

## Prosecuting Physicians For Opioid Prescriptions

By Adam J. Sheppard

The misuse, abuse, and addiction to prescription opioids are a serious problem in America. “Of the 21.5 million Americans 12 or older who had a substance abuse disorder in 2014, 1.9 million had a disorder involving prescription pain relievers.” <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>. “Since 1999, the amount of prescription opioids sold in the United States has nearly quadrupled.” <https://www.cdc.gov/drugoverdose/epidemic/>

One response by the federal government has been to more aggressively prosecute physicians who unreasonably prescribe opioids. See [http://www.deadiversion.usdoj.gov/crim\\_admin\\_actions/doctors\\_criminal\\_cases.pdf](http://www.deadiversion.usdoj.gov/crim_admin_actions/doctors_criminal_cases.pdf) (“Cases Against Doctors,” last updated March 31, 2016). However, the issue of whether a physician was legally justified in prescribing pain medication is fraught with ambiguity. Indeed, “[o]pioids have been regarded for millennia as among the most effective drugs for the treatment of pain.” <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/>. And there is currently “no nationally accepted consensus” for how to best treat chronic pain (not including pain due to cancer). See <http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf> (the American Academy of Pain Medicine). Thus, it is unclear at what point a physician who prescribes opioids runs afoul of the federal drug laws.

The government generally charges physicians under the Controlled Substance Act. The Act states, in part, that, “except as provided by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to distribute[] or dispense a controlled substance.” 21 U.S.C. 841(a)(1). The government uses the same law to prosecute dealers of street-drugs. Congress did provide an exemption for physicians and certain others (e.g., manufacturers, nurses, and pharmacists) to lawfully distribute or dispense drugs within the course of their professional practice. See 21 U.S.C. 822(b); 21 C.F.R. § 1306.04.

For a prescription to be considered effective, it “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. To avoid criminal liability, physicians may point to their “good faith” beliefs that a prescription was issued for a “legitimate medical purpose” and within “the usual course of professional practice.” See *United States v. Moore*, 423 U.S. 122, 96 S. Ct. 335, (1975); *United States v. Hogan*, 2009 WL 4043084, \*1 (W.D. Mich. 2009);

Whether a physician’s conduct was for a “legitimate medical purposes” and within the “usual course of a professional practice” is an objective standard, i.e., whether the physician acted in accordance within the tenets of medical professionalism. See *United States v. Smith*, 573 F.3d 639, 648 (8th Cir. 2009). The issue is case-specific; it involves a totality of the circumstances analysis. See *id*; *United States v. ALN Corp.*, 1993 WL 402803, \*2 (D. Conn. 1993).

Factors that indicate the lack of a “legitimate medical purpose” and/or acting outside of “the course of a professional practice” include: the lack of a physical examination of the patient or only a cursory examination before issuing the prescription; the patient advises the doctor of some improper motive for wanting the medication such as staying awake or partying; the physician tells patients where to get their prescriptions filled; prescriptions for large quantities over a short period of time; a large number of uniform dosages of prescriptions (this belies the proposition that the prescription was tailored to the individual patient); the physician has reason to believe the patient is giving the medication to others; the relationship between the drug prescribed and the treatment of the condition alleged; issuing the prescription after learning of a patient’s addiction; or asking patients about the type or quantity of drugs they want. See *United States v. Dileo*, 625 F. App’x 464, 476 (11th Cir. 2015); *United States v. Augst*, 984 F.2d 705, 713 (6th Cir. 1992) (citing, *United States v. Kirk*, 584 F.2d 773, 783 (6th Cir. 1978)).

Neither the government nor the defendant is required to present expert testimony on the issue of “a legitimate medical purpose” or whether the defendant’s actions were in the “usual course of professional practice.” *United States v. Polito*, 111 F.3d 132 (6th Cir. 1997); *United States v. Word*, 806 F.2d 658, 663-64 (6th Cir. 1986), 111 F.3d 132 (6th Cir. 1997). However, expert testimony – e.g., from a pain specialist – is often helpful. See e.g., *United States v. Joseph*, 709 F.3d 1082, 1097 (11th Cir. 2013).

The prosecution of physicians under the Controlled Substances Act remains a controversial issue. On the one hand, such prosecutions help combat the epidemic of opioid abuse and the diversion of drugs to illegitimate channels. On the other hand, such prosecutions can have a chilling effect on a physician’s decision to prescribe pain medication to patients in need. Practitioners who are called upon to represent physicians must carefully study the patient files and pharmacology at issue. Consultation with an expert witness is generally advisable.

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