# DEA Enforcement Report: New Priorities and Strategies in Response to the Opioid Crisis

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# DEA Enforcement Report: New Priorities and Strategies in Response to the Opioid Crisis

As the opioid crisis continues to devastate individuals and communities in the United States, the Drug Enforcement Administration (DEA) is responding vigorously by stepping up its enforcement activity — particularly targeting companies that fail to comply with the agency's anti-diversion requirements.

The DEA has said that it will use "all available tools to address this crisis at every level." The agency has wielded its criminal and civil enforcement authorities to hold noncompliant distributors, corporate officials and pharmacies accountable. It has shut down businesses, indicted companies and senior executives, and forced firms to pay millions in civil penalties.

This whitepaper, brought to you by the experts at Thompson Controlled Substances, tracks the latest DEA enforcement trends, analyzes important recent cases and settlements, and outlines the agency's new authorities under the recently enacted SUPPORT for Patients and Communities Act.

## A Snapshot of Controlled Substance Diversion

The DEA's 2018 National Drug Threat Assessment (NDTA) reported that controlled prescription drugs (CPDs) continue to be responsible for most drug-involved overdose deaths in the United States. CPDs are the second most commonly abused substance in the United States.

The leading factor in CPD abuse is the need for relief from physical pain. According to the 2016 National Survey on Drug Use and Health (NSDUH), sponsored by the Substance Abuse and Mental Health Services Administration, most individuals who reported misuse of pain relievers — 62.3 percent of those aged 12 or over — cited pain as the reason for the abuse. Others who misused CPDs did so to get high (13 percent) or to relieve tension (11 percent). The average age of a person when his or her first misuse of a CPD occurred was 25.8 years, the NSDUH reported.

Those who misuse pain relievers frequently obtain them from a friend or relative (53 percent), the DEA reported in the NDTA. However, 37.5 percent of misusers reported getting CPDs through prescriptions or stealing them from doctors' offices, clinics, hospitals or pharmacies. About 35.4 percent used prescriptions from a single doctor, and 1.4 percent used prescriptions from multiple doctors. In November 2018, the CDC reported that U.S. life expectancy had declined over the previous few years, largely due to deaths from drug overdoses and suicide. The DEA has predicted that CPD availability and abuse will continue to pose "a significant drug threat" to the United States.

**Opioids: The Leading Cause of Accidental Death in the U.S.**

Among CPDs, opioids have become the leading cause of accidental death in the United States, with far more Americans currently dying from opioid misuse than from traffic accidents or violence.

According to the Centers for Disease Control and Prevention (CDC), more than 351,000 persons have died due to opioid overdoses since 1999. Every day, approximately 130 deaths in the United States are caused by opioids. About 40 percent of the deaths involve prescription drug abuse.

Nearly 13 billion dosage units of opioid narcotics were sold to retailers in the United States in 2017.

Of particular concern to enforcement officials is fentanyl, an extremely strong Schedule II synthetic opioid used as a painkiller and anesthetic. Large quantities of fentanyl in the form of transdermal patches or lozenges are diverted from the legitimate U.S. drug market.

The problem is exacerbated by the availability of illicitly produced fentanyl, much of it trafficked into the United States from China and Mexico. In addition, as regulatory changes in the United States, China and Mexico target current forms of fentanyl-related substances, new forms are continually being produced to circumvent the new regulations.

Such attempts to evade the scope of DEA regulations have prompted the agency to use its scheduling authorities to target so-called designer drugs, which produce pharmacological effects that are similar to those produced by regulated drugs but whose molecular structures have been manipulated sufficiently to place them outside the legal definition of the parent drugs from which they were derived. For example, in late 2017 the DEA announced emergency scheduling under 21 U.S.C. §811(h) of seven illicit fentanyl analogues. Such temporary scheduling gives the agency two years (with a possible extension of one addition year) to complete a permanent scheduling procedure for the substances.

**Origins of the Opioid Epidemic**

The National Institute on Drug Abuse has traced the origins of the U.S. opioid epidemic to the late 1990s, when pharmaceutical manufacturers "reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and health care providers began to prescribe them at greater rates."

The steep growth in opioid consumption "is unique to the United States," a December 2018 House Energy and Commerce Committee report noted. For example, as of 2016, the United States accounted for 99.1 percent of the total world consumption of hydrocodone, a moderately potent opioid widely used for the treatment of acute or chronic pain.

From 1999 to 2015, the number of overdose deaths in the United States — caused mostly by opioids — more than tripled, from 16,849 to 52,404 annually. The age-adjusted rate of drug overdose deaths increased between 1999 and 2017 from 6.1 per 100,000 standard population to 21.7 per 100,000.

The opioid crisis in some ways mirrored the amphetamine abuse crisis of the 1960s, which was marked by excessive manufacture and irresponsible prescribing of the stimulant. That crisis was a major factor that led to the 1970 enactment of the Controlled Substances Act, which enabled the DEA to control new drugs of abuse, to move drugs from one schedule to another to add stricter controls, and to set annual production and manufacturing quotas.

## Enforcement Focus on Wholesale Distributors

By 2005, according to the House committee report, the DEA "realized that traditional policing of individual doctors and pharmacies was no longer an effective approach against the oncoming avalanche of opioids from rogue internet pharmacies and pill mills."

Consequently, the agency's enforcement focus began to turn to drug wholesale distributors, which the report called "a chokepoint in the pharmaceutical supply chain." These companies transfer drugs from manufacturers to clinics, hospitals and pharmacies.

The DEA undertook an educational campaign to make wholesale distributors aware of their obligations to prevent the diversion of controlled substances — in part by monitoring, detecting, investigating, refusing and reporting suspicious orders (21 U.S.C. §823(b)(1), 21 C.F.R. 1301.74). The agency held one-on-one meetings with distributors to point out how their customers' ordering habits could indicate the presence of diversion, including the possibility that drugs were being shipped to illicit internet pharmacies. Also, in 2006 and 2007 the DEA sent three letters to all registered distributors summarizing their legal obligations to conduct due diligence and report suspicious orders.

The agency took major enforcement action in 2007 and 2008 against the three largest U.S. wholesale distributors — McKesson Corp., Cardinal Health Inc. and AmerisourceBergen Corp. — that led to settlements for alleged violations of the Controlled Substances Act. Two of the settlements involved multimillion-dollar fines.

However, distributors continued to ship huge quantities of opioids, and distributors continued to be assessed with multimillion penalties a decade later.

## Three Recent Enforcement Actions Targeting Wholesale Distributors

### (1) Rochester Drug Co-Operative Inc.

*For the First Time, the Government Brings Criminal Charges Against a Distributor and its Executives for the Illegal Distribution of Controlled Substances*

In April 2019, the Department of Justice (DOJ) brought criminal charges against Rochester Drug Co-Operative Inc. (RDC), a regional wholesale drug cooperative and one of the 10 largest wholesale distributors of pharmaceutical products.

The government accused the company of conspiracy to violate U.S. narcotics laws, conspiracy to defraud the DEA, and willingly failing to file suspicious order reports with the agency.

A criminal information containing the charges was filed in the U.S. District Court for the Southern District of New York (*United States v. Rochester Drug Co-Operative, Inc.*, No. 1:19-cr-00290 (S.D.N.Y.)).

This was the first time that a drug distributor had been indicted on federal criminal charges related to the opioid crisis in the United States and the illegal diversion of controlled substances.

A former chief executive officer and a former chief compliance officer of the Rochester, N.Y.-based company were also charged with unlawfully distributing controlled substances and conspiring to defraud the DEA.

RDC's former chief executive officer, Laurence F. Doud III, and its former chief compliance officer, William Pietruszewski, were charged with narcotics conspiracy and conspiring to defraud the DEA. In addition, Pietruszewski was charged with failing to file suspicious order reports.

In announcing the charges, Geoffrey S. Berman, the U.S. attorney for the Southern District of New York, said, "This prosecution is the first of its kind: executives of a pharmaceutical distributor and the distributor itself have been charged with drug trafficking, trafficking the same drugs that are fueling the opioid epidemic that is ravaging this country."

Ray Donovan, a special agent with the DEA, said that the "historic investigation" that led to the charges "unveiled a criminal element of denial in [the company's] compliance practices and holds them accountable for their egregious noncompliance according to the law."

The company entered into a five-year deferred prosecution agreement (DPA) with the government, which was approved by the court.

**Agreed Statement of Facts**

At the time of the filing of the criminal charges, the company had more than 1,300 pharmacy customers and more than $1 billion in revenue per year.

In an agreed statement of facts incorporated into the DPA, the company admitted that from at least January 2012 through March 2017 it distributed controlled substances to pharmacies that it knew or reasonably should have known were dispensing drugs for illegitimate purposes. It also admitted that it intentionally avoided confirming the pharmacies' illicit activity (21 U.S.C. §841, 21 U.S.C. §846, 21 C.F.R. Part 1301).

In addition, RDC acknowledged that it sought to obstruct DEA oversight over the company's practices, including by misrepresenting to the agency the company's due diligence practices and knowingly failing to file suspicious order reports with the DEA about its customers' suspicious orders (18 U.S.C. §371, 21 U.S.C. §842(a)(5), 21 U.S.C. §842(c)(2)(A)).

**Disregarding Diversion 'Red Flags'**

According to the statement of facts, RDC dispensed controlled substances to pharmacy customers that its own compliance department had concluded displayed "red flags" associated with the diversion of the drugs.

Among the "red flags" observed among RDC customers were the following:

- dispensing large quantities of highly abused controlled substances;
- purchasing little else besides those drugs;
- dispensing controlled substances "in quantities consistently higher than accepted medical standards";
- accepting a high percentage of cash from patients purchasing controlled substances;
- dispensing to "out-of-area" patients;
- filling prescriptions issued by practitioners who were on the company's "watch list" or under DEA investigation; and
- being terminated by another distributor.

"Nonetheless, despite these warnings," according to the statement of facts, "RDC continued to sell controlled substances — including oxycodone and fentanyl —to these customers, opened new accounts without conducting due diligence before opening, and delayed or avoided terminating pharmacy customers that RDC knew were dispensing controlled substances for illegitimate purposes, and to pharmacies that it should reasonably have known and intentionally avoided confirming were dispensing controlled substances for illegitimate purposes."

**Defrauding the DEA**

RDC also acknowledged that it was aware beginning in at least 2007 that it was required to maintain a program to guard against the diversion of controlled substances by its customers and to report suspicious orders and customers to the DEA. "RDC repeatedly represented to the DEA that it had standard operating procedures for conducting due diligence on customer accounts and reporting suspicious orders to the DEA," the company admitted. "These statements were untrue."

Instead, according to the statement of facts, the company:

- opened new accounts for pharmacy customers without first conducting due diligence on the pharmacies;
- released orders of controlled substances to pharmacies that RDC believed were dispensing those controlled substances "for other than legitimate medical purposes";
- increased order limit thresholds so that pharmacies could increase the amounts of controlled substances that they could order from RDC;
- shipped orders that RDC's compliance program determined were suspicious; and
- knowingly failed to report suspicious orders to the DEA.

The company acknowledged that for five years its senior management, including Doud, "were involved in and directed such conduct, and concealed RDC's practices from the DEA."

**Sales Growth**

Even as the company was aware of the growing opioid abuse crisis in the United States, RDC saw a rapid expansion of its controlled substance sales. Between 2012 and 2016, the company's annual sales of oxycodone tablets grew from 4.74 million to 42.23 million (an increase of approximately 800 percent), and its annual sales of fentanyl tablets grew from approximately 63,500 to approximately 1.32 million (an increase of about 2,000 percent).

Because the company was a stock cooperative whose shareholders included its largest pharmacy customers, RDC's largest purchasers of controlled substances directly benefited from the company's growth. The company paid so-called patronage dividends that were calculated based on the quantity of drugs and other products that each pharmacy purchased from RDC. The pharmacies with the largest purchases received the largest dividend payments.

During this time, Doud's compensation was directly tied to RDC's pre-patronage dividend earnings. His "substantial" bonuses were based on RDC pre-patronage dividend earnings and/or cash flow. These bonuses, which were never fully disclosed to the RDC board or its shareholders, "increased in amount as RDC's sales of controlled substances grew, which created a significant monetary incentive to bring on new customers that posed significant risks under the [Controlled Substances Act]."

**Compliance Operations**

Consistent with DEA requirements, beginning at least in 2011 RDC had policies and procedures for preventing the diversion of controlled substances to illegal channels. The company's compliance department reviewed orders and dispensing data and employed field auditors who visited pharmacies to conduct due diligence.

However, according to the statement of facts, "despite RDC's obligation to maintain effective controls against the diversion of controlled substances, it failed to properly staff or provide sufficient resources to its compliance department, which was tasked with maintaining those controls against diversion."

As of 2012, the department consisted only of Pietruszewski, a former RDC operations manager who had no prior compliance experience or training, and an administrative assistant. Even with additional hiring, up until 2017 RDC had only a handful of employees working in the compliance department, "many of whom had little or no background in compliance."

From at least 2013 through 2016, Doud complained about the financial burden of RDC's compliance operations, saying that "there is no return on what we are doing." He refused to increase the company's compliance staff even during a time when sales of controlled substances were growing, and even when outside counsel warned that the compliance department had insufficient resources.

As a result of Doud's staffing decisions, the compliance department "lacked the training and resources to effectively monitor RDC's sales of controlled substances, and on many occasions shipped orders of controlled substances without conducting due diligence."

**Shipments Continue Despite 'Red Flags'**

For at least 100 customers between 2012 and 2016, the compliance department identified "red flags" of unlawful distribution of controlled substances, but RDC continued to ship controlled substance orders to the customers. As of September 2014, the company's outside counsel estimated that around 125 pharmacy customers required further due diligence to ensure that they were dispensing controlled substances in compliance with the law.

Between October 2012 and October 2013, one pharmacy — a purchaser of large amounts of oxycodone and fentanyl — increased its monthly purchases of oxycodone from 70,000 units per month to over 200,000 units per month, with similar patterns of ordering growth continuing into 2016. RDC's compliance department flagged the purchases as suspicious "on multiple occasions," but the company continued to supply the controlled substances to the pharmacy until around June 2017.

Some customer pharmacies were dispensing quantities of controlled substances that were "consistently higher than accepted medical standards."

Others accepted cash from a large percentage of patients obtaining highly abused controlled substances — another "red flag" practice because cash transactions can be concealed from detection by insurance companies, state regulators and law enforcement. The DEA and outside auditors repeatedly informed RDC that pharmacies accepting more than 10 percent of controlled substances payments in cash exhibited a "red flag" of diversion, and the company's compliance department identified "multiple" customers that accepted cash payments that greatly exceeded the 10 percent threshold. Nevertheless, RDC "continued to distribute controlled substances to those customers."

Similarly, the compliance department identified "multiple" pharmacy customers that filled prescriptions for patients who had traveled from "great distances," including from different states, to fill prescriptions for controlled substances. However, RDC continued to distribute controlled substances to those customers even after the company's compliance department had identified the "red flag" and reported it to senior management.

The compliance department also discovered that pharmacy customers were filling prescriptions issued by medical practitioners who were prescribing controlled substances outside the scope of their medical practice or specialty. In fact, the company supplied "multiple" pharmacies that filled prescriptions written by physicians who were under DEA investigation and who later were prosecuted and convicted on charges of diversion. At least six such physicians were flagged on RDC's watch list, but the company continued to distribute controlled substances to pharmacies that filled prescriptions that they wrote.

Through emails, in-person meetings and telephone calls, the compliance department expressed its concerns about these "red flags" regularly to senior management, including Doud. However, at Doud's direction, RDC "largely ignored these warning signs, continued to distribute controlled substances to customers that were illegitimately dispensing these narcotics, and refused to terminate or cut off sales of controlled substances to those customers."

Generally, instead of terminating its relationships with the companies, Doud directed RDC's employees to "educate and work with" the customers — particularly if the customers were shareholders or board members or if they were indebted to the company. If RDC "were to determine that it needed 'to stop selling to even one store,'" the compliance department "would 'always consult with [Doud] first.'"

As a result, RDC "rarely terminated its relationships with pharmacy customers, and continued to supply customers with controlled substances for months or years after encountering substantial evidence that the drugs those pharmacies dispensed were being used illicitly."

Between 2012 and February 2017, RDC terminated its relationship with only 17 of its 1,300 pharmacy customers — "and in multiple cases, the reason for termination was not compliance-related," according to the statement of facts. Typically, the company would terminate a customer relationship only when the customer refused to comply with RDC's requests or when continuing the relationship "exposed RDC to immediate legal consequences."

**RDC System for Identifying 'Orders of Interest'**

In September 2006 and December 2007, RDC was among DEA-registered distributors of controlled substances that received letters from the agency that discussed the requirements of 21 C.F.R. §1301.74(a). The December 2007 letter stated, in part:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the [DEA] in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

The letters also provided guidance on the identification and reporting of suspicious orders to the DEA.

In 2007 or early 2008, Doud ordered the development of a program to identify and monitor suspicious orders. By March 2009, the company had created its system for identifying suspicious orders and reporting them to the DEA.

Generally, the system identified "orders of interest" — controlled substance orders that exceeded the predetermined ordering thresholds set for a customer. The system identified when a pharmacy exceeded its "allowable limit" threshold for purchases, which was based on its average of monthly purchases over a 12-month period. When a pharmacy exceeded its allowable limit, the compliance staff would scrutinize its orders, dispensing data and other documentation for "red flags" indicating the diversion of controlled substances.

During a regularly scheduled audit in June 2009, RDC showed the DEA its computer system for identifying suspicious orders and explained the system's procedure, which included reporting to the agency all orders identified as suspicious. The company also provided information about the system to the DEA in March 2012 and July 2013.

A September 2014 analysis of the system by the company's outside counsel recommended changes to the system, and a revised standard operating procedure for conducting customer due diligence and suspicious order monitoring was finalized in January 2015. Under the revised procedure, before selling controlled substances to any customer, RDC was required to obtain and review drug dispending data and evaluate whether the customer dispensed controlled substances for legitimate medical purposes. In January and February 2017, the procedure was again revised following a DEA audit the previous November.

**Consent Decree: Failure To File ARCOS Reports**

In August 2013, the DEA and the U.S. Attorney's Office for the Southern District of New York initiated an investigation into RDC's failure to file with the DEA Automation of Reports and Consolidated Orders System (ARCOS) reports — monthly reports of sales and shipments of controlled substances (including Schedule I and II drugs, narcotic Schedule III drugs and other select substances) that are required of manufacturers and distributors (21 C.F.R. §1304.33).

The investigation led to a July 2015 consent decree in which RDC admitted to violating the Controlled Substances Act by failing to file ARCOS reports. Under the terms of the consent decree, RDC paid a $360,000 civil penalty and was required to compile the missing ARCOS data and report the data to the DEA (*United States v. Rochester Drug Co-Operative, Inc.*, No. 1:15-cv-5219 (S.D.N.Y.)).

**Opening Accounts Without Due Diligence**

Despite a 2015 company policy, RDC often did not conduct due diligence on all pharmacies' dispensing practices before onboarding them as customers.

Often, the compliance department found, pharmacies known among distributors to present compliance risks were cut off by other distributors and turned to RDC for their controlled substances. "We are picking up rejects from other distributors," an RDC compliance department field auditor told the department.

Nevertheless, at Doud's direction, the company's sales team "continued to open new accounts and begin selling to problematic new customers, some of which had previously had their distribution arrangements with other wholesalers terminated."

When the compliance department was slow to authorize the sale of controlled substances to new customers, Doud complained about the delay, saying, "I know we have to do due diligence, but we have the tail wagging the dog. … This has to stop. … Do the compliance after opening. And close it if it looks funny."

In July 2015, the company decided to begin opening new accounts without completing its due diligence on the customers. RDC made the change without changing its written policy and without notifying the DEA, despite the advice of the compliance department.

For "multiple" new customers that had not been subject to due diligence, RDC "discovered significant problems in the dispensing records … including high dosage opioid prescriptions and accepting a high percentage of cash from patients." These were signs that the customers were unlawfully distributing controlled substances.

In June 2016, Doud directed the company to accelerate RDC's account opening process. He issued the directive, he said, because "the government has recently told the DEA to lay off wholesalers … and concentrate on fixing the problems with more addiction problems." Doud insisted on going ahead with the policy despite concerns expressed by two of RDC's compliance field auditors.

After the change was implemented, compliance staff continued to find "red flags" indicating that new customers that had not been subject to due diligence were diverting controlled substances to illegitimate channels.

**RDC's Failure To File Suspicious Order Reports with the DEA**

Despite the company's automated system for detecting suspicious controlled substances orders, and despite its suspicious order reporting policies (which the company conveyed to the DEA), RDC failed to report suspicious orders to the agency, according to the statement of facts.

Between 2012 and 2016, out of more than 1.5 million orders for controlled substances from pharmacy customers, including hundreds of thousands of orders for frequently abused drugs such as oxycodone, fentanyl and hydrocodone, RDC reported only four suspicious orders to the DEA.

In fact, the company failed to report to the DEA "at least 2,000 orders of controlled substances made by its pharmacy customers that should have been reported as suspicious pursuant to … 21 C.F.R. §1301.74(b) and the guidance contained in letters from the DEA."

Among the suspect dispensing patterns exhibited by these pharmacies were the following:

- A high percentage of a pharmacy's controlled substance sales, particularly sales of oxycodone 30 mg tablets, were paid for in cash rather than through insurance.
- An unusually high proportion of a pharmacy's overall dispensing consisted of controlled substances.
- A disproportionate percentage of a pharmacy's controlled substance purchases were for highly abused drugs, such as oxycodone 30mg tablets or fentanyl patches or spray.
- A pharmacy filled prescriptions for controlled substances for many patients who lived great distances from the pharmacy.
- A pharmacy frequently filled prescriptions for quantities or dosages of controlled substances that were higher than accepted medical standards.
- A pharmacy filled prescriptions for controlled substances written by prescribers on RDC's internal watch list.

Even in the “rare instances” when the “red flags” prompted RDC to terminate pharmacy customers, the company did not file suspicious order reports with the DEA for orders placed by the customers.

This was because Doud “directed that RDC should be ‘the knight in shining armor’ for independent pharmacies and should work with pharmacies instead of reporting them.” Similarly, Pietruszewski instructed his compliance staff that 'we do not turn in a store' merely based on suspicions of wrongdoing by the customer, but rather choose 'to educate and work with our customers.'

In fact, RDC’s compliance department “took steps to prevent reporting of suspicious orders and the future flagging of orders.” Even for the 8,300 orders flagged by its system, the company did not comply with its own compliance procedures, but instead filled nearly all the orders without trying to determine whether there was a legitimate explanation for an increase in a pharmacy customer’s order volume.

RDC compliance staff routinely marked the flagged orders as “not suspicious,” falsely noted that dispensing data supported the increase in controlled substance orders and released orders to pharmacies without reviewing their current dispensing data. In addition, Pietruszewski often released flagged orders in the evening or during the weekend for large customers or for pharmacies owned by board members.

Moreover, the compliance department prevented the identification of suspicious orders by increasing the threshold limit of controlled substances that a pharmacy could purchase from RDC. “Throughout the relevant time period,” the statement of facts reported, "RDC manipulated customers’ ‘allowable limit' thresholds but did not report orders.”

Notably, after the DOJ served a document request on RDC in February 2017 and a subpoena on the company the following November, the company “reported hundreds of suspicious orders to the DEA relating to customers that it [had] had for years.” In fact, RDC reported at least 400 suspicious order reports in each year after RDC became the subject of a federal investigation.

**Deferred Prosecution Agreement, Forfeiture**

In the DPA, RDC stipulated that the facts set forth in the Statement of Facts were true. The company also admitted its responsibility for the acts of its officers and employees.

RDC also agreed to pay a $20 million forfeiture to the United States for earnings due to its violations of the Controlled Substances Act. The forfeiture was to be paid over five years.

In addition, the company agreed to ongoing cooperation with the DOJ in any government investigation or prosecution of RDC’s current or former officers, employees or customers.

The company also agreed to “promptly” report to the DEA all suspicious orders and any customers “that it knows or has reason to believe are distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose.”

RDC also agreed to reform and enhance its Controlled Substances Act compliance program through, among other things, the appointment of a standing Controlled Substances Compliance Committee that included at least two independent directors who had no ties to the company.

The government also required RDC to appoint an independent compliance monitor to supervise the company's compliance systems and processes for a period of three years to help reduce the risk of any recurrence of RDC's misconduct.

A parallel civil settlement resolved RDC's civil liability under the Controlled Substances Act related to violations following the time of the July 2015 consent decree (*United States v. Rochester Drug Co-Operative, Inc.,* No. 1:19-cv-3568 (S.D.N.Y.))

**Criminal Charges Against RDC Executives**

The government charged Doud with one count of conspiracy to distribute controlled substances. The charge carried a maximum sentence of life in prison and a mandatory minimum sentence of 10 years. He was also charged with one count of conspiracy to defraud the United States (*United States v. Doud,* No. 1-19-cr-00285 (S.D.N.Y.)). Doud pleaded not guilty to the charges and was released on $500,000 bond.

Three days earlier, the government charged William Pietruszewski with one count of conspiracy to distribute controlled substances and one count of conspiracy to defraud the United States. He also was charged with one count of willfully failing to file suspicious order reports with the DEA, which carried a maximum sentence of one year in prison. Pietruszewski pleaded guilty to the charges pursuant to a cooperation agreement that day. Sentencing was scheduled for Oct. 18, 2019 (*United States v. Pietruszewski,* No. 19-cr-00282 (S.D.N.Y.)).

## (2) Morris & Dickson Co. L.L.C.

### *Distributor Successfully Challenges DEA's Immediate Registration Suspension, Fails in its Challenge to the Constitutionality of DEA Procedures, Agrees to $22 Million Settlement*

In May 2019, the DEA and the Office of the U.S. Attorney for the Western District of Louisiana announced that the distributor Morris & Dickson Co. L.L.C. had agreed to pay $22 million in civil penalties to resolve claims that the company violated the Controlled Substances Act by failing to report suspicious orders of hydrocodone and oxycodone.

The Shreveport, La.-based company was the largest privately-owned wholesale pharmaceutical distributor in the United States and the fourth largest wholesale distributor in the country. It had total revenues of more than $4 billion in the fiscal year that ended in January 2018.

Since January 2014, Morris & Dickson has distributed controlled substances to approximately 800 retail pharmacies in 17 states, with a total distribution of more than 600 million dosage units.

**DEA, DOJ Investigation**

A DEA Office of Diversion Control investigation was sparked in October 2017, when the agency became aware of high-volume sales of oxycodone and hydrocodone from Morris & Dickson to five of the top ten purchasing pharmacies in Louisiana.

The investigation allegedly revealed that since January 2014 the company had failed to report over 12,000 suspicious retail pharmacy orders.

The agency acted under the authority granted by 21 U.S.C. §824(d), which allows an immediate suspension of a DEA registration where there is a finding that "there is an imminent danger to the public health or safety."

The suspension action applied only to the distribution of controlled substances and did not affect noncontrolled pharmaceutical drugs that the company distributed.

With the issuing of the suspension order, Morris & Dickson was given the opportunity for an administrative hearing within 60 days. Following the hearing, the DEA's acting administrator was to make a final decision on whether the company's registration should be permanently revoked.

**District Court Blocks Immediate Registration Suspension**

On May 3, 2018, the day it was served with the order, Morris & Dickson filed a complaint for injunctive relief in the U.S. District Court for the Western District of Louisiana, saying that the DEA's registration suspension order "was issued and took effect without any notice of opportunity to be heard." The company asked the court to block the order "to prevent irreparable injury to Morris & Dickson, its customers and the public" (*Morris & Dickson Co., L.L.C. v. Sessions,* No. 5:18-cv-00605 (W.D. La.)).

The company filed the complaint along with a motion for a temporary restraining order (TRO) asking the court to block the DEA's enforcement of its registration suspension order.

In its complaint, the company challenged whether the DEA had met the "heightened" imminent danger standard, insisting that the agency could not "circumvent mandatory administrative procedures designed to give a registrant notice and an opportunity to be heard before it is suspended."

Morris & Dickson argued that the DEA's immediate registration suspension was arbitrary and capricious, in part because, in the company's view, it did not address the problem of unusually large orders for controlled substances placed by the Louisiana pharmacies.

"The license suspension order will not halt or reduce diversion of controlled substances by anyone and, therefore, does not diminish the 'imminent danger' that DEA alleges," the company said. "The customers of Morris & Dickson that retain DEA registrations will continue to receive controlled substances from other distributors. In fact, because these distributors may not have the same robust anti-diversion controls as Morris & Dickson does, the license suspension order likely will exacerbate the risk of diversion, if it has any effect at all."

The company also agreed to "immediately terminate shipments of controlled substances to all customers identified in the license suspension order" until the district court held a hearing on the company's complaint and/or the registration suspension was lifted.

In its request for a TRO, the company argued that there was a substantial likelihood that it would succeed on the merits of its claim that the DEA order was unlawful and violated the company's due process rights; that the company and its customers would suffer irreparable harm if shipments of "vital" medicines containing controlled substances were disrupted; that the harm the company would suffer outweighed the harm to the government, if any, that would result from a court injunction against the agency; and that the public interest would be harmed if temporary relief were not granted.

Opposing the motion for a TRO, the government said that the DEA's investigation had provided "ample basis" for the agency to conclude that Morris & Dickson had "generally failed to take adequate precautions against drug diversion" as required by law.

The company, the government said, was "not entitled to circumvent the DEA's regulatory authority and discretion under the [statute] and obtain a [TRO] allowing it to continue to distribute controlled substances during the pendency of the administrative process regarding its failures to comply with the regulation."

Moreover, the government asserted, "if a DEA registrant can fail to uphold its obligations to prevent diversion for an extended period as set forth in the [immediate suspension order], and then parry an 'imminent danger' determination with post-suspension promises to do better, the DEA will effectively lose the immediate suspension power Congress granted it in Section 824(d)."

The company replied that the DEA had offered "no evidence of imminent danger to the public health and safety." Moreover, it said, the DEA had had "full access" to Morris & Dickson's Schedule II controlled substance orders through the ARCOS reporting system, but it had not previously moved to suspend any company activities or communicate any concern to the company. "This lack of action on DEA's part belies its claim of threatened imminent death, serious bodily harm, or abuse of a controlled substance," the company said.

On May 8, 2018, the district court granted Morris & Dickson's motion for a TRO, finding a substantial likelihood that the DEA's issuing of the immediate suspension order was arbitrary and capricious. The court ordered the DEA not to enforce its immediate registration suspension order until at least May 22. It also ordered briefing on the company's request for a preliminary injunction and scheduled a hearing on the request for May 22.

On May 18, 2018, the DEA's acting administrator, Robert W. Patterson, entered an order rescinding the agency's immediate suspension of Morris & Dickson's registration. The company filed a notice of dismissal of its suit against the government three days later.

"This is a striking vindication for our family company," Paul Dickson, the company's president, said in a May 18 release. "The proves what we've said all along — that DEA's hasty action was unjustified. We have always taken our responsibility to prevent diversion seriously."

Dickson stressed that the company was taking steps to enhance its suspicious order monitoring system "into what will be recognized as a state-of-the-art diversion control system. … We look forward to working with the DEA and other critical members of the health care community on model drug diversion control and patient safety measures."

**Constitutional Challenge to DEA Administrative Adjudication**

In October 2018, Morris & Dickson challenged the proceedings before the DEA administrative law judge on constitutional grounds (Morris & Dickson Co. L.L.C. v. Sessions, No. 5:18-cv-01406-EEF-MLH (W.D. La.)).

The company contended that the judge presiding over its administrative hearing was improperly appointed by the DEA administrator rather than by the president or the attorney general. It also argued that DEA administrative law judges were improperly shielded from removal from office by two layers of internal agency oversight, thereby obstructing the ability of the president and attorney general to oversee them properly.

The district court held in December 2018 that it lacked jurisdiction over Morris & Dickson's challenge to the ongoing administrative adjudication, concluding that Congress intended claims arising during DEA registration revocation proceedings to pass from the DEA to a federal appeals court, and that appellate court review could occur only after the matter was adjudicated by the agency (*Morris & Dickson Co. v. Whitaker,* 360 F. Supp. 3d 434 (W.D. La. 2018)).

**May 2019 Settlement**

The DEA's continuing investigation against Morris & Dickson eventually led to the May 2019 settlement with the company.

Under the settlement, Morris & Dickson agreed to pay $22 million to the United States in exchange for the government's releasing the company from civil penalties under 21 U.S.C. §842 and from claims for injunctive relief under 21 U.S.C. §843 with respect to the alleged failure to identify suspicious controlled substance orders, to notify the DEA about those orders, and to maintain effective anti-diversion controls between January 2014 and March 2019.

According to a May 24, 2019, DEA statement, the company also agreed during the course of the investigations "to make significant upgrades to its compliance program by investing millions of dollars to hire additional staff and implement new protocols and standards to ensure compliance with federal regulations requiring them to report suspicious orders of controlled substances."

The government retained the right to initiate DEA administrative actions related to the company's conduct that would not result in civil penalties. It also retained the right to bring criminal charges related to the company's conduct.

The settlement agreement stated that Morris & Dickson had not admitted liability with respect to the conduct covered by the agreement.

DEA Special Agency in Charge Brad L. Byerley said that a company's failure to report suspicious orders as required "contributes to the opioid epidemic, which has caused devastating harm to individuals and our communities. The settlement with Morris & Dickson demonstrates the resolve by DEA to use all available tools to address this crisis at every level and reduce the availability of highly addictive, dangerous drugs."

In a May 24, 2019, statement, Morris & Dickson said that it had entered into the civil settlement so that it could "focus on continuing to dependably deliver life-saving medications to hospitals, pharmacies and health care facilities."

The company stressed that it had not admitted any liability and that it wanted "to avoid delay, expense, inconvenience and uncertainty."

"We share the goal of preventing diversion of controlled substances with the DEA and stand ready to work with it to meet these shared goals," the company said. "As part of our efforts, we'll continue to work collaboratively with state and national officials to reveal those that would abuse the system so we can stop it in real time."

## (3) Miami-Luken Inc.

### *A Distributor, Two Former Company Officials, and Pharmacists who Owned Two of the Distributor's Pharmacy Customers Are Charged with Conspiring to Illegally Distribute Controlled Substances*

Less than three months after bringing conspiracy charges against RDC, the DEA brought conspiracy charges against another distributor of controlled substances and former officials of the company (*United States v. Rattini,* No. 1:19-cr-00081-SJD (S.D. Ohio)).

A federal grand jury charged Springboro, Ohio-based Miami-Luken Inc., the company's former president and former compliance officer, and the pharmacist owners of two West Virginia pharmacies that were customers of the distributor with conspiracy to illegally distribute controlled substances — a crime punishable by up to 20 years in prison.

The company and its officials — former President Anthony Rattini and former Compliance Officer James Barclay — allegedly distributed millions of opioids and other painkillers to doctors and pharmacies in rural Appalachia "even after being advised by the DEA of their responsibilities as a wholesaler to ensure drugs were not being diverted and to report suspicious orders," the agency said.

Miami-Luken was a regional distributor with customers in the Midwest and Appalachia. It ceased operations in October 2018.

In the 14-page indictment, filed in July 2019 in the U.S. District Court for the Southern District of Ohio, the government charged that between January 2008 and December 2015 the defendants conspired to violate 21 U.S.C. §841(a) by "knowingly and intentionally" distributing and dispensing "a mixture and substance containing a detectable amount of oxycodone and hydrocodone, Schedule II and III controlled substances, outside the scope of professional practice and not for a legitimate medical purpose."

The defendants "unlawfully enriched themselves" by distributing "large amounts of opioids to known pill mills" and facilitating the diversion of oxycodone and hydrocodone for illicit use in Ohio, Kentucky and West Virginia, the DOJ said.

Part of the alleged conspiracy was the failure of the company and its two officials "to maintain effective controls against diversion of controlled substances," "to exercise due care in confirming the legitimacy of all orders," and "to report suspicious orders to the DEA." The company and executives also "continued to ship the dangerous addictive drugs to pharmacies in rural Appalachia, where the opioid epidemic was at its peak," the government said — even while "knowing the controlled substances were being diverted or likely to be diverted."

They also allegedly filled “suspicious orders” for “millions of dosage units of oxycodone and hydrocode” placed by the two pharmacy owners: Devonna Miller-West, the owner of Westside Pharmacy, Oceana, W.Va., and Samuel R. (Randy) Ballengee, the owner of Tug Valley Pharmacy, Williamson, W.Va. The two pharmacy owners were licensed as pharmacists by the state of West Virginia.

**Details of Suspect Distributions**

Like other distributors, in 2006 and 2007 Miami-Luken received the three DEA letters advising it of its obligation to report suspicious orders to the agency, according to the December 2018 House Energy and Commerce Committee report. The DEA also met with Miami-Luken representatives in 2008 to discuss that obligation.

In September 2008, the indictment alleged, Miami-Luken “distributed more than 10,000 dosage units of oxycodone” to a pharmacy — even after the pharmacy “returned thousands of dosage units of oxycodone to Miami-Luken indicating that it would no longer fill orders for an unnamed physician … due to concerns about illegal distribution.” The following month, the distributor allegedly shipped more than 100,000 dosage units of the drug to the pharmacy “despite knowing the pharmacy and prescribing physician were under DEA investigation for illegal distribution.” And beginning in November 2008, the company allegedly sent more than 750,000 dosages of oxycodone directly to the physician.

“Despite these red flags,” distribution to [the pharmacy and the physician] continued,” the government said. “In fact, from 2008 through 2010, [the company] distributed more than 1.8 million dosage units of oxycodone to [the pharmacy].”

Moreover, between 2012 and 2014, another pharmacy received more than 2.2 million dosage units of oxycodone and more than 200,000 dosage units of hydrocodone from the distributor, prosecutors said. Despite Miami-Luken’s internal threshold limit of 86,000 dosage units for oxycodone, the distributor allegedly shipped 139,000 dosage units to the pharmacy in March 2013.

The indictment documented similarly large alleged shipments of controlled substances to six other pharmacies that were far in excess of the monthly threshold limits set for them.

Miami-Luken obtained utilization reports on these pharmacies that included the payment methods that the pharmacies accepted, the government said. The two company executives “knew pharmacies that accepted cash-only payment was a red flag of diversion,” according to the indictment.

**Focus on Two Pharmacies**

The DOJ also said that Miami-Luken had distributed “tens of thousands of dosage units” to the two indicted pharmacists and others in violation of the company’s own internal control policy.

*Westside Pharmacy*

Despite setting an internal threshold limit for Westside Pharmacy of 6,000 dosage units of oxycodone per month, the indictment alleged, the distributor sent the drug to the pharmacy at levels far exceeding that limit — for example, 68,400 dosage units in March 2011, 63,900 dosage units in May 2011 (a month in which the distributor’s internal records called for the pharmacy’s purchases to be monitored), 50,300 dosage units in December 2012, and 54,700 dosage units in January 2014.

In total, the House committee found, Miami-Luken shipped more than 4.38 million doses of hydrocode and oxycodone to Westside Pharmacy between 2009 and 2015. The town of Oceana, W.Va., where the pharmacy is located, had a population of 1,394 in 2010.

Moreover, according to the report, following a May 2011 analysis of Westside Pharmacy's dispensing information, Miami-Luken was aware that Westside Pharmacy "was filling prescriptions for doctors located hours away, and that a large number of prescriptions for hydrocodone and oxycodone were paid for with cash." Despite this knowledge, the distributor "continued to supply the pharmacy with more than 3.36 million opioids over the next four years."

In May 2015, Miami-Luken conducted another analysis of Westside Pharmacy's dispensing information, the House committee found. That analysis revealed that three physicians wrote 74 percent of the oxycodone prescriptions that the pharmacy filled between February 2015 and April 2015.

In the wake of the analysis, Westside Pharmacy told Miami-Luken that it would no longer fill prescriptions written by several physicians whom the distributor had identified in its analysis.

By the following October, however, Miami-Luken determined that Westside Pharmacy continued to fill prescriptions written by two of those physicians. Nevertheless, the distributor did not immediately terminate the pharmacy or restrict its ability to order controlled substances.

In fact, a month later, in November 2015, Miami-Luken "approved an increase to Westside Pharmacy's oxycodone threshold despite being aware of the pharmacy's prior deceit and 'red flags' related to its dispensing practices and prescribing physicians," according to the House committee report.

*Tug Valley Pharmacy*

Miami-Luken's drug shipments to Tug Valley Pharmacy began in August 2008. The following month — the first full month of the pharmacy's purchases — Tug Valley bought 120,700 dosage units of hydrocode from the distributor, the government alleged.

The House committee found that the number of pills that Miami-Luken shipped to Tug Valley Pharmacy increased by 350 percent between 2008 and 2009. Total distributions by the company to Tug Valley between 2008 and 2014 allegedly totaled more than 6 million dosage units of hydrocodone, according to the indictment.

The distributor "regularly" exceeded the threshold limit of 36,000 dosage units per month set for Tug Valley, the DOJ said. For example, in December 2013 the pharmacy allegedly received 67,200 dosage units of hydrocodone from Miami-Luken.

**Reports to DEA**

The House committee found that in October 2012 Miami-Luken sent its first customer termination report to the DEA based on concerns about the customer's business practices. Only later — in May 2014 — did the distributor start sending the DEA order-specific reports about rejecting customers' controlled substance orders after the customers hit their monthly thresholds.

According to the report, Miami-Luken bought a suspicious order monitoring (SOM) system in 2013 but did not implement it until 2015.

Before the system's implementation, the report said, company employees "independently interpreted what constituted a suspicious order." A company official told House Energy and Commerce Committee staff that before 2013 Miami-Luken had made only "rudimentary efforts" to comply with its legal responsibility to report suspicious orders, and company employee decisions about what constituted a suspicious order were made based on "one's feeling."

"When Miami-Luken's internal [SOM] system flagged many of these orders," the company and the two executives "failed to conduct any due diligence or report the suspicious orders of [the pharmacy] to the DEA, as is required by law," the DOJ alleged.

**November 2015 DEA Order to Show Cause**

In November 2015, the DEA issued an order to show cause (OTSC) to Miami-Luken notifying the distributor that the agency was taking action to revoke its DEA registration. The agency cited the company's alleged failure to maintain effective controls against diversion of controlled substances between 2007 and 2015 (*In re Miami-Luken* (DEA Administrative Court Nov. 23, 2015)).

In one example included in the OTSC, the DEA said that Miami-Luken shipped more than 3.48 million doses of hydrocodone to a Sav-Rite pharmacy in Kermit, W.Va., between February 2008 and November 2011 but failed to report any of the pharmacy's orders as being suspicious — despite the fact that Miami-Luken had raised concerns about the pharmacy's hydrocodone purchases to the agency in February 2008, and despite the fact that another Sav-Rite pharmacy in the area (also one of Miami-Luken's controlled substance customers) had been closed and forced to surrender its DEA registration following a March 2009 federal raid.

The OTSC also cited Miami-Luken's distributions of controlled substances to Westside Pharmacy as a reason for revoking the company's DEA registration.

In December 2015, shortly after receiving the OTSC, Miami-Luken terminated its relationship with Westside Pharmacy.

**Allegations Against the Pharmacists**

The indictment alleged that the pharmacists "purchased excessive amounts of controlled substances from Miami-Luken" and "failed to ensure that controlled substances were distributed properly, for a legitimate purpose, ignoring obvious signs of abuse and diversion."

They, along with Miami-Luken and the two executives, allegedly distributed oxycodone, hydrocodone to customers "outside the scope of professional practice and not for a legitimate medical purpose," the government said.

# New DEA Enforcement Tactics Targeting Pharmacies: Oakley Pharmacy Inc. and Xpress Pharmacy

## *DOJ Hits Pharmacies with Ex Parte TRO, Preliminary Injunction, False Claims Act Allegations*

In February 2019, in what it called a "first of its kind" enforcement action in a case of alleged pharmacy diversion of controlled substances, the DOJ filed with the U.S. District Court for the Middle District of Tennessee a sealed complaint against two Tennessee pharmacies along with an ex parte motion for a temporary restraining order (TRO) and a preliminary injunction. The government sought to stop the pharmacies, their owner and three pharmacists from dispensing controlled substance medications (*United States v. Oakley Pharmacy, Inc.*, No. 2:19-cv-00009 (M.D. Tenn.)).

Unusually, the complaint alleged violations of both the Controlled Substances Act and the federal False Claims Act. Only rarely has the DEA invoked the False Claims Act in its enforcement actions — as it did as part of an action that led to a $31.5 million settlement with PharMerica Corp. in May 2015 resolving allegations that the company had dispensed Schedule II controlled substances without valid prescriptions.

Moreover, the government filed the complaint and motion in federal district court without pursuing a DEA administrative action to obtain an immediate suspension order.

The DOJ said that the action against the Tennessee defendants was part of a coordinated effort by the department's Prescription Interdiction & Litigation (PIL) Task Force, which includes senior DOJ and DEA officials, to combat the U.S. opioid crisis.

In a DOJ announcement of the action the following day, D. Christopher Evans, special agent in charge of the DEA's Louisville Field Division, said that the enforcement action "should serve as a warning to those in the pharmacy industry who choose to put profit over customer safety."

"Pharmacists serve on the front lines of America's opioid epidemic, and they share responsibility with physicians to protect those whom they serve from the dangers associated with prescription medications," Evans said. "We will be vigilant in holding them accountable."

**DOJ Allegations**

The government alleged that Oakley Pharmacy Inc., dba Dale Hollow Pharmacy, and Xpress Pharmacy of Clay County, both based in Celina, Tenn., and the individual defendants dispensed and billed Medicare for prescription drugs in violation of the two statutes.

The complaint alleged that the defendants' unlawful dispensing of opioids had been tied to the deaths of several people and that at least five others had been treated for overdoses after obtaining controlled substances from the pharmacies.

According to the DOJ, the pharmacies and pharmacists filled many prescriptions for controlled substances “outside the usual course of professional practice and in violation of the pharmacists’ corresponding responsibility to ensure that prescriptions were written for a legitimate medical purpose” (21 C.F.R. §1306.04).

The complaint outlined “red flags” of diversion and abuse that the defendants allegedly ignored as they “routinely” dispensed controlled substances — including prescriptions for unusually high dosages, prescriptions for opioids and other controlled substances in dangerous combinations, and patients traveling "unusual" distances to have prescriptions filled.

**Prior Encounters with DEA, State Pharmacy Board**

The DOJ sought the TRO based on the defendants’ history over “several years” of encounters with both the DEA and the Tennessee State Board of Pharmacy.

In January 2016, the pharmacies’ owner entered into an agreed order with the pharmacy board placing Dale Hollow’s pharmacy license on probation for five years. As stated in the order, the pharmacy’s staff admitted to dispensing early refills without documenting any necessity, failing to locate hard copies of controlled substance prescriptions for a family member of the pharmacist-in-charge, and possessing bottles of medication from other pharmacies.

In May 2016, the DEA audited Dale Hollow after learning that the pharmacy was the second largest purchaser of buprenorphine in 2016 in the area covered by the agency’s Nashville District Office and that Dale Hollow had filled multiple prescriptions for customers who had travelled long distances.

In June 2016, one of the defendant pharmacists expressed his concerns to the DEA about several Dale Hollow practices, including the pharmacy’s unusually large orders for buprenorphine and the owner’s occasional instructions to fill controlled substance prescriptions a day or two earlier than the refill date. He also told the agency that some customers visited Dale Hollow in small groups to fill prescriptions for the same drug. (The pharmacist had had his pharmacy license placed on two years’ probation by the state pharmacy board in July 2015 for providing early refills and dispensing controlled substances to a family member without a prescription.)

In March 2017, the pharmacy’s owner signed a memorandum of agreement (MOU) between Dale Hollow and the DEA that noted Controlled Substances Act discrepancies at the pharmacy. The MOU memorialized the pharmacy’s agreement that it would comply with the federal statute and with Tennessee requirements, including “regulations pertaining to the dispensation of buprenorphine products for opioid addiction treatment.”

In June 2018, during a scheduled DEA investigation of Dale Hollow, agency officials saw customers “show up multiple times, including several times in one day and on back-to-back days.”

During the inspection, the owner stated that doctors needed to be investigated because they were the ones writing prescriptions, and that pharmacists and pharmacies were not responsible because they merely filled prescriptions. He also said that he did not believe that there was an opioid problem, attributing reports of the problem to “media hype.”

The DEA asked the owner to surrender Dale Hollow’s DEA registration number, but the owner declined to do so.

The other defendant pharmacist entered into two consent orders with the state board of pharmacy. In 2004, his pharmacy license was revoked for two years due to his use of cocaine, benzodiazepines and alcohol. In December 2008, the pharmacist entered into a consent order and paid a $500 fine due to allegations that he mis-filled a patient's prescription.

In September 2016, the pharmacist told the DEA that Dale Hollow filled prescriptions for drug addicts and said that it was his right to fill prescriptions a day early.

**False Claims Act Allegations**

In the complaint, the government alleged that the defendants "schemed to obtain substantial, improper reimbursements for controlled substances from the Medicare program."

Between 2012 and 2018, according to the DOJ, Medicare paid Dale Hollow more than $1.4 million for controlled substances, including more than $1 million for opioids alone. Xpress was paid more than $1 million for controlled substances during the same period, with $730,000 of that amount being paid for opioids.

During 2017, nearly one in five medications that Dale Hollow dispensed to Medicare beneficiaries was a controlled substance — "significantly above the national average," the government said.

The DOJ likened the pharmacies' Medicare billing practices for controlled substances to those of a "pill mill," alleging that the pharmacies "were in essence 'prescription mills' and a 'narcotics delivery system.'"

"Because scores of controlled substance prescriptions dispensed by Dale Hollow and Xpress did not constitute valid prescriptions that complied with federal and Tennessee state law and were not issued for a legitimate medical purpose or for a medically accepted indication," the government alleged, "Medicare would not have paid for the tainted Part D controlled substances medications during the applicable period if Medicare had known that the prescriptions were illegitimate and invalid."

**DOJ's Arguments for a TRO**

In a memorandum of law filed in support of its motion for a TRO, the DOJ alleged that the defendants knowingly dispensed controlled substances without valid prescriptions.

The department also alleged that the defendants had filled prescriptions in violation of the Controlled Substances Act "on at least 150 occasions in 2018, and hundreds and likely thousands of times over the past three years."

"Defendants routinely filled prescriptions for large quantities of powerful opioids and other controlled substances that they knew or had reason to know lacked any legitimate medical purpose," the government alleged.

Alternatively, the DOJ argued that the defendants had knowingly and intentionally dispensed controlled substances outside the usual course of pharmacy practice.

The "red flags" associated with prescriptions filled by the two pharmacies, the government said, indicated that the defendants "filled those prescriptions in violation of their corresponding duty" under 21 C.F.R. §1306.04 "and outside of the usual course of the professional practice of pharmacy."

The “red flags,” the government said, included:

- combinations of dangerous opioids known for potential abuse;
- high opioid dosage levels;
- long distances traveled by patients presenting prescriptions;
- insufficient diagnoses to support certain prescriptions;
- cash payments;
- fills of brand-name drugs rather than generic medications;
- family groups receiving similar controlled substance regimes;
- doctor shopping; and
- pharmacy shopping.

Also, the government noted that one prescription for a controlled substance filled by Dale Hollow was unsigned — “a facially invalid dispensation.”

The government told the court that the defendants were “continuing to fill controlled substance prescriptions through 2019 for the majority of patients for whom … past controlled substance prescriptions were improperly and illegitimately dispensed.”

**DOJ: Registration Suspension Not Enough**

In the memorandum of law, the DOJ told the court that the DEA was separately considering issuing immediate suspension orders for the DEA registrations of Dale Hollow and Xpress Pharmacy. However, it noted, if issued, the orders “would only apply to suspend the two defendant pharmacies’ DEA registration number but would not restrain anything with regard to the individual defendants.”

Also, the government said, “an [immediate suspension order] is an administrative remedy subject to administrative process and challenges and may lack the finality of the injunctive relief sought in this lawsuit.”

The DOJ alleged that the defendants’ unlawful filling of prescriptions had contributed to the opioid crisis and that the scope of the defendants’ unlawful conduct and the harm it caused “likely far exceed[ed]” the allegations that the government had made based on the prescriptions that were known to federal officials.

The government called for the district court to issue a TRO without notice, as permitted under Federal Rule of Civil Procedure 65 in cases where “specific facts … clearly show that immediate and irreparable injury, loss, or damage will result to the movant.”

In addition, the DOJ told the court that the government anticipated executing search warrants the next day to obtain dispensing records, files and other evidence located at the two pharmacies. The government argued that advance notice of the enforcement action might prompt the defendants to alter, delete or destroy the evidence. It told the court that it anticipated notifying the defendants of the action against them while the search warrants were executed.

**TRO Granted**

On the same day that the government filed its complaint and motion for a TRO, the district court granted the motion, issuing an order specifying that the TRO would run for two weeks. The court also gave the government permission to serve a copy of the TRO order on the defendants as it executed its search warrants at the two pharmacies.

The TRO barred the pharmacies and individual defendants from distributing or dispensing any controlled substances and called for them to surrender all controlled substances in their possession to DEA agents upon service of the TRO on the defendants.

The court order also temporarily barred the defendants from altering, deleting, destroying or transferring any records in their possession or control related to the distribution or dispensation of controlled substances.

The next day, the district court ordered that the government's filings be unsealed.

Later, acting on consent motions and joint motions as to each of the defendants, the court converted the TRO to a preliminary injunction.

## The SUPPORT Act: New Tools To Fight Diversion

Bipartisan federal legislation enacted in October 2018 to combat the U.S. opioid addiction crisis included amendments to both the Controlled Substances Act and the Federal Food, Drug, and Cosmetic Act intended to help prevent the diversion of opioids and other controlled substances.

The Substance Use-Disorder Prevention that Promises Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Pub. L. No. 115-271, has been called the largest legislative effort to combat a single drug crisis in history.

**Amendments to the Controlled Substances Act**

The SUPPORT Act amended the Controlled Substances Act through provisions that:

- require registrants to design systems to identify suspicious orders, and when such orders are identified, to notify the DEA;

- require the DEA to establish a centralized database for collecting reports of suspicious orders from registrants and to share the reports with the states; and

- establish factors that the DEA must consider when setting annual opioid quotas (including diversion, abuse, overdose deaths and public health impacts), and, if it approves an increase in an opioid quota, require the agency to explain why the public health benefits of the increase "clearly outweigh" the consequences of having more of the controlled substance available for sale and potential diversion.

Also under the statute, manufacturers and distributors have access to anonymized ARCOS information to help them identify, report and stop suspicious opioid orders. An enhancement of the ARCOS system announced by the DEA in February 2019 allows registered manufacturers and distributors to view and download the number of distributors and the amount (in both grams and dosage units) that each distributor sold to a prospective customer in the last six months. Manufacturers and distributors can use the tool to help identify and report suspicious orders.

For example, if a query indicates that multiple suppliers have sold unusual quantities of opioid analgesics to a new distributor's prospective pharmacy customer, the information may serve as a "red flag" to the new distributor and prompt it to perform due diligence on the pharmacy.

The law includes civil and criminal penalties for manufacturers and distributors that fail to use ARCOS data to determine whether an order is suspicious. The civil penalty can be up to $100,000, and the criminal fine may be up to $500,000.

The statute increases civil and criminal penalties for manufacturers and distributors that fail to report suspicious orders and keep accurate records.

Also, the DEA must now share distributor and pharmacy information about drug supply chain amounts, outliers and trends with regulatory, licensing and law enforcement agencies, as well as attorneys general. The information must be shared semiannually.

In addition, the legislation addresses the diversion of controlled substances at the retail pharmacy level. It directs the Department of Health and Human Services (HHS) to help develop and disseminate training programs and materials identifying the circumstances under which pharmacists may decline to fill controlled substance prescriptions — such as when they suspect that prescriptions are fraudulent, forged, or of doubtful, questionable or suspicious origin. HHS must also develop and disseminate training programs and materials on the federal requirements related to refusals to fill the prescriptions.

**FDA Provisions**

Title III, Subtitle A of the SUPPORT Act describes changes to Food and Drug Administration (FDA) procedures for regulating the development and sale of products that contain controlled substances.

The statute authorizes HHS to order manufacturers, importers, distributors or pharmacists to stop distributing a controlled substance if there is a reasonable probability that the substance would cause serious adverse health consequences or death.

A party subject to such an order would be entitled to an informal hearing to determine whether the recall is justified by evidence, and if so, the recall actions required, including notification of those affected.

Also, HHS must conduct a risk assessment to determine whether recalling the controlled substance presents a greater health risk than not recalling it.

The department may refuse admission of a controlled substance into the United States if it is under a recall order.

The subtitle also requires the FDA to work with U.S. Customs and Border Protection (CBP) to develop and periodically update a list of controlled substances that the FDA will refer to CBP when they are offered for import via international mail and appear to violate applicable laws, including the Controlled Substances Act, the Controlled Substances Import and Export Act, and the Federal Food, Drug, and Cosmetic Act.

Also, the FDA now has the authority to debar a person:

- who has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substances; or
- who has engaged in a pattern of importing (1) controlled substances prohibited from importation under the Tariff Act of 1930 or (2) adulterated or misbranded drugs that are (a) not designated in an authorized electronic data interchange system as a product regulated by the FDA or (b) knowingly or intentionally falsely designated in such a system as a product regulated by the FDA.

A "pattern of importing" means importing a drug "in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer."

In addition, the statute clarifies the FDA's postmarket authorities for opioids and other drugs that may have reduced efficiency over time by amending the definition of "adverse drug experience." The FDA must issue guidance on the circumstances under which it may require postmarket studies or clinical trials to assess the potential reduction of a drug's effectiveness and how such a change could affect the drug's benefits and its potential risks to the patient.

## What to Expect: Continued Intense DEA Enforcement Activity — And What You Need to Do

Recent DEA enforcement actions demonstrate that the agency is likely to continue to pursue aggressive enforcement actions in cases where manufacturers, distributors and pharmacies fail to comply with DEA requirements — particularly when the noncompliance involves opioid drug products.

Given the continuing public, press and congressional scrutiny of the DEA's response to the opioid crisis, it is likely that the agency will seize opportunities to hold companies accountable for a range of offenses. Moreover, the DOJ will not shy away from indicting present and former company executives and managers in such cases, particularly when their allegedly violative behavior extends over a period of time or demonstrates a willful disregard of DEA requirements.

Companies should continue to monitor DEA enforcement activity to spot trends in the agency's compliance priorities and enforcement policies. They should watch for novel or aggressive procedural moves on the DOJ's part, and they should expect an increasing preference by department officials for more rapid, forceful and wide-ranging enforcement actions. Specifically, look for the department to seek more TROs, preliminary injunctions and other court orders to produce swifter, broader restraints on noncompliant behavior. Also, look for the DEA to exercise its new enforcement authorities under the SUPPORT Act.

In addition, companies should continue to learn from DEA enforcement actions as they happen and scrutinize their own internal policies and practices in light of the facts involved in those cases. For example, companies should take note of the increasing numbers of diversion "red flags" cited by the DEA and the DOJ and make sure that those warning signals are incorporated into their compliance policies — and that the "red flags" become routine hallmarks of diversion for use in the course of the companies' compliance activities.

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