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Alert

## White Collar Courier: Delivering News and Providing Guidance in White Collar Matters

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**The new DOJ initiative – aggressively investigating and prosecuting pain management practitioners**

### ***Part Three: Anatomy of a “Pill Mill” Investigation***

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In part one of this series, I detailed how the U.S. Department of Justice has focused its attention on the aggressive investigation and prosecution of “pill mill” cases. See [“Part One: DOJ Devotes Resources, Vows to Come After ‘Pill Mills.’”](#) In part two, I discussed what consequences doctors and other medical professionals could face as the result of a “pill mill” investigation. See [“Part Two: What’s At Stake for Prescribing Professionals in ‘Pill Mill’ Cases.”](#) In this installment, I give a detailed explanation of how the government investigates these cases.

#### **I. DATA ANALYSIS**

“Pill mill” investigations often start when the investigative agency<sup>1</sup> receives a tip – for instance, from a competing doctor, a pharmacist, a patient, or a disgruntled former employee – that a doctor is overprescribing drugs or drugs are being “diverted” from the practice (in other words, patients are “diverting” the drugs from their intended legitimate use for some illicit purpose, such as selling them on the street). Just as many investigations arise from data mining by investigators to uncover allegedly inappropriate prescribing patterns or doctors who are “statistical outliers” in terms of the type and amount of drugs they prescribe. In fact, in recently announcing the creation of the DOJ’s new “Opioid Fraud and Abuse Detection Unit,” U.S. Attorney General Jeff Sessions stated that the unit’s focus would be on opioid-related health care fraud “using data to identify and prosecute individuals that are contributing to th[e] prescription opioid epidemic.”<sup>2</sup> The following are examples of data sources that investigators use in investigating “pill mill” cases.

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<sup>1</sup> The federal agencies who investigate “pill mill” cases include the DEA, the FBI, the Department of Health & Human Services – Office of Inspector General, the Food & Drug Administration – Office of Criminal Investigations, and the IRS – Criminal Investigation Division (primarily regarding alleged money laundering and illegal kickback schemes). Various state agencies investigate these cases as well.

<sup>2</sup> The full press release can be found [here](#).



## » PDMP Data

Every state except Missouri has a prescription drug monitoring program (“PDMP”), an electronic database that tracks all controlled substance prescriptions statewide, based on information submitted by the dispensing pharmacy or doctor to a central clearinghouse. The PDMP data generally reflects the drug prescribed (type, strength, and quantity), the prescribing doctor, the patient, and the pharmacy at which the prescription was filled. Doctors can access this database for various purposes, such as pulling a patient’s history of filling controlled drug prescriptions to determine if the patient is “doctor shopping” – that is, getting multiple opioid prescriptions from multiple doctors at the same time. But the data is also accessible to investigators who use it, for example, to identify doctors who are writing high numbers of prescriptions for high doses of opioids or to determine whether doctors are prescribing repeated patterns of the same drugs or “cocktails” such as the “Holy Trinity,” a combination of an opioid, a carisoprodol (muscle relaxer), and a benzodiazepine (anti-anxiety drug), which the government maintains is a sure sign of an unscrupulous “pill mill” doctor.

In addition to being a goldmine of information for investigators, prosecutors typically attempt to admit the PDMP data at trial. In the Mobile, Alabama “pill mill” case I helped prosecute (*See “Part One: DOJ Devotes Resources, Vows to Come After ‘Pill Mills’”*), the government admitted PDMP data into evidence showing that during the four-year time period at issue, the two doctors wrote over 300,000 prescriptions for controlled drugs, including 6,000 prescriptions for “TIRF” drugs, a fentanyl-based<sup>3</sup> drug which the FDA has approved only for the treatment of breakthrough pain in cancer patients. The PDMP data also reflected that the doctors were the number one and two prescribers of fentanyl in the state.

## » ARCOS Data

ARCOS (the Automation of Reports and Consolidated Orders System) is an automated, comprehensive drug reporting system the DEA maintains which monitors the flow of controlled substances – from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing / retail level. ARCOS accumulates these transactions, which are then summarized into reports. Investigators use these reports, for example, to identify pharmacies that are receiving unusually high volumes of controlled drugs. And, once again, prosecutors will attempt to admit this evidence at trial. In the Mobile, Alabama case, the government admitted ARCOS reports into evidence showing that one of the doctors was, for several consecutive years, the number one distributor in the state of oxycodone, morphine, and fentanyl.

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<sup>3</sup> Fentanyl is a particularly powerful narcotic painkiller (a schedule II controlled substance) which is reportedly 100 times more potent than morphine and 40-60 times more potent than pure heroin. It comes in various dispensing forms, including an oral spray, dissolvable tablet placed under the tongue, a buccal tablet placed in the cheek, and a nasal spray.

## » Insurance Claims Data

Investigators also regularly obtain claims data from Medicare, Medicaid, and private insurance companies such as Blue Cross Blue Shield to show that there are “statistical outlier” doctors who are billing these insurance companies for large amounts of opioids. In that vein, CMS (the Centers for Medicare & Medicaid Services) contracts with outside “program integrity” companies who monitor and analyze claims / billing data to uncover suspected Medicare and Medicaid “fraud, waste, and abuse.” The results of these audits are often shared with investigators.

## II. RECORD SEARCHES

Investigators typically obtain the financial records of the pain management practice and its doctors in an effort to uncover evidence that the practice is a “cash only” business or the doctors are allegedly involved in illegal kickback and money laundering schemes (both of which were charged against the doctors in the Mobile, Alabama case). In addition, the government will use this financial data in an effort to locate, seize, and forfeit money and assets the doctors derived from the operation of their alleged “pill mill.” Investigators will also search disciplinary records to determine if the target doctor has a history of administrative discipline by the state medical board for allegedly inappropriate prescribing practices.

## III. SURVEILLANCE

Investigators commonly utilize surveillance tactics to monitor the activities of “street level” drug dealers. And they have carried over these tactics to the investigation of alleged “pill mills.” Investigators will personally surveil the practice or install “pole cameras” – video cameras installed on nearby utility poles – to record activities at the practice around the clock. Investigators look for what they claim are sure signs of a “pill mill” operation, such as long lines of people standing outside the practice and leaving after only a short visit, or unusual hours of operation to allegedly cater to drug-seeking patients. Through surveillance, investigators also attempt to identify patients who may be willing to testify or provide evidence against the practice or participate in an undercover operation, as explained in the next section.

## IV. UNDERCOVER OPERATIONS

A common investigative tactic in “pill mill” investigations is the use of undercover agents who pose as patients and schedule multiple appointments with the targeted “pill mill” doctor to obtain opioids. These meetings are secretly audio / video recorded. Some investigators opt to use actual, existing patients of the practice (if they are willing) to conduct these undercover meetings. The investigators analyze the recordings to determine if, for example, the doctor: met with the “patient” for a very short time period; failed to conduct a thorough physical exam and obtain a full medical history; failed to encourage alternatives to opioid treatment such as physical therapy; ignored signs of addiction;

suggested symptoms the “patient” should claim to feel; or instructed the patient to use a particular pharmacy.

In the Mobile, Alabama case, the government presented evidence at trial that an undercover agent posed as a patient and had four appointments with one of the targeted doctors during a six-month period. During the initial visit, the “patient” told a pain clinic employee that he had been self-medicating with opioids he had “bought on the street.” Thereafter, the doctor met with the “patient” for 43 seconds and prescribed him 90 oxycodone pills. During each subsequent visit, which occurred approximately a month apart, the “patient” received similar opioid prescriptions without even being seen or treated by the doctor.

## **V. ADMINISTRATIVE INSPECTIONS**

The DEA has a large cadre of “diversion investigators” (“DI’s”) who have the authority to conduct administrative inspections of premises registered or regulated by the agency after giving proper notice to the registrant. DI’s can use their authority to obtain an administrative inspection warrant (“AIW”) any time a registrant refuses to consent to an inspection or the DI believes that a civil or administrative sanctions are likely to result from the inspection. An AIW, however, has its limits – DI’s can only “inspect,” not “search,” a location, and only records required to be kept by DEA regulations may be inspected and copied. But, DI’s can, and often do, provide their findings to law enforcement investigators.

## **VI. SEARCH WARRANTS**

After the “covert” portion of an investigation is complete, investigators will “raid” the pain management practice and execute a search warrant, during which they will seize paper documents and “mirror image” the hard drives of the practice’s computers. Among other things, the investigators will target medical files and charts, financial records (such as payment records and ledgers), communications (including e-mails) by and between the targeted doctors and their employees, and employee personnel files.<sup>4</sup> During the search warrant execution, the investigators will attempt to interview office personnel and even the targeted doctors.

## **VII. EXPERT WITNESSES**

Investigators will provide the patient files and other pertinent records obtained during the search to expert witnesses, typically doctors who are pain management specialists. The government-retained doctors will inevitably testify at trial that, based on their records review, the target doctor was illegally

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<sup>4</sup> Investigators may attempt to obtain these documents by issuing a Grand Jury or administrative subpoena to the practice. But this is rare – because they typically do not want to alert the practice that it is being investigated before the investigation is complete.

prescribing drugs for illegitimate purposes. Thus, it is imperative that white collar attorneys who represent doctors and other healthcare professionals in a “pill mill” case retain – as early as possible – their own experts who can review the same records and opine that the doctor was engaged in the legitimate practice of medicine, not a criminal enterprise. Indeed, “pill mill” trials will often be decided by a “battle of the experts.”

White Collar Courier quote of the day:

**“ [T]here are continuing tensions between [law enforcement and medical] professionals, especially in the context of drugs. Law enforcement inhabits a professional space in which drugs (including abused prescription drugs) are the enemy: dangerous, deadly, and harmful. Physicians inhabit a professional space in which prescription drugs are useful tools, often helpful, and rarely deadly. These professional spaces converge at controlled substances, most of which have simultaneous potential for causing great harm and providing great benefit.”<sup>5</sup>**

→ Next Up: Part Four – ‘Pill Mill’ Red Flags and Strategies to Avoid Them

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**To discuss the information further, please contact:**

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or the Burr & Forman attorney with whom you regularly work.

*No representation is made that the quality of legal services to be performed is greater than the quality of legal services performed by other lawyers.*

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<sup>5</sup> Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanctions?* 42 AM. J.L. & MED. 7, 26 (2016).