opioids.

For example, in April 2018, the government intervened in several consolidated FCA lawsuits involving the marketing of Subsys, a sublingual spray form of fentanyl. See, e.g., U.S. ex rel. Guzman v. Insys Therapeutics, Inc., et al., 13-cv-5861 (C.D. Calif.). Given that Medicare pays several billion dollars every year for claims involving opioids, there would appear to be fertile ground for FCA enforcement.

But the FCA's use may be more limited than it first appears in the opioid context. First, the FCA ultimately can only indirectly combat opioid-related misconduct by targeting false claims to the government that involve those medications, and the theories of FCA liability—e.g., claims rendered false due to lack of medical necessity or because they are tainted by an Anti-Kickback Statute violation—are not unique to opioids. Second, medical-necessity cases can be among the most difficult to prevail on given the subjective nature of medical judgment, especially for medications that have broad indications for use as many prescription opioids do. Third, false or fraudulent marketing can often be a basis for an FCA case, but there is legal authority that truthful, non-misleading off-label marketing does not violate the Food Drug and Cosmetic Act, see U.S. v. Caronia, 703 F.3d 149 (2nd Cir. 2012), which may remove one avenue for establishing falsity in cases involving prescription drugs.

Notwithstanding those potential limitations, given the resources and focus DOJ has devoted to opioid-related enforcement, it is likely that the FCA will be aggressively used wherever possible.

D. Regulatory enforcement

Separate from criminal and civil enforcement efforts, the government continues to ramp up regulatory actions in an effort to address the opioid crisis. A DEA opioid surge from February and March of this year resulted in 28 arrests, 54 enforcement actions, and 283 administrative actions including scheduled inspections, letters of admonition, memoranda of agreement/understanding, surrenders for cause of DEA registrations, orders to show cause, and the immediate revocation of DEA registrations.

Additionally, in May the DEA ordered Louisiana-based wholesale pharmaceutical distributor Morris & Dickson to stop selling opioids based on the company's alleged failure to report unusually large shipments of narcotics to the government as required. Before the immediate suspension of Morris & Dickson, DEA had not used that regulatory tool in six years.

On July 11, 2018, DOJ announced a final version of a regulatory rule that will allow DEA to consider the extent to which a drug is diverted for abuse in setting annual opioid production limits. If DEA believes that a particular opioid or opioids are being diverted for misuse, the new rule allows DEA to reduce the amount allowed to be produced in a given year. The government's objectives in enacting the new rule are to encourage vigilance by opioid manufacturers, assist DEA in responding to the changing drug environment, protect the public and ensure that the country has enough opioids for legitimate medical, scientific, research and industrial needs. See https://www.justice.gov/opa/pr/department-justice-announces-regulatory-steps-address-opioid-epidemic.

HHS-OIG is also using its exclusionary authority to combat the opioid crisis. From June 2017 through May 2018, OIG excluded 587 providers for misconduct related to opioids. According to OIG statistics, the majority of excluded individuals were nurses (68 percent), followed by doctors (11 percent), and pharmacy services professionals (7 percent). The states with the most exclusions were North Carolina (53), New York (51), Ohio (45), Massachusetts (41), and Oklahoma (37). In addition, the FDA is addressing the opioid epidemic by targeting online sales of illegal opioids. In June 2018, the agency issued warnings to nine online networks

demanding that they stop illegally marketing unapproved and misbranded versions of opioids in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. The letters advise that if the companies fail to correct the violations, the government will pursue injunctions or product seizures.

IV. Coordinated Enforcement Efforts

Because of the complexity and breadth of the opioid crisis, the government is tackling enforcement issues from a multi-agency perspective. The Heroin and Opioid Task Force, the first federal opioid related task force, was formed by DOJ in 2013. Since August 2017, DOJ has instituted at least three additional opioid focused task forces in an effort to combat the public health crisis.

The Opioid Fraud and Abuse Detection Unit was formed in August 2017 and focuses on using data analytics to determine who is prescribing and dispensing the most drugs and whose patients are dying of overdoses. As part of the rollout of the new unit, 12 new federal prosecutor positions dedicated to opioid enforcement were allocated to districts in Alabama, California, Florida, Kentucky, Maryland, Michigan, Nevada, North Carolina, Ohio, Pennsylvania, Tennessee, and West Virginia.

The Joint Criminal Opioid Darknet Enforcement Team, or J-CODE, was instituted in January 2018 to investigate the use of the internet to sell drugs. There have been two nationwide J-CODE operations to date. The most recent, in June 2018, resulted in the seizure of 333 bottles of synthetic opioids, over 100,000 tramadol pills, 100 grams of fentanyl, more than 100 firearms, $3.6 million in U.S. currency and gold bars, and another $20,000+ of Bitcoin and other cryptocurrencies.

Finally, as noted above, in February 2018, DOJ announced the Prescription Interdiction & Litigation (PIL) Task Force, which focuses on enforcement actions against manufacturers and distributors, including doctors and pharmacies. For the last two years opioid enforcement efforts have been included and emphasized in DOJ's national healthcare fraud takedown. This year's event occurred in June and was the largest to date. Of note, 162 individuals, including 32 physicians, were charged for their roles in prescribing and distributing opioids and other narcotics.

V. Conclusion

Just as the opioid crisis defies any single solution overall, it is unlikely that any single enforcement strategy will prove to be a magic bullet. Indeed, as with any intractable social and public health problem, there is a limit to what any legal enforcement can achieve. Nonetheless, this will continue to be an active area for both government agencies and the plaintiffs' bar, and we expect significant legal developments in the months and years to come. Which strategies and steps will prove to be most effective, of course, remains to be seen.

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