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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 Two: What's At Stake for Medical Professionals In 'Pill Mill' Cases

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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 this installment, I discuss the varied consequences doctors and other medical professionals potentially face as a result of a "pill mill" investigation.

I. CRIMINAL PROSECUTION

A litany of criminal charges can be heaped on medical professionals at the conclusion of a "pill mill" investigation. Exactly what charges the government pursues will obviously depend on the facts and circumstances of each particular case. One charge that will inevitably be included in every "pill mill" indictment is an alleged violation of the Controlled Substances Act ("CSA"). The CSA governs the distribution and dispensing of various listed drugs, including narcotics, that are prescribed by doctors and other licensed medical providers. To issue a controlled substance, a doctor must be licensed to practice by a state authority and must have a DEA registration number.

Under the CSA, controlled substances are placed into one of five "schedules" based on whether they have a currently accepted medical use in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. The schedules are summarized as follows:

- **Schedule I** – these drugs have no acceptable medical use and a high potential for abuse. Examples include heroin and LSD, among others.
- **Schedule II** – these drugs have acceptable medical uses and a high potential for abuse. Most opioids are Schedule II drugs. Examples include: morphine (e.g., Avinza®); oxycodone (e.g., OxyContin®); hydrocodone (e.g., Lortab®); hydromorphone (e.g., Dilaudid®); and fentanyl (e.g., Subsys®).
- **Schedule III** – these drugs have acceptable medical uses and a potential for abuse that is less than schedule I and II drugs. One example is buprenorphine (e.g., Suboxone®).

- **Schedule IV** – these drugs have acceptable medical uses and a low potential for abuse relative to Schedule III drugs. Examples include: alprazolam (e.g., Xanax®); clonazepam (e.g., Klonopin®); diazepam (e.g., Valium®); and lorazepam (e.g., Ativan®).
- **Schedule V** – these drugs have acceptable medical uses and a low potential for abuse relative to Schedule IV drugs. Examples include cough preparations containing codeine.

To be convicted under the CSA, the government must prove that (1) the defendant doctor knowingly and intentionally distributed or dispensed a controlled substance, and (2) did so "for no legitimate medical purpose and outside the usual course of professional practice." Many "pill mill" defendants have argued that this standard is unconstitutionally vague because it does not define with enough certainty exactly what prescribing conduct is illegal, but this argument – at least to this point – has never worked.[1] One court has summarized the standard as simply "whether the doctor ha[s] knowingly and intentionally left the field of medicine altogether to become a criminal drug dealer."[2] But, in actuality, determining whether a doctor has illegally prescribed drugs under this standard is never simple and will necessarily involve a "battle of the experts," as detailed in "Part Three: Anatomy of a 'Pill Mill' Investigation."

Pain management professionals should be aware that doctors are not the only individuals who can be prosecuted under the CSA. In fact, non-licensed professionals, such as nurses and pain clinic and pharmacy owners, can be subject to liability under the CSA based on conspiracy and/or aiding and abetting theories; in other words, the government will attempt to prove that the non-licensed professional either conspired with or aided abetted a doctor in illegally prescribing drugs.

A criminal conviction for violating the CSA may result in a vast array of prison sentences under the federal Sentencing Guidelines, a set of advisory sentencing rules that establish a uniform policy for individuals convicted of felony crimes in federal court. The exact range may vary significantly from case-to-case, depending primarily on the type and quantity of controlled substances involved. These ranges can be staggeringly severe. In the Mobile, Alabama pill mill case I helped prosecute, *See* "Part One: DOJ Devotes Resources, Vows to Come After 'Pill Mills,'" the doctors each faced a guidelines range of imprisonment of 30 to 240 *years*, although the court sentenced them well below that range (20 and 21 years, respectively) – as it had the discretion to do. In addition to applicable guidelines range in each case, the CSA provides for statutorily "enhanced" sentences in certain circumstances. For instance, if the government proves that a patient's death resulted from the distribution of a Schedule II controlled substance, the convicted doctor will face a sentence of *no less* than 20 years and up to life in prison.

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[1] *See, e.g., United States v. MacKay*, 715 F.3d 807, 824 (10th Cir. 2013) (finding that the CSA is not unconstitutionally vague as applied to a pain management doctor); *United States v. Deboer*, 966 F.2d 1066, 1068-69 (6th Cir. 1992) (denying void-for-vagueness challenge to the CSA because a pharmacist's responsibilities giving rise to unlawful conduct were "clearly defined"); *United States v. Birbragher*, 576 F. Supp. 2d 1000, 1012-13 (N.D. Iowa 2008) (finding the CSA provides adequate notice of the proscribed conduct by doctors).

[2] *United States v. MacKay*, 20 F. Supp. 3d 1287, 1297 (D. Utah 2014).

Note that, as mentioned, although an alleged violation of the CSA will be at the core of every "pill mill" indictment, there is laundry list of other charges the government can – and often does – pursue, including, among others: healthcare fraud, mail and wire fraud, prescription "misbranding," money laundering, violations of the Anti-Kickback Statute, and violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO").

II. SEIZURE AND FORFEITURE

In almost every "pill mill" case, the government will attempt to seize (take possession of) and forfeit (take ownership of) bank accounts, business assets, and personal assets of the targeted medical professional based on a theory that they are "proceeds" of the alleged "pill mill" operation or somehow "facilitated" the purported criminal enterprise. For example, following the doctors' convictions in the Mobile, Alabama case, the government seized and forfeited their bank accounts, investment and retirement accounts, college fund accounts, houses, beach-fount condominiums, and 20-plus luxury automobiles.

III. CIVIL LIABILITY

On top of criminal prosecution, a "pill mill" investigation could result in a civil lawsuit by the government against the targeted doctor or medical professional, to the extent they have billed a federal health care program. For instance, the government might bring a direct suit under the False Claims Act ("FCA"), alleging that the doctor made false diagnoses, prescribed drugs for non-covered indications, or prescribed excessive or "medically unnecessary" drugs for Medicare or Medicaid patients. Likewise, the government may join in a "qui tam" suit which is initiated by a "whistleblower" – such as a current or former employee of the practice – claiming that the targeted doctor or practice has violated the FCA and other laws. In the Mobile, Alabama case, the doctors' criminal prosecution was actually preceded by a *qui tam* lawsuit filed by the practice's clinical supervisor alleging that the doctors submitted false claims to federal health care providers by, among other things, overbilling for urine drug screen tests and billing for doctor office visits when patients were actually seen by non-licensed staff members.

IV. ADMINISTRATIVE PROCEEDINGS

In addition to facing criminal prosecution, the loss of assets, and civil liability, doctors investigated or charged in a "pill mill" case can be subject to a number of administrative sanctions. The DEA, in particular, has a range of administrative actions it can take, such as: issuing a letter of admonition to the registrant providing notice of a violation of the applicable law / regulations; requiring the registrant to enter into a memorandum of understanding agreeing to take certain corrective steps to avoid revocation of the registrant's DEA certificate; or, for the most serious alleged violations, pursuing a show cause order to appear before an administrative law judge, during which the DEA will advocate for revocation of the registrant's DEA certificate.

Like the DEA, state professional boards (such as medical licensure and pharmacy boards) have disciplinary authority and can sanction practitioners for professional violations, such prohibiting a doctor from prescribing specific schedules of drugs, suspending a doctor's medical and/or dispensing license, or revoking his or her license to practice medicine.

Further, the Centers for Medicare & Medicaid Services ("CMS") may limit, suspend, or revoke a provider's Medicare billing privileges for, among other things, noncompliance with Medicare enrollment requirements, a felony conviction related to controlled substances, or a pattern of improper prescribing or billing practices. Likewise, state Medicaid agencies can impose various administrative sanctions against providers, including outright exclusion from the program.

White Collar Courier quote of the day: "Prescription opioids are an important tool for physicians in treating pain but also carry significant risks of harm when prescribed inappropriately or misused by patients or others. Recent increases in opioid-related morbidity and mortality ha[ve] reignited scrutiny of prescribing practices by law enforcement, regulatory agencies, and state medical boards."[3]

→ Next Up: "Part Three: Anatomy of a 'Pill Mill' Investigation"

To discuss the information further, please contact:

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[3] 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).