F·L·O·R·I·D·A
DEFENDER

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Rx DEFENDING THE PRESCRIPTION CASE

Prescription: Violate Title 18 U.S.C. Section 846 and 841

Side effects include imprisonment, fines, supervised release, special assessments, attorney's fees and loss of livelihood

Rx DEFENDING THE PRESCRIPTION CASE

by David Barksdale

Allan F. Brooke II

and Ashley W. Greene

You page through the indictment. This is one nasty case. The charge is conspiracy to distribute controlled substances, with a handful of individual counts, as well as several counts of healthcare fraud and money laundering. The prosecutor told you that the drugs this woman "sold" were among the most addictive people could buy and constantly calls her a "pusher," and refers to "life-wrecking, soul-shattering, family-destroying drugs masquerading as medicine." Nevertheless, when you interview this client, you see a smallish woman in her fifties, composed and intelligent. She sits across from you and claims she has never been in trouble before in her life. The human facts are bad, the medical science is daunting, the potential penalties are huge. This is the prescription drug case: Is she a doctor or a drug dealer?

PAIN IN AMERICA

These cases require an understanding of pain and the medical profession's struggle to treat it. Pain is real and it disrupts many lives. Medicine, especially opioids, can give relief and allow people to function in their families, workplaces and communities. Misused, they can lead to addiction or even death. Prescription drug prosecutions reflect the conflicting societal interests in the medical relief of chronic pain (which affects the daily life, work and family of millions of people) and the elimination of drug abuse (with its concomitant social ills).

Millions of Americans suffer from acute pain — which will exist for a relatively short time — or chronic pain — which may persist months or years. The annual national economic cost in medical treatment and lost productivity associated with chronic pain is up to $635 billion."[1] "Physicians…face a dual imperative of ensuring the availability of opioids to patients with legitimate medical need while minimizing the potential for their misuse."[2] Over the last 20 years, there has been an increasing awareness that pain is not just a symptom of injury and illness, but it is itself a medical condition with consequences for the individual and for society. In the late-1990s, it became common for medical providers to call pain "the fifth vital sign," a critical part of the assessment and treatment of patients.[3] (The four other vital signs are body temperature, pulse rate, blood pressure and respiratory rate).

Opiates have been used to treat pain for centuries. Most modern pain medications are chemically related to derivatives of the opium poppy. Where the derivatives occur naturally in the opium poppy, they are referred to as *opiates* (e.g. morphine, codeine and thebaine), whereas similar synthetic or semi-synthetic medicines are referred to as *opioids* (e.g., hydrocodone, oxycodone, hydromorphone). The FDA has approved numerous opioids for the relief of "moderate to severe" pain, including Chronic Non Cancer Pain (CNCP). Various organizations — federal, state, private and international — have participated in ongoing dialogues concerning the use of such medicines. These dialogues have not always resulted in clear guidance for doctors.

There are no maximum dosages for these drugs, either medically or legally. For example, there is no "maximum daily dosage" of oxycodone such as "450 mg/day" or even "*x* mg/lb/day." There is also no legal "safe harbor" daily dosage below which a physician might be assured that she would not be prosecuted. There is spirited debate in health care about the proper use of opioids to treat pain, but it is well within accepted medical practice to treat chronic non-cancer pain with opioids.[4]

LEGAL BACKGROUND AND ISSUES: WHEN IS A PHYSICIAN A DRUG DEALER?

When a person is caught with a kilo of cocaine, applying the law is easy — people aren't supposed to have cocaine. But applying criminal narcotics laws to the prescription of pain medication can be odd and complicated. After all, doctors[5] are allowed to prescribe pain medication, and do so lawfully every day. Many readers have been prescribed medication such as hydrocodone. Presumably, far fewer readers have seen cocaine, outside of the movies or a police property room, but the same federal laws are used to prosecute street

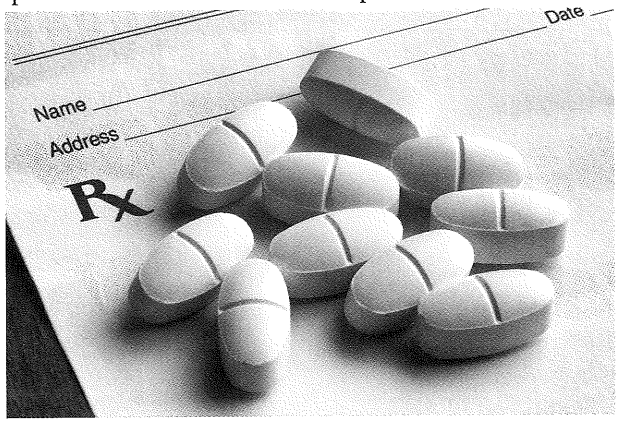
drugs and prescription medication: The Controlled Substance Act, 21 U.S.C. 841. So, when should a health care provider be viewed by the criminal law as a drug dealer?

It is well-settled that regulation of the practice of medicine occurs primarily at the state level, and that in connection with the Controlled Substances Act, Congress has not "set general, uniform standards of medical practice." *Gonzales v. Oregon*, 546 U.S. 243, 271 (2006) (noting a single exception in the area of "medical treatment of narcotic addiction."[6]) Nevertheless, the practice of medicine is heavily impacted by federal law, including regulations promulgated by the FDA and DEA. Private organizations, including the American Medical Association, The Federation of State Medical Boards of the United States, Inc., state medical associations, The American Pain Society, and The American Academy of Pain Medicine, also contribute to the understanding of appropriate medical practice.

> In 1970, the CSA was enacted [w]ith the main objects of combating drug abuse and controlling legitimate and illegitimate traffic in controlled substances, [creating] a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules.

Gonzales, at 250. Sections 828 and 844 exempt physicians from the ban so long as they act "in course of [their] professional practice...." By regulation, "a prescription for a controlled substance... must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. §1306.04.

In federal prosecutions based on prescribed pain medication, the question is whether a prescription was for "legitimate medical purpose" issued by a practitioner "acting in the usual course of his professional practice"? Most believe that criminal laws should clearly and plainly define the actions which people should expect to send them to prison. Unfortunately, the legal standard of "legitimate medical purpose...in the usual course of professional practice" is neither clear nor plain.



The DEA Museum website (www.goodmedicinebadbehavior.org, see particularly the section on pain management) states, "[t]here are no specific guidelines concerning what is required to support a conclusion that an accused doctor acted outside the usual course of professional practice when prescribing medicines for pain." Indeed, the DEA concedes

> [t]here is a lack of consensus among physicians as to all the circumstances that warrant the use of opioids to treat pain.... The courts have recognized there are no definitive criteria laying out precisely what is legally permissible, as each patient's medical situation is unique and must be evaluated based on the entirety of the circumstances. *Id.*

States, of course, have their own medical boards and administrative codes. Is the physician to be judged by a local, state or national standard? Is an internist to be evaluated by the same criteria as the pain management specialist? In 2012, the Eleventh Circuit brought some clarity to the question, by noting that in the absence of national standards governing professional practice for the treatment of chronic pain, state standards would govern professional practice. *United States v. Tobin*, 676 F.3d 1264, 1275-1276 & n. 8, 10 (11th Cir. 2012), *abrogated on other grounds* by *United States v. Davila*, 133 S. Ct. 2139 (2013). But, *compare United States v. Mack*, 709 F.3d 1082, 1094-1096 (11th Cir. 2013).

The application of law to facts in the Eleventh Circuit is a combination of objective and subjective evaluation. A physician's good faith belief that she was acting for legitimate medical purposes is relevant. *Tobin*, 676 F. 3d 1264, 1282-1283. The jury should thus consider whether she subjectively believed her prescriptions served a legitimate medical purpose. Whether a physician was practicing outside the usual course of professional practice, however, is evaluated from an objective standpoint, using state standards. *Id.* n.10.

Florida law clearly and specifically states that opioids "may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins." The law explicitly warns against *undertreatment*, and states:

> Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regularly agencies may also result in inappropriate or inadequate treatment of chronic pain patients.

F.A.C. 64B8-9.013(1)(b).

Florida physicians are required to "as appropriate, comply with a request for pain management or palliative care...." Fla. Stat. §765.1103. Under Florida's Patient's Bill of Rights, Fla. Stat. §381.026, "a patient has the right to access any mode of treatment that is, in his or her own judgment and the judgment of his or her health care practitioner, in the best interests of the patient" (4)(d)(3). Nevertheless, a

> patient is responsible for providing

> to the health care provider... accurate and complete information about present complaints, past illnesses, hospitalizations, medications, and other matters relating to his or her health.

Id. at (6). A physician practicing within the standard of case may treat chronic pain patients with controlled substances in significant amounts, even if the patient is addicted. *See Forlaw v. Fitzer*, 456 So. 2d 432 (Fla. 1984); *Johnston v. Dept. of Professional Regulation*, 456 So. 2d 939 (Fla. 1st DCA 1984).

Prescription cases often include conspiracy counts. A good faith standard applies to the conspiracy elements, such that a conviction "under Section 846 requires evidence of willfulness on the part of the defendant." *Tobin*, 676 F. 3d at 1284. The Government must prove that the co-conspirator entered into an agreement to achieve an unlawful objective. An alleged co-conspirator's lack of knowledge regarding illegal objectives of the conspiracy and his good faith belief that his conduct was legal are both relevant to the charge of conspiracy. *Id.* at 1285. Medical facility employees, such as nursing assistants, may be in a strong position to argue that they only did the job they were hired for, and cannot be guilty of conspiracy where doctors made the medical decisions.

Several reported decisions (collected in the footnotes) provide context and under-standing for the defense of prescription cases.[7] There is a vast background medical literature. The DEA periodically updates information about physician prosecutions at www.deadiversion.usdoj.gov/crim_admin_actions/.

MEDICAL CHARTS

Medical charts are always daunting. Often poorly copied, they are hard to decipher and harder still to understand. Nevertheless, there is no substitute for comprehending the medical charts as a way of re-creating the facts which faced the physician-defendant. The lawyer needs an expert interpreter and the client can be a real asset. Though the medical field is turning to electronic records, many charts still are kept by hand, especially in smaller practices. Just as lawyers have their individual preferences for file maintenance, there is no specific format for a medical chart. Defense counsel should not assume that the police or prosecutor has a thorough knowledge and understanding of the medical charts. It may well be that the medical charts are good evidence of a physician's lack of criminal intent. In some cases, the prosecutor may focus only on certain patients. Although HIPAA concerns must be addressed, it may be helpful to illustrate the doctor's overall body of work, including patients whose treatment is not included in the charging document. Put simply, if the Government questions ten charts but the doctor properly treated another 100 patients, the other 100 will raise real doubts that the doctor is "nothing more than a drug dealer."

Physicians operating in good faith will often discharge patients who present showing signs of drug abuse. Reasons for discharge may include non-compliance with pain management contracts; needle marks or other evidence of street drug usage; or periodic drug test results that are negative for the prescriptions, thereby suggesting the patient is diverting the medication. The defense team may consider how to prove the number of patient discharges to show the physician's good faith. This may involve an independent witness or the defense expert to count and categorize the reasons for discharge.

The Florida Administrative Code provides some minimal guidance for record keeping. These standards can be used to illustrate, perhaps through a Government or defense expert, that the physician's treatment is within the normal course of professional practice. For example, for osteopathic physicians, F.A.C. 64B15-14.005(3)(f) provides that the medical chart should provide at the minimum:

- The complete medical history and a physical examination, including history of drug abuse or dependence as appropriate;
- Diagnostic, therapeutic and laboratory results;
- Evaluations and consultations;
- Treatment objectives;
- Discussion of risks and benefits;
- Treatments;
- Medications (including date, type, dosage, and quantity prescribed);
- Instructions and agreements;
- Drug testing results; and
- Periodic reviews.

It may be possible to show through the Government or defense expert that the questioned charts consistently provide all of this information, thus cutting against criminal intent.

The guidelines for medical records can be a way to organize the defense expert's review of patient charts. The expert can use a checklist to evaluate charts for compliance with the administrative code. Experts, like all people, tend to have bias in what they focus on. Using a checklist can prompt an objective review of individual charts. These Florida Administrative Code standards[8] may also be useful for cross-examination of the Government expert.

PATIENTS

A bone is broken, and the fracture shows on an x-ray. Cancer cells show up on slides after a biopsy. Thyroid problems are revealed through blood tests. Pain — every bit as real — has no corresponding diagnostic test. The experience of pain is as subjective as it is personal, but it is nonetheless real, and a physician must treat it. While doctors must take steps to identify drug abuse, the reality is that patients are not always candid with physicians. It is important for the jury to understand the difficulties facing the physician who is being lied to by the patient.

Of course not all those who visit the doctor will prove to be patients seeking medical treatment. In preparing for trial, it is useful to break patients down into categories: 1) undercover law enforcement officers attempting to mislead the doctor, 2) drug seekers who lie about

their condition, and 3) real patients.

In preparing to cross examine undercover law enforcement officers and drug seekers, it is important to highlight the dishonest statements they made to the doctor and staff—whether in writing or verbally. The doctor's actions will also be scrutinized. How thorough was the doctor's examination and background questioning for the patient? If the patient received regular refills, did the doctor employ periodic drug testing? Was there an effort to titrate the dose (titration is the adjustment of the dosage to the minimum effective prescription)? Did the physician refer the patient for alternative treatment, such as surgical intervention or physical therapy?

The prosecution may present patients whose condition and testimony can actually highlight the benefits of medication. Many patients exaggerate symptoms to obtain more pain medication, but have real health problems ameliorated by pain medications. If the patient was in an accident, have her describe the details. The medical history given by the patient to the doctor's office may provide fertile ground for cross examination. The medical charts may contain evidence about how medication helps the patient work and perform everyday tasks.

The defense team may want to interview legitimate patients, to demonstrate appropriate care. The physician-client may be able to identify specific patients in this regard. This can be powerful evidence, since drug dealers have no legitimate customers, but it is important not to underestimate the ability of the government to cast doubt on the medical needs of the legitimate patients.

EXPERT WITNESSES

The government will use experts to opine that prescriptions were not issued in the normal course of professional practice and for legitimate medical purpose. This will include one or more physicians, and, if the case involves deaths, medical examiners. The government expert will review some or all patient medical charts. Sometimes, the government will list separate pharmacology experts to discuss the specifics of the medicine and its impact on the body.

It is useful to know about an expert's own practice and whether she actually treats pain patients rather than pursuing academic research or practicing in addictionology or another specialty. Often the Government will provide its expert with a selection of a doctor's charts. An expert's opinion may be less persuasive if she only reviewed a relatively small number of the overall charts. Through discovery and the expert report, it is important to determine who decided which medical charts were chosen for review by the Government expert, and how they were chosen. The medical charts may permit defense counsel to establish helpful information through the government's expert, especially if the chart contains adequate documentation of history and physical, periodic drug testing, titration of medication, or referrals for other treatment such as surgery consults and physical therapy.

Most government experts will agree that tens of millions of people suffer from chronic pain, that the healing profession has to an extent re-educated itself to recognize that pain is a real thing, and that medications are a legitimate part of the treatment of pain. They will agree that pain is largely subjective, and that ailments affect people differently. Experts should acknowledge that opioids can be prescribed for moderate to severe pain, and that their use is not limited to end-of-life conditions.

The government expert may also concede that while physicians must be careful to try to recognize drug abuse, the healthy physician-patient relationship must be premised on trust. Physicians cannot cross examine their patients like police detectives. And just as different lawyers handle cases in different ways, different doctors may use different treatment techniques.

Expert testimony can present confrontation issues, especially under the robust *Crawford v. Washington*, 541 U.S. 36 (2004) case law which has re-invigorated the Confrontation Clause of the Sixth Amendment. For example, in *U.S. v. Ignasiak*, 667 F.3d 1217 (11th Cir. 2012), the Government introduced autopsy reports through a medical examiner who did not perform the autopsies. The Eleventh Circuit reversed because the defendant was not able to confront and cross examine the medical examiners who did the autopsies and prepared the reports. *Id.* at 1237.

For a government expert, the defense will seek disclosure of a list of cases in which the expert has testified on behalf of the state or federal Government (as well as the compensation paid); the expert's hourly rate and total compensation for the current case; and any civil or criminal state, federal, or regulatory investigations or charges against the expert.

The government will often emphasize the sheer number of pills prescribed, effectively arguing that with this many pills somebody must be doing something wrong. Here, again, the Florida practice standards in the Florida Administrative Code are important. Physicians are instructed by regulation that, "[t]he Board [for Medicine or Osteopathic Medicine] will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing".[9] The defense may consider a motion to exclude sheer numbers as lacking context and being unduly prejudicial. *But, see United States v. Merrill*, 513 F.3d 1293 (11th Cir. 2008) (probative value of more than 33,000 prescriptions for controlled substances was not outweighed by the danger of unfair prejudice).

MOTIONS PRACTICE

Depending on the specificity in the charging document, the following are some matters for a motion for statement of particulars:

- The identity of all individuals whose prescriptions the Government alleges are unlawful.
- The standard of care the Government believes against which the physician's conduct should be measured,

including the source for that standard of care (regulations, laws, other sources).
- What a physician specifically did or did not do to violate the standard of care.

Prescription fraud cases can involve many players, including multiple cooperating defendants and many patients. Much potential *Brady* or *Giglio* material may be available. The evidence can be difficult for the prosecution to marshal, and the reality is that some *Brady/Giglio* material might not even make it to the prosecutor's attention. The larger the case, the larger the potential for inadvertent failure to disclose.[10]

It is well-settled, however, that "the suppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence is material either to guilt or punishment, irrespective of the good faith or bad faith of the prosecution." *Brady v. Maryland*, 373 U.S. 83, 87 (1963). This includes impeachment and exculpatory evidence. *Youngblood v. West Virginia*, 547 U.S. 867, 869 (2006). The prosecution must establish procedures to ensure that all favorable evidence known to any Government agent is disclosed. *Kyles v. Whitley*, 514 U.S. 419, 438 (1995). "In the state's favor, it may be said that no one doubts that police investigators sometimes fail to inform a prosecutor of all they know. But neither is there any serious doubt that 'procedures and regulations can be established to carry (the prosecutor's) burden and to ensure communications of all relevant information on each case to every lawyer who deals with it.'" *Id.* at 438, *quoting Giglio v. U.S.*, 405 U.S. 150, 154 (1972).

The defense might consider specific *Brady/Giglio* requests for information such as the following:
- Government interviews of patients which were favorable to the defense, such as patients who describe themselves to the investigators as legitimate pain patients.
- Patients who told investigators that they had made misrepresentations about their medical condition or prescription histories to try to obtain prescriptions.
- Witness criminal records.
- Any explicit or implicit threats to witnesses or alleged co-conspirators.
- All documentation of monetary or other consideration paid to confidential sources or other witnesses.
- Existence and substance of any verbal or written promises between the Government and witnesses or their families, including leniency at sentencing.
- Patient medical records from other healthcare providers.

It may be appropriate to file motions *in limine* asking the court to prohibit the use of derogatory, non-relevant terms such as "pill mill" or "script doctor" and to exclude any reference to societal problems with pain clinics or to prescription pain pill problems. Even if not granted, such motions may serve to temper the language of the prosecutor and prosecution witnesses.

PARALLEL ADMINISTRATIVE PROCEEDINGS

A physician may receive notice that the Drug Enforcement Administration seeks administrative revocation of the physician's authority to prescribe controlled substances. This parallel administrative proceeding can provide opportunity for discovery. On the other hand, the physician, with the assistance of counsel, has to decide whether to give testimony. The DEA administrative judges usually do not stay the proceedings pending the outcome of criminal investigations. Moreover, the DEA lawyers will often narrow their cases to only a few patients, and so the discovery benefit for the criminal case is only limited.

To revoke the prescribing license, the DEA has to show "substantial evidence" (21 C.F.R. 1301.44, as applied by case law) that the registrant:
- has materially falsified any application…;
- has been convicted of a felony under this subchapter or subchapter II of this chapter, or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;
- has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had a suspension, revocation, or denial of his registration recommended by competent State authority;
- has committed such acts as would render his registration under Section 823 of this title *inconsistent with the public interest* as determined under such section; or
- has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of title 42.

21 U.S.C. §824 (emphasis supplied).

This standard—"inconsistent with the public interest"—makes it difficult for the physician to prevail when the DEA seeks revocation of the physician's registration to prescribe controlled substances.

JURY INSTRUCTIONS

The jury instructions in these cases must supplement the standard instructions for violations of the Controlled Substances Act. The jury must be informed that practitioners prescribing for legitimate medical purposes within the usual course of professional practice are not violating the law. Further, a controlled substance is prescribed by a physician for a legitimate medical purpose in the usual course of professional practice and, therefore, lawfully, if she prescribed the controlled substance in good faith as part of her medical treatment for the patient in accordance with the standards of medical practice generally recognized and accepted in the state.[11] The jury may consider the totality of the circumstances, including evidence

of accepted professional standards of care in effect at that time, and expert testimony regarding the wide range of treatment options and that physicians have discretion to choose among those options. The jury must also understand this is not a medical malpractice case. The physician has only violated Section 841 when the government has proved beyond a reasonable doubt that the physicians' actions were not for legitimate medical purposes or were outside the usual course of professional practice. The lawyer, of course, will want to review jury instructions from other cases that were requested or given.

CONCLUSION

We all want our doctors to be caregivers. The role of a physician is not to mass produce a commodity, but to look at individual patients and make individualized treatment decisions. No doubt there are some physicians who have converted their medical licenses into licenses to sell prescription drugs. It is properly the role of the defense attorney to demonstrate that the defendant was making individualized medical decisions; not "pushing" drugs in violation of state and federal law.

[1] Board on Health Sciences Policy (HSP), *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*, "Summary" (revised March 2012) (excerpted online at http://books.nap.edu/openbook.php?record_id=13172&page=1).

[2] G.M. Reisfield, et al., "Review: Rational Use and Interpretation of Urine Drug Testing in Chronic Opioid Therapy," *Annals of Clinical and Laboratory Science*, 37:4 (2007).

[3] See, e.g., Veterans Health Administration, Pain as the 5th Vital Sign Toolkit (rev. ed. Oct. 2000).

[4] For a lawyer who is talking with a prosecutor or to a jury, part of the challenge is to develop medical issues without either oversimplifying or confusing the audience. Some key medical and legal definitions of terms are found in the attached glossary.

[5] These cases may involve either a medical doctor or osteopath. Although these days D.O.s and M.D.s work interchangeably in all medical facilities and are not distinguished for most legal purposes, Florida has a Board of Medicine and a Board of Osteopathic Medicine, and the regulatory structures are formally distinct. For doctors of medicine, the Standards for the Use of Controlled Substances for the Treatment of Pain in the Florida Administrative Code are 64B8-9.013. For osteopaths, the Standards for the Use of Controlled Substances for the Treatment of Pain in the Florida Administrative Code are 64B15-14.005. These standards may be important to proving the client followed state standards. The Federation of State Medical Boards of the United States, Inc. adopted a revised Model Policy for the Use of Controlled Substances for the Treatment of Pain on May 1, 2004. This model was codified by many states in whole or in part, including Florida. The Model Policy was revised in July 2013 as the Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain. The Florida Administrative Code provisions for the Standards for the Use of Controlled Substances for the Treatment of Pain are variations of the Model Policy.

[6] In 2008, Congress enacted a second exception, establishing a national standard for internet prescriptions. See *U.S. v. Tobin*, 676 F.3d 1264, 1276-1277 (11th Cir. 2012).

[7] The following are notable cases: *Gonzales v. Oregon*, 546 U.S. 243 (2006) (striking down the Attorney General rule assisting suicide was not a legitimate medical purpose and could lead to the revocation of a physician's DEA registration; the Supreme Court stated, "[a]ll would agree, we should think, that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense." *Id.* at 258); *United States v. Moore*, 423 U.S. 122 (1975); United States v. Joseph, 709 F.3d 1082 (11th Cir. 2013) (detailed analysis of jury instructions); *United States v. Ignasiak*, 667 F.3d 1217 (11th Cir. 2012); *United States v. Webb*, 655 F.3d 1238 (11th Cir. 2011); *United States v. Johnston*, 322 Fed. Appx. 660 (11th Cir. 2009); *United States v. Merrill*, 513 F.3d 1293 (11th Cir. 2008) (probative value of more than 33,000 prescriptions for controlled substances was not outweighed by the danger of unfair prejudice); *United States v. Williams*, 445 F.3d 1302 (11th Cir. 2006), abrogated on other grounds by *United States v. Lewis*, 492 F.3d 1219 (11th Cir. 2007); *United States v. Bourlier*, 2011 WL 30301 (N.D. Fla. 2011) (order denying a physician's motion to dismiss indictment); *United States v. Steele*, 147 F.3d 1316 (11th Cir. 1998) (prosecution of pharmacist); *United States v. Betancourt*, 734 F.2d 750 (11th Cir. 1984) (prosecution for unlawful dispensing of methaqualone); *United States v. Hernandez*, No. 07-60027-CR, 2007 WL 2915854 (S.D. Fla. Oct. 4, 2007) (ruling on various pretrial motions in prescription case); *U.S. v. Greenfield*, 554 F.2d 179 (5th Cir. 1977) (physician not guilty where a patient, through lies and deception, convinces a physician of a legitimate medical purpose for prescriptions).

[8] 64B8-9.013(3)(f); 64B15-14.005(3)(f).

[9] FAC 64B15-14005(1)(g) [osteopathy]; FAC 64B8-9.013(1)(g) [medicine].

[10] For example, in *United States v. Ignasiak*, 667 Fed. 3d 1217 (11th Cir. 2012), the prosecutor after trial filed under seal a notice that the Government's medical expert had on multiple occasions used a counterfeit badge of United States Marshal credentials to carry firearms on airplanes and had entered a pretrial diversion program with another United States Attorney's Office. The Ignasiak trial prosecutor apparently did not know about the Government expert's conduct, or the diversion agreement. The Ignasiak conviction was reversed on other grounds, and the Eleventh Circuit stated, "[t]o say that the defense would have preferred to use this information to discredit Dr. Jordan's testimony is almost certainly an understatement." *Id.* as 1238.

[11] *Tobin*, 676 F.3d at 1282-1283. But, compare *United States v. Mack*, 709 F.3d 1082, 1094-1096 (11th Cir. 2013).

DAVID BARKSDALE practices white collar and non-white collar criminal defense at The Bedell Firm. He is Board Certified in Criminal Trial. David is listed in The Best Lawyers in America (White Collar and Non-White Collar Criminal Defense), Florida Trend's Legal Elite (Hall of Fame) and Super Lawyers (Florida's Top 100, 2013 and 2014). He is a member of the Executive Council of the Florida Bar's Criminal Law Section. Along with the co-authors, David tried a prescription case in the Middle District of Florida which resulted in acquittals.

ALLAN F. BROOKE II has degrees in physics, astronomy, literature, theology and law. He graduated from Vanderbilt University in 1979, and Dallas Theological Seminary in 1986. In 1992, he graduated with honors from the University of Texas School of Law, where he was an Executive Editor of the Texas Law Review and an Associate Editor of the American Journal of Criminal Law. He has repeatedly been listed in The Best Lawyers in America and similar publications. His current areas of concentration include white-collar criminal defense, appellate litigation, and complex commercial litigation. He speaks and teaches frequently on legal, theological and literary topics

ASHLEY W. GREENE is an attorney at The Bedell Firm. Her practice includes both state and federal criminal defense work. She graduated magna cum laude from Duke University in 1997. She graduated with honors from Northwestern School of Law in 2002 and was appointed to the Order of the Coif. After graduating law school, She practiced two years as a Skadden Fellow attorney at Atlanta Legal Aid Society, Inc., then spent a year and a half at the State Attorney's Office in Jacksonville, prosecuting both misdemeanor and felony cases. She serves on the Florida Supreme Court Criminal Law Jury Instruction Committee.

GLOSSARY OF MEDICAL TERMS

(including selected legal definitions, where existing)

ACUTE PAIN, SUBACUTE PAIN, CHRONIC PAIN. *Acute pain* is relatively short in duration, with specific, expected causes. *Chronic pain* is of extended duration, and its causes may be poorly understood. Subacute pain is of intermediate duration.

Acute pain and *chronic pain* are legally defined:

(a) **Acute Pain.** For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies....

(d) **Chronic Pain.** For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

Fl. Admin. Code 64B15-14.005 (2)(a, d) ("Standards for the Use of Controlled Substances for Treatment of Pain") (2006).

ADDICTION, DEPENDENCE, PSEUDOADDICTION, AND SUBSTANCE ABUSE. The definition of *addiction* and these related terms, is not entirely settled in medicine and psychiatry, and popular and legal definitions diverge. It is important to use these terms carefully and consistently.

Legally, however, *addiction*, *physical dependence*, *pseudoaddiction* and *substance abuse* are distinct concepts defined in Florida law:

(b) **Addiction.** For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction....

* * *

(f) **Physical Dependence.** For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) **Pseudoaddiction.** For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) **Substance Abuse.** For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Fl. Admin. Code 64B15-14.005 (2006) (2)(b, f-h).

ANALGESIC TOLERANCE, TOLERANCE. The safe and effective dose of an analgesic (such as oxycodone) will typically increase for a given patient even where the underlying cause does not develop. Whereas *x* mg of a drug may dull the patient's pain on day one, it may be necessary to prescribe 5*x* mg of the drug to achieve the same palliative effect after the patient has taken the medicine for a month. This is not equivalent to abuse, but is a known medical effect:

Tolerance is the phenomenon whereby chronic exposure to a drug diminishes its antinociceptive or analgesic effect, or creates the need for a higher dose to maintain this effect. In other words, the tolerant organism is less susceptible to the pharmacological effects of a drug as a consequence of its prior administration.

S.M. South and M.T. Smith, International Association for the Study of Pain, "Analgesic Tolerance to Opiods" (December 2001) (citing Foley KM. Neurol Clin 1993; 11:503-522).

This effect is explicitly recognized in the law:

Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

Fl. Admin. Code 64B15-14.005 (1)(c).

The terms are defined in the law:

(c) **Analgesic Tolerance.** For the purpose of this rule, *analgesic tolerance* is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction....

(i) **Tolerance.** For the purpose of this rule, *tolerance* is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Fl. Admin. Code 64B15-14.005 (2)(c, i).

METABOLITES. Products of the metabolism of medications or foods, thus typically found in the blood, tissues, or urine. Thus, for example, benzoylecgonine is the major metabolite of cocaine which can be detected in the urine of someone who has used cocaine recently.

OPIATES, OPIOIDS. Naturally occurring derivatives of the opium poppy, such as morphine, codeine and thebaine, are typically referred to as *opiates*, whereas similar synthetic or semi-synthetic compounds (e.g. hydrocodone, oxycodone, hydromorphone) are often referred to as *opioids*.

TITRATION. In a clinical setting, *titration* is the process of adjusting the dosage and amount of a medication until the optimum effect (e.g. maximum pain relief with acceptable side effects) is achieved.