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Defending Hippocrates:

Representing Physicians in the Wake of the Opioid Epidemic

In the wake of the opioid epidemic, federal and state prosecutors are becoming increasingly aggressive in investigating and prosecuting DEA registrants who deviate from professional norms.[1] If a physician prescribes controlled substances "for other than a legitimate medical purpose" or "outside the course of professional practice,"[2] 21 U.S.C. § 841(a) and 21 C.F.R. § 1306.04 make it a felony punishable by up to 20 years in prison.

United States v. Moore was the first case in which the Supreme Court determined that a physician could be prosecuted under the Controlled Substances Act ("CSA").[3] In *Moore*, the Supreme Court held that physicians were not exempt from prosecution under the conventional drug delivery prohibition of 21 U.S.C. § 841(a)(1) and could be convicted for prescribing "outside the usual course of professional practice."[4] The court's opinion in *Moore* hinged on the fact that Dr. Moore clearly was not acting in any way as a physician.[5] The court did not go so far as to say that Dr. Moore could be prosecuted for departing from ordinary standards of medical practice.[6] In the wake of *Moore*, federal circuits have struggled with the phrases "legitimate medical purpose" and "usual course of professional practice." This misunderstanding has led to the judicial creation of a criminal "standard of care" for appropriate prescribing.

The Supreme Court stayed relatively silent regarding the standard required to convict a physician of unlawful distribution until 2005. That year the Court decided *Gonzales v. Oregon* and reaffirmed that the regulation of medical practice is reserved for the states and that the CSA does not regulate the practice of medicine beyond prohibiting a doctor from acting as a "pusher" instead of a physician.[7] The Supreme Court determined that states' rights to regulate the practice of medicine were only preempted insofar as the CSA prevents doctors from using their prescription-writing powers *as a means to engage in illicit drug trafficking as conventionally understood.*[8] However, the *Gonzales* decision was pigeonholed by lower courts as merely a prohibition on the attorney general's authority to define the bounds of legitimate medical practice and not a reminder by the Supreme Court that § 841 is only to be applied to doctors who abandon their medical role and become drug pushers.[9]

Since *Gonzales*, varying federal circuit interpretations of the statutory language of 21 U.S.C. § 841(a)(1) regarding "legitimate medical purpose" and "course of usual professional practice" have held doctors to heightened, and often shifting, standards used to criminalize conduct such as failure to recognize signs of drug diversion or failure to perform a physical exam.[10] DEA guidance suggests that the term "legitimate medical purpose" means "in accordance with a standard of medical practice generally recognized and accepted in the United States."[11] Other courts have disagreed with this approach, holding that mere violations of the standard of care do not equate to criminal conduct.[12] The problem with the application of an objective "standard of care" to physician prescribing is that no objective empirical evidence

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supports a specific standard of care, and physicians widely disagree about the propriety of administering narcotics for short term pain or to addicts.[13] Even physicians in the pain management community struggle with the standard to be applied to prescribing practices.[14] As a result of the fundamental shift from the Supreme Court's decision in *United States v. Moore*, federal drug trafficking cases against physicians are the only realm in which juries are tasked with applying complicated medical concepts to vague elements in order to determine if a physician should be convicted and sentenced to decades in prison due to a medical disagreement.

Current interpretations of 21 U.S.C. § 841(a) as applied to physicians provide prosecutors ample room to expand the conduct necessary to substantiate a violation of the statute.[15] However, through pretrial motion practice, jury instructions, expert witness testimony, and additional strategies, practitioners can tip the scales by narrowing the applicable standard and mitigating against the risk that a physician could be convicted for mere malpractice.[16]

This article will provide practitioners with a thorough review of the applicable standards applied to prescriber prosecutions, a discussion of both landmark Supreme Court cases and their impact, a discussion of the current trend in prescriber prosecutions, and strategies to effectively litigate these very difficult cases.

The Meaning of Legitimate Medical Purpose and Usual Course of Professional Practice

a. 'Legitimate Medical Purpose' and 'Outside the Course of Professional Practice'

Pursuant to 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."[17] However, these definitions are hardly clear and leave a lot open for interpretation. DEA Administrative Law Judge John J. Mulrooney II provides the best illustration of the meaning and interplay of these two crucial phrases:

> By way of example, a practitioner registrant who prescribes an opioid to someone who demonstrates an etiology consistent with the need for pain treatment (e.g., a broken back, recent surgery, intractable pain) may have prescribed the medication for a legitimate medical purpose, but when it is done without the establishment of a bona fide doctor-patient relationship, without the creation of a chart, or without the requisite documentation, it is likely to have been issued outside the course of a professional practice. Conversely, a practitioner who has a bona fide doctor-patient relationship with a patient and who keeps meticulous and detailed notes about controlled pain medications that the practitioner prescribes where there is no apparent organic pain source, the potency and frequency of the medication are unwarranted, or the patient has manifested objective indications of addiction, may well be prescribing in the usual course of professional practice, but not for a legitimate medical purpose. The two bases may be (and frequently are) co-morbidly present, but that does not support the proposition that the phrases are interchangeable.[18]

DEA agency decisions shed light on what the DEA believes constitutes prescribing "outside the usual course of professional practice" or "for other than a legitimate medical purpose":

The prescribing of a controlled substance (and the continued prescribing of a controlled substance) under the following circumstances establishes that a physician lacked a legitimate medical purpose and acted outside of the usual course of professional practice and therefore violated the CSA:

- without performing an appropriate physical examination,
- without utilizing appropriate diagnostic testing,
- failing to devise and document a written treatment plan,
- failing to periodically reassess the effectiveness of the treatment,
- continuing to prescribe controlled substances without pursuing alternative therapies,
- repeatedly and continually prescribing without referring the patient to appropriate specialists, and
- failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.[19]

Circuit courts have also attempted to define examples of when a physician's conduct fails to adhere to the standard in 21 C.F.R. § 1306.04. Lack of a physical examination has been widely held as evidence of a violation of the standard.[20] In *United States v. Rosen*, the court held that conduct that suggests that a defendant distributed a prescription without a legitimate medical purpose and outside the usual course of professional practice includes conduct when "an inordinately large quantity of controlled substances was prescribed; large numbers of prescriptions were issued; no physical examination was given; the physician issued prescriptions to a patient known to be delivering the drugs to others, and there was no logical relationship between the drugs prescribed and treatment of the condition."[21] The Eleventh Circuit upheld a conviction against a physician based on evidence that the prescriptions he issued were "excessive and inappropriate quantities and combinations of controlled substances" and that in doing so he acted "outside the usual course of professional practice."[22]

In *United States v. Orta-Rosario*, the Fourth Circuit found that the defendants' acts were beyond the bounds of professional practice, which was supported by evidence that the defendants did not conduct any physical examinations before prescribing controlled substances over the internet, defendants permitted nonmedical personnel to write prescriptions with presigned blank prescription forms, the dosage amounts were questionable, and liberal prescription refills were not based on legitimate medical purposes.[23] In *United States v. McIver*, the Fourth Circuit believed that inconsistent urine drug screens, ignoring signs of diversion, traveling significant distances, combinations of medications there were "no reason to be prescribing," and combinations of high doses of medication were evidence of lack of legitimacy.[24] Recent trends may establish a lower threshold for federal prosecutions.

Evidence of the Standard of Care Is Generally Admissible with a Cautionary Instruction

Evidence of the applicable "standard of care" is admissible but should be accompanied by an instruction that a "deviation of the standard of care alone

is not sufficient to sustain a conviction."[25] In the Sixth Circuit, Dr. Paul Volkman, a physician charged with drug trafficking under 21 U.S.C. § 841(a), challenged a requested jury instruction derived from *Gonzales v. Oregon* that would require the jury to find that Dr. Volkman used his prescription-writing power "as a means to engage in the illicit drug-dealing and trafficking as conventionally understood" in order to convict.[26] Despite the standard being specifically adopted from the Supreme Court's only § 841 decision in the last 30 years, the court rejected the language requested in *Volkman* and instead pivoted back to the statutory language that "knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict."[27] However, the Sixth Circuit did uphold a cautionary instruction ultimately given to the jury, which read, "carelessness or negligence or foolishness on [Dr. Volkman's] part is not the same as knowledge and is not enough to find him guilty on any of these counts."[28] The court went further to say as follows:

> You've heard the phrase "standard of care" used during the trial by several witnesses. When you go to see a doctor as a patient, the doctor must treat you in a manner that meets the applicable standard of care that physicians of similar training would have given to you under the same circumstances. If a doctor fails to provide you with that care, the doctor may be found negligent in a civil lawsuit. This case is not about whether the defendant acted negligently or whether he committed malpractice. Rather, in order for you to find the defendant guilty, you must find that the government has provided to you beyond a reasonable doubt that the defendant's action was not for a legitimate medical purpose in the usual course of professional practice.[29]

The court stated, "We conclude that these instructions amply and accurately conveyed the meaning of legitimate medical purpose to the jury."[30] The Sixth Circuit, in upholding *Volkman*'s jury instruction, clearly believes that departure from a standard of care or the practice generally accepted in the community does not render a prescription without a "legitimate medical purpose" or outside "course of professional practice."[31] The instruction in *Volkman* is a model instruction that should be given in every case.

The Seventh Circuit aligns with the Sixth Circuit in the sense that the government must prove "something more than conduct below the usual standard of care to show an absence of a valid medical purpose."[32] In *United States v. Chube* (Chube II), Dr. Chube sought to exclude all expert testimony that suggested a violation of the standard of care applicable to civil medical malpractice cases.[33] The doctor argued that such testimony admitted during trial confused the jury and reduced the government's burden from criminal intent to negligence.[34] While the trial court did not grant the motion, the judge repeatedly spelled out the difference between the civil standard and criminal standard to the jury, and defense counsel was permitted to discuss the different standards during opening, closing, and cross-examination.[35]

The Fourth Circuit in *United States v. Alerre* upheld a jury instruction much more similar to the Supreme Court's dicta in *Moore,* which stated that the jury could "not convict on the distribution and drug conspiracy charges if it found only that defendants' practices fell below that line of what a reasonable physician would have done."[36] The court further stated, "In order to convict on the distribution and drug conspiracy charges, the jury was required to find beyond a reasonable doubt that the defendants were selling drugs, or conspiring to do so, and not practicing medicine."[37]

The Ninth Circuit took the standard of care issue head on in *United States v. Feingold.*[38] Dr. Feingold's counsel argued that a physician should not be subject to prosecution for mere deviations of the standard of care, even if done intentionally, because it would permit the attorney general to prosecute any physician who steps outside the bounds of conventional medical protocols in order to provide some sort of special treatment for uniquely needy patients.[39] In reviewing a line of its prior CSA precedent, the Ninth Circuit unequivocally held:

> An instruction is improper if it allows a jury to convict a licensed practitioner under § 841(a) solely on a finding that he has committed malpractice, intentional or otherwise. Rather, the district court must ensure that the benchmark for criminal liability is the higher showing that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice.[40]

The Ninth Circuit acknowledged that it previously refused to overturn practitioner convictions simply because jury instructions deferred to the national standard of care.[41] However, the court cautioned that by doing so, "a district court may impermissibly lower the standard for criminal liability by instructing the jury to determine whether a practitioner-defendant has complied or attempted to comply with the standard of care."[42] The Ninth Circuit ultimately held that an instruction is improper if it permits a jury to convict a practitioner solely on the finding that he has committed malpractice, intentional or otherwise.[43] The Ninth Circuit affirmatively stated that "a practitioner becomes a criminal not when he is a bad or negligent physician, but when he ceases to be a physician at all."[44]

The U.S. Court of Appeals for the First Circuit believes that the term "usual course of professional practice" references violations of the "standard of care," and the "good faith" instruction is the fundamental difference between malpractice and criminal liability.[45] While the First Circuit agrees with *Feingold* that a physician is insulated from prosecution as a result of a mere departure from the standard of care, it held that evidence that a physician consistently failed to follow generally recognized procedures "tends to show that in prescribing drugs he was not acting as a healer but as a seller of wares."[46] The court found it important, when assessing whether under the current standard a physician could be convicted for mere malpractice, that the "good faith" instruction inoculates a defendant from being found guilty when he or she prescribes in "good faith" because the "good faith" defense is not an available defense in malpractice cases.[47]

Conversely, in the Second Circuit, the mistaken but well-intentioned physician can be convicted for a simple departure from the standard of care. The Second Circuit in *United States v. Vamos* reasoned that medical practitioners have limited authority to engage in the distribution of controlled substances.[48] According to the Second Circuit, a practitioner is stripped of that authority

when he or she acts in a manner that is not generally accepted in the medical community. The Second Circuit acknowledged the argument that "subjecting physicians to an objective reasonableness standard exposes a physician to criminal responsibility for nothing more than malpractice," but dismissed the argument on the basis that a jury must still find proof beyond a reasonable doubt that the physician acted outside the scope of medical practice.

Evidence of 'Red Flags'

"Red flag" evidence has become a mainstay of physician prescribing prosecutions and has acted as a de facto standard of care. The DEA began using "red flag" indicators to determine which doctors should be the subject of increased scrutiny by having undercover officers pose as patients who exhibit one or more "red flags."[49] However, "red flags" are not established using empirical data, but are rather an amalgamation of common "drug-seeking" characteristics collected by DEA agents that are used as an investigative tactic to show knowledge on the part of the physician of the illegality of his or her practice.[50]

At least one circuit has upheld the use of red flag evidence to establish deliberate ignorance. In 2007, the DEA investigated Dr. Johnston using an officer posing as a patient.[51] The undercover officer presented to Dr. Johnston's practice and complained of pain radiating down his leg. Dr. Johnston commented on the long distance the patient traveled to see her and the undercover officer replied that he was living with his mother nearby. Dr. Johnston told the undercover officer that he had a herniated disc that was causing the pain and "sooner or later" he would need an MRI, which was not needed immediately. The officer later testified at trial that he attempted to exhibit numerous red flags, including the following: (1) he was the former patient of a doctor that was previously indicted; (2) he was using medication obtained from friends to self-treat his pain; (3) he traveled a long distance to Dr. Johnston's office for care; (4) he exhibited some drug-seeking behavior including asking for the medication by name; and (5) he ran out of medication early.[52] The DEA also sent another undercover officer posing as a patient who mirrored the conduct of the prior undercover officer and presented with several red flags. The government called a physician to testify as an expert, and the physician explained the concept of red flags. Dr. Johnston was convicted and appealed the conviction, arguing that the admission of testimony about red flags permitted the government's expert to testify to legal conclusions and was contrary to the Supreme Court's decision in *Daubert* because the government failed to establish that such testimony was reliable or relevant.[53] The U.S. Court of Appeals for the Eleventh Circuit did not agree with Dr. Johnson's arguments, instead adopting the theory that the term "red flags" is synonymous with warning signs and was not used to create a medical standard.[54]

Can the mistaken but well-intentioned physician be convicted for a simple departure from the standard of care?

A federal judge in the Eastern District of Michigan raised some skepticism regarding the concept of red flags in the case of *United States v. Binder*. In *Binder,* the prosecution sought to present the evidence of a DEA agent who testified that a large number of Dr. Binder's files contained red flags.[55] The government did not present an expert physician to testify that the actual treatment of the patients evidenced lack of a legitimate medical purpose and compliance with the usual course of professional practice.[56] Recognizing the lack of probative value of law enforcement-created "profile evidence," the trial judge dismissed the case, stating that "where the government presents only 'pattern' or 'red flag' evidence sifted from a large number of patient files, particularly where no expert determination was made as to the suitability of the treatment in each case, the evidence is insufficient, without more, to demonstrate guilt beyond a reasonable doubt."[57]

In circular fashion, the DEA red flags are creeping into the common medical lexicon as the standard of care. In a 2017 article published in the *Permanente Journal*, Dr. Timothy Munzing sought to provide a definitive approach to the standard of care for prescribing opioids for noncancer pain.[58] In his article, Dr. Munzing presents a list of red flags developed from a document published by "stakeholders" in the opioid market, such as the major pharmacy chains, several large insurance companies, the Federation of State Medical Boards, various medical societies, and professional organizations.[59] Despite the warning on the document clearly stating that the document is not intended to inform or create a standard of care, it finds its way in Dr. Munzing's journal article that seeks, of all things, to establish a standard of care. Moreover, the "stakeholder" document does not provide any empirical data or support that the red flags are actual signs of apparent or drug-seeking behavior. In fact, no empirical study exists that shows a causal link between red flags and drug abuse, addiction, or overdose. The list contains the following red flags:

- Early refills/claims that the medications were lost or stolen — even with a police report.
- Age 35 years or younger, especially combined with other red flags.
- Concurrent use of multiple pharmacies.
- Obtaining controlled substances from multiple physicians or "doctor shopping."
- Excessive amounts or drug combinations.
- Obtaining or buying controlled substances from family, friends, or others.
- Giving or selling controlled substances to family, friends, or others.
- Use/abuse of alcohol or drugs — current or past.
- Use of tetrahydrocannabinol/marijuana, even with a medical marijuana card.
- Use of drug culture street lingo for the names of the medications or other drugs.
- Inconsistent results from urine drug screens or the prescription drug monitoring program report.
- Driving long distances to see the physician for controlled substances.

- ❖ Multiple family members or those residing in the same household receiving identical or similar controlled substances.
- ❖ Similar or identical prescribing (e.g., medication selection, strengths) regardless of specifics of symptoms such as pain severity, examination findings, diagnosis, etc. (lack of individual management plans).
- ❖ Failure to improve without adjustment of management plan.
- ❖ Drug overdoses.

Interestingly, the list of red flags developed in the "stakeholder challenges" document cite back to DEA decisions spanning from 2008 to 2012, DEA guidance letters issued by the DEA's deputy assistant administrator of the Office of Diversion Control, and the DEA Practitioner's Manual wherein the DEA administrator discusses "warning signs" that physicians and pharmacists should recognize as possible evidence of diversion.[60] The DEA administrative cases that support the use of red flags as evidence against physicians all have two things in common: (1) they are DEA decisions wherein the DEA administrator determined that the practitioner issued controlled substances in violation of the CSA and 21 C.F.R. § 1306.04; and (2) they are cases against pharmacies where the DEA administrator alleged that the pharmacy distributed drugs despite "obvious warning signs," i.e., red flags.[61] The DEA's decisions from 2008 to 2012 have caused an echo chamber effect, ultimately causing a DEA-created standard to bleed into the common lexicon of physician prescribing.

The term "red flag" is a concept created by law enforcement that has been adopted by the medical profession in an effort to remain in compliance with DEA regulations. Despite this fact, red flags have been applied in cases against physicians as a quasi "standard of care" and physicians have been charged and even convicted for prescribing in the face of one or more red flags.[62] However, no empirical evidence exists to support the theory that red flags are signs of diversion. As such, red flags should not be entitled to any deference — as the late Justice Scalia noted: "The Justice Department, of course, has a very specific responsibility to determine for itself what [criminal statutes mean], in order to decide when to prosecute; but we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference."[63]

Unfortunately, for physicians, the red flag model can easily ensnare honest and well-meaning physicians. The characteristics used by law enforcement to portray "drug-seeking patients" are also qualities exhibited by legitimate patients that are undertreated.[64] Deception is difficult to detect, and physicians as healers have an inherent truth bias.[65] The lack of empirical data to support the theory that red flags are signs of drug-seeking patients and not legitimate patients places physicians in an untenable position. According to Dineen and DuBois, "labeling physicians as misprescribers for merely being fooled is improper. … Physicians have inappropriately faced sanctions simply for being fooled."[66] In fact, recent research has determined that even after training to detect fake pain complaints, people could not detect real pain versus faked pain more than 55 percent of the time.[67] When it comes to something as intangible as "pain," deceiving physicians and playing on their inherent "truth bias" and punishing them for not recognizing law enforcement-created, nonmedical signals exhibited by undercover officers create fear in the medical profession. Moreover, treating physicians this way does nothing to resolve the real cause of the "opioid epidemic."

If the prosecution seeks to introduce red flag evidence, defense counsel should object on the grounds that it is not based on reliable scientific or other specialized knowledge. If a court admits evidence of red flags, it should be accompanied by an appropriate cautionary instruction. Moreover, the DEA agent proponent of red flag testimony should be thoroughly cross-examined on the lack of empirical data related to red flags. In addition, the defendant's medical expert should testify that red flag behaviors are not determinative of apparent drug use or drug diversion.

Trial Strategies

a. Defense Expert

Finding an expert who is willing to defend a physician facing scrutiny from the federal government is a difficult task. Many physicians are reluctant to take the witness stand against the federal government for fear of facing scrutiny themselves. However, with some diligence and thorough research of literature supporting medical decision-making, experts can be found.

It is important to ensure that the expert chosen is competent to testify about the standard for opioid prescribing and has significant experience prescribing. Criminal health care matters are much different than civil malpractice matters and are not bound by state statutes that require the expert to be of a certain specialty or spend a certain amount of time practicing in his or her field. However, if the defendant is a specialist, such as a pain management specialist or an interventional anesthesiologist, much can be made on cross-examination of the government's failure to call a physician that understands the complexity of the treatment offered to a particular patient.

The government will likely have its expert review a small sample of "cherry picked" patient files that show the physician in the worst light. Files with inconsistent urine drug screens, little or no documentation, evidence of apparent behaviors, and demographics inconsistent with legitimate pain treatment. Conversely, the defense expert should review a statistically significant random sample set of patient files in addition to the patients specifically referenced in the indictment. This will ensure that the expert sees a valid cross section of the entire practice as opposed to the inherently biased sample chosen by the government. The government may attempt to argue that the discussion at trial of patients not made at issue in the indictment is irrelevant — however, this is rarely the case. Generally, the government chooses to offer evidence of patient treatment not included specifically in charged conduct by charging a violation of 21 U.S.C. § 846 and alleging that the additional patient interactions are acts in furtherance of the conspiracy.

Choosing a random sample of patients is particularly helpful in the event of a conviction because sentencing guidelines in drug cases are based on the total "weight" of the drugs attributed to the practitioner for relevant conduct purposes.[68] Prosecutors generally base "relevant conduct" on all prescriptions issued by a physician during the "conspiracy" if they believe the practitioner was practicing in a "pill mill." If the expert reviews a random sample, the expert report can be provided at sentencing to attempt to reduce the "relevant conduct" by arguing that even if the jury convicted the defendant based on a review of "cherry picked" files, not all patient interactions were unlawful.

The defense expert should author a report thoroughly discussing his or her review of the patient files and the applicable standard for determining

whether conduct is "outside the usual course of professional practice" and "not for a legitimate medical purpose." This can be accomplished by showing the difference between the different standards applicable in the medical community. (See Figure 1.)

Figure 1

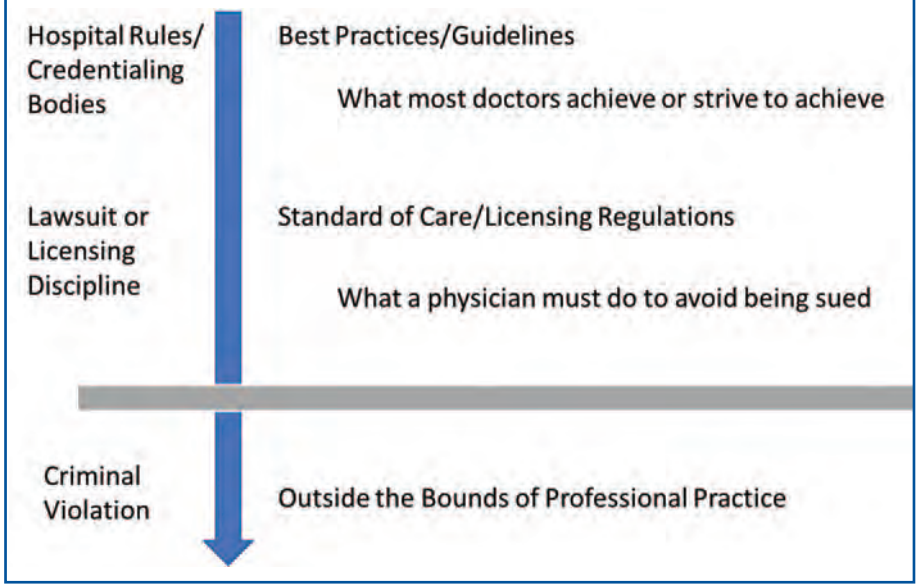

Figure 2

Date	Visit	Med	Strength	Quantity	UDS	Vitals	Exam	Physician

b. Opposing Expert

The most successful attacks against the opposing expert testimony is the standard applied and the selection of patient files. Most government experts choose to point out red flags and deviations of the standard of care including failure to recognize inconsistent urine drug screens, poor documentation, failure to conduct a physical examination, and improper history and physical. While problematic, the issues outlined above are not determinative of bad faith in prescribing. The expert's methodology should be challenged during motions practice. The trial court must determine whether an expert's testimony rests on a reliable foundation and is relevant to the "task at hand."[69] An expert witness who only relies on his or her own subjective view of proper medicine and does not adhere to a standard should not meet this test.[70] Moreover, *Gonzales v. Oregon* makes clear that the structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the states' police powers.[71] Therefore, the government expert should adhere to a state standard for determining the bounds of professional practice.[72] If the government expert fails to apply a common standard applicable to the defendant prescriber, the expert should be challenged on the fact that his or her subjective belief and independent review of literature are hardly the basis for a statewide minimum standard of practice.

c. Presenting Patient Data

The number of patient files and the manner of presentation is likely to be a contentious issue at trial. Often the government picks a certain number of patient files for its expert to review and does not provide the defense notice of its selection until trial preparations are well underway or completed. Therefore, it is imperative for the defense to present its own selection of patient files (in conspiracy cases) in order to rebut the government's use of "cherry picked" files introduced to show acts in furtherance of the conspiracy.

At trial, patient files should be appropriately redacted and defense counsel should consider utilizing summary charts to display patient data in a way that the jury can understand. Summary charts should be prepared by a medical professional familiar with medical/legal terminology if significant interpretation is required to convert medical records into a usable format. Figure 2 shows an example that can be used to compile patient data into an understandable format.

d. Prescription Drug Monitoring Evidence

Most, if not all, drug prosecutions against prescribers involve some form of evidence from a prescription drug monitoring program. Prescription drug monitoring programs ("PDMP") are databases kept by states and their medical boards. PDMPs are designed to ferret out drug-seeking patients by tracking all prescriptions filled by a patient. Pharmacies are required, generally by state statute, to report all controlled substance prescriptions to the database. The information is compiled in a readily understood format and then can be accessed by prescribers and pharmacists to determine if a patient is filling a prescription. As of January 2018, 25 states have required that all prescribers check their state's PDMP before prescribing a controlled substance.[73]

Without PDMPs, the prosecution would need to subpoena each prescription it intended to introduce into evidence. The impact of PDMPs is that the prosecution has a powerful tool to aggregate prescription data to determine an appropriate guideline amount under U.S.S.G. § 2D1.1 and to wow the jury with sordid stories of a physician prescribing hundreds of thousands of pills. Moreover, the government can use charts and graphs indicating the physician's prescribing trends to show a drastic increase in prescribing or a drastic decrease when the prescriber is facing government scrutiny.

While PDMP data is certainly a tool that favors the government, the defense may find some benefit from strategic use of PDMP data. For instance, the defense can show that the physician weaned patients to lower doses, prescribed nonaddictive alternatives, varied dosage and quantity to titrate patients, or cycled medications to achieve a greater therapeutic effect. Defense counsel should become intimately familiar with PDMP data and seek to make use of this valuable statistical tool at trial — the government certainly will.

Conclusion

A strong defense in any 21 U.S.C. § 841 prosecution against a prescriber requires a narrowing of the standard, solid expert testimony, and a strong presentation of the patient's medical need for the prescriptions issued by the physician. Federal prosecutions are shifting toward prosecution for mere violations of the standard of care. It is imperative that the

defense bar reject any effort to charge and subsequently convict a physician for deviations from the standard of care. It must remain the case that to convict a physician for a violation if 21 U.S.C. § 841(a), the physician must have ceased practicing medicine and instead engaged in illicit drug trafficking.

Notes

1. *Compare United States v. Moore*, 423 U.S. 122 (1975) and *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978) (failure to conduct a physical exam and failure to recognize signs of diversion was evidence of an unlawful purpose).

2. 21 U.S.C. § 841(a); *see also* 21 C.F.R. § 1306.04.

3. *United States v. Moore*, 423 U.S. 122 (1975); 21 U.S.C. § 801 *et. seq.*

4. *United States v. Moore,* 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.

5. *Id.*

6. Oral Argument at 01:02; 46, *United States v. Moore*, 423 U.S. 122 (1975), https://www.oyez.org/cases/1975/74-759.

7. *Gonzales v. Oregon*, 546 U.S. 243, 269 (2005).

8. *Id.*

9. *United States v. Feingold*, 454 F.3d 975, 1011 n.2 (9th Cir. 2006) (*Gonzales* held only that the attorney general lacked power to define legitimate medical practices so as to directly oppose state law); *see also United States v. Ahuja*, 209 F. Supp. 3d 489, 495 (D. Conn. 2016).

10. *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006); *United States v. Kaplan*, 895 F.2d 618, 620-21 (9th Cir. 1990) (issuing prescriptions absent a physical exam is evidence of conduct "outside the course of usual professional practice"); *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978) (failure to conduct a physical exam and failure to recognize signs of diversion were evidence of an unlawful purpose).

11. 71 FR 52716. *See also United States v. Norris*, 780 F.2d 1207, 1209 n.2 (5th Cir. 1986).

12. *Feingold*, 454 F.3d at 1007-08.

13. Michael Potter et al., *Opioids for Chronic Nonmalignant Pain: Attitudes and Practices of Primary Care Physicians in the UCSF/Stanford Collaborative Research Network,* 50 J. Fam. Prac. 145, 148 (2001).

14. Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States' Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia's Alternative Regulatory Approach,* 47 Colum. J. Transnat'l L. 210, 226-227 (for example, physicians widely disagree about the propriety of administering narcotics for short-term pain or to addicts, and there is little agreement about the addiction risks that narcotics present).

15. *United States v. Birbragher,* 603 F.3d 478, 488 (8th Cir. 2010) (noting the absence of any successful vagueness challenge to § 481).

16. *United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009).

17. 21 C.F.R. § 1306.04(a) (2017).

18. John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 425-426 (2017).

19. *Fiaz Afzal, M.D.,* 79 Fed. Reg. 61651, 61652 (Drug Enf't Admin. Oct. 14, 2014).

20. *United States v. Katz,* 445 F.3d 1023, 1031 (8th Cir. 2006); *United States v. Kaplan,* 895 F.2d 618, 620-21 (9th Cir. 1990) (issuing prescriptions absent a physical exam is evidence of conduct "outside the course of usual professional practice"); *United States v. Rosen,* 582 F.2d 1032 (5th Cir. 1978) (failure to conduct a physical exam and failure to recognize signs of diversion were evidence of an unlawful purpose).

21. *United States v. Rosen*, 582 F.2d 1032, 1036 (5th Cir. 1978); *United States v. Joseph,* 709 F. 3d 1082 (2013).

22. *United States v. Merril,* 2008 U.S. App. Lexis 982 (2008).

23. *United States v. Orta-Rosario,* 469 Fed. Appx. 140 (4th Cir. 2012).

24. *United States v. McIver,* 470 F.3d 550 (4th Cir. 2006).

25. *United States v. Volkman,* 736 F.3d 1013, 1020 (6th Cir. 2013).

26. *Id.*

27. *Id.* at 1021.

28. *Id.* at 1022.

29. *Id.*

30. *Id.*

31. *Id.*

32. *United States v. Chube,* 538 F.3d 693, 698 (7th Cir. 2008).

33. *Id.* at 697.

34. *Id.*

35. *Id.* at 699.

36. *United States v. Alerre,* 430 F.3d 681, 687 (4th Cir. 2005).

37. *Id.*

38. *United States v. Feingold,* 454 F.3d 1001, 1010 (2006).

39. *Feingold,* 454 F.3d at 1010.

40. *Id.*

41. *See United States v. Hayes,* 794 F.2d 1348, 1351 (9th Cir. 1986) (the Ninth Circuit upheld a conviction in which good faith was defined as a practitioner making an honest effort to conform to the standard of medical practice generally recognized and accepted in the country).

42. *Feingold,* 454 F.3d at 1011.

43. *Id.*

44. *Id.*

45. *United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018).

46. *Id.* (quoting *United States v. Alerre*, 430 681, 691 (4th Cir. 2005)); *see also United States v. Wexler*, 522 F.3d 194, 204 (2d Cir. 2008); *United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006).

47. *Id.* at 45.

48. *United States v. Vamos,* 797 F.3d 1146 (2d Cir. 1986).

49. *See, e.g., United States v. Lovern*, 590 F.3d 1095, 1102 (10th Cir. 2009).

50. *See id.* ("red flag" testimony by a DEA diversion investigator with over 15 years of experience admitted because "courts have routinely upheld the admission of expert testimony from law enforcement officers seeking to identify for the jury typical indicia of drug trafficking activity").

51. *United States v. Johnston,* 322 Fed. Appx. 660, 662 (11th Cir. 2009).

52. *Id.*

53. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

54. *Johnston*, 322 Fed. Appx. at 662.

55. *United States v. Binder,* 26 F. Supp. 3d 656 (2014).

56. *Id.*

57. *Id.*

58. Timothy Munzing, M.D., *Physician Guide to Appropriate Opioid Prescribing for Noncancer Pain,* 21 Perm. J. 16-169 (2017).

59. American Academy of Family Physicians et al., *Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances*, Mount Prospect, IL: National Association of Boards of Pharmacy (Mar. 2015 [cited Mar. 31, 2017]), https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf.

60. *Id.* (citing United States Drug Enforcement Administration; *Practitioner's Manual*, at 30 (2006); *Holiday CVS, L.L.C., d/b/a CVS Pharmacy,* Nos. 219 and 5195, Decision and Order, 77 FR 108, 62, 315 (Dept. of Justice, Oct. 12, 2012); *East Main Street Pharmacy,* Affirmance of Suspension Order, 75 FR 207, 66149 (Dept. of Justice, Oct. 27, 2010); *Holiday CVS, L.L.C. v. Holder,* 839 F. Supp. 2d 145 (D.D.C. 2012); *Townwood Pharmacy*, 63 Fed. Reg. 8, 477 (Dept. of Justice, Feb. 19, 1998); *Grider Drug 1 & Grider Drug 2*, 77 Fed. Reg. 44, 069 (Dept. of Justice, July 26, 2012) (Decision and Order); *The Medicine Dropper,* 76 Fed. Reg. 20 (Dept. of Justice, Apr. 11, 2011); *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 363 (Dept. of Justice, Jan. 2, 2008); *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409 (2008)).

61. *See, e.g., Medicine Shoppe-Jonesborough,* 30 Fed. Appx. At 413, *supra* note 60.

62. *United States v. Lovern,* 590 F.3d 1095, 1102 (10th Cir. 2009).

63. *Crandon v. United States,* 494 U.S. 152, 177 (1990).

64. K.K. Dineen & J.M. DuBios, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42(1) Am. J. Law Med. 7-52 (2016) (citing Beth Jung & M.M. Reidenberg, *Physicians Being Decieved,* 8 Pain Med. 433 (2007) ("[o]ur review of [DEA] … actions against physicians who prescribed opioids found that some of these actions were based on prescriptions given to undercover agents. In several high-profile prosecutions of physicians for prescribing opioids, prosecutors claimed that the doctors should have known the individuals were feigning pain solely to obtain the prescriptions") (citation omitted); M.M. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients,* 81 Clinical Pharmacology & Therapeutics, 903, 904 (2007) [PubMed] (finding that in many of the cases they reviewed between 2004 and 2005, the focus was on the fact that undercover officers had "fooled" the physician); Hailey Branson-Potts, *Woman Says Doctor in Murder Case Provided Her Hundreds of Pills Weekly,* L.A. Times: Blogs (Jun. 15, 2012, 6:11 PM), http://latimesblogs.latimes.com/lanow/2012/06/doctor-charged-with-murder-supplied-addict-with-hundreds-of-addictive-pills-each-week-former-patient.html [perma.cc/U5B2-6WB9] ("[i]n two weeks of testimony, prosecution witnesses have said they exaggerated or lied to [the doctor] about suffering pain and walked away with their desired prescriptions after little or no examination")).

65. *Id.*

66. *Id.*

67. M.S. Bartlett, G.C. Littlewort, M.G., Frank & K. Lee, *Automatic Decoding of Facial Movements Reveals Deceptive Pain Expressions,* 24(7) Curr Biol. 738-43 (Mar. 31, 2014).

68. U.S.S.G. § 2D1.1.

69. *Daubert v. Merrell Dow Pharms. Inc.,* 509 U.S. 579; 113 S. Ct. 2786; 125 L. Ed. 2d 469 (1993).

70. *But see United States v. Stokes,* 2018 U.S. Dist. LEXIS 217131 (N.D. Ga. Oct. 19, 2018) (an expert's view of appropriate prescribing survives a *Daubert* challenge if it is based on scientific literature).

71. *Gonzales*, 546 U.S. 243 (2006).

72. *Wesley Pope, M.D.,* 82 Fed. Reg. 14944, 14945 (Drug Enf't Admin. Mar. 23, 2017).

73. PEW, *When Are Prescribers Required to Use Prescription Drug Monitoring Programs?* The Pew Charitable Trusts (Jan. 24, 2018), https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2018/when-are-prescribers-required-to-use-prescription-drug-monitoring-programs.

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