Over the past two decades, over 200,000 people have overdosed and died from abusing highly addictive prescription opioids, in what has come to be known as the “Opioid Crisis.” Recently, the U.S. Department of Justice (“DOJ”) has begun taking legal action to fight the Opioid Crisis through the filing of criminal charges against pharmaceutical companies and drug distributors, as well as their executives, in an effort to hold these companies and individuals accountable for their role in the crisis. The DOJ’s recent efforts have included bringing criminal charges against Insys Therapeutics, Inc., Rochester Drug-Cooperative, Inc, and Miami-Luken Inc., and their executives. Among the laws cited by the DOJ as having been violated by these companies are the Controlled Substances Act [21 U.S.C. §§ 801-971], the Anti-Kickback Law [15 U.S.C. § 1320a-7b(b)], and the False Claims Act [31 U.S.C. §§ 3729-3733].

The Insys Therapeutics Case

Insys was a pharmaceutical company which developed and manufactured an opioid drug called Subsys, a form of fentanyl, a highly addictive and potentially lethal drug. In 2012, the Food & Drug Administration (“FDA”) approved Subsys for the management of pain in adult cancer patients who were already taking opioids to treat cancer pain, but who found the opioids they were taking to be insufficient to treat their intense pain.

Following FDA approval, however, Insys engaged in illegal marketing practices to encourage prescriptions of Subsys to be issued even when unnecessary or in violation of the restrictions placed on the drug’s use by the FDA. To do so, Insys operated a “speakers program” through which Insys paid medical practitioners to give speeches about Subsys. In reality, however, this program was simply a pretext for paying bribes to the practitioners to induce them to prescribe Subsys to their patients, even when the prescriptions were unnecessary. Indeed, most of the physicians and practitioners who participated in the speakers program were in specialties other than oncology. Insys also engaged in insurance fraud through the operation of the Insys Reimbursement Center (“IRC”). Because many insurers would not provide reimbursement for Subsys unless the beneficiary had received prior authorization for his or her Subsys prescription, the IRC sought to “facilitate” the process by lying or making deliberately misleading statements to Medicare Part D Sponsors and/or Pharmacy Benefits Managers in order to obtain federal reimbursement for Subsys prescriptions that otherwise would not have been approved.

On December 8, 2016, the U.S. Attorney’s Office for the District of Massachusetts brought criminal charges against six former Insys executives and managers. The charges against
these executives included conspiracy to commit racketeering, conspiracy to commit wire and mail fraud, and conspiracy to violate the Anti-Kickback Law. On May 2, 2019, a federal jury found Insys’ founder and four former executives guilty of racketeering charges. These executives could face up to 20 years in prison for these convictions.

On June 5, 2019, Insys agreed to a $225 million resolution of the criminal and civil actions against the company. This agreement included a deferred prosecution agreement with the DOJ, a $195 million settlement of civil allegations that the company had violated the False Claims Act, and a 5-year Corporate Integrity Agreement (“CIA”) and Conditional Exclusion Release with the U.S. Department of Health and Human Services. As part of the CIA, Insys was required to establish a compliance program, appoint a compliance officer, and create a compliance committee. Only 5 days after agreeing to this settlement, however, Insys filed for Chapter 11 bankruptcy.

The Rochester Drug Co-Operative Case

Rochester Drug Co-Operative is one of the 10 largest pharmaceutical distributors in the United States, with more than 1,300 pharmacy customers and $1 billion in annual revenue. For at least 5 years, RDC distributed dangerous, highly addictive opioids to pharmacy customers, even though it knew that many of these opioids were ultimately being sold and used illicitly. At the direction of senior management, RDC supplied large quantities of oxycodone, fentanyl, and other opioids to pharmacy customers which its own compliance personnel had determined were dispensing the drugs to individuals who had no legitimate medical need for them. In doing so, RDC executives, including former CEO Laurence Doud III and former Chief Compliance Officer William Pietruszewski, made a deliberate decision to ignore red flags raised by RDC’s compliance department.

On April 23, 2019, the Manhattan U.S. Attorney’s Office and the Drug Enforcement Administration (“DEA”) announced criminal charges against RDC, Doud, and Pietruszewski, for unlawfully distributing oxycodone and fentanyl, conspiring to defraud the DEA, and failing to comply with its legal obligation to report thousands of suspicious orders of controlled substances to the DEA. Doud could face up to life in prison for the conspiracy to distribute charges. RDC subsequently entered into a consent decree pursuant to which RDC agreed to accept responsibility for its conduct and pay a $20 million penalty. RDC also agreed to reform and enhance its Controlled Substances Act compliance program and submit to supervision by an Independent Monitor.

Key Takeaways

As evidenced by these recent criminal cases, as well as various civil cases, the Government is actively investigating and prosecuting pharmaceutical and drug distribution companies and their executives for their roles in the Opioid Crisis. Thus, these companies should act now to ensure that they are in compliance with all federal laws and regulations concerning the production, marketing, and distribution of opioid painkillers. This includes ensuring an appropriate “culture of compliance” and “tone at the top” of the organizations.
Above all, executives and board members of these companies must take the Opioid Crisis and their responsibilities to the public very seriously.
Representing Drug Companies in High-Profile Opioid Cases:

Lessons from the Insys Therapeutics and Rochester Drug Co-Operative Cases

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Scenario

- You are an in-house or outside counsel for a pharmaceutical company or drug distributor that produces and/or distributes opioid pain medicines.

- Competing pharmaceutical and distribution companies have been facing increasing scrutiny and legal actions related to their production and distribution of similar opioids.
  
  - Civil and, in some cases, even criminal charges have been brought against certain companies and their executives.

- How do you protect your company from facing the same fate?
The Opioid Crisis

• In the past two decades, more than 200,000 people have overdosed and died from prescription opioids, which are also highly addictive.

• In 2017 alone, opioids caused a record 47,600 overdose deaths in the U.S. according to the U.S. Centers for Disease Control and Prevention.

• Examples of prescription opioids include fentanyl and oxycodone.

• Fentanyl, a synthetic opioid, is 30 to 50 times more potent than heroin, is the deadliest drug in the U.S., and as little as two milligrams is potentially lethal.

• Oxycodone is an opioid used to treat moderate to severe pain. When taken by mouth, its usual application, it has 1½ times the effect of morphine, and overdoses are common.
The Opioid Crisis (con’t.)

• This is partly a result of efforts by pharmaceutical companies beginning in the late 1990s to reassure the medical community that patients would not become addicted to prescription opioid pain relievers.

• As a result, doctors and other medical providers began prescribing opioids at far higher rates, leading to widespread diversion and misuse of these drugs before it became clear that these medications were indeed highly addictive.
The Government’s Response

• Recently, the U.S. Department of Justice (“DOJ”) has begun taking legal action, including the filing of criminal charges, to combat the opioid crisis, and to hold pharmaceutical companies, drug distribution companies, and their executives accountable for their role in the crisis.

• This includes recent criminal cases brought against Insys Therapeutics, Inc. (“Insys”) and Rochester Drug Co-Operative, Inc. (“RDC”).

• This also includes civil and/or criminal cases brought against other pharmaceutical and distribution companies and their executives, including Purdue Pharma, Cardinal Health, AmerisourceBerger, Miami-Luken Inc., and McKessen Corp.
The Controlled Substances Act:  
21 U.S.C. §§ 801-971

• The U.S. Controlled Substances Act ("CSA") regulates the manufacture, distribution, and use of substances that can have a detrimental effect on public health and welfare.

• To manufacture or distribute controlled substances, including fentanyl and oxycodone, an entity must register with the Drug Enforcement Administration ("DEA") and comply with laws and regulations imposed by the CSA.
The Controlled Substances Act (con’t.)

• Pursuant to 21 U.S.C. § 823(a)(1) and (b)(1), registered drug manufacturers and distributors are required to maintain “effective control[s] against diversion of particular controlled substances” into “other than legitimate medical, scientific, and industrial channels.”

• Registered distributors are also responsible for reporting suspicious orders to the DEA, which are defined by regulation as including “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” [21 C.F.R. § 1301.74(b)]
THE INSYS THERAPEUTICS CASE
The Insys Therapeutics Case: Background

• Insys is a pharmaceutical company which developed and manufactured a drug called Subsys.
  • Subsys is a form of fentanyl, a powerful but highly addictive opioid painkiller.
  • Subsys is up to 100 times more potent than morphine.

• In 2012, the FDA approved Subsys for the management of pain in adult cancer patients.
  • The approval was limited to those patients who were already taking opioids to treat cancer pain, but who had found the opioids they were taking to be insufficient to treat their intense pain.
Insys Therapeutics: Marketing Practices

• Following FDA approval, Insys engaged in illegal marketing practices to encourage medical practitioners to prescribe Subsys even when the use of Subsys was unnecessary.

• Insys operated a “speakers program” through which it paid Subsys prescribers to give speeches about the drug.

• Often no speeches were given, however, and the programs were really nothing more than free expensive dinners for practitioners and their family and friends.

• Thus, the program was really a pretext for paying bribes to medical practitioners for the purpose of inducing them to prescribe Subsys to their patients.
Insys also provided kickbacks to medical practitioners in other forms, including providing jobs to relatives and friends, visits to strip clubs, and lavish meals and entertainment.

Despite the FDA’s restrictions, Insys also promoted the use of Subsys to treat patients who did not have cancer.

Most of the physicians who Insys paid as part of the speaker program were in specialties other than oncology.
Insys Therapeutics: Insurance Fraud

• Many insurers, including Medicare Part D Plans, would not provide reimbursement for Subsys unless the beneficiary had received prior authorization for his or her Subsys prescription.

• A number of medical factors material to insurers’ decisions on whether to reimburse for Subsys included:
  • Whether the patient had cancer.
  • Whether the patient was opioid tolerant.
  • Whether the patient had difficulty swallowing.
To increase Subsys sales, Insys established the Insys Reimbursement Center (“IRC”) to facilitate the process of obtaining prior insurance authorization for Subsys prescriptions.

In many instances, IRC employees lied or made deliberately misleading statements to Medicare Part D Sponsors and/or Pharmacy Benefits Managers in order to obtain federal reimbursement for Subsys prescriptions that otherwise would not have been approved.

IRC employees frequently misrepresented patients’ medical conditions in order to obtain insurance authorization that otherwise would have been denied.
Insys Therapeutics: Criminal Charges Against Insys Executives

• On December 8, 2016, the U.S. Attorney’s Office for the District of Massachusetts brought criminal charges against six former Insys executives and managers, including former CEO and President Michael L. Babich.

• The charges included:
  
  • Conspiracy to commit racketeering;
  
  • Conspiracy to commit wire and mail fraud; and
  
  • Conspiracy to violate the Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b), which prohibits the exchange of remuneration—which the statute defines broadly as essentially anything of value—for referrals for services that are payable by a federal health care program.

• “I hope that today’s charges send a clear message that we will continue to attack the opioid epidemic from all angles, whether it is corporate greed or street-level dealing.”

_Carmen M. Ortiz, U.S. Attorney in Massachusetts_
Insys Therapeutics: Guilty Verdicts for Insys Execs

• On May 2, 2019, a federal jury found Insys’ founder and four former executives guilty of racketeering charges.

• Insys’ former chief executive, Michael Babich, had previously pled guilty to conspiracy and mail fraud charges.

• These executives could face up to 20 years in prison for these convictions.
Insys Therapeutics: Resolution of the Legal Actions

• On June 5, 2019, Insys agreed to a $225 million global resolution of the criminal and civil actions against the company.

• Insys agreed to a deferred prosecution agreement with the DOJ in which Insys pled guilty to five counts of mail fraud and agreed to pay a $2 million fine and $28 million in forfeiture.

• Insys also agreed to pay $195 million to settle civil allegations that the company had violated the False Claims Act, 31 U.S.C. § 3729.
  
  • The False Claims Act provides for treble damages and civil penalties against any company or person who knowingly submits a false or fraudulent claim for payment or approval to the U.S.

• Insys also entered into a 5-year Corporate Integrity Agreement (“CIA”) and Conditional Exclusion Release with the U.S. Department of Health and Human Services.
Insys Therapeutics: The Settlement Agreement

• Under the CIA, Insys was required to establish and maintain a compliance program, including the appointment of a Compliance Officer responsible for:

  • Developing and implementing policies, procedures, and practices to ensure compliance with the requirements set forth in the CIA, as well as FDA requirements.

  • Making periodic reports regarding compliance matters directly to Insys’ Board of Directors.

  • Monitoring the day-to-day compliance activities engaged in by Insys.

• Additionally, Insys was required to create a Compliance Committee to support the Compliance Officer, to assist in analyzing Insys’s risk exposure, and to oversee the monitoring of internal and external audits and investigations.
Insys was also required to develop and implement written policies and procedures regarding the operation of its compliance program.

• Among other things, the policies and procedures had to address appropriate ways for Insys to market its products in compliance with the Anti-Kickback Statute, the False Claims Act, and applicable FDA requirements.

• Insys was also required to provide training and education to employees, executives, and board members concerning Insys’s compliance program.
Insys Therapeutics: Insys Today

• On June 10, 2019, only 5 days after agreeing to the $225 million settlement, Insys filed for Chapter 11 Bankruptcy

• Insys listed $175.1 million in assets and $262.5 million in debt.

• The DOJ is Insys’s largest unsecured creditor.
THE ROCHESTER DRUG CO-OPERATIVE CASE
The Rochester Drug Co-Operative Case: Background

• Rochester Drug Co-Operative (“RDC”) was founded in 1905, and describes itself as “a true regional wholesale drug cooperative.”

  • “RDC is . . . a marriage of a buying cooperative and a traditional drug distribution company created for the purpose of helping Independent Pharmacists compete in today’s healthcare environment.”

• RDC is one of the 10 largest pharmaceutical distributors in the United States.

  • RDC has more than 1,300 pharmacy customers and $1 billion in annual revenue.
Rochester Drug Co-Operative: Criminal Activity

• For at least 5 years, RDC distributed dangerous, highly addictive opioids to pharmacy customers, even though it knew that many of these opioids were ultimately being sold and used illicitly.

• At the direction of senior management, RDC supplied large quantities of oxycodone, fentanyl, and other dangerous opioids to pharmacy customers that its own compliance personnel determined were, in many cases, dispensing those drugs to individuals who had no legitimate medical need for them.
Rochester Drug Co-Operative: Criminal Activity (con’t.)

• RDC executives, including former CEO Laurence Doud III and former Chief Compliance Officer William Pietruszewski, made a deliberate decision to ignore red flags raised by RDC’s compliance department.

• Because reporting customers to the DEA would likely lead to investigations and possibly the shut down of those customers, RDC’s senior management directed the company’s compliance department not to report them.

• Instead, RDC continued supplying those customers with dangerous controlled substances that RDC knew, in many cases, were being dispensed and used for illicit purposes.
Rochester Drug Co-Operative: Increased Sales

• Doud allegedly directed the increase in sales of oxycodone from 4.7 million dosages to 42.2 million (an increase of about 800%) between 2012 and 2016.

• During that same period, sales of fentanyl grew from 63,000 dosages to more than 1.3 million dosages (an increase of about 2,000%).
Rochester Drug Co-Operative: Criminal Charges Against the Company and its Execs

- On April 23, 2019, the Manhattan U.S. Attorney’s Office and the DEA announced criminal charges against RDC, Doud, and Pietruszewski, for unlawfully distributing oxycodone and fentanyl, conspiring to defraud the DEA, and failing to comply with its legal obligation to report thousands of suspicious orders of controlled substances to the DEA.

- Pietruszewski pled guilty to multiple conspiracy charges related to the distribution of a controlled substance, fraud, and failing to report suspicious sales.

- Doud was charged with conspiracy to distribute controlled substances and conspiracy to defraud the United States.

- If convicted, Doud could face up to life in prison for the conspiracy to distribute charges.
Rochester Drug Co-Operative: DOJ Statements Concerning the Criminal Charges

• “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. Our Office will do everything in its power to combat this epidemic, from street-level dealers to the executives who illegally distribute drugs from their boardrooms.”

  U.S. Attorney Geoffrey S. Berman, Southern District of New York

• “Today’s charges should send shock waves throughout the pharmaceutical industry reminding them of their role as gatekeepers of prescription medication. The distribution of life-saving medication is paramount to public health; similarly, so is identifying rogue members of the pharmaceutical and medical fields whose diversion contributes to the record-breaking drug overdoses in America.”

  Ray Donovan, DEA Special Agent in Charge, New York Field Office
Rochester Drug Co-Operative: Settlement of Criminal Charges

• RDC entered into a consent decree pursuant to which RDC agreed to accept responsibility for its conduct by making admissions, stipulating to the accuracy of a statement of facts, and paying a $20 million penalty.

• RDC also agreed to reform and enhance its Controlled Substances Act compliance program, and to submit to supervision by an Independent Monitor.
Rochester Drug Co-Operative: Settlement of Criminal Charges (con’t.)

• RDC’s Board of Directors is also obligated to establish a Controlled Substances Compliance Committee (“CSCC”).

• The CSCC is required to report regularly to RDC’s Board of Directors on compliance issues, and to regularly review reports from the government’s Independent Monitor.
Rochester Drug Co-Operative: Settlement of Criminal Charges (con’t.)

- RDC is required to establish a Controlled Substances Monitoring Program ("CSMP") designed to prevent and detect violations of the Controlled Substances Act.

- Under the CSMP, RDC is required to review and enhance its methodology for detecting potentially suspicious orders from pharmacy customers.
  - RDC is prohibited from fulfilling any orders that exceed a customer’s legitimate order threshold without conducting a thorough and diligent investigation to determine whether the order is suspicious and must be reported to the DEA.

- The Controlled Substances Compliance Committee must also review RDC’s CSMP requirements, and every two years recommend to the Board any necessary updates to systems or procedures to ensure that the CSMP remains current and in compliance with all federal and state regulations.
THE MIAMI-LUKEN CASE
Miami-Luken Inc.: Background

• Miami-Luken Inc. was a drug distribution company located near Dayton, Ohio which supplied pharmaceuticals to more than 200 pharmacies in Ohio, West Virginia, Indiana and Tennessee.

• From 2008 until 2015, the company generated more than $173 million in sales per year.
  • More than 70% of the profits came from wholesale drug distribution.

• In January 2019, Miami-Luken announced it would be shutting down operations after facing mounting lawsuits and the DEA’s efforts to revoke its licenses.
Miami-Luken Inc.: Criminal Charges

• On July 18, 2019, a federal grand jury in the Southern District of Ohio charged Miami-Luken, its former president, Anthony Rattini, its former Chief Compliance Officer, James Barclay, and two pharmacists, with conspiring to distribute controlled substances.

• According to the indictment Miami-Luken and its executives sought to enrich themselves by distributing millions of doses of painkillers to doctors and pharmacies in rural Appalachia, where the opioid epidemic was at its peak.
Miami-Luken Inc.: Criminal Charges Against CCO and Founder

• Miami-Luken and its executives continued to distribute millions of pills to pharmacies even after being advised by the DEA of the company’s responsibility as a wholesaler to ensure that drugs were not being diverted, and to report suspicious orders.

• Miami-Luken’s Chief Compliance Officer, Barclay, and founder, Rattini, allegedly ignored obvious signs of abuse by its customers.

• For example, Barclay and Rattini ignored red flags, and Miami-Luken distributed more than 2.3 million oxycodone pills and 2.6 million hydrocodone pills to a pharmacy located in one small town of only 1,394 people.
KEY TAKEAWAYS
Key Takeaways: The Time to Act is Now

• The Government is actively investigating and prosecuting pharmaceutical companies and drug distribution companies and their executives for their roles in the opioid crisis.

• Thus, pharmaceutical and drug distribution companies should act now to ensure that they are in compliance with all federal laws and regulations concerning the production, marketing, and distribution of opioid painkillers.
Key Takeaways: Payments to Physicians Must Be Legitimate

- Pharmaceutical companies should by now certainly be aware that payments to treating physicians or medical providers can lead to serious consequences.

- Prosecutors and regulators can easily determine when “consulting” or “speaker programs” are actually designed to improperly compensate physicians and medical providers for prescriptions and referrals.
Key Takeaways: Executives are No Longer Immune

• Pharmaceutical and drug distribution company executives are no longer immune from the consequences of corporate misconduct.

• Executives and Board members should be very mindful of the “tone at the top,” and must take the opioid crisis seriously.

• Management’s focus on profitability at the expense of compliance can lead to a company culture that disregards the legal obligations of the CSA and other federal and state laws and regulations.
Key Takeaways: Fostering a “Culture of Compliance”

• Companies should foster a “culture of compliance.”

• Executives and Board Members must be committed to dedicating the necessary resources to compliance, even when it may impact short-term revenues.

• This includes fostering an atmosphere in which employees feel comfortable reporting potential wrongdoing of clients, co-workers, and superiors without fear of retribution.
Key Takeaways: Fostering a “Culture of Compliance” (con’t.)

- Pharmaceutical manufacturers and drug distributors must establish bona fide compliance programs.

- Using the Insys and RDC settlement agreements as examples, companies should:
  - Establish compliance committees.
  - Develop programs to ensure that suspicious behavior and activities among sales staff or customers are detected and reported to the appropriate authorities.
  - Establish educational programs for employees concerning federal and state laws and regulations relating to the company’s sales and distribution of opioids.

- Companies must listen to and follow the advice of these compliance committees, and must adhere to newly established compliance programs.
Key Takeaways: Suggested Practices to Manage Compliance Risk

• Use advanced methods for identifying high-risk trends, patterns and suspicious orders, such as data analytics of sales.

• Develop monitoring tools that can be used to identify, and potentially predict, problematic marketing and sales activities.

• Conduct due diligence on distributors, pharmacies and other supply-chain parties to identify high-risk business partners.

• Implement comprehensive and accessible compliance materials, including digitizing program materials that can easily be updated.

• Ensure that there is an effective compliance reporting chain.

• Track stats on compliance inquiries to identify “hot spots”.

• Have a visible compliance presence in high-risk areas, such as having compliance personnel conduct surprise visits to paid speaking engagements.
Key Takeaways: Considerations for Potential Post-Settlement Monitoring

• Post-settlement monitoring, while sometimes necessary, can be a significant distraction and resource drain on an organization.

• Consider using professionals with relevant experience as independent monitors when negotiating and executing post-settlement Corporate Integrity Agreements and/or Deferred Prosecution Agreements.

• Key steps in negotiations and execution when a monitor is required include:
  • Clearly define the scope of the monitor’s mandate.
  • When possible, implement fixes in controls and processes before settlement terms are finalized and the monitor is put in place.
  • Prepare for the entity to be monitored, such as by collecting and organizing documents.
  • Support ongoing monitoring activities to ensure the success of any required monitoring.

• Preparation and proactive conduct can reap benefits, such as a smoother monitoring process, the avoidance of surprises and side investigations, limiting the scope and cost of a monitor, and perhaps even avoiding a monitor altogether.
Conclusion

Now you know why pharmaceutical and drug distribution companies must be extremely careful, must enforce strict compliance procedures, and must follow all applicable rules and regulations when selling opioids. But the same advice is applicable to companies which are selling other drugs, and indeed, for other companies which are subject to significant governmental regulations, such as, for example, financial institutions, defense contractors, and airplane manufacturers, just to name a few. Robust, strictly enforced compliance programs are necessary, as is a “culture of compliance” from the very top.

A failure to follow this advice could be devastating and could lead to a company ending up in the Government’s cross-hairs.
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