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# A Bitter Pill to Swallow: The Need for a Clearly-Defined Course of Professional Practice When Prescribing Opioids for the Legitimate Medical Purpose of Treating Pain

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# NOTE

# A BITTER PILL TO SWALLOW: THE NEED FOR A CLEARLY-DEFINED COURSE OF PROFESSIONAL PRACTICE WHEN PRESCRIBING OPIOIDS FOR THE LEGITIMATE MEDICAL PURPOSE OF TREATING PAIN

## I. INTRODUCTION

The following premise, translated from its original Greek, is a portion of the Hippocratic Oath. An oath that, although antiquated, still prescribes some of the fundamental principles for "ideal conduct" by physicians: "I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect."[1] This oath, attributed to Hippocrates and held sacred among physicians, is an oath whereby physicians swear to treat patients to the best of their abilities.[2] The relevance of this oath to the medical community is exemplified by the fact that most practitioners take a modern version of this oath upon graduation from medical school.[3] Although the principles of this oath are paramount to the practice of medicine, some physicians have lost sight of the teachings of Hippocrates, placing monetary gain before the health and lives of their patients, and essentially, providing potentially-lethal prescription drugs simply because the patient is willing to pay for them.[4]

Since the 1990s, doctors have prescribed opioid medications to treat non-cancer-related chronic pain, such as that which stems from back injuries and arthritis.[5] This type of pain "includes any painful condition

1. *The Hippocratic Oath and Others*, MCMASTER UNIV. HEALTH SCI. LIBRARY, https://hslmcmaster.libguides.com/c.php?g=306726&p=2044095 (last updated April 26, 2019, 11:46 AM).

2. William C. Shiel Jr., *Medical Definition of Hippocratic Oath*, MED. NET https://www.medicinenet.com/script/main/art.asp?articlekey=20909 (last visited Sept. 17, 2019).

3. Christopher J. Kim, *The Trial of Conrad Murray: Prosecuting Physicians for Criminally Negligent Over-Prescription*, 51 AM. CRIM. L. REV. 517, 520-23 (2014).

4. *See id.* at 522-23 (discussing the statement issued by Michael Jackson's family after his death from drugs prescribed by his personal physician, "that '[physicians] cannot sell their services to the highest bidder and cast aside their Hippocratic Oath to do no harm'").

5. *Opioid Prescribing: Where You Live Matters*, CTRS. FOR DISEASE CONTROL &

that persists for at least three months and is not associated with malignant disease."[6] Accompanying this trend of prescribing opioids for chronic pain is a drastic increase in the rate and volume with which opioids are prescribed throughout the United States.[7] There were more than 59,000 opioid-related deaths that occurred in the United States during 2016.[8] On October 26, 2017, the Department of Health and Human Services "declare[d] the opioid crisis a public health emergency," at the order of President Trump.[9]

Prescribers are the primary source of the prescription opioids that are fueling the epidemic.[10] The Centers for Disease Control and Prevention ("CDC") has indicated that roughly half of all overdoses attributed to opioids involve prescription painkillers and that the approximate 250,000,000 opioid prescriptions written in 2013 were enough to supply every adult in the nation with their "own bottle of pills."[11] Although tremendous, these numbers are not a fair representation of the entire medical community, as only a small percentage of prescribers in each state are responsible for at least half of all opioid prescriptions written.[12]

The regulation of controlled substances occurs on both the federal and state levels; on the federal level, through the Controlled Substances Act ("CSA") which derives its authority from the Commerce Clause of the United States Constitution,[13] and on the state level through the controlled substances acts of individual states, which garner authority from the state police powers conferred by the Tenth Amendment.[14] This causes variations in regulation from state-to-state[15] and makes the huge disparity between the highest and lowest-prescribing counties in the

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PREVENTION, https://www.cdc.gov/vitalsigns/opioids/index.html (last visited Sept. 17, 2019).

6. Jason W. Busse et al., *Guideline for Opioid Therapy and Chronic Noncancer Pain*, 189 CAN. MED. ASS'N J. E659, E659 (May 8, 2017).

7. *Opioid Prescribing: Where You Live Matters*, *supra* note 5.

8. Julie Hirschfeld Davis, *In Declaration, No New Funds for Drug Crisis*, N.Y. TIMES, Oct. 27, 2017, at A1, https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

9. *Id.*

10. Michael C. Barnes & Gretchen Arndt, *The Best of Both Worlds: Applying Federal Commerce and State Police Powers to Reduce Prescription Drug Abuse*, 16 J. HEALTH CARE L. & POL'Y 271, 276 (2013).

11. Alyssa M. McClure, Note, *Illegitimate Overprescription: How* Burrage v. United States *Is Hindering Punishment of Physicians and Bolstering the Opioid Epidemic*, 93 NOTRE DAME L. REV. 1747, 1750-51 (2018).

12. *See* Cassandra Rivais & Bruce D. White, *The Opioid Epidemic Is Not New: Time to Change the Practice of Medicine*, 11 ALB. GOV'T L. REV. 58, 69 (2017) (discussing the disproportionate prescription practices among the opioid prescribers throughout the states, according to the Prescription Behavior Surveillance System).

13. *See* Barnes & Arndt, *supra* note 10, at 279-81; *see also* U.S. CONST. art. I, § 8, cl. 3.

14. *See* Barnes & Arndt, *supra* note 10, at 279-80 (discussing state and federal authority to regulate controlled substances); *see also* U.S. CONST. amend. X.

15. Barnes and Arndt, *supra* note 10, at 279.

United States unsurprising.[16] The CDC has noted that "[r]ates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among clinicians on how to use opioid pain medication."[17]

Section 841(a) of the CSA, entitled "Unlawful acts," reads as follows: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—(1) to manufacture, distribute, or dispense, a controlled substance; or (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance."[18] The CSA provides an exemption for physicians[19] and requires physicians who prescribe controlled substances to register with the Attorney General.[20] Registered physicians must comply with the CSA's provisions that govern registrants.[21] The CSA "require[s] that prescriptions of controlled substances 'must be . . . for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'"[22] This language has proven difficult for the courts to apply, and without clearer guidelines for prescribing opioid painkillers, doctors face legal risks and uncertainty when treating patients for chronic pain.[23] Although the CSA dictates this unclear standard,[24] there is no administrative oversight when a physician writes a prescription, and a physician's approach to treatment remains up to his or her discretion.[25] When a physician is deemed to have prescribed unlawfully—outside of the bounds set forth by the CSA—he or she may be prosecuted under section 841 of the Act and held criminally liable.[26] As an unfortunate

16. *See Opioid Prescribing: Where You Live Matters*, *supra* note 5. The CDC reported a six-fold differential in the prescribing of opioids between the highest and lowest prescribing counties in 2015. *Id.*

17. Deborah Dowell et al., *CDC Guidelines for Prescribing Opioids for Chronic Pain—United States, 2016*, 65 CTRS. FOR DISEASE CONTROL & PREVENTION 1 (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

18. 21 U.S.C. § 841 (2012).

19. United States v. MacKay, 715 F.3d 807, 814 (10th Cir. 2013).

20. 21 U.S.C. § 823 (2012); *see* Diane E. Hoffman, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 265 (2008) (discussing the Drug Enforcement Administration's administration and enforcement of the CSA).

21. *Id.*

22. *Id.* (quoting 21 C.F.R. § 1306.04(a) (2008)).

23. *Id.* at 265-66.

24. *See* Katherine Goodman, Note, *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, 223 (2008) (describing a broad overview of the CSA in comparison to its South Australian Counterpart).

25. *Id.* at 219.

26. *See* United States v. Moore, 423 U.S. 122, 124 (1975) (holding "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional

consequence of this criminal liability, many patients who are truly afflicted with chronic pain suffer because their treating physicians will not prescribe opioids for non-cancer-related chronic pain out of the fear that they will be prosecuted for doing so.[27]

In Part II, this Note will discuss the history of the opioid epidemic, including its death toll and current trajectory, the regulatory history surrounding the prescribing of controlled substances, and the varying applications of the CSA throughout the federal courts.[28] Part III will examine both permissive federal guidelines and state statute-based guidelines for prescribing opioids.[29] Part IV will propose a model statute encompassing various guidelines and standards analyzed in the preceding sections, that, if adopted, would help clarify what constitutes the course of professional practice with respect to prescribing opioids.[30] Part V will sum up the need for this proposed statute in a country wrought with opioid-related deaths and no definitive standard for prescribing them; it will also urge state legislatures to adopt statutes like the one proposed to help define the proper course of professional practice for prescribing opioids.[31]

## II. REMOVING THE MASK OF UNCERTAINTY: THE PAST, PRESENT, AND FUTURE OF REGULATION IN RESPONSE TO THE OPIOID EPIDEMIC

The United States is facing an opioid epidemic that claimed more American lives in 2016 than both the Iraq and Vietnam wars combined.[32] It is extraordinarily troubling that prescription opioids contributed to almost half of these deaths.[33] At the federal level, the CSA limits prescriptions for controlled substances to those prescribed by physicians for a legitimate medical purpose and within the course of their professional practice.[34] However, in light of the impotent guidelines provided by the federal government, this standard remains unclear, and it is ultimately left to a jury of untrained individuals to decide whether or

practice").

27. *See* Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 85 (2004) (discussing how the fear of criminal prosecution causes doctors to withhold opioid pain medications from patients suffering from chronic pain that does not stem from cancer).

28. *See infra* Part II.

29. *See infra* Part III.

30. *See infra* Part IV.

31. *See infra* Part V.

32. McClure, *supra* note 11, at 1769.

33. *Id.*

34. *See infra* Part II.B.

not a physician acted outside of the course of his or her medical practice on the basis of competing expert testimony.[35]

Subpart A provides an overview of the opioid epidemic, including its rise from changing trends in opioid prescribing in the 1990s, following its evolution over the years, its current trajectory, and its massive death toll.[36] Subpart B then explores the various roles of state and federal governments and provides a historical overview of regulation with respect to controlled substances in the United States.[37] Finally, Subpart C analyzes case law from the Supreme Court of the United States and various federal circuit courts, highlighting the difficulties associated with applying section 841(a) of the CSA to a jury trial where a physician is prosecuted for his or her prescribing controlled substances, specifically opioids.[38]

### *A. Death Toll of Epidemic Proportion*

One of the primary directives of the medical community is to "do no harm."[39] Despite this aim, the United States is suffering at the hands of an opioid epidemic that killed over 200,000 people within its borders from 1999 to 2016[40]—reaching "epidemic" status in "professional literature and public discourse" in the past decade[41]—and continues to kill at a rate of roughly ninety Americans per day.[42] This is alarming, given that approximately half of the total overdose deaths amounting to this epidemic involve prescription opioids, according to the CDC,[43] and about ninety-five percent of the prescription drugs abused by non-medical users originate from prescriptions written by physicians.[44]

35. *See infra* Part II.C.

36. *See infra* Part II.A.

37. *See infra* Part II.B.

38. *See infra* Part II.C.

39. United States v. Volkman, 736 F.3d 1013, 1017 (6th Cir. 2013).

40. McClure, *supra* note 11, at 1751.

41. *See* Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context; Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 L. & PSYCHOL. REV. 2, 45-46 (2016) (discussing the emergence of the term "opioid epidemic" in the context of the rising death toll associated with prescription opioids).

42. McClure, *supra* note 11, at 1752.

43. *Id.* at 1750-51.

44. Barnes & Arndt, *supra* note 10, at 276; *see also* FED. DRUG ADMIN, FDA EDUCATION BLUEPRINT FOR HEALTH CARE PROVIDERS INVOLVED IN THE TREATMENT AND MONITORING OF PATIENTS WITH PAIN, FED. DRUG ADMIN. 3 (2018), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf. [hereinafter *Monitoring of Patients with Pain*]; *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, FED. DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems ("The increasing availability of prescription opioids since the 1990's has been accompanied by an epidemic of opioid addiction. The Substance Abuse and Mental Health Services Administration's *National Survey of Drug Use and Health* has shown that most people who use prescription analgesics 'nonmedically' obtain them from friends or family, who it is believed

Notably, opioids act as a gateway-drug "with nearly 80 percent of heroin users having previously used prescription painkillers."[45] The CDC has acknowledged a correlation between the amount of opioid-induced overdoses and the number of opioids prescribed.[46] What is especially alarming is the rapid growth of this epidemic in recent years.[47] Since 1999, the death toll from prescription opioids has increased over-fourfold, killing more individuals in 2016 than the HIV epidemic at its height.[48] If this epidemic continues on its current path, it will claim up to 650,000 lives due to opioid overdoses in the next ten years.[49] This enormous number of deaths is comparable to those attributed to HIV and AIDS over a forty-year period.[50] Notwithstanding the negative impact of these devastating drugs in recent years, the Food and Drug Administration ("FDA") continues to approve them for medical use; the newest drug, Dsuvia, is the strongest yet, with a potency 1000-times the strength of morphine.[51] Such a potent drug is likely to prove more lethal and subject to abuse than its predecessors, which have claimed more lives than any other drug in the last two decades.[52]

### *B. State and Federal Regulation Regarding the Prescription of Opioids*

The regulation of physicians and the practice of medicine is traditionally left to the states.[53] Regulation by state medical boards encompasses "most aspects of the practice of medicine, including licensure and continuing education requirements for physicians,

obtained the drugs from a doctor's prescription.").

45. William J. Ihlenfeld II, *Medical Ethics and the Law: Poor Prescribing Practices Help Fuel West Virginia's Drug Epidemic*, W. VA. LAW., Apr.-June 2015, at 35.

46. *Id.* ("According to the Centers for Disease Control and Prevention, the increase in the United States of overdoses from prescription opioids has mirrored the increase in sales of prescription opioids.").

47. McClure, *supra* note 11, at 1751.

48. *Id.* at 1751-52.

49. *Id.*

50. *Id.* at 1752.

51. Ashley May, *FDA Approves Opioid Painkiller 1,000 Times Stronger Than Morphine*, USA TODAY, (Nov. 5, 2018, 11:44 AM), https://www.usatoday.com/story/news/nation-now/2018/11/05/fda-approves-opioid-painkiller-stronger-than-morphine-fentynal/1889389002.

52. *See id.* (looking to the statement of Massachusetts Senator Ed Markey that "an opioid that is a thousand times more powerful than morphine is a thousand times more likely to be abused, and a thousand times more likely to kill," as well as a recent DEA "report showing that prescription drugs were responsible for the most overdose deaths of any illicit drugs since 2001.").

53. Becky Walker James & Kathryn Lohmeyer, *Painful Prescriptions: A Workable Legal Standard for Doctors Who Prescribe Pain Medication Has Yet to Be Established*, L.A. LAW., Feb. 2013, at 14, https://www.lacba.org/docs/default-source/lal-back-issues/2013-issues/february-2013.pdf.

maintenance of standards of professional conduct and medical practice, and disciplinary actions against doctors found to have engaged in unprofessional or dishonorable conduct."[54] Some state medical boards have also authored guidelines with respect to prescribing drugs and the treatment of pain, and offer insight on how to identify drug abuse and wean patients off of addictive painkillers.[55]

The power to regulate the prescription of controlled substances is split between the federal government and individual state governments.[56] At the federal level, the act of prescribing is regulated by the CSA.[57] At the state level, individual state controlled substance acts are used to regulate the use of controlled substances.[58] When the states garner their authority to regulate the practice of medicine from the Tenth Amendment's police powers, the federal government retains concurrent power to regulate controlled substances pursuant to the Commerce Clause of the Constitution.[59]

The CSA was passed by Congress in 1970 as Title II of the Comprehensive Drug Abuse Prevention and Control Act.[60] It was enacted to regulate all controlled substances, replacing its predecessor, the Harrison Act of 1914, the scope of which was strictly limited to narcotics.[61] The Drug Enforcement Agency ("DEA"), which administers and enforces the CSA, "was established in 1973 and is a unit of the FBI within the U.S. Department of Justice."[62]

The DEA, the FDA, and the National Institute on Drug Abuse are responsible for oversight of the CSA's five schedules, which classify controlled substances based on "several factors, including the potential for abuse, the risk to public health, and the risk of psychological or physiological dependence."[63] Before a new drug can be prescribed it must be approved by the FDA for effectiveness and safety in accordance with the Food, Drug, and Cosmetic Act; but once approved, the FDA may not dictate how that drug is used within the course of a physician's practice.[64]

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54. *Id.*

55. John A. Gilbert & Barbara Rowland, *Practicing Medicine in a Drug Enforcement World*, *in* 27 HEALTH L. HANDBOOK 392, 411 (2015).

56. Barnes & Arndt, *supra* note 10, at 279-80.

57. *Id.* at 279.

58. *Id.*

59. *Id.* at 280-81.

60. Dilcher, *supra* note 27, at 86; *see also* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242-84.

61. Hoffman, *supra* note 20, at 263-64.

62. *Id.* at 264.

63. Dilcher, *supra* note 27, at 87.

64. *See* Sarah E. M. Buzzee, Comment, *The Pain Relief Promotion Act: Congress's Misguided Intervention of End-of-Life Care*, 70 U. CIN. L. REV. 217, 226-27 (2001) (discussing the FDA's role

Schedule I substances are those deemed to have no medical use presently, and their potential for abuse is high.[65] Drugs in Schedules II–V are considered to have a medical purpose and are classified based on their potential for abuse compared to other drugs.[66] In order to prescribe the substances listed in Schedules II–V, a physician is required to have a DEA registration, regardless of whether their state license allows for the prescription of other medications.[67] This registration requirement was designed to allow the DEA to monitor physicians to ensure that drugs are not diverted into illegitimate channels.[68] However, the CSA does not address who gets to determine "what constitutes a 'legitimate medical purpose.'"[69] The Supreme Court has held the view that "direct control of medical practice in the States is beyond the power of the Federal Government," and that "[w]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances"; but, "[m]ere pretense of such practice . . . cannot legalize forbidden sales . . . ."[70] To determine whether a physician lawfully prescribed opioids for a legitimate medical purpose and within the course of their professional practice, the courts must typically look to expert testimony—offered by both prosecution and defendant physicians at trial—and case-specific facts.[71] This is because there are no clear guidelines for determining the scope of a physician's professional practice that pertains to prescribing opioids.[72] Unfortunately, experts in the field hold widely varying views regarding what is appropriate when prescribing opioids for the treatment of chronic pain.[73]

Every state has regulations and statutes governing the prescription of controlled substances, and many states observe the drug schedules provided by the CSA.[74] Most state controlled substance acts now follow the CSA as a model and require that prescriptions for controlled substances be "written for a legitimate medical purpose in the usual course

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in the approval of new drugs).

65. Hoffman, *supra* note 20, at 264.

66. *See* John A. Gilbert, Jr., *DEA Regulation of Controlled Substances and Listed Chemicals*, 65 FOOD & DRUG L.J. 623, 624 (2010) (discussing the scheduling of controlled substances under the CSA).

67. Dilcher, *supra* note 27, at 88-89.

68. *See* Buzzee, *supra* note 64, at 228.

69. *Id.*

70. Linder v. United States, 268 U.S. 5, 18 (1925).

71. Ihlenfeld, *supra* note 45, at 35-36; *see also* 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, 381-82 (2017).

72. Ihlenfeld, *supra* note 45, at 35-36.

73. Hoffman, *supra* note 20, at 270-71.

74. Dilcher, *supra* note 27, at 99-100.

of professional practice."[75] However, this was not always so, and it can be drawn from this shift—from many states not recognizing legitimate medical purpose in their statutes governing controlled substance prescriptions in the early 2000s—that states now recognize legitimate medical purpose in their laws in response to the opioid epidemic.[76] What constitutes prescribing "within the scope of a legitimate medical purpose" varies from state to state, but "the general consensus is that physicians are required to conduct a physical exam, evaluate the patient's medical history, follow up on the efficacy of treatment, and adjust the prescription as needed, and most importantly, physicians must document everything in the patient's file."[77] Some states further delineate the bounds of professional practice by limiting the amount of a controlled substance that a physician can prescribe at one time, or by restricting prescriptions written for known abusers.[78]

### *C. Varying Applications of Section 841(a) of the CSA Throughout the Federal Courts*

For a physician to write a lawful prescription in accordance with the CSA, it must be written for a "legitimate medical purpose" and within "the usual course of [the physician's] professional practice."[79] Prescriptions that do not meet these requirements are not considered legitimate under the CSA, and, as such, prescribers who provide illegitimate prescriptions are subject to the applicable penalties for violating the Act.[80] Although the federal circuit courts generally agree that this is the proper standard to convict a physician for violating section 841(a) of the CSA,[81] they "have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the course of professional practice,' in a way that will provide definitive guidelines that address all of the varied situations physicians might encounter."[82] This

75. Gilbert & Rowland, *supra* note 55, at 410-11.

76. Dilcher, *supra* note 27, at 99-100 (stating "[a]ll of the state laws permit prescriptions for controlled substances, although, unlike federal law, most do not specifically recognize the legitimate medical use of controlled substances."); *see also* Gilbert & Rowland, *supra* note 55, at 410-11 ("As the prescription drug abuse epidemic continues to spread, states have attempted to follow the DEA's lead in fighting against overprescribing.").

77. Gilbert & Rowland, *supra* note 55, at 411.

78. Dilcher, *supra* note 27, at 100.

79. Goodman, *supra* note 24, at 221 (quoting 21 C.F.R. § 1306.04(a) (2006)).

80. *Id.*

81. *Id.* at 223.

82. Hoffman, *supra* note 20, at 283 (quoting Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,715, 52,717 (Sept. 6, 2006) (to be codified at 21 C.F.R. pt. 1306)).

lack of a finite standard is reflected by the varying applications of section 841(a) among the federal circuit courts.[83]

In *United States v. Moore*,[84] the Supreme Court established that "registered physicians can be prosecuted under Section 841 [of the CSA] when their activities fall outside the usual course of professional practice."[85] Moore had been charged with 639 counts of distribution or dispensation of Schedule II methadone in violation of section 841(a)(1)—later reduced to forty counts—and was convicted on twenty-two counts, for which he received a sentence of "concurrent terms of five to 15 years' imprisonment on 14 counts" to run consecutively with "concurrent terms of 10 to 30 years on the remaining eight counts," as well as, $150,000 in fines.[86] The trial court's conviction of Moore was reversed by the D.C. Circuit Court of Appeals, which determined Moore was exempt from the statute due to his status as a registrant under the CSA, before being reversed by the Supreme Court.[87] Moore had written 11,169 prescriptions from September 1971 to February 1972, writing over 100 prescriptions per day on fifty-four occasions during this period, and billed his patients on the basis of the number of pills prescribed.[88]

Since the Supreme Court's ruling in *Moore*, defining what constitutes prescribing within "the usual course of professional practice" under section 841 of the CSA has proven difficult among the lower courts due to the minimal guidance provided by *Moore* on the issue.[89] For determining whether a physician prescribed within the "course of professional practice" the Fourth Circuit Court of Appeals allows an objective good faith defense, and the Ninth Circuit Court of Appeals permits a subjective one.[90] The Eleventh Circuit Court of Appeals has "rejected a good faith standard of intent" when faced with a physician who "failed to ensure that his patients had a legitimate medical need and were suited for treatment involving controlled substances."[91] To convict on charges for "causing and aiding and abetting the illegal distribution and

83. *See* James & Lohmeyer, *supra* note 53, at 17 (explaining the differing applications of the standard to convict under § 841 among various circuit courts).

84. 423 U.S. 122 (1975).

85. *Id.* at 124.

86. *Id.* at 124-25, 146.

87. *Id.* at 124.

88. *Id.* at 126.

89. *See* Michael C. Barnes & Stacey L. Sklaver, *Active Verification and Vigilance: A Method to Avoid Civil and Criminal Liability When Prescribing Controlled Substances*, 15 DEPAUL J. HEALTH CARE L. 93, 122 (2013) (noting that "*Moore* provided little guidance on this issue [of 'the usual course of professional practice'] because the case involved a physician who abdicated all professional responsibility").

90. Goodman, *supra* note 24, at 230-31.

91. Barnes & Sklaver, *supra* note 89, at 127-28.

dispensation of a controlled substance" pursuant to section 841(a)(1), the Second Circuit Court of Appeals has found it unnecessary to provide reference to the *Moore* standard.[92] The Fourth Circuit Court of Appeals exemplifies the difficulty of applying this standard through its application in the cases of Dr. William Hurwitz of Virginia and Dr. Ronald McIver of South Carolina,[93] as well as their earlier decision in *United States v. Tran Trong Cuong*.[94] In *Tran Trong Cuong*, the Fourth Circuit allowed for the subjective good faith jury instruction that they would later deny Dr. Hurwitz.[95] In the cases of Hurwitz and McIver, the Fourth Circuit found that willful blindness was enough to convict physicians for "knowingly prescribing [opioids] to patients who resell drugs," however, to very different outcomes.[96]

In *United States v. Tran Trong Cuong*, the Fourth Circuit found that, although the lower court had allowed the prosecution's expert to judge Dr. Tran's prescription practices against the civil medical malpractice standard, the evidence against Dr. Tran clearly established a violation of section 841 in light of a jury instruction that correctly stated the criminal standard.[97] The district court applied the following good faith section in its instructions to the jury:

> A doctor dispenses a drug in good faith in medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully. Good faith in this context means good intentions in the honest exercise of best professional judgment as to a patient's need. It means the doctor acted in accordance with what he believed to be proper medical practice. If you find the defendant acted in good faith in dispensing the drug, then you must find him not guilty.[98]

92. United States v. Singh, 390 F.3d 168, 178, 186 (2d Cir. 2004).

93. Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 701 (2009). "Two high profile prosecutions exemplify this disturbing trend: the case of William Hurwitz in Virginia, who was re-convicted in 2007 after a 'successful' appeal to the Fourth Circuit, and the case of Ronald McIver of South Carolina, whose appeal to the Fourth Circuit was denied in 2006." *Id.*

94. 18 F.3d 1132, 1138 (4th Cir. 1994).

95. United States v. Hurwitz, 459 F.3d 463, 478-80 (4th Cir. 2006) (discussing why the subjective good faith jury instruction applied in *Tran Trong Cuong* was inappropriate in the present case and that the district court did not err in denying its application to Dr. Hurwitz).

96. Hellman, *supra* note 93, at 701 ("Both men were sentenced to federal prison, with Dr. Hurwitz receiving a sentence of fifty-seven months and McIver receiving a sentence of thirty years. In each case, the court instructed the jury that it could convict the doctor under a statute that prohibits *knowingly* prescribing to patients who resell drugs if the jury found merely that the physician was *willfully blind* to this fact.").

97. *Tran Trong Cuong*, 18 F.3d at 1137-39.

98. *Id.* at 1138.

The district court convicted Dr. Tran for violating section 841 of the CSA,[99] and in doing so, supplied the following elements for his charges: "(1) that Dr. Tran distributed or dispensed a controlled substance, (2) that he acted knowingly and intentionally, and (3) that his actions were not for legitimate medical purposes in the usual course of his professional medical practice or beyond the bounds of medical practice."[100] The Fourth Circuit acknowledged that the district court's application of the "without a legitimate medical purpose" standard was stricter than that applied in *Moore*, but permissible nonetheless, and beneficial to Dr. Tran.[101]

The Fourth Circuit reversed the conviction of Dr. Tran on all 127 counts against him,[102] and instructed that Dr. Tran could not be retried on eighty counts related to twenty patients who had each been issued four prescriptions by Dr. Tran because the patients did not testify; rather, the evidence for these counts was offered by the prosecution's expert,[103] and was therefore insufficient to convict.[104] The other counts against Dr. Tran were reversed because of an evidentiary issue and could still be retried.[105]

Despite its reversal, the Fourth Circuit acknowledged that the evidence against Dr. Tran was sufficient such that a jury could have reasonably found that he had violated section 841(a)(1).[106] The evidence against Dr. Tran indicated he would prescribe controlled substances for relatively minor conditions that would not typically require treatment with a controlled substance, and he would maintain patients on this course of treatment for sometimes years at a time without follow-up examinations or additional testing.[107] Dr. Tran had also prescribed controlled substances to patients who were clearly addicts, including some Dr. Tran knew to be getting drugs from other physicians, patients exhibiting drug-seeking behavior, and an admittedly addicted patient exhibiting needle marks.[108]

In *United States v. Hurwitz*,[109] the Fourth Circuit concluded that "good faith is relevant to § 841 charges against a registered physician" when it vacated Dr. Hurwitz's convictions and remanded the case for the district court's failure to give a good faith jury instruction before convicting Dr. Hurwitz.[110] In *Hurwitz*, the Fourth Circuit applied the same

99. *Id.* at 1133.
100. *Id.* at 1141.
101. *Id.* at 1138.
102. *Id.* at 1144.
103. *Id.* at 1135.
104. *Id.* at 1144.
105. *Id.* at 1141, 1144.
106. *Id.* at 1141.
107. *Id.* at 1139.
108. *Id.* at 1139-40.
109. 459 F.3d 463 (4th Cir. 2006).
110. *Id.* at 482-83.

essential elements for a section 841 violation that it had in *Tran Trong Cuong*.[111] Nonetheless, the Fourth Circuit rejected the application of Hurwitz's requested subjective good faith instruction and asserted that the correct instruction would be an objective one, accounting for generally accepted medical standards.[112] The good faith instruction requested by Hurwitz was "essentially identical"[113] to that applied in *Tran Trong Cuong*,[114] however, the Fourth Circuit justified its divergence from this earlier decision on the basis that Dr. Tran's good faith was not at issue, and its explanation that in *Tran Trong Cuong* "the portion of the instructions that included the good-faith instructions were broader than necessary to comply with *Moore*."[115] The instruction supplied in *Tran Trong Cuong* applied good faith in the context of the legitimate medical purpose element.[116] However, the Fourth Circuit found that the more appropriate standard was an objective one—targeted at the course of professional practice element—because to allow a subjective standard would permit physicians to disregard accepted canons of medicine and treat patients by any chosen means, as long as the physician believed the treatment was appropriate for a recognized medical purpose.[117]

Hurwitz had been convicted by the district court of "forty-six counts of drug trafficking" under section 841(a) of the CSA for his high-dose opioid approach to pain management.[118] One expert for the government testified that the dosages prescribed by Hurwitz far-exceeded the accepted

111. *Id.* at 475 (citing to *Tran Trong Cuong*, among other cases, in support of the elements quoted from *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995): "we have held that to convict a doctor for violating § 841, the government must prove: (1) 'that the defendant distributed or dispensed a controlled substance'; (2) that the defendant 'acted knowingly and intentionally'; and (3) 'that the defendant's actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice.'"); *cf. supra* text accompanying note 100 (discussing the elements of a charge under § 841 of the CSA as applied in *Tran Trong Cuong*).

112. *Hurwitz*, 459 F.3d at 479.

113. *Id.*

114. *Id.* at 478-79. Hurwitz requested the following instruction, almost identical to the subjective good faith instruction afforded in *Tran Trong Cuong*:

> If a doctor dispenses a drug in good faith to medically treat a patient, then the doctor has dispensed the drug for a legitimate medical purpose and in the course of medical practice. That is, he has dispensed the drug lawfully. 'Good faith' in this context means good intentions in the honest exercise of best professional judgment as to a patient's needs. It means the doctor acted according to what *he believed to be proper medical practice*.

*Id.* at 479 (emphasis added); *cf. supra*, text accompanying note 98 (discussing the lower court in *Tran Trong Cuong* instruction to the jury on the standard of good faith).

115. *Hurwitz*, 459 F.3d at 479; *see also supra* text accompanying note 101 (discussing the Fourth Circuit's application of the "without a legitimate medical purpose" standard).

116. *Hurwitz*, 459 F.3d at 479.

117. *Id.*

118. *Id.* at 467-68. Hurwitz was also "convicted of . . . one count of drug trafficking resulting in death, [and] two counts of drug trafficking resulting in serious bodily injury" under the same. *Id.*

dosages of 195-350 milligrams of morphine or its equivalent accepted among practitioners for high-dose opioid therapy, where Hurwitz had been prescribing a median daily dosage of 2000 milligrams to patients from 1998–2002.[119] Hurwitz and his witnesses testified that these dosages were appropriate because "the body quickly develops resistance to the dangerous side-effects of opioids (such as respiratory depression), which then permits an escalation of the dosage until pain relief is obtained," and that once the body has built up such a resistance there is no limit to the "quantity of opioids that can be prescribed if necessary to control pain."[120]

In *United States v. McIver*,[121] the Fourth Circuit affirmed the conviction of Dr. Ronald McIver for various violations of the CSA, including seven counts in violation of section 841(a)(1).[122] McIver operated a clinic specializing in the treatment of chronic pain, for which McIver "had prescribed massive quantities of [addictive Schedule II opioids including] oxycodone, Dilaudid, OxyContin, methadone, and morphine."[123] The charges against McIver resulted from his treatment of ten patients, one of whom was deceased, with the other nine testifying at trial.[124] In order to convict McIver on the counts pursuant to section 841(a)(1), the jury was charged to find that the government had proven "(1) that Appellant knowingly or intentionally distributed a controlled substance; (2) with knowledge that it was controlled under the law; and (3) that he did so 'outside the usual course of professional practice.'"[125]

On appeal, McIver only challenged the instructions given for element three of his charges.[126] Contrary to McIver's assertion "that by referring to 'norms of professional practice' in the jury instructions, the district court improperly allowed the jury to convict on a civil, rather than a criminal, standard of proof," the Fourth Circuit found that when viewed together in their entirety, the jury instructions applied by the district court "adequately articulated a criminal standard of proof."[127] Reviewing these instructions, the Fourth Circuit found numerous reasons that the given instructions set forth the appropriate criminal standard:[128] (1) the lower court had properly articulated the government's "beyond a reasonable doubt" burden of proof as encompassing the entire charge; (2) the district

119. *Id.* at 467.
120. *Id.* at 468.
121. 470 F.3d 550 (4th Cir. 2006).
122. *Id.* at 552-53.
123. *Id.* at 552-53, 553 nn.3-7.
124. *Id.* at 553.
125. *Id.* at 556 (quoting United States v. Moore, 423 U.S. 122, 124 (1975)); *cf.* supra note 111.
126. *Id.* at 556, n. 9.
127. *Id.* at 557-58.
128. *Id.* at 559.

court had properly defined the scope of conduct prohibited under section 841 as using the "authority to prescribe controlled substances" to do so "outside the course of professional practice"—the threshold required by *Moore*—and "*for other than a legitimate medical purpose*," thus, arguably benefitting McIver "by placing a heavier burden on the government than otherwise required to establish criminal liability";[129] (3) that a good faith instruction was provided, noting that good faith is not an applicable defense for medical malpractice but is for charges stemming from section 841;[130] and (4) that the district court had sufficiently explained to the jury the differences between convicting on a civil standard compared to convicting on a criminal standard.[131]

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129. *Id.* at 559.

> For you to find that the government has proven this essential element, you must determine that the government has proven beyond a reasonable doubt that the defendant was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or dispensing controlled substances for other than a legitimate medical purpose, in other words, the personal profit of the physician. Put another way, the government must prove as to each count beyond a reasonable doubt that the defendant dispensed the specific controlled substance other than for a legitimate medical purpose and not with the bounds of professional medical practice.

*Id.* at 557; *cf. supra* text accompanying note 125 (discussing the jury instructions provided pursuant to 841(a)(1)).

130. *Hurwitz*, 459 F.3d at 559-60.

> If a doctor dispenses a drug in good faith, in medically treating a patient, then the doctor has dispensed that drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully. Good faith in this context means good intentions, and the honest exercise of professional judgment as to the patient's needs. It means that the defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a defendant acted in good faith in dispensing the drugs charged in this indictment, then you must find that defendant not guilty.

*Id.* at 556, n. 9.; *cf. supra* note 114.

131. *McIver*, 470 F.3d at 560.

> There has been some mention in this case from time to time of the standard of care. During the trial the words medical malpractice may have been used. Those words relate to civil actions. When you go to see a doctor, as a patient, that doctor must treat you in a way so as to meet the standard of care that physicians of similar training would have given you under the same or similar circumstances. And if they fall below that line or what a reasonable physician would have done, then they have not exercised that standard of care, which makes them negligent and which subjects them to suits for malpractice. That is not what we're talking about. We're not talking about this physician acting better or worse than other physicians. We're talking about whether or not this physician prescribed a controlled substance outside the bounds of his professional medical practice.

*Id.* at 556-57.

The Fourth Circuit also found that the district court had not erred by allowing the prosecution's expert to testify that McIver had "treated patients outside the course of legitimate medical practice," which McIver argued, amounted to "inadmissible legal conclusions." Additionally, the court determined that the district court had not erred in its decision that allowing McIver's expert to testify to "whether a minority group of doctors who treat pain aggressively with opioids acted 'within the bounds of medical practice,'" was an impermissible legal conclusion.[132] The court determined that the language employed by the prosecution's expert fell "within the limited vernacular that is available to express whether a doctor acted outside the bounds of his professional practice," and that the testimony of McIver's witness that was allowed was similar enough to the line of questioning denied, making any possible error harmless.[133]

In *United States v. Feingold*,[134] the Ninth Circuit affirmed the lower court's conviction of Dr. Jeffrey Feingold—a naturopathic physician practicing in Arizona—on 185 counts of unlawful distribution in violation of section 841(a) of the CSA.[135] Feingold argued that the lower court had improperly admitted expert testimony opining to the national standard of care regarding opioid prescribing and in doing so misled the jury and allowed them to convict him on a finding of negligence, thus conflating the criminal and civil standards of liability.[136] Additionally, Feingold argued that the instructions provided to the jury did not supply the requisite intent for a criminal conviction.[137] Feingold copiously prescribed large quantities of various drugs, including the opioids Percocet, hydrocodone, Vicodin, oxycodone, and Oxycontin, providing refills as early as one to two days from the initial prescription.[138] In one instance, Feingold wrote twenty-eight oxycodone and Oxycontin prescriptions for a single patient over the course of a month, with each prescription totaling 120 pills.[139] In another instance "he prescribed as many as 2,000 pills in a single month, despite the fact that the recommended maximum dosage would have allowed the consumption of only 186, to a patient who testified that he resold the pills to others."[140]

The Ninth Circuit agreed with Feingold's assertion that it was improper to convict under section 841(a) of the CSA for only a finding

132. *Id.*
133. *Id.*
134. 454 F.3d 1001 (9th Cir. 2006).
135. *Id.* at 1004, 1014.
136. *Id.* at 1005-07.
137. *Id.* at 1007.
138. *Id.* at 1004-05.
139. *Id.* at 1004.
140. *Id.* at 1004-05.

that a physician did not prescribe in accordance with the standard of care, but disagreed that having an expert testify to the standard was "*irrelevant* or *prejudicial*."[141] The Ninth Circuit found that such testimony was offered to determine that a physician prescribed without a legitimate medical purpose outside the course of professional practice and that "[k]nowing how doctors generally ought to act is essential for a jury to determine whether a practitioner has acted not as a doctor, or even as a *bad* doctor, but as a 'pusher' whose conduct is without a legitimate medical justification."[142]

The Ninth Circuit also agreed with Feingold that the jury must be charged to look to the subjective intent of the prescriber and find that his actions were intentional to convict under section 841.[143] Despite their agreement, the Ninth Circuit found that, taken as a whole, the instructions provided by the district court adequately charged the jury to examine Feingold's intent, having made at least four references to his "state of mind."[144] The Ninth Circuit determined that "any imprecision in the jury instructions as to the standard for criminal liability was harmless beyond a reasonable doubt," and that the evidence against Feingold was sufficient to affirm his conviction.[145] However, the Ninth Circuit vacated and

141. *Id.* at 1007.

142. *Id.*

143. *Id.*

144. *Id.* at 1006, 1008-09. The district court also provided the following good faith instruction to the jury:

> A controlled substance is distributed by a practitioner in the usual course of his professional practice if the substance is distributed by him in good faith in medically treating a patient. Good faith is not merely a practitioner's sincere intention towards the people who come to see him, but, rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country. Thus, good faith in this context means an honest effort to prescribe for a patient's condition in accordance with the standard of medical practice generally recognized and accepted in the country. However, practitioners who act outside the usual course of professional practice and prescribe or distribute controlled substances for no legitimate medical purpose may be guilty of unlawful distribution of controlled substances.

*Id.* at 1006; *cf. supra* note 130.

145. *Feingold*, 454 F.3d at 1012.

> The evidence against Dr. Feingold was overwhelming. He prescribed drugs to people whom he knew to be addicts, to people whom he had never examined, to people whom he had never met, and to undercover law enforcement officials who did little more than tell him they wanted narcotics. He continued to prescribe Schedule II narcotics even after the state of Arizona had made it illegal for naturopathic physicians to do so, and after local pharmacists had specifically refused to fill some of his prescriptions because he lacked authorization to write them. Further, he dispensed drugs in quantities that, according to the government's experts, probably would have killed his patients, and certainly would have destroyed their livers, if they had actually consumed

remanded his twelve-year sentence because the district court had erroneously assumed the guidelines used were mandatory.[146]

In *United States v. Merrill*,[147] the Eleventh Circuit Court of Appeals affirmed the district court's conviction of Dr. Thomas Merrill on ninety-eight out of 100 counts—among other charges including wire and health care fraud—seventy-five of which were for "illegally prescribing narcotics outside the course of professional practice under the Controlled Substances Act," and nine of which "alleged that death resulted from either the health care fraud or the use of the narcotics prescribed outside the course of professional practice."[148] The district court relied on the testimony of an expert in the fields of prescribing controlled substances and pain management, who categorized the prescribing practices of Dr. Merrill as "unbelievable," "ill-advised," "an invitation to disaster," "inappropriate," "bizarre," "inconceivable," "astonishing," and "incredible," based on his review of records for eighty of Dr. Merrill's patients.[149] Five of Merrill's patients died from overdoses and their autopsies revealed drugs that Merrill had prescribed them within the three weeks preceding their deaths, and three of these patients had pill bottles from prescriptions issued by Merrill nearby when their bodies were found.[150] Merrill had written over 33,000 prescriptions from January 2001 to May 2004, 99.4% of which were written for controlled substances.[151] Out of the prescriptions for controlled substances, 81% were for Diazepam (5907 prescriptions), Alprazolam (4326 prescriptions), and a total of 16869 prescriptions for the opioids hydrocodone and oxycodone.[152] Merrill received six concurrent life sentences.[153]

In *United States v. Pellmann*,[154] the Seventh Circuit Court of Appeals found that expert testimony was not necessary to affirm the district court's

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> the drugs in the amounts he prescribed. Moreover, Dr. Feingold repeatedly *admitted* during his testimony that his practice of prescribing controlled substances was 'outside the course of professional practice' . . . claim[ing] that he was an incompetent doctor who was honestly trying to help his patients manage pain, [and] didn't know that they were abusing drugs due to his lack of training about the use of opioids, and never *intended* to flout professional protocol.

*Id.* at 1012-13.

146. *Id.* at 1013-14.
147. 513 F.3d 1293 (11th Cir. 2008).
148. *Id.* at 1297.
149. *Id.* at 1297-98.
150. *Id.* at 1298-99; *cf. supra* note 145.
151. *Merrill*, 513 F.3d at 1299-1300; *cf. supra* note 145.
152. *Merrill*, 513 F.3d at 1300; *cf. supra* note 145.
153. *Merrill*, 513 F.3d at 1297.
154. 668 F.3d 918 (7th Cir. 2012).

conviction of Pellmann under section 841(a) of the CSA.[155] Pellmann, a Wisconsin radiologist, used fentanyl—a short-acting Schedule II opioid 100-times the strength of morphine—to treat his patients' pain.[156] The DEA began investigating Pellmann after he ordered over 7000 units of fentanyl in 2009.[157] He had ordered 260 units or less in the four preceding years.[158] The DEA's investigation uncovered that a large percentage of these fentanyl prescriptions were issued to a nurse at Pellmann's clinic—Jacquelynn Evans—who Pellmann allegedly treated for trigeminal neuralgia,[159] of which he kept no records.[160]

Pellmann challenged his conviction under section 841(a) on the ground that the government had not offered expert testimony to establish that he had acted outside of the course of professional practice, and he attempted to distinguish his actions from that of a "drug pusher" because his charge arose from interactions with only one patient.[161] In light of the evidence against Pellmann,[162] the Seventh Circuit found that:

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155. *Id.* at 919.

156. *Id.* at 920.

157. *Id.* Pellmann also ordered a large amount of morphine in 2009, after having ordered none in the years preceding. *Id.*

158. *Id.*

159. *Id.* at 920-22.

> At trial, Evans testified that Pellmann began administering fentanyl in March 2009 to treat severe mouth pain stemming from a fractured tooth, which Pellmann diagnosed as trigeminal neuralgia and described as the 'suicide disease,' because of the high rates of suicide associated with the condition. . . . [H]e also provided fentanyl for Evans to administer to herself.

*Id.* at 921-22.

160. *Id.* at 921.

161. *Id.* at 923-24.

162. *Id.* at 924-25.

> Obviously, the facts here do not fall within these more common 'drug pusher' cases: Pellmann was not charged with prescribing controlled substances to hundreds of patients, conducting perfunctory examinations, or issuing cookie-cutter prescriptions. Still, there was certainly ample evidence, considered together, for a reasonable jury to determine that Pellmann acted outside of his professional practice and not for a legitimate medical purpose, including: (1) during 2009, Pellmann ordered *30 times* his previous average, annual needs of fentanyl and morphine for his entire practice, all of the excess going to Evans; (2) Pellmann regularly administered fentanyl and morphine to Evans at her home and at Pellmann's home, both of which resembled (for lack of a better description) drug houses; (3) Pellmann maintained no records of distribution of drugs to Evans or his treatment of her, including his apparently concocted diagnosis of trigeminal neuralgia; (4) Pellmann's treatment of Evans was wholly outside his use of fentanyl and morphine in his professional practice; (5) Pellmann's employees were kept in the dark about his claimed treatment of Evans; and (6) following his arrest and initial arraignment, Pellmann again took Evans to a hotel and administered drugs in direct violation of a court order. . . . [T]his evidence is not only sufficient to support the jury's conviction, it is overwhelming.

> [W]hile expert testimony might have aided the jury and the district court would not have erred by admitting such testimony if offered by either party—the government was not required to present expert testimony, especially in light of overwhelming evidence of Pellmann's unprecedented and undocumented prescriptions of profoundly addicting and potent painkillers, which he personally administered in multiple, private houses and hotel rooms Pellmann shared with Evans for long-term treatment of a condition he was unqualified to diagnose and did not treat in his own area of practice. Similarly, while Pellmann was allowed to opine that Evans' claimed medical condition justified this drug regimen, the jury had an ample evidentiary basis to reject it, even without contrary expert opinion.[163]

In *United States v. Singh*,[164] the Second Circuit Court of Appeals affirmed the conviction of Dr. Arvinder Singh on various charges relating to his medical practice, including "twenty-four counts of causing and aiding and abetting the illegal distribution and dispensation of controlled substances, in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2."[165] Singh operated a pain management clinic out of Albany Memorial Hospital but was often not in the clinic to treat patients.[166] Although Singh employed other physicians in his practice, and nurses are not permitted by law to write prescriptions for Schedule II drugs, by pre-signing—sometimes entire books of—triplicate prescription forms, and having his nursing staff fill in the requisite prescription information later, Singh was able to issue prescriptions for controlled substances even when he was not present in the clinic.[167]

Despite Singh's contention "that the District Court 'wrote the essential element of distributing out of the statute and the indictment' in giving the [jury] instruction," the Second Circuit found that the provided instructions correctly set forth the requisite elements constituting "the substantive crime of illegally distributing or dispensing a controlled substance."[168] The Second Circuit concluded that the district court

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*Id.* (emphasis added); *cf. supra* text accompanying notes 150-51 (discussing the facts of *Merrill* where the doctor wrote over 30,000 prescriptions for controlled substances in a three-year period).

163. *Pellmann*, 668 F.3d at 926.

164. 390 F.3d 168 (2d Cir. 2004).

165. *Id.* at 178, 194.

166. *Id.* at 175.

167. *Id.* at 176.

168. *Id.* at 184-85. The challenged portion of the jury instruction stated:

> In order to prove that a person violated Title 21, United States Code, Section 841(a)(1) as set forth in those counts, 42 through 65, the substantive crime of illegally distributing or dispensing a controlled substance, the Government must prove—must establish beyond a reasonable doubt each of the following elements that make up the crime. Three elements are, first, the drugs prescribed were Schedule II Controlled Substances; second, the drugs were prescribed;

permissibly substituted the term "prescribed" for "distributing and dispensing," as the charges stemmed from illegal prescriptions.[169] The Second Circuit also noted that the district court did not err by convicting Singh "without reference to the standard in *Moore* [where] he caused and aided and abetted the distribution or dispensation by others not authorized to do so."[170] The Court of Appeals found that Singh's contention regarding the *Moore* standard, had, in fact, been accommodated in the following portion of the jury instruction afforded:

> If, however you find that it was defendant Singh who prescribed the schedule II controlled substances, then you should consider whether defendant Singh did so "in the usual course of medical practice" and "for a legitimate medical purpose." In other words you must determine whether defendant Singh acted in good faith. Good faith in this context means with reasonable and good intentions and the honest exercise of best professional judgment as to a patient's needs; that is, that defendant Singh acted in accordance with what he reasonably believed to be proper medical practice. The Government bears the burden of proving the lack of good faith beyond a reasonable doubt.[171]

The Second Circuit also found that Singh was appropriately charged as a principal pursuant to 18 U.S.C. § 2, maintaining that someone who aids and abets a section 841(a)(1) offense is still in violation of the CSA.[172] Further, the court found that Singh's contention to this respect, that the jury had been allowed to convict him of offenses not indicated in the indictment, was without merit where, "[t]he indictment charged him with pre-signing the triplicate prescription forms that his nurses later used illegally to distribute and dispense specific controlled substances to individual patients"; the evidence before the district court adequately proved the charges; and the jury was instructed:

> [Y]ou may find defendant Singh guilty of the offense charged if you find beyond a reasonable doubt that the Government has proven that another person actually committed the offense with which defendant Singh is charged and that defendant Singh caused and/or aided or abetted that person in the commission of the offense.[173]

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> and third, that the person who prescribed the Schedule II Controlled Substances knowingly prescribed them and was not authorized to do to [sic].

*Id.* at 185; *cf. supra* text accompanying notes 143-44 (discussing the jury instructions provided in *Feingold*).

169. *Singh*, 390 F.3d at 185.

170. *Id.* at 186.

171. *Id.*; *cf. supra* note 144 (discussing the good faith instruction provided in *Feingold*).

172. *Singh*, 390 F.3d at 186-87.

173. *Id.*

Although there is currently no definitive standard for what constitutes a physician's "course of professional practice" under section 841(a) of the CSA,[174] the cases noted in this Subpart highlight various prescribing practices that are symptomatic of a physician's divergence from his or her respective course of practice.[175] Such practices include billing a patient based on the number of opioids prescribed;[176] writing an exorbitant number of opioid prescriptions, or prescriptions for large quantities of pills, over an unusually short period of time;[177] prescribing doses of opioids well-beyond those accepted by other prescribers for the same purpose;[178] prescribing opioids for minor ailments that do not typically require opioids for treatment;[179] maintaining a patient on an opioid regimen for an extended period without additional examination or testing;[180] prescribing opioids to patients who are obviously addicted;[181] pre-signing prescriptions;[182] and having multiple patients overdose and die due to opioids the physician prescribed.[183] The circuits do not disagree that bad behavior by physicians is indicative of a section 841(a) violation, rather, the divergence exists around the elements of knowledge and good faith.[184] Regardless of whether a physician is held to an objective or subjective good faith standard, or whether a physician's willful blindness will supplant the knowledge requirement,[185] a physician charged with violating section 841(a) is normally judged in-light of objective evidence that is supported by expert opinion, and used to quantify the prescribing at-issue as either in or outside of the course of the physician's personal professional practice.[186] Thus, by constraining the situations in which physicians can prescribe opioids in good faith, states can narrow what constitutes a physician's course of professional practice with respect to prescribing opioids.[187]

174. Hoffman, *supra* note 20, at 283-84.
175. *See supra* Part II.C.
176. *See supra* text accompanying note 88.
177. *See supra* text accompanying notes 88, 138-39, 151-52, 163.
178. *See supra* text accompanying note 119.
179. *See supra* text accompanying note 107.
180. *See supra* text accompanying note 107.
181. *See supra* text accompanying note 108.
182. *See supra* text accompanying note 167.
183. *See supra* text accompanying note 150.
184. *See supra* notes 90-91, 95-96 and accompanying text.
185. *See supra* text accompanying notes 90, 96.
186. *See supra* text accompanying note 71.
187. *See infra* Part III.

## III. PERMISSIVE FEDERAL GUIDELINES AND STATE STATUTES AND THEIR IMPLICATIONS ON THE COURSE OF PROFESSIONAL PRACTICE FOR PRESCRIBING OPIOIDS TO TREAT PAIN

Typically, whether or not a physician's prescription practices are found to violate the CSA is determined by competing expert testimony.[188] Nonetheless, certain instances—where physician misconduct is so obvious that it denotes an utter lack of a legitimate medical purpose for the prescription issued—lend themselves to a jury determination without such expert testimony.[189] In essence, juries are left to make medical judgments as to the boundary separating the practice of medicine and pill pushing and to determine whether or not the physician crossed that line.[190] The treatment of pain is undeniably held by the scientific and medical communities as a legitimate medical purpose for the prescription of opioids.[191] However, differentiating lawful and unlawful prescribing under the CSA is particularly perplexing due to pain's intangible nature and the varying views on how to properly treat it.[192] Pain's subjectivity requires that physicians rely on patient declarations of pain and incorporate their assessments into their patient's treatment.[193] Additionally, the unclear and arguably subjective "usual course of his professional practice" dictated by Section 1306.04(a) of the Code of Federal Regulations, in regards to prosecuting prescribers under Section 841 of the CSA, has not yielded a clear-cut rule among the courts in its application.[194] Subpart A of this section will explore non-authoritative guidelines offered by the DEA and CDC regarding the prescription of opioids.[195] Subpart B examines state statutes from Washington and New York that provide mandatory guidelines with regard to prescribing opioids and help narrow the scope of what constitutes the course of professional practice for prescribing opioids.[196]

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188. Gilbert & Rowland, *supra* note 55, at 401.

189. *Id.* at 401-02.

190. *See* James & Lohmeyer, *supra* note 53, at 17.

> Inasmuch as the CSA 'conveys an unwillingness to cede medical judgments to an executive official who lacks medical expertise,' it follows that Congress cannot have intended to cede juries medical judgments about the legitimacy of prescribing pain medications to patients who report pain to their doctors. Yet this is precisely what jurors are asked to do in cases involving doctors accused of prescribing medications without a legitimate medical purpose. Jurors are asked to find the line between practicing medicine and pushing pills.

*Id.*

191. *See id.* at 16 (discussing the recognition by the medical and science communities of the legitimate medical use of opiate analgesics to treat pain, as reflected in the Business and Professions Code of California).

192. Goodman, *supra* note 24, at 223-24.

193. *See* Dilcher, *supra* note 27, at 117-18 (discussing that the subjective nature of pain interferes

### *A. Permissive National Prescribing Guidelines: A Noble Attempt but Powerless Nonetheless*

At the state level, "there is [currently] no consistent and cohesive approach" to the regulation of opioid prescribing.[197] Attempts to clarify proper prescription practices with respect to opioids have been made by both the FDA[198] and the CDC.[199] These guidelines are permissive and simply serve as suggestions for what constitutes proper prescribing practices.[200] Alternatively, states such as Washington and New York have adopted regulatory schemes that state mandatory guidelines for prescribing opioids, and in doing so, have defined some aspects of the appropriate course of professional practice for prescribing opioids to their respective populations.[201]

#### 1. FDA Risk Evaluation and Mitigation Strategies and Evidence-Based Guidelines

Through the passage of the of the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Congress granted the FDA the power to implement Risk Evaluation and Mitigation Strategies ("REMS"), through which the FDA can require pharmaceutical companies "to propose strategies to mitigate certain risks of drugs that have high or suspected high risk of abuse and overdose."[202] This Congressional grant does not, however, give the FDA any authority over physicians as to how they may prescribe a drug,[203] but does allow the FDA to require prescribers to register with the FDA, in addition to their registering with the DEA.[204] Additionally, the FDA can use REMS that require pharmaceutical companies to provide patient-labeling inserts,

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with its incorporation into the practice of medicine because physicians rely on objective tests to assess pain).

194. Hellman, *supra* note 93, at 707-08 (discussing how applying the standard set forth by § 1306.04(a) as it pertains to prosecuting physicians under § 841 of the CSA has proven difficult and garnered a number of interpretations among the circuit courts).

195. *See infra* Part III.A.

196. *See infra* Part III.B.

197. Angelo J. Cifaldi & Lisa English Hinkle, *Regulations and Policies Affecting a Physician's Prescribing Authority*, 2016 AHLA SEMINAR PAPERS 2, 9 (Feb. 8, 2016).

198. *See infra* Part III.A.1.

199. Dowell et al., *supra* note 17.

200. *See infra* text accompanying note 203, 228.

201. N.Y. Pub. Health Law § 3331(5)(b) (McKinney 2018); Cifaldi & Hinkle, *supra* note 197, at 10.

202. Barnes & Arndt, *supra* note 10, at 296.

203. *Id.* at 297-98.

204. Christopher J. Frisina, *Let FDA Regulate Its Own Drugs!: An Argument for Narcotic Control and Enforcement Under the Risk Evaluation and Mitigation Strategies (REMS)*, 27 LOY. CONSUMER L. REV. 238, 265 (2015).

medication guides, and provider communication plans—via conference presentation, mail, or some other means—to both patients and providers to inform them of the risks associated with a particular FDA-approved drug.[205]

The FDAAA allows the FDA to condition its approval of a subject drug on a drug manufacturer's submission of REMS reports that require "such elements as are necessary to assure the safe use of the drug," including: (1) that a prescriber have specific training, experience, or certification; (2) special certification of pharmacies; (3) setting in which the drug can be dispensed; (4) dispensation to patients upon evidence of safe use; (5) patient monitoring; and (6) patient enrollment in a drug registry.[206] This provision is notable because on September 18, 2018, the FDA approved the new REMS for opioid analgesics that cover immediate-release opioids for outpatient-use—which had not been previously covered—and long-acting and extended-release opioids.[207] This is the first time the REMS program is requiring that "training be made available to health care providers who are involved in the management of patients with pain, and not only to prescribers."[208]

The REMS is also requiring that a wider range of information, including opioid alternatives, be covered by the education.[209] The FDA's goal for this new REMS "is to reduce unnecessary and/or inappropriate exposure to opioids by making certain that Health Care Providers ("HCPs") are properly informed about appropriate prescribing recommendations, that HCPs understand how to identify abuse by individual patients, and know how to get patients with opioid use disorder into treatment."[210] However, this REMS's requirements pertain to pharmaceutical companies and prescribers are not actually required to do

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205. *Id.* at 263.

206. *Id.*; *see also* 21 U.S.C. § 355-1(f) (2018). In regard to the prescriber training, experience, or certification elements of these REMS, section 355-1(f)(3)(A) specifically states:

> [H]ealth care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider).

21 U.S.C. § 355-1(f)(3)(A).

207. *FDA Takes Important Steps to Encourage Appropriate and Rational Prescribing of Opioids Through Final Approval of New Safety Measures Governing the Use of Immediate-Release Opioid Analgesic Medications*, FED. DRUG ADMIN. (Sept. 18, 2018), https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-encourage-appropriate-and-rational-prescribing-opioids-through-final.

208. *Id.*

209. *Id.*

210. *Opioid Analgesic Risk Evaluation*, *supra* note 44.

anything in accordance with the new REMS to prescribe opioids, although the FDA is currently considering the pursuit of mandatory education and how to effectuate it.[211]

In regard to this voluntary training, the FDA has outlined the desired learning objectives for providers who prescribe opioids, in its *FDA Education Blueprint for Healthcare Providers Involved in the Treatment and Monitoring of Patients with Pain* ("Blueprint").[212] This document discusses the importance of continued provider education in light of the current opioid epidemic,[213] as well as the purpose of this REMS education.[214] The Blueprint acknowledges the competing public health problems associated with prescription opioids—the adequate treatment of patients with chronic pain and the opioid epidemic—and provides recommendations with regard to patient assessments prior to prescription,[215] creating pain treatment plans,[216] and managing patients who are prescribed opioids for pain.[217] In regard to patient assessments, the Blueprint urges that providers know how to make effective assessments of patients before initiating a pain management program and that such assessments should include:

> (1) Patient history; (2) Screening tools to evaluate the known risk factors for the development of chronic pain after an acute injury or disease; (3) Screening tools to evaluate the known risk factors for opioid use disorder (OUD) or abuse; (4) Queries of state prescription drug monitoring programs (PDMPs); (5) Pain assessment scales/tools; (6) Functional assessment scales; (7) Physical examination; (8) Family planning, including information about use of contraceptives, pregnancy,

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211. *Id.*

> There is no mandatory federal requirement that prescribers or other HCPs take the training and no precondition to prescribing or dispensing opioid analgesics to patients. However, the FDA's Opioid Policy Steering Committee continues to consider whether there are circumstances when the FDA should require some form of mandatory education for HCPs, and how the agency would pursue such a goal.

*Id.*

212. *See Monitoring of Patients with Pain*, *supra* note 44, at 1.

213. *Id.* at 2-3.

> Adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioids have emerged as major public health problems. It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as they pertain to their patients as well as from a public health perspective. The data continue to show problems associated with prescription opioid analgesics.

*Id.* at 2.

214. *Id.* at 4.

215. *Id.* at 5.

216. *Id.* at 6.

217. *Id.* at 10.

> intent/status and plans to breastfeed; (9) Psychological and social evaluation; [and] (10) Diagnostic studies when indicated.[218]

With respect to patient management, the Blueprint lists things for providers to consider before initiating opioid treatment for both acute and chronic pain, as well as ongoing and long-term management of patients' pain.[219] Some notable considerations for initiating treatment include consulting a prescription drug monitoring program ("PDMP") before initiating treatment and weighing risks and appropriate dosing to treat pain for its expected duration.[220] For long-term and ongoing patient management the considerations provided in the Blueprint sound in the tune of review, calling for a recurring review of the patient goals; review of PDMPs; evaluation of patients for opioid use disorder; and "[m]onitoring patient adherence to the treatment plan, especially regarding misuse and abuse."[221] The Blueprint also specifies that physicians should know how to wean patients off of opioids and the associated risks, and should be able to identify withdrawal symptoms and know how to manage them.[222]

Although the FDA Blueprint recognizes the areas in which prescribers "should be knowledgeable," it does not provide any of the actual knowledge a prescriber should have when treating a patient with opioids—that is, it does not state what dose should actually be used in a given situation—and is arguably rendered less effective by the fact that this education is voluntary.[223] However, in a statement made on August 22, 2018, the FDA Commissioner, Scott Gottlieb, M.D., acknowledged one area in need of redress that is helping to fuel the opioid epidemic—prescription duration.[224] Dr. Gottlieb then went on to say that one of the ways the FDA believes it can work with providers to address this health

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218. *Id.* at 5-6; *cf. supra* note 145.

219. *Monitoring Patients with Pain*, *supra* note, 44 at 10-11.

220. *Id.* at 6, 10-11.

221. *Id.* at 10-11.

222. *Id.* at 11.

223. *See id.* at 4, 10-12.

224. Scott Gottlieb, *Statement by FDA Commissioner Scott Gottlieb, M.D., on New Steps to Advance the Development of Evidence-Based, Indication-Specific Guidelines to Help Guide Appropriate Prescribing of Opioid Analgesics*, FED. DRUG ADMIN. (Aug. 22, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm617908.htm.

> Our analyses suggest that the first prescription for many common, acute indications could typically be for many fewer pills—maybe just a day or two of medication rather than a 30-day supply, which is typically prescribed. In some cases, the excess pills that aren't used by patients may end up being diverted to illicit markets or misused or abused by friends or family members. In other cases, patients who are prescribed more medication than necessary may find themselves at increased risk for misuse, abuse, and addiction.

*Id.*

crisis is through the creation of "evidence-based guidelines on appropriate opioid analgesic prescribing to treat acute pain resulting from specific medical conditions and common surgical procedures," in collaboration with the National Academies of Sciences, Engineering, and Medicine.[225] However, as the FDA has no authority to decree how a physician is to use a given drug within the course of his or her practice once it has been approved, these guidelines, like the REMS, will simply serve as an example of appropriate provider behavior, and will not define a compulsory course of professional practice with respect to prescribing opioids.[226]

2. CDC Guideline for Prescribing Opioids for Chronic Pain

In 2016, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to "provide[] recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care."[227] In this permissive guideline, the CDC addresses multiple issues with regard to prescribing opioids, including when treatment with opioids should be initiated or maintained, and how a physician should determine the appropriate drug and dosage to provide.[228]

The CDC recommends that physicians avoid prescribing opioids for chronic pain unless they determine the risk to the patient is less than the combined benefit to both the patient's function and level of pain.[229] The CDC notes a number of alternatives to opioid therapy for chronic pain derived from specific ailments—for example, "weight loss for knee osteoarthritis"—and urges physicians to consider such alternatives before prescribing opioids.[230] The guidelines also suggest that physicians should initially prescribe immediate-release opioids when treating patients with opioids for chronic pain, noting a higher risk of overdoses found where patients were initiated on extended-release opioids.[231] Further, the CDC advises prescribing the "lowest effective dosage" when starting a patient on opioids, and reminds physicians that the "[b]enefits of high-dose opioids for chronic pain are not established."[232] The CDC suggests that

225. *Id.*

226. Buzzee, *supra* note 64, at 226-27.

227. Dowell et al., *supra* note 17, at 1.

228. *See id.*

229. *Id.* at 16.

230. *Id.* at 17.

231. *Id.* at 17-18.

232. *Id.* at 22. "The clinical evidence review found only one study addressing the effectiveness of dose titration for outcomes related to pain control, function, and quality of life (KQ3). This randomized trial found no difference in pain or function between a more liberal opioid dose escalation strategy and maintenance of current dosage." *Id.*

when treating with opioids for acute pain, a three-day opioid prescription should suffice and that more than a seven-day supply is likely excessive.[233] The CDC advises following up with a patient within the first month of being prescribed opioids—and additional follow-ups every month or less—and to consider whether or not to taper-off the patient or continue a given dose.[234] They also recommend checking prescription drug monitoring programs to review a patient's prescription history and urine testing patients before initiating opioid therapy to check for non-reported drug-use that could cause an overdose if combined with opioids.[235] It is also recommended that opioids not be prescribed in conjunction with benzodiazepines and that doctors "should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder."[236] Similar to the REMS and prospective opioid-prescribing guidelines set-forth by the FDA, these CDC *recommendations* do not mandate compulsory procedures for prescribers to follow when treating pain with opioids, and therefore, do not define a prescriber's course of professional practice.[237]

### *B. State-Mandated Prescribing Standards*

In order to curb the misuse of controlled substances, some states have set up regulations that restrict a prescriber's ability to prescribe these drugs, removing their ability to prescribe as they choose.[238] Two ways states accomplish this end are by restricting the situations in which a prescriber can prescribe pain medication and by restricting the quantities and dosages for which these drugs are prescribed.[239] Alternatively, some states have provided voluntary prescribing guidelines, specifically targeted at the prescription of opioids.[240] However, because these guidelines are voluntary, they do not, themselves, establish a standard of care for prescribers.[241] In response to a rise in prescription-opioid overdoses, Washington state restricted prescriber prescription practices in

233. *Id.* at 16.
234. *Id.* at 25.
235. *Id.* at 21.
236. *Id.* at 32.
237. *See supra* text accompanying note 226.
238. Dilcher, *supra* note 27, at 103-04.
239. *Id.* at 104.
240. *See* ARIZ. DEP'T OF HEALTH, ARIZONA OPIOID PRESCRIBING GUIDELINES 1, 5 (2018), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelinesrecommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf.
241. *See id.* at 2, 5; *see also* COLO. DEP'T OF REGULATORY AGENCIES, POLICY FOR PRESCRIBING AND DISPENSING OPIOIDS iii (2014), https://www.colorado.gov/pacific/dora/opioid_guidelines.

2010 by passing a bill specifically targeting the treatment of chronic-pain[242] to curtail opioid abuse and diversion.[243] This bill, Engrossed Substitute House Bill 2876 ("ESHB 2876"),[244] states dose-limits and "requires consultation with a pain management provider for any patient on daily doses of opioids at or over 120 mg (in morphine equivalents)."[245] The law also requires patients to sign treatment agreements and demands physicians create care plans and oversee patient compliance with them.[246] It should be noted that these guidelines are consistent with those offered by the FDA and CDC, aside from their authority to command compliance.[247]

Despite its aim to curb prescription opioid overdoses, the bill was not well-received by physicians, many of whom feared prosecution under the law.[248] As a result of ESHB 2876, and the fear it invoked, many prescribers ceased prescribing opioids to treat chronic pain and abandoned patients that they had been treating.[249] Critics of the bill view the doses permitted as ineffective for the treatment of chronic pain and attribute increased patient suffering to its passing and the resulting fear that physicians will be prosecuted for their prescription practices.[250] Since 2010, prescription opioid-related deaths in Washington have taken a slight downward trend;[251] however, heroin overdose deaths rose steadily from 2010-2015.[252]

New York also statutorily defines aspects of a prescriber's course of professional practice in regard to opioids.[253] In New York, "a practitioner, within the scope of his or her professional opinion or discretion, may not prescribe more than a seven-day supply of any Schedule II, III, or IV opioid to an ultimate user upon the initial consultation or treatment of such user for acute pain."[254] This particular provision of New York's Public Health Law clearly states that a physician acts outside of the course of

242. Dineen, *supra* note 41, at 59.

243. Lucas Newbill, *Violating Free Speech in the War on Opioid Addiction: The Washington Legislature's Voice in the Doctor's Office*, 52 GONZ. L. REV. 95, 95-96 (2017).

244. Dineen, *supra* note 41, at 59 n. 413.

245. *Id.* at 59.

246. *Id.* at 60.

247. *See supra* Part III.A.

248. Dineen, *supra* note 41, at 59-60.

249. *Id.* at 60.

250. *Id.* at 59-60.

251. *Opioid-Related Deaths in Washington State, 2006-2016*, WASH. ST. DEPT. OF HEALTH 1 (May 2017), https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf (showing an overall decrease in the number of prescription opioid overdose deaths from 2010-2015, with increased death tolls in 2010 and 2015).

252. *Id.*

253. N.Y. PUB. HEALTH LAW § 3331 (McKinney 2018).

254. HEALTH § 3331(5)(b).

their professional practice when prescribing more than a seven-day supply upon the initiation of treatment for acute pain.[255] New York also restricts patients from being maintained on opioids for pain treatment for greater than three months, or beyond the time tissue normally takes to heal.[256] If a physician feels that a patient's condition requires opioid treatment beyond this period, he or she must be following a written plan based on recognized guidelines contained in the patient's medical record.[257] New York expressly prohibits prescribing controlled substances to addicts, except in specific circumstances.[258] Further, New York prohibits refills on Schedule II, and certain Schedule III and IV substances, without a new prescription.[259]

New York Penal Law Section 220.65 makes it a class C felony for a physician to unlawfully sell a controlled substance or a prescription for a controlled substance.[260] A physician is in violation of the statute where "he knowingly and unlawfully sells a prescription for a controlled substance" and defines that "a person sells a prescription for a controlled substance unlawfully when he or she does so other than in good faith in the course of his or her professional practice."[261] This provision provides the same good faith protection for providers allowed by the federal circuit courts in prosecutions under section 841(a)(1) of the CSA, but more narrowly restricts its prohibition to unlawful sales.[262]

Where New York clearly defines specific aspects of a physician's professional practice,[263] jurors lacking in medical knowledge do not need to place as much reliance on conflicting expert testimony to see where a provider has prescribed unlawfully, and thus, has acted outside of the course of his or her professional practice.[264] Conversely, if a provider prescribes opioids in accordance with provisions mandating the course of their professional practice, it should be apparent to a jury that they have done so lawfully.[265]

As previously acknowledged, the treatment of pain has been held by physicians and scientists as a legitimate medical purpose for the

255. *Id.*
256. HEALTH § 3331(8).
257. *Id.*
258. HEALTH § 3350.
259. HEALTH § 3339.
260. N.Y. PENAL LAW § 220.65 (McKinney 2008).
261. *Id.*
262. *Id.*; *cf. supra* Part II.C.
263. *See* Barnes & Sklaver, *supra* note 89, at 114-15 (mentioning the ways in which New York and other states require physicians to actively verify a patient's need before prescribing controlled substances).
264. *See supra* Part II.C.
265. *See supra* Part II.C.

prescription of opioids.[266] According to the CDC "[a]n estimated 20% of patients presenting to physician offices with noncancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription."[267] One inference that can be drawn from this estimate is that it is completely within the course of professional practice to prescribe opioid medications when a patient presents with pain; another, however, is that prescribers too-quickly prescribe opioids to patients complaining of pain before considering alternative treatment.[268] In a state that provides statutory guidelines limiting the scope of a physician's professional practice, jurors charged with determining whether the physician prescribed opioids lawfully need-not make such inferences as frequently as jurors in states that do not.[269] However, the effects of these statutory mandates have questionable implications on patient behavior where opioid-treatment is withdrawn.[270]

## IV. PROPOSED SOLUTION: NARROWING THE VIEW OF WHAT CONSTITUTES PRESCRIBING OPIOIDS WITHIN THE "COURSE OF PROFESSIONAL PRACTICE" FOR THE "LEGITIMATE MEDICAL PURPOSE" OF TREATING PAIN BY DEFINING THE SITUATIONS IN WHICH A PHYSICIAN CAN PRESCRIBE OPIOIDS IN GOOD FAITH UNDER STATE CONTROLLED SUBSTANCE ACTS

In order to fight the opioid epidemic claiming tens of-thousands of American lives per year, while balancing this aim with the competing fears of prosecution and untreated-pain,[271] this Note proposes the following model statute to narrow the scope of what constitutes a physician's course of professional practice, specifically in regard to prescribing opioids for treating pain:[272]

> A physician acts in good faith when prescribing opioids for the legitimate medical purpose of treating pain,[273] where he or she:
> (a) does so legally;[274] and (b) his or her area of practice qualifies use of

266. *See supra* note 191 and accompanying text.
267. Dowell et al., *supra* note 17, at 1.
268. *See id.* at 2.
269. *See* Dilcher, *supra* note 27, at 95.
270. *See supra* notes 251-52 and accompanying text.
271. *See supra* note 27 and accompanying text.
272. *See infra* notes 273-81 and accompanying text.
273. *See supra* note 191 and accompanying text.
274. United States v. Feingold, 454 F.3d 1001, 1012 (9th Cir. 2006) (noting that Feingold illegally prescribed Schedule II substances in violation of an Arizona law forbidding naturopathic physicians to do so).

> the chosen course of treatment;[275] and (c) in light of admissible evidence[276] a reasonable physician in the same or similar area of medical practice [277] would conclude that he or she: (1) exercised professional judgment in an honest attempt to treat the patient to the best of his or her ability;[278] and (2) prescribed with competence[279] and respect for widely-accepted[280] and established treatment-standards.[281]

States that adopt this statute can clarify the course of a physician's professional practice for prescribing opioids by defining the defense to their respective CSA instead of imposing liability for non-compliance with additional restrictions on a physician's practice.[282] Given the elusive nature of pain and a physician's need to rely on a patient's subjective manifestations to treat it,[283] it is no surprise that opioid regulation and prescription practices vary greatly among the states.[284] This statute is designed to overcome these inconsistencies, by objectively quantifying a physician's subjective intentions for treating a patient and modifying the reasonable physician civil malpractice approach to reflect the views of a reasonable physician that is similarly situated to the prescriber in terms of medical practice.[285] However, this reasonable physician does not just look to the physician's intent, but to his or her competence and adherence to established standards,[286] such as those provided by the FDA and CDC.[287]

Through this objective-subjective approach, the statute would define good faith under the adopting state's CSA, while also providing physicians a concrete example of how to prescribe opioids in accordance with the standard provided by *Moore*.[288] Physicians prescribing opioids in

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275. United States v. Pellmann, 668 F.3d 918, 921 (7th Cir. 2012). Pellmann, a primary care physician, used copious amounts fentanyl and morphine to treat a patient he diagnosed with trigeminal neuralgia, "a condition he was unqualified to diagnose and did not treat in his own area of practice." *Id.* at 926.

276. *See* United States v. Tran Trong Cuong, 18 F.3d 1132, 1141 (4th Cir. 1994). The Fourth Circuit reversed Tran's conviction because of the improper introduction of expert testimony. *Id.*

277. United States v. McIver, 470 F.3d 550, 556 n.9 (4th Cir. 2006) (borrowing from the "reasonable physician" standard discussed by the Fourth Circuit).

278. *Tran Trong Cuong*, 18 F.3d at 1138 (rephrasing the definition of "[g]ood faith" provided in Tran's subjective jury instruction); *cf. supra* text accompanying note 218.

279. *Feingold*, 454 F.3d at 1013. Feingold "claimed that he was an incompetent doctor who was honestly trying to help his patients manage pain" and that the charges against him arose as a result of his lack of training. *Id.*; *cf. supra* text accompanying note 206.

280. *See supra* Part III.A.

281. *See supra* note 232 and accompanying text.

282. *See infra* Part V.

283. *See supra* notes 192-193 and accompanying text.

284. *See supra* text accompanying notes 15-17.

285. *See supra* note 131.

286. *See supra* text accompanying notes 280-281.

287. *See supra* Part III.A.

288. United States v. Moore, 423 U.S. 122, 138-40 (1975). Before convicting Moore of violating

good faith, in accord with the statute, could prescribe confidently, knowing that they did so for a legitimate medical purpose and within the course of his or her professional practice.[289] This knowledge should effectively eliminate the fears that physicians will be prosecuted for prescribing, and that patients' pain will go untreated.[290]

## V. CONCLUSION

Opioids are killing Americans at an alarming rate and something must be done to stop this tragic loss of life.[291] Although the CSA provides a scope within which physicians may prescribe these deadly substances, the Act does not clearly define the appropriate boundaries for prescribing them.[292] This becomes problematic because in situations where doctors are charged under the statute, it is essentially up to a jury of untrained individuals to make medical decisions as to what is appropriate prescription practice.[293] By combining various approaches of the circuit courts and defining the situations a physician can prescribe in good faith under a state's CSA, the statute proposed in this Note offers a clear and lawful course of professional practice for prescribing opioids to treat pain.[294] Although the boundaries afforded by the proposed statute are not expressly defined in terms of appropriate dosages or prescription durations, by approaching a physician's prescribing practices and subjective intent from the objective viewpoint of a similarly-situated physician, and accounting for legality, prescriber competence, and respect to widely-accepted and established prescribing-standards, the proposed statute—if adopted—would offer an approach to prescribing, that if carefully observed, would effectively make it impossible for a jury to find that a physician prescribed opioids outside the course of his or her professional practice, beyond the reasonable doubt necessary to convict under section 841(a)(1) or an equivalent state provision.[295]

In other words, if a physician prescribes opioids in accordance with

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section 841(a)(1), the trial court instructed the jury:

> [B]eyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute (methadone) by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally accepted in the United States.

*Id.*; *see also supra* note 171 and accompanying text; *cf. supra* notes 273-80 and accompanying text.

289. *Moore*, 423 U.S. at 138-40.

290. *See supra* text accompanying notes 248-250.

291. *See supra* Part II.A.

292. *See supra* Part II.B.

293. *See supra* Part II.C.

294. *See supra* Part IV.

295. *See supra* Part III.A.

the statute, there is no reason to fear prosecution, and therefore no reason to curtail treatment of patients with legitimate pain.[296] By removing the physician's fear that he or she will be prosecuted, the statute should also alleviate a patient's fear of untreated pain.[297] Thus, this Note urges the legislatures of the fifty states to adopt this proposed statute so that good doctors can be confident they are lawfully prescribing opioids to treat pain, and those acting as "pushers" can be readily identified and prosecuted, in the hopes that removing them and their poisonous prescriptions from society is just the pill this Great Nation needs to recover from the opioid epidemic.[298]

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296. *See supra* Part III.A.2.

297. *See supra* Part III.B.

298. *See supra* Part IV.

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