A Primer on Investigating Doctors Who Illegally Prescribe Opioids

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Although much of the blame for the current opioid epidemic has been placed at the feet of the medical community for overprescribing opioids, the vast majority of physicians in the United States prescribe opioids to their patients for a legitimate medical purpose. However, in spite of efforts at education and raising the community awareness of the dangers of overprescribing opioids, there remains a minority of physicians who knowingly prescribe opioids for their personal gain outside of a legitimate medical purpose. The investigation of those physicians is the focus of this article.

I. The Opioid Crisis

In 2015, over 52,000 Americans lost their lives to drug overdoses.[1] In 2016, that number was over 64,000.[2] That represents the largest increase in death toll in American history.[3] As Attorney General Jeff Sessions pointed out in a speech in Charleston, West Virginia, in September 2017, "That would be the highest drug death toll and the fastest increase in that death toll in American history. And every day this crisis continues to grow, as more than 5,000 Americans abuse painkillers for the first time." He noted, "More Americans die of drug overdoses than died from car crashes or died from AIDS at the height of the AIDS epidemic."[4]

General Sessions pointed out the cost of these statistics, "These trends are shocking and the numbers tell us a lot—but they aren't just numbers. They represent moms and dads, brothers and sisters, neighbors and friends. They represent unique, irreplaceable people, and fellow Americans."[5] Telling of a recent event he attended, he said:

> I recently had the opportunity to address the National Alliance for Drug Endangered Children. It was during this event that I was able to view this crisis through the eyes of a child—just imagine for a moment you are a helpless toddler who cries for their mother to wake up and she never does, or the poor infant that is wailing in the NIC-U due to opioid withdrawal—you just entered this world and are already suffering and for sins you did not commit.[6]

[1] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017).
[2] Attorney General Sessions, Remarks at the DEA Graduation Ceremony (Jan. 26, 2018).
[3] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017).
[4] Attorney General Sessions, Remarks at "West Virginia on the Rise: Rebuilding the Economy, Rebuilding Lives" About the Opioid Epidemic (Sept. 21, 2017).
[5] *Id.*
[6] *Id.*

He also discussed the monetary cost of opioid addiction:

> It is estimated that prescription opioid addiction costs our economy some $78 billion a year . . . Drug abuse reduces the productivity of our workers, eliminates many otherwise qualified individuals from our work force due to addiction and criminal records, and puts a strain on health care programs like Medicaid. It is filling up our emergency rooms, our foster homes, and our cemeteries.[7]

In a speech in Harrisburg, Pennsylvania, later that month, General Sessions spoke of two recent instances in that state:

> They [the statistics] represent the 26-year-old pregnant mother who overdosed in Charleston, accidentally killing both herself and her unborn child. They represent the couple who were found dead in their Kernville home a week after they had overdosed on heroin. Their five-month-old daughter was found with them—dead from starvation and dehydration.[8]

In a speech to DEA graduates in January 2018, General Sessions shared, "No community in America has been immune to this crisis. I personally know people whose families have been bankrupted and torn apart by drug addiction. These days it is a safe assumption that most of you do, too."[9]

In remarks in Washington D.C. in February 2018, General Sessions explained the scope of the problem:

> In the United States . . . we consume the vast majority of the world's hydrocodone and more than 80 percent of its oxycodone. It is estimated that we use many times more opioids than is medically necessary for a population our size. Millions of Americans are living with an addiction . . . The Medicare prescription drug program paid more than $4 billion for opioids in 2016.[10]

"Every day, 180 Americans die from drug overdoses. This epidemic actually lowered American life expectancy in 2015 and 2016 for the first time in decades, with drug overdose now the leading cause of death for Americans under age 50."[11]

II. Attorney General Sessions' Response

Since taking office, General Sessions made addressing this epidemic by fighting the overprescribing of opioids by health care professionals a top priority of the Department of Justice. In August 2017, he announced the formation of the Opioid Fraud and Abuse Detection Unit.[12] This pilot program uses data analytics to identify and prosecute health care professionals who are contributing to the prescription opioid epidemic by diverting or dispensing prescription opioids for illegitimate purposes.[13] The data identifies which physicians are writing opioid prescriptions at a rate that far exceeds other

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[7] *Id.*
[8] Attorney General Sessions, Remarks to Law Enforcement About the Opioid Epidemic (Sept. 22, 2017).
[9] Attorney General Sessions, Remarks at the DEA Graduation Ceremony (Jan. 26, 2018).
[10] Attorney General Sessions, Remarks Announcing the Prescription Interdiction and Litigation Task Force (Feb 27, 2018).
[11] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces New Prescription Interdiction and Litigation Task Force (Feb. 27, 2018).
[12] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017).
[13] Jennifer Barrett, *Program Targets Opioid Fraud and Abuse*, PHARMACY TIMES (Aug. 4, 2017); Attorney General Sessions, Remarks at the DEA Graduation Ceremony (Jan. 26, 2018).

physicians. The data also identifies how many of a doctor's patients died within sixty days of receiving an opioid prescription. The data also identifies pharmacies that are dispensing disproportionately large amounts of opioids.[14] As part of the program, the Department also funded twelve experienced Assistant United States Attorneys for a three year term to investigate and prosecute heath care fraud related to prescription opioids. The unit's task is to root out pill mills and prosecute health care professionals who abuse opioid prescriptions.[15] General Sessions warned doctors and pharmacists:

> [T]oday, we are announcing a new effort to target our federal resources against this epidemic. If you are a doctor illegally prescribing opioids for profit or a pharmacist letting these pills walk out the door and onto our streets based on prescriptions you know were obtained under false pretenses, we are coming after you. We will reverse these devastating trends with every tool we have.[16]

"This data analytics team will help us find the tell-tale signs of opioid-related health care fraud by identifying statistical outliers . . . Fraudsters might lie, but the numbers don't."[17] General Sessions added: "With these new resources, we will be better positioned to identify, prosecute, and convict some of the individuals contributing to these tens of thousands of deaths a year. The Department is determined to attack this opioid epidemic, and I believe these resources will make a difference."[18] The new prosecutors "working with the FBI, DEA, the Department of Health and Human Services, as well as our state and local partners, will help us target and prosecute doctors, pharmacies, and medical providers who are exploiting this epidemic to line their pockets."[19]

In September 2017, General Sessions announced grant funding to address the opioid problem:

> [T]oday, I am announcing that we will be awarding nearly $20 million in federal grants to help law enforcement and public health agencies address prescription drug and opioid abuse. This is an urgent problem and we are making it a top priority. I believe that these new resources and new efforts will make a difference, bring more criminals to justice and ultimately save lives. And I'm convinced this is a winnable war.[20]

General Sessions pointed out the important role of partnerships in winning the war:

> But in order to end this crisis, we must work together. Eighty-five percent of all law enforcement officers serve at the state and local level, and your work is essential to our success. Strengthening partnerships between law enforcement officers at all levels is a central theme of my tenure at the DOJ, and I hope you will help me do that.[21]

In November 2017, General Sessions ordered each of the United States Attorneys to designate an Opioid Coordinator in their district.[22] The role of the coordinator is to work with federal, state, and local

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[14] *Id.*
[15] Adora Namigadde & Gabe Rosenberg, *In Columbus Speech, Sessions Announces Program Targeting Opioid Prescribers*, NPR (Aug. 2, 2017).
[16] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017).
[17] Attorney General Sessions, Remarks at "West Virginia on the Rise: Rebuilding the Economy, Rebuilding Lives" (Sept. 21, 2017).
[18] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017).
[19] Attorney General Sessions, Remarks at "West Virginia on the Rise: Rebuilding the Economy, Rebuilding Lives" (Sept. 21, 2017).
[20] Attorney General Sessions, Remarks to Law Enforcement About the Opioid Epidemic (Sept. 22, 2017).
[21] *Id.*
[22] Attorney General Sessions, Remarks at the DEA Graduation Ceremony (Jan. 26, 2018).

law enforcement and prosecutors to identify and prosecute over prescribing and over dispensing cases.[23] General Sessions emphasized the importance of working as a team and the importance of the goal at the DEA graduation ceremony. He urged graduates:

> Let me conclude by making this clear: we are in this together. We support you and embrace your mission, one that represents a top priority of the Department of Justice. Go at your work honorably and with enthusiasm and determination. Be creative. Come up with better ideas. We can defeat this evil presence that is killing our people, destroying our families, and weakening our nation.[24]

In January 2018, General Sessions announced a DEA surge to combat prescription opioid diversion:

> I am announcing today that, over the next 45 days, DEA will surge Special Agents, Diversion Investigators, and Intelligence Research Specialists to focus on pharmacies and prescribers who are dispensing unusual or disproportionate amounts of drugs. DEA collects some 80 million transaction reports every year from manufacturers and distributors of prescription drugs. These reports contain information like distribution figures and inventory. DEA will aggregate these numbers to find patterns, trends, statistical outliers—and put them into targeting packages. That will help us make more arrests, secure more convictions—and ultimately help us reduce the number of prescription drugs available for Americans to get addicted to or overdose from these dangerous drugs.[25]

In February 2018, General Sessions appointed an experienced federal prosecutor to serve as the National Director of Opioid Enforcement and Prevention Efforts at the Department of Justice.[26] He directed her to "help us formulate and implement initiatives, polices, grants, and programs relating to opioids, and coordinate these efforts with law enforcement."[27] He also announced the creation of the Prescription Interdiction and Litigation (PIL) Task Force.[28] The PIL Task force includes senior officials from the offices of the Attorney General, the Deputy Attorney General, the Associate Attorney General, the Executive Office for U.S. Attorneys, the Civil Division, the Criminal Division, and the Drug Enforcement Administration.[29] General Sessions said, "The PIL Task Force will focus in particular on targeting opioid manufacturers and distributors who have contributed to this epidemic. We will use criminal penalties. We will use civil penalties. We will use whatever tools we have to hold people accountable for breaking our laws."[30] General Sessions warned physicians and pharmacists who are breaking the law, "These are not our last steps. We will continue to attack the opioid crisis from every angle. And we will continue to work tirelessly to bring down the number of opioid prescriptions, reduce the number of fatal overdoses, and to protect the American people."[31]

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[23] *Id.*
[24] *Id.*
[25] Attorney General Sessions, Remarks on Efforts to Reduce Violent Crime and Fight the Opioid Crisis, (Jan. 30, 2018).
[26] Attorney General Sessions, Remarks Announcing the Prescription Interdiction and Litigation Task Force (Feb. 27, 2018).
[27] *Id.*
[28] Press Release, U.S. Dep't of Justice, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018).
[29] *Id.*
[30] Attorney General Sessions, Remarks Announcing the Prescription Interdiction and Litigation Task Force (Feb. 27, 2018).
[31] *Id.*

III. A Primer on Investigating Doctors for Overprescribing Opioids

As AUSAs across the nation join General Sessions in this fight against doctors who illegally prescribe opioids, many find themselves confronting this type of case for the first time. What are the investigative tools they can use to investigate the doctors? How do they tell the bad doctors from those not violating the law? What should they be looking for during the investigation to identify the doctors illegally prescribing opioids? Hopefully, this article will begin to answer some of those questions. It is a primer on these investigations. There are other, more comprehensive, in-depth resources that treat all aspects of working these cases, from identifying the doctor, to investigating his practice, to the indictment, through the trial, and to sentencing,[32] but this article will serve as a starting point for conducting the investigation.

Investigating doctors for illegal opioid distribution is not an easy task. The investigation is often difficult and complex. What follows are the basics—the elements you have to prove, how to identify the doctor who is illegally prescribing opioids, how to build your case inside and outside of the doctor's office, and some issues you may encounter along the way to an indictment.

Physicians who illegally prescribe opioids[33] are typically prosecuted under the same criminal statute as traditional drug dealers[34]—21 U.S.C. § 841(a)(1), which provides, "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally:—(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."[35]

Unlike prosecutions against the traditional drug dealer, however, to prosecute an illegally prescribing physician the prosecutor must show that the physician acted outside of the scope of professional practice or without a legitimate medical purpose.[36]

The government must show that the defendant knowingly and intentionally distributed a controlled substance and that in so doing, the defendant acted and intended to act without a legitimate medical purpose and outside the usual course of professional practice.[37] As Benjamin Barron points out in his article, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, "[t]here is little (if any) meaningful distinction between acting with a 'legitimate medical purpose' and acting within 'the usual course of practice,' and multiple cases have upheld indictments or jury instruction that include one term but not the other."[38] Barron also points out that, "[i]n the context of medical practice,

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[32] *See* Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115 (Nov. 2016); Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, 64 U.S. ATT'Y BULL. 65 (Sept. 2016).

[33] Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115, 116 (Nov. 2016) (" . . . the term 'opioid,' which describes any substance, regardless of its precise properties, which produces morphine-like effects through action on opioid receptors [in the brain] . . . Over the years, a number of opioids have been developed by pharmaceutical companies to treat pain, including, but not limited to fentanyl, oxycodone, hydrocodone, and hydromorphone.").

[34] *Id.* at 124.

[35] 21 U.S.C. § 841(a)(1) (2012).

[36] United States v. Moore, 423 U.S. 122, 124, 96 S. Ct. 335, 337, 46 L. Ed. 2d 333 (1975); *See* 21 C.F.R. § 1306.04(a) ("a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.").

[37] Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, 64 U.S. ATT'Y BULL. 65, 66 (Sept. 2016).

[38] *Id.*

'dispensing' includes the act of filling a prescription or directly giving a drug to a patient, while 'distribution' and 'delivery' include the act of writing a prescription."[39]

The courts engage in a case-by-case analysis of the evidence. Whether the opioids were prescribed outside of the scope of professional practice or without a legitimate medical standard is judged by an objective, not a subjective, standard.[40] The term professional practice means generally accepted medical practice under the prevailing standards of treatment. As Barron writes:

> The term 'usual course of professional practice' is objective, and 'implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment [citation omitted].' Thus a defendant's 'idiosyncratic view of proper medical practices' cannot constitute the 'usual course of professional practice [citations omitted].'[41]

Although it may be relevant to show motive, the government is not required to show that the physician prescribed the opioids out of greed or other malicious motive such as in return for sexual favors.[42]

Although the charge of distribution of a controlled substance may be one the prosecutor is familiar with, the scope and tools of the investigation, and exactly what evidence will prove the charge, may be unfamiliar. First, let's look at the tools of the investigation.

IV. Tools of the Investigation

A. Agency and Other Records

1. DEA

As you might expect, the DEA plays an integral role in the regulation of physicians who prescribe opioids. In his article*, Overview of the Drug Enforcement Administration Diversion Control Program*, Louis J. Milione summarizes that regulation:

> The CSA [Controlled Substance Act] . . . gives DEA the authority to administer and regulate the legitimate manufacture, prescribing, and dispensing of controlled substances and listed chemicals by providing for a 'closed' system of drug distribution for legitimate handlers of such drugs, along with criminal penalties for transactions outside the legitimate chain [citation omitted]. This closed system was created in an effort to deter, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply of controlled substances is available for legitimate medical . . . purposes . . . The DCP's [DEA's diversion control program] regulatory function is accomplished through routine regulatory inspections, by providing guidance to registrants, and by controlling and/or monitoring the manufacture, distribution, [and] dispensing . . . of controlled substances.[43]

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[39] *Id.*
[40] *Moore*, 423 U.S. at 136, 96 S. Ct. at 343.
[41] Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, 64 U.S. ATT'Y BULL. 65, 66-67 (Sept. 2016).
[42] *See* United States v. Singh, 54 F.3d 1182, 1188 (4th Cir. 1995).
[43] Louis J. Milione, *Overview of the Drug Enforcement Administration Diversion Control Program*, 64 U.S. ATT'Y BULL. 11 (Sept. 2016).

DCP uses the regulatory process to monitor doctors who possess DEA registration certificates. The doctors are required to keep records of their controlled substance activity.[44] With proper notice, DEA Diversion investigators have the authority to conduct inspections of doctors' offices to review those records.[45] If a doctor refuses inspection, the Diversion Investigator has the authority to obtain an administrative inspection warrant.[46] The DEA Tactical Diversion Squads are the criminal enforcement wing of the DCP.[47] It is the mission of agents assigned to these squads to "combine varied resources and expertise in order to identify, target, investigate, disrupt, and dismantle those individuals or organizations involved in diversion schemes."[48] Diversion squads participate in the purchase of evidence, payment for information, surveillance, undercover operations, and executing search warrants.[49] DEA is the prosecutor's closest partner when working cases against overprescribing doctors.

2. ARCOS

The Automation of Reports and Consolidated Orders System (ARCOS) is an online reporting system which includes reports from all DEA registrants who distribute specific controlled substances, including opioids.[50] ARCOS can be a great source of data, particularly with regard to the volume of controlled substances being dispensed by certain professionals.[51]

3. PDMP

Nearly every state has a prescription drug monitoring program (PDMP). Barron describes the PDMP as "a government-run electronic database tracking prescriptions for controlled drugs statewide, based on information submitted by the dispensing pharmacy or doctor to a central clearinghouse."[52] "[G]enerally, the data kept . . . includes the drug prescribed (type, strength, and quantity), the prescribing doctor, the patient, and the pharmacy at which the prescription is filled."[53] Barron sets out the use of PDMP records:

> PDMP data will show whether the doctor is prescribing repeating patterns of the same controlled drugs or cocktails (including cocktails like opiates and sedatives that, when taken together, are particularly dangerous); whether the dosages are uniform (evidencing a lack of individualized treatment or drug strengths in excess of ordinary treatment); and whether the drugs are being filled at only one or a select set of pharmacies (reflecting collusion).[54]

Some states make even more aggressive use of PDMPs. Tara Kunkel, in her article, *Data-Driven Approaches to Responding to the Opioid Epidemic*, describes Arizona's PDMP:

> In 2014, the Arizona Board of Pharmacy, which operates Arizona's PDMP, began issuing prescriber report cards based on data maintained in the state's PDMP. The report cards

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[44] *Id.*
[45] *Id.* at 14.
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.* at 15.
[50] Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115, 125-26 (Nov. 2016).
[51] Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, 64 U.S. ATT'Y BULL. 65, 69 (Sept. 2016).
[52] *Id.* at 68.
[53] *Id.*
[54] *Id.*

> detail the provider's prescribing history, including their ranking compared to the 'average' prescriber of the same specialty and a summary or graphical representation of their prescribing history . . . The prescriber report cards are generated and distributed by the PDMP every quarter. They are sent to prescribers who have issued at least one controlled substance prescription during the previous quarter . . . Each prescriber receives a report specific to his or her prescribing history. The report also shows comparisons to other prescribers with the same specialty within the county and statewide . . . The report card categorized the prescriber's prescribing as 'normal,' 'high,' 'severe,' or 'extreme.' A letter is sent with the report explaining the program and emphasizing its purpose in promoting appropriate prescribing for the selected drugs.[55]

As Peña and McNeilly point out in their article, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Health Care Providers*, PDMPs:

> [E]xist in nearly every state, and with the use of administrative subpoenas, investigators can access this data to see what prescriptions are being written, who is writing them, who is receiving them, who is filling them, where they are filling them, how often they are filling them, and how the putative patients are paying for them. Diligent physicians and pharmacists should be checking the PDMP during the course of their practice, so obtaining these records for certain patients can also be a helpful way for law enforcement to get a sense of what the medical professional knew at the time of prescribing, or what he should have known.[56]

4. State Disciplinary Records

On occasion, you will learn that the doctor was disciplined by the state authorities for prescribing opioids illegitimately. This discipline is good evidence that the doctor is on notice that his prescribing behavior is not legitimate.

5. Pharmacy Records

At the overt stage of your investigation, consider subpoenaing the prescription records from the pharmacies the doctor used most frequently. You can obtain a doctor profile from the pharmacies by subpoenaing them using the doctor's DEA registration number. This will tell what the doctor is prescribing, the amounts of controlled substance he is prescribing, and the time lapse between prescriptions. If your subpoena reveals thousands of prescriptions, even if the prescriptions are not tied to specific counts of the indictment, these records may be admissible under Federal Rule of Evidence 404(b) to show knowledge, motive and pattern of conduct.[57] You can also subpoena a pharmacy to provide prescription records for a specific patient.

6. Patient Records

A patient's medical records are usually obtained with either a Rule 41 search warrant or a grand jury subpoena. Care must be taken, however, to comply with the standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in obtaining, using, or disclosing the medical records. It is important to obtain these records and for your expert to review them.

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[55] Tara Kunkel, *Data-Driven Approaches to Responding to the Opioid Epidemic*, 64 U.S. ATT'Y BULL. 79 (Sept. 2016).
[56] Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115, 125 (Nov. 2016).
[57] FED. R. EVID. 404(b).

B. Surveillance/Pole Cameras

Surveillance of the parking lot of the doctor's office can provide valuable information. Pole cameras are especially useful because you can learn the volume of his business. The car tags will tell you if a large number of his patients are from out of state. You can also get a sense for how long the patients are inside the office. Surveillance will also aid the agents in selecting potential cooperating witnesses.

C. Witnesses

Determining which type of evidence to use for the "inside the exam" room evidence is an important decision in these cases. You can use cooperating patients, undercover agents, or both.

1. Cooperators

Cooperating patients or former patients of the doctor can be an invaluable source of information about his practice, but they come with the customary baggage of witnesses who are drug abusers. As Peña and McNeilly point out:

> Drug-seeking witnesses are problematic for a number of reasons, including perception problems and continuing drug-seeking issues. Whenever dealing with drug-seeker witnesses, it is important to remember a prosecutor's discovery obligations pursuant to *Brady* and *Giglio*. These types of witnesses will often continue seeking controlled substances during the pendency of the litigation. Not only should the prosecution inquire of any bad acts from the witness, the prosecution should also obtain a recent criminal history from law enforcement.[58]

Debrief them on how they heard about the doctor, what they told the doctor about their pain during the appointment, the length and extent of the examination they received from the doctor, whether the doctor discussed other treatment options instead of pain medication, whether the doctor conducted any diagnostic tests, how they paid the doctor, and the role of the doctor's staff in prescribing the pain medication. Who suggested the exact opioids they received—them or the doctor? Were they permitted to "phone in" requests for pain medication refills? Were they able to obtain refills before the original prescription ran out?

2. Undercover Agents

If at all possible, you should use undercover officers in your investigation. They avoid the *Brady-Giglio* issues that often accompany cooperating witnesses, they are more reliable as witnesses, and at trial they don't carry the impeachment baggage of a cooperating drug addict. Also, if possible, use multiple undercover officers. That will remove the defense that the doctor simply made a mistake examining this one patient. Barron suggests:

> My rule of thumb is to use two to three undercover patients, each of whom conducts around three patient visits, although fewer may be necessary in the case of a particularly blatant criminal operation. The strategy of using multiple visits by multiple patients offers important benefits. Showing a pattern of illicit prescriptions undermines any defense argument concerning good-faith error or entrapment. Moreover, this strategy highlights deficiencies in the practitioner's ongoing course of treatment (*e.g.,* increasing the potency of the prescribed drugs without a medical basis, ignoring continuing signs of addiction, or

[58] Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115, 138 (Nov. 2016).

failing to inquire whether the injury purportedly justifying the original prescription had abated).[59]

DEA will undoubtedly provide an undercover who will know how to conduct themselves in the examination room, but a few things should be kept in mind. The undercover should be careful about what information she provides on the medical history questionnaire she fills out as a new patient. This will be an important document in a later prosecution. Claims of severe or intense pain on the questionnaire will later bring into question what the doctor was treating—the information he obtained during the exam or the information on the questionnaire. During the exam, the undercover should try to obtain pain medication without complaining of a type or severity of pain that would justify the prescription of a controlled substance. All undercover visits should be audio and video recorded.

3. Experts

It is essential that you use a medical expert during your investigation. The expert should be someone who practices in the same area as the doctor and has a working knowledge of and experience with pain management and the various means, including opioids, to control pain. The expert should be very familiar with how to conduct a proper medical examination for a patient complaining of pain, the types of diagnostic tests that should be run before prescribing opioids, the various opioids and what type of pain they are used to treat, how they interact with each other and other medications, and the dangers of prescribing opioids, including addiction and side effects. The expert doctor needs to be able to tell you, based on all of the facts developed in the investigation, whether the doctor's prescription practices fell outside of the course of professional medical practice and whether the prescriptions were written for a legitimate medical purpose.

D. Search Warrants

When the covert stage of the investigation is over and it is time to start the overt stage, you may consider starting that stage with a search warrant. You will want to search for both patient records and business records. The patient records will provide the obvious—dates of patient visits, diagnostic tests, if any, performed, the diagnoses, and the medications prescribed. The business records will show the nature of the payments, the volume of the business, and the amount of income and disbursement. Also, during the execution of the search warrant is the best time to interview the doctor's office staff. Ask them about the flow and volume of patients in the office and the doctor's examination and prescription practices. Did the doctor obtain prior medical records of his patients? Did the doctor refer his patients to pain specialists? Was it the practice of the doctor to send his patients for diagnostic tests before prescribing opioids? How did the patients pay? Did they recommend that the patients fill the prescription at one particular pharmacy? Did the doctor ever prescribe opioids without an office visit? Did they suspect many of the patients were drug addicts and if yes, why?

Peña and McNeilly also recommend interviewing the doctor:

> [T]here is no downside in attempting to obtain a proper interview of the [doctor]. If the [doctor] tells the truth, it will go a long way to understanding the extent of the damage caused and provide powerful evidence in the prosecution of substantive offenses. If the [doctor] makes false statements, those statements are admitted at trial in a different light when they are presented as the basis of a false statements charge rather than exculpatory statements. Caution must be exercised to ensure the [doctor] is not a represented party; and

[59] Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, 64 U.S. ATT'Y BULL. 65, 69 (Sept. 2016).

that, if there is an issue regarding custodial detention, that the [doctor] is *Mirandized* and that the interview is recorded . . .[60]

V. Evidence to Prove the Charge

No one piece of evidence alone will prove your case. You are looking for a pattern of conduct, not an individual instance of over-prescribing opioids. As you work the investigation and interview patients, former patients, staff, former staff, and if possible, use undercovers, the following are indicators or red flags you may discover that, when grouped together in a sufficient number, will show a pattern of illegal conduct.

The most common way to initially identify the doctor who is illegally prescribing opioids is street intelligence. Check with your local, state, and federal drug units. What are their opioid addict cooperators telling them about where they obtain their opioid prescriptions? Once you identify the suspected doctor, you want to learn about his practice, what happens inside of his waiting room, what happens inside of the examination room, what happens in the lab, and all you can about the prescriptions he writes.

A. The Doctor's Practice

The most direct way to learn about the doctor's practice is surveillance. Pole cameras can prove invaluable in conducting surveillance. Look for an extremely high patient volume for an office of that size. Are there long lines of waiting patients outside the practice's front door? Are there out of state tags on the cars the patients are driving? Are they traveling long distances to visit the doctor? Are the patients' visits brief—in and out? Are there nurses at the practice or only clerical staff? Does the doctor even require an office visit to prescribe an opioid, or can the patient simply call in with a request? Check with the local coroners in the county of the practice and surrounding counties. Has the practice had patient deaths from overdose?

B. Inside the Doctor's Office Waiting Room

By interviewing cooperating witnesses and office staff or by using undercover agents, you can learn what happens inside the doctor's office.

Are patients required to provide a medical history during their first visit? Does the doctor or his staff prepopulate the patient charts with information about the patient's complaints of pain? Does the doctor or his staff write out prescriptions for opioids and place them in the patient's file prior to the office visit? Does the practice even keep patient records, files, or prescription logs? If they do, are they accurate? Who determines what opioid to prescribe—the doctor or a non-medical staff person?

Is it a cash-only practice? Does the doctor charge excessive fees for office visits? Are the patients providing services, such as sex, or trading goods as payment for the opioid prescriptions? Is there a direct correlation between the cost of the office visit and the quantity of opioids the doctor prescribes?

C. Inside the Examination Room

Here is some conduct that should serve as red flags about the examination itself. First, does the doctor even perform a medical examination, or if he does, is it only cursory? Do the patients direct the doctor on what opioids they want prescribed? Does the doctor tell them that he cannot prescribe certain opioids unless the patient complains of specific pain? In other words, does he coach them on their symptoms? Does he fail to warn the patients about the dangers and side effects of the opioids he

[60] Jamie A. Peña & Peter A. McNeilly, *Investigating and Prosecuting Opioid Diversion and Tampering Cases Involving Medical Professionals and Institutional Healthcare Providers*, 64 U.S. ATT'Y BULL. 115, 136 (Nov. 2016).

prescribes? Does he fail to suggest alternatives to opioids, such as surgery, tens units, physical therapy, or massage therapy? Does he fail to refer them to specialists for their pain? Doctors involved in illegal prescribing do not want other doctors reviewing patient files. Does the doctor ignore obvious signs of opioid addiction in the patient? When the doctor and the patient discuss the prescription, do they use the street names for the drugs?

D. In the Lab

Does the doctor fail to order lab work such as blood work or urine screens? If the blood or urine screen indicates that the patient is taking illegal drugs, does the doctor continue to prescribe the opioids? If the blood or urine work indicates that the patient is not taking the opioids prescribed to him, this is an indication the patient is selling the opioids on the street. Does the doctor continue to write him prescriptions for the opioids?

E. The Prescription

When you review the actual prescriptions and the doctor's prescription practice, several red flags may pop up. Is the doctor prescribing an unusually large number of opioids in a short period of time? Is the doctor prescribing the same amount and dose of opioids for all of his patients? Is he prescribing excessive amounts of opioids in individual prescriptions? Or, in order to avoid creating concerns at the pharmacy, is he limiting the number of dosages in the prescriptions by writing two prescriptions at the same time for the same opioid? Is he prescribing opioids for an unreasonable period of time? Is he increasing the dosages of opioids long after anything in the patient's medical records would support such an increase? Does he frequently prescribe opioids for medications the patient reportedly "lost"? Is he providing refills before the original prescription should have run out? Is the doctor directing the patients to go to specific pharmacies to fill their opioid prescription?

The above are just some of the indicators that a doctor is illegally prescribing opioids. Alone, none of them will make your case. However, several of them grouped together will show a pattern and enable you to prove that a doctor is prescribing outside of the scope of professional practice or without a legitimate medical purpose.

VI. Conclusion

These are important cases, but they can also be difficult and time consuming cases. Hopefully this primer will give prosecutors facing their first illegally prescribing physician case the basics to launch an investigation. Fortunately, within the United States Attorneys' community and the Department of Justice family there are numerous resources to help you further your education beyond the basics outlined here. It

is clear that we are facing an opioid epidemic, and it is equally clear that these prosecutions are one of our most important weapons in the fight against that epidemic. Good luck.

ABOUT THE AUTHOR

❑ **K. Tate Chambers** graduated from the Southern Illinois University School of Law, after which he clerked for United States District Court Judge Richard Mills when Judge Mills was serving on the Illinois Appellate Court. Tate joined the United States Attorney's Office for the Central District of Illinois in 1984 and has served in several capacities, including Associate United States Attorney, Appellate Chief, OCDETF Lead Task Force Attorney, Branch Chief, and in the Coordinator positions for PSN, Violent Crime, Gangs, and Community Outreach. Tate also served as the National PSN Coordinator in EOUSA at Main Justice in Washington, D.C. from 2007 to 2010 and on the Evaluation and Review Staff in D.C. as a Criminal Program Manager from 2010 to 2011. Currently he serves as an Assistant Director of the Office of Legal Education, EOUSA, at the National Advocacy Center in Columbia, South Carolina, where he is the Editor in Chief of the United States Attorneys' Bulletin. Tate is retired from the Illinois Army National Guard where he served in the Judge Advocate General Corps.