CLOSING THE BRIDGE FROM PRESCRIPTION TO ADDICTION: HOW A FEDERAL STATUTE CAN SAVE THE EFFECTS OF (UN)CONTROLLED SUBSTANCES AMID THE OPIOID CRISIS

Olivia Cox*

* Juris Doctor Candidate, University of Memphis Cecil C. Humphreys School of Law (expected 2024). I would like to thank Professor Donna Harkness and Professor Sonya Garza for their constructive insight and encouragement throughout the Note-writing process. Thank you to Kenneth Groce, Ryan Rosenkrantz, and Claire Rowland for guiding me in the development of my Note. Lastly, many thanks to the members of the *Virginia Journal of Social Policy & the Law*, especially Maya Artis, Abigail Ferrell, and Abigail Hauer, for their valuable contribution to publishing my Note.

CLOSING THE BRIDGE FROM PRESCRIPTION TO ADDICTION: HOW A FEDERAL STATUTE CAN SAVE THE EFFECTS OF (UN)CONTROLLED SUBSTANCES AMID THE OPIOID CRISIS

Olivia Cox

The escalating opioid epidemic illustrates the dire consequences of prescription abuse and the inadequate response from current legal standards. In 2022, the Supreme Court decided Ruan v. United States*. At issue in* Ruan *was the requisite mens rea for the unauthorized prescribing of controlled substances under federal law. Rejecting an objective standard, the Court held that prosecutors must prove beyond a reasonable doubt that medical professionals knowingly or intentionally prescribed controlled substances in an unauthorized manner. But the Court failed to delineate clear guidelines for valid prescriptions, subjecting medical prescribers to the vague, inconsistent, and overly lenient standards of the Controlled Substances Act. This Note critiques the vagueness of federal laws and their inconsistent application across jurisdictions and proposes a federal solution to regulate the prescribing of opioids. The proposed federal criminal statute — the Tracking and Regulation of Used Substances and Treatment (TRUST) Act — aims to establish a balance between penalizing overprescription and ensuring legitimate pain management, emphasizing the need for legislation that incorporates both subjective intent and objective medical standards.*

INTRODUCTION

Growing up, Matthew Stavron had dreams of becoming a professional motocross racer.[1] However, as an extreme sport athlete, Matthew suffered multiple serious injuries beginning when he was just thirteen years old.[2] Desperate for pain relief, Matthew saw Dr. Hsiu Ying Lisa Tseng, a physician in Rowland Heights, California, who prescribed him a combination of OxyContin, Soma, and Xanax.[3] Less than thirty-six hours later, Matthew's mother found him lying on the bathroom floor in a fetal position, surrounded by pills.[4] Matthew had died of an overdose.[5] Unbeknownst to Matthew's parents, the Drug Enforcement Agency had been investigating Dr. Tseng for five months prior to his death, after several

---

[1] This story is based on People v. Tseng, 241 Cal.Rptr.3d 194 (2018); *see also* Aly Vander Hayden, *'Drug Dealing' California Doctor Arrested After 14 Patients Die from Overdoses*, OXYGEN (Sept. 5, 2020, 7:00 PM), https://www.oxygen.com/license-to-kill/crime-news/doctor-hsiu-ying-lisa-tseng-convicted-patient-deaths (describing Matthew's life story and Dr. Tseng's prosecution).

[2] Hayden, *supra* note 1.

[3] *Id.*

[4] *Id.*

[5] *Id.*

pharmacists reported the enormous and outrageous amounts of controlled substances Dr. Tseng was prescribing to patients.[6] Ultimately, Dr. Tseng was sentenced to life imprisonment for second degree murder and the unlawful prescribing of controlled substances to patients, but not before thirteen more of her patients died of an overdose shortly after visiting her.[7]

Human ingenuity has ignited a detrimental reliance on a class of opioid drugs that create a false sense of well-being. The rampant illegitimate prescribing of opioids and related overdoses has facilitated an ongoing crisis throughout the United States that has shattered countless lives, families, communities, and societies at large. For the first time in 100 years, the United States' average life expectancy has declined as a result of related opioid overdoses and suicides.[8] The United States has not experienced a similar decline since the military deaths in World War I and the influenza pandemic.[9] Compared to other countries, the rates of opioid use disorder (OUD) and opioid overdoses in the United States have risen rapidly and surpassed unprecedented levels, resulting in an epidemic.[10] The U.S. Department of Health and Human Services recent data estimates that at least two million Americans have an OUD linked to prescription opioids.[11]

The opioid epidemic's toll has swept the entirety of the United States and has expanded across various age groups, ethnicities, races, and regions.[12] Recognizing the profound effects of the crisis, Former President

---

[6] *Id.*

[7] *Id.*

[8] Sarah Deweerdt, *The Natural History of an Epidemic*, 73 NATURE 10, 10 (2019).

[9] Deweerdt, *supra* note 8, at 10.

[10] COMM. ON PAIN MGMT. AND REGUL. STRATEGIES TO ADDRESS PRESCRIPTION OPIOID ABUSE, PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE (Richard J. Bonnie, Morgan A. Ford, & Jonathan K. Phillips eds., 2017), https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf_NBK458660.pdf. The United States constitutes the greatest consumer of morphine, a potent pain reliever, accounting for more than fifty percent of all global consumption. Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States' Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia's Alternative Regulatory Approach*, 47 COLUM. J. TRANSNAT'L L. 210, 212 (2008). Not only have other countries not experienced the same rapid rise in opioid abuse and overdoses, but most high-income countries have increased their life expectancies for decades. Deweerdt, *supra* note 8, at 10 (noting that in most high-income countries, life expectancy has been steadily increasing for decades).

[11] BONNIE ET AL., *supra* note 10. Nearly half of chronic pain patients with substance use disorder (SUD) diagnoses have reported that opioids prescribed to relieve their pain were the root cause of their disorder. *Id.*

[12] Kumiko M. Lippold et al., *Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-Involved Overdose Deaths Among Adults Aged ≥ 18 Years in Metropolitan Areas – United States, 2015–2017*, 68 MORBIDITY &

Trump declared the opioid epidemic a public health emergency in October of 2017.[13] In 2020 alone, over 68,000 deaths were caused by an overdose on opioids — a steady rise from previous years.[14] To place this number in perspective, current national trends suggest that each year more people die of overdoses than the collective number of deaths in the Vietnam War, the Korean War, or any armed conflict since the end of World War II.[15] In addition to the pain and suffering experienced by patients, families, and communities, the opioid crisis has also caused major social and economic harm.[16] The "total 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement."[17] The Centers for Disease Control and Prevention (CDC) reported that the leading factor in the increase of opioid misuse, addiction, and related deaths is the rapid prescribing of opioids as a pain management method.[18]

Despite the severity of the opioid crisis, the Supreme Court has failed to provide a clear legal standard delineating what constitutes a valid description. In *Ruan v. United States*, the Supreme Court held that the "knowingly or intentionally" mens rea applies to the Controlled Substances Act's authorization clause. The Court ultimately failed to address the scope of authorization,[19] leaving healthcare professionals and prosecutors no guidance on what constitutes prescriptions written within the

---

MORTALITY WKLY REP. 967 (Nov. 1, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6843a3.htm.

[13] *Ending America's Opioid Crisis*, TRUMP WHITE HOUSE, https://trumpwhitehouse.archives.gov/opioids/ (last visited Oct. 7, 2022).

[14] *Overdose Death Rates*, NAT'L INST. ON DRUG ABUSE (Feb. 9, 2023), https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates.

[15] BONNIE ET AL., *supra* note 10. It is further estimated that ninety Americans die each day from an overdose involving an opioid. *Id.*

[16] Additionally, the opioid crisis has adjusted the federal budget by increasing federal spending on health care, the child welfare system, and efforts to reduce drug trafficking. *The Opioid Crisis and Recent Federal Policy Responses*, CONG. BUDGET OFF. (Sept. 2022), https://www.cbo.gov/system/files/2022-09/58221-opioid-crisis.pdf. Effectively, federal spending on benefits, such as Medicare and Social Security, has been reduced due to the vast opioid-related deaths. *Id.* Tax revenues have also been reduced because of lost earnings resulting from reduced longevity and from a loss of economic productivity. *Id.*

[17] *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (May 27, 2020), https://perma.cc/QA5B-JM6R. It is estimated that the public sector has endured one-quarter of the cost in health care, substance abuse treatment, public insurance, and criminal justice system costs. Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 MED. CARE 901 (2016).

[18] Cale Coppage, Comment, *From Prescription to Addiction: Treating the Cause of the Opioid Epidemic and Improving the FDA's Risk Evaluation and Mitigation Strategies (REM) Program*, 71 ADMIN. L. REV. 103, 104 (2020).

[19] Xiulu Ruan v. United States, 142 S. Ct. 2370, 2381 (2022).

"usual course of professional practice" and "for a legitimate medical purpose." The Court's dogmatic decision emphasizes the impermissibly vague and substantially overbroad standards governing medical professionals.[20] This Note argues that the current federal laws regulating the prescribing of opioids and the courts' inconsistent standards are unconstitutionally vague and only magnify the effects of the opioid epidemic.

Part II of this Note describes the origin of the opioid crisis and the history of the federal laws relating to opioid use in the United States. Part II further analyzes the Eleventh and Tenth Circuits' holdings in *United States v. Ruan* and *United States v. Khan*, respectively, and the consolidation of these cases in *United States v. Ruan*, a recent decision by the United States Supreme Court. Part III argues that the unconstitutionally vague standards neither punish physicians who overprescribe controlled substances, nor deters other physicians from engaging in that practice, and thus, the standards contribute to the devastating and deadly effects of the opioid crisis. Finally, Part IV advocates for Congress to enact a federal criminal statute that punishes healthcare professionals who overprescribe controlled substances, deters others from accelerating the harmful effects of prescription opioids, and simultaneously encourages prescribers to treat patients within the ethical bounds of medical practice by providing consistent and clear guidelines.

I. GENESIS OF THE OPIOID EPIDEMIC AND ITS EVOLUTION

The Controlled Substances Act (CSA) serves as the principal statute combatting drug abuse and criminalizing drug trafficking of controlled substances in the United States.[21] The CSA provides a legal framework to regulate classes of drugs — whether used for medical or recreational purposes — which pose a significant risk of abuse.[22] The statute also regulates doctors who prescribe controlled substances in deviation from his or her usual course of professional practice and without a legitimate medical purpose.[23] In enacting the CSA, Congress intended to both protect the public health from the vast distribution of controlled substances in the illicit market and ensure that patients have access to legitimate pain management.[24] Notwithstanding the enactment of the CSA, the volume of opioid

---

[20] The defendants in *Ruan* were physicians, but this Note refers to prescribing practitioners as well, including advanced practice registered nurses (APRN) and physician assistants, who are permitted to prescribe controlled substances in accordance with their certificates of authorization from the Drug Enforcement Agency.

[21] 21 U.S.C. §§ 801-971.

[22] *The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress*, CONG. RSCH. SERV. (Oct. 9, 2019), https://crsreports.congress.gov/product/pdf/R/R45948/2.

[23] 21 U.S.C. § 841(a)(1).

[24] *Id.*

prescriptions increased from 42.8 million in 2000 to more than 255 million in 2012.[25]

A. History of Opioid Use in the United States

The United States has faced an opioid epidemic since the mid-1990s in three interrelated waves.[26] In the years prior to the first wave, physicians prescribed opioids sparingly for only acute pain relief from injury, surgery, cancer, or terminal illness. A liberalization of prescription opioids resulting from a new formulation of opioids, which were quickly manufactured and marketed, sparked a precipitous rise in opioid use in the United States.[27] This created the first wave of the opioid crisis.[28] Accentuating this wave, users took advantage of the lack of uniformity between state laws by obtaining numerous opioid prescriptions and then selling their excess pills illegally on the street.[29]

The second wave began in 2010 as a result of a steady increase in overdose deaths attributable to heroin.[30] Studies have revealed that people with a history of using prescription opioids are thirteen times more likely to start using heroin than those with no history of prescription opioid abuse.[31] The results of this study came to fruition in the second wave as the heroin overdoses were connected to the use of opioids. A few years later, a significant increase in overdose deaths involving synthetic opioids, specifically illicitly manufactured fentanyl, ignited the third wave of the opioid crisis.[32] Between 2013 and 2016, overdose deaths from fentanyl increased by 88% per year.[33] These three waves unfolded into the unruly state of the opioid epidemic today. Regarding this current crisis, there are two ongoing, major contributors: (1) the federal government's failure to consistently regulate drug treatment and (2) the expanded use of prescription opioids for illegitimate pain management.

---

[25] Brian D. Sites et al., *Increases in the Use of Opioid Analgesics and the Lack of Improvement in Disability Metrics Among Users*, 39 BMJ J. 1, 1 (2014); *US Opioid Dispensing Rate Map*, CDC (Nov. 10, 2021), https://www.cdc.gov/drugoverdose/rxrate-maps/index.html.

[26] *Understanding the Epidemic*, CDC, https://www.cdc.gov/opioids/basics/epidemic.html (June 1, 2022).

[27] BONNIE ET AL., *supra* note 10.

[28] *Id.*

[29] Deweerdt, *supra* note 8, at 12.

[30] CDC, https://www.cdc.gov/opioids/data/analysis-resources.html (June 1, 2022). Data from the US National Center for Health Statistics demonstrate that from 2010-2016, heroin overdose deaths increased nearly fivefold. Deweerdt, *supra* note 8, at 12.

[31] Deweerdt, *supra* note 8, at 12.

[32] *Id.*

[33] *Id.*

B. Federal Controlled Substances Laws

The federal government first implemented efforts to reform the opioid crisis in the early 20th century.[34] In 1909, Congress passed the Opium Exclusion Act which prohibited the smoking of opium.[35] Shortly thereafter, Congress enacted the Harrison Narcotics Tax Act of 1914 ("Harrison Act"), which created tracking, registration, recordkeeping, and taxing requirements for individuals and entities involved in the narcotics supply chain, with an exception for patients who possessed drugs prescribed to them "in good faith by a physician . . . registered under this Act."[36] It expressly permitted doctors to dispense or distribute narcotics to patients "in the course of his professional practice only."[37] Under the Harrison Act, the use of opium for non-medical reasons was criminalized.[38] As scientific research and the rise in addicts began revealing the addictive nature of heroin, Congress enacted the Anti-Heroin Act in 1924 and banned the use of heroin for both medical and other purposes.[39]

The Controlled Substances Act (CSA), which establishes federal policy to regulate the distribution and dispensation of controlled substances,[40] relaxed the strict anti-opioid promulgations of the Harrison Act.[41] When enacting the CSA in 1970, Congress recognized that many of the controlled substances under the statute's regulation "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."[42] It was enacted with the main objectives of curtailing drug abuse, monitoring the lawful and unlawful traffic of controlled substances, and criminalizing the unauthorized distribution and dispensation of substances within its schedules.[43] The CSA categorizes controlled substances into five schedules based on their accepted medical use in treatment, their accepted safety for use under medical supervision, and their potential for abuse and addiction.[44] Controlled substances listed

---

[34] 26 U.S.C. § 4701.

[35] Dale Gieringer, *The Opium Exclusion Act of 1909 (The US War on Drugs Commences)*, O'SHAUGHNESSY'S ONLINE, https://beyondthc.com/the-opium-exclusion-act-of-1909-the-us-war-on-drugs-commences/ (last visited Mar. 31, 2023).

[36] 26 U.S.C. § 4701.

[37] *Id.*

[38] *Id.*

[39] *History of Heroin*, COMBAT OPIOID ADDICTION, http://www.ongov.net/health/opioids/history.html (last visited Dec. 16, 2022).

[40] Nicole R. Ortiz & Charles V. Preuss, *Controlled Substances Act*, NAT'L LIBR. MED., https://www.ncbi.nlm.nih.gov/books/NBK574544/ (Sept. 21, 2022).

[41] Richard D. deShazo et al., *Backstories on the US Opioid Epidemic. Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. MED. 595, 598 (2018).

[42] 21 U.S.C. § 801(1).

[43] 21 U.S.C. § 841.

[44] *Controlled Substances Schedules*, U.S. DEPT. OF J., https://www.deadiversion.usdoj.gov/schedules/ (last visited Mar. 19, 2023).

in the Schedule I category are highly addictive and have no accepted medical use for treatment in the United States; therefore, no prescriptions may be legally issued for these drugs.[45] Most prescription opioids are regulated as Schedule II drugs — classified as those with a "high potential for abuse which may lead to severe psychological or physical dependence."[46]

Currently, prescribers of controlled substances fall within the purview of the CSA.[47] A healthcare professional is authorized to distribute controlled substances "in the course of his professional practice" when licensed with a certificate of registration from the Drug Enforcement Administration (DEA) and assigned a DEA number.[48] The DEA is charged with enforcement under the CSA and retains the power to revoke licensure when a physician is determined to have violated authorization.[49] Further, as a condition of authorization, federal regulations provide that a prescription for a controlled substance is effective only if it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[50] However, neither the statute nor the regulation define these phrases. Prosecutions of doctors who prescribe controlled substances are generally brought under § 841(a)(1) of the CSA, which makes it unlawful "for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance."[51]

Although physicians may receive authorization to prescribe controlled substances, the Supreme Court has held that the CSA does not grant complete immunity to authorized prescribers who exceed the bounds of their "usual course of professional practice."[52] For example, in *United States v. Moore*, Dr. Moore was convicted for the knowing and unlawful distribution and dispensation of methadone in violation of § 841(a)(1).[53] When properly prescribed, methadone functions as a long-acting opioid

---

[45] Ortiz & Preuss, *supra* note 40. Such drugs within the Schedule I class include diacetylmorphine (heroin), lysergic acid diethylamide (LSD), and marijuana. *Id.*

[46] BONNIE ET AL., *supra* note 10, at 25. Few opioids are not regulated as Schedule II drugs. Opioids that contain less than ninety milligrams of codeine per dosage unit and buprenorphine (used to treat OUD) are classified as Schedule III drugs — those that have a "potential for abuse less than substances in Schedules I or II" and whose "abuse may lead to moderate or low physical dependence of high psychological dependence." *Id.* at n.4.

[47] 21 U.S.C. § 841(a).

[48] 21 U.S.C. § 802(21).

[49] U.S. Dep't. of Justice, Pharmacist's Manual (2022).

[50] 21 C.F.R. § 1306.04(a) (2021).

[51] 21 U.S.C. § 841(a).

[52] United States v. Moore, 423 U.S. 122 (1975).

[53] *Id.* at 124. Methadone is an addictive drug commonly used to treat opioid use disorder. *Methadone*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/methadone (Jan. 25, 2023).

agonist and reduces opioid craving and withdrawal.[54] If methadone is prescribed without limitation, however, it can create "euphoric highs" like heroin.[55] Dr. Moore evaluated new patients in a cursory manner which usually consisted of a request to see the patient's needle marks and an unsupervised urine sample.[56] Dr. Moore would then prescribe the quantity requested by the patient with the vague instruction "take as directed for detoxification."[57] Some patients used the pills to get high and others sold them or gave them to friends or relatives.[58] Still, Dr. Moore argued that his registration per se exempted him from criminal liability altogether under § 841(a).[59]

In *Moore*, the issue was whether a registered prescriber could be prosecuted under 841(a)(1).[60] The Court held that doctors can be subject to criminal liability under § 841 when their activities fall outside the usual course of professional practice, and therefore only the lawful acts of registered prescribers are exempted.[61] It reasoned that physicians who exceeded the bounds of professional practice could be prosecuted under the Harrison Act, the predecessor of the CSA.[62] While Congress enacted the CSA to provide a more flexible penalty structure than used under the Harrison Act, the CSA was meant to strengthen, rather than to weaken, preexisting "law enforcement authority in the field of drug abuse."[63] The Court also noted that, when passing the CSA, Congress intended to "confine authorized medical practice within *accepted* limits,"[64] and that "physicians who go beyond *approved practice* remain subject to serious criminal penalties.[65] Therefore, the Court found that Dr. Moore exceeded the bounds of professional practice when "in practical effect, he acted as a large-scale 'pusher' not as a physician."[66] A physician who makes no objectively reasonable "honest" effort to conform to that standard is not relying in "good faith" on the registration.[67]

In 2006, the Court revisited the "legitimate medical purpose" language of the authorization regulation in *Gonzales v. Oregon*.[68] The issue in *Gonzales* concerned an Interpretive Rule of the Attorney General who

---

[54] *Methadone*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/methadone (Jan. 25, 2023).

[55] *Moore*, 423 U.S. at 125.

[56] *Id.* at 126.

[57] *Id.* at 127.

[58] *Id.*

[59] *Id.* at 131.

[60] *Id.* at 124.

[61] *Id.* at 124, 132.

[62] *Id.* at 132.

[63] *Id.*

[64] *Id.* at 142.

[65] *Id.* at 144.

[66] *Id.* at 142-43.

[67] *Id.* at 142-43 n.20.

[68] Gonzales v. Oregon, 546 U.S. 243 (2006).

declared his intent to restrict the use of controlled substances in physician-assisted suicide, despite its contradiction of an Oregon law that expressly permitted doctors to dispense or prescribe a lethal dose of drugs at the request of a terminally ill patient.[69] Nonetheless, the Attorney General viewed that "assisting suicide is not a 'legitimate medical purpose' within the meaning of [the authorization regulation], and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act."[70] Rejecting this view, the Supreme Court confirmed that the CSA does not define "legitimate medical purpose" and held that the Attorney General did not have the authority under the CSA to define the phrase.[71] The Court attributed the statute's silence to its reliance "upon a functioning medical profession regulated under the States' police powers" as well as the ideas and limitations of federalism.[72] However, the Court ultimately acknowledged the federal government's power to set national uniform standards regarding medical practice.[73] Further, the Court noted that it had never considered "the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug pusher instead of a physician,"[74] but ultimately found that the "[CSA] manifests no intent to regulate the practice of medicine generally."[75]

C. Circuit Split Over the Elements of a Valid Prescription

Since *Moore* and *Gonzales*, the circuit courts have struggled with determining the elements of effective prescription regulation; specifically, whether the "usual course of professional practice" and "legitimate medical purposes" prongs of the effective prescription regulation are to be read in the conjunctive or disjunctive. Some courts have interpreted the *Moore* decision as a conjunctive analysis, requiring prosecutors to prove both a departure from the usual course of professional practice *and* no legitimate medical purpose.[76] For example, the Second and Fourth Circuits have adopted the conjunctive test, holding that the prescription must be issued for a legitimate medical purpose and by a practitioner acting in the usual course of professional practice for the prescription to be valid.[77] Similarly, the Ninth Circuit found that even an intentional violation of the accepted

---

[69] *Id.* at 249, 254.
[70] *Id.* at 261.
[71] *Id.* at 274-75.
[72] *Id.* at 270.
[73] *Id.* at 271.
[74] *Id.* at 269.
[75] *Id.* at 270.
[76] Kelly K. Dineen Gillespie, *Ruan v. United States: "Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care*, 2022 CATO SUP. CT. REV. 271, 292 (2022).
[77] United States v. Vamos, 797 F.2d 1146, 1151 (2d. Cir. 1986); United States v. McIver, 470 F.3d 550, 559 (4th Cir. 2006).

medical standard of care is insufficient to establish criminal liability under the CSA. Therefore, it has refused to assess a physician's culpability exclusively on whether he exceeded the bounds of his professional practice.[78] Even if a physician deviates from the medical standard of care, the Ninth Circuit has held that he would not be subject to criminal liability if he had a good faith belief that a legitimate medical purpose existed in prescribing controlled substances.[79]

Over time, as the fatal effects of opioid abuse heightened, a majority of circuits began viewing the test as disjunctive, requiring the government to prove that the defendant had *either* (1) departed from the "usual course of professional practice" in prescribing the controlled substances *or* (2) not prescribed the controlled substances for a legitimate medical purpose."[80] For example, the Tenth Circuit held that a practitioner unlawfully distributes a controlled substance if she prescribes the substance either outside the usual course of medical practice or without a legitimate medical purpose.[81] The court relied on the Supreme Court's assertion in *Moore* that "registered physicians can be prosecuted under § 841 [of the CSA] when their activities fall outside the usual course of professional practice."[82] Similarly, the Seventh Circuit affirmed jury instructions providing that the government had to prove that the defendant-physician distributed controlled substances other than for a legitimate medical purpose or outside the bounds of professional medical practice.[83]

Alternatively, the Fifth Circuit has relied on a single element to convict a prescriber under § 841(a), requiring that the dispensing be done "other than for a legitimate medical purpose and in the usual course of his professional practice."[84] While this facially appears to be a conjunctive reading, the Fifth Circuit has clarified that that there is no clearly established case law in its circuit regarding whether the government must prove that the dispensing was done *both* without a legitimate medical purpose *and* outside the usual course of professional conduct.[85] To the contrary, the Fifth Circuit has recognized that the two phrases "legitimate medical purpose" and "usual course of professional conduct" are often used interchangeably.[86]

---

[78] United States v. Feingold, 454 F.3d 1001, 1010 (9th Cir. 2006). The court stated that, although a reference to the accepted standard of medical practice in the United States is relevant in an evaluation of whether the practitioner's motive in prescribing controlled substances was legitimate or only pretextual, it is not determinative of criminal liability, as held by the Fourth Circuit. *Id.*

[79] *Id.* at 1010.

[80] Gillespie, *supra* note 76, at 294.

[81] United States v. Nelson, 383 F.3d 1227, 1233 (10th Cir. 2004).

[82] *Id.* at 1232 (quoting United States v. Moore, 423 U.S. 122, 124 (1975)).

[83] United States v. Bek, 493 F.3d 790, 798-99 (7th Cir. 2007).

[84] United States v. Rosen, 582 F.2d 1032, 1033 (5th Cir. 1978).

[85] United States v. Fuchs, 467 F.3d 889, 901 (5th Cir. 2006).

[86] *Id.*

D. Ruan v. United States

In light of the circuit split and the abundant exploitation of medical licenses to illicitly prescribe controlled substances, the Supreme Court, in 2022, attempted to unify the burden of proof necessary to convict physicians under the CSA. *Xiulu Ruan v. United States*[87] consolidated two cases involving medical doctors licensed to prescribe controlled substances. Petitioner-physicians Xiulu Ruan and Shakeel Kahn were both charged with unlawfully dispensing and distributing drugs in violation of federal law.[88] Ruan operated a medical clinic in Mobile, Alabama.[89] From 2011 to 2015, the clinic issued nearly 300,000 controlled substances prescriptions, a majority of which were for CSA Schedule II drugs — the most powerful and dangerous drugs that may be lawfully prescribed.[90] Ruan repeatedly wrote prescriptions for the extremely dangerous "Holy Trinity," a combination of opioids, benzodiazepines, and carisoprodol.[91] Ruan rarely evaluated patients before writing the prescriptions, and he falsified medical records, indicating that he had performed medical exams which never occurred.[92] Moreover, his practice was primarily financed through stock ownership in various pharmaceutical manufacturing companies.[93] Ultimately, Ruan was convicted by a jury trial and sentenced to over 20 years in prison.[94]

Similarly, Kahn began his medical practice in Ft. Mohave, Arizona, specializing in pain management.[95] When local pharmacies began refusing to fill Kahn's prescriptions, he was forced to open a second office in Casper, Wyoming.[96] Kahn consistently engaged in the illicit practice of exchanging prescriptions for cash, matching his fees for opioid prescriptions to the street price of the pills — a fact he routinely disclosed to his patients.[97] If a patient could not afford to pay Kahn's asking price, he withheld prescriptions or prescribed fewer pills.[98] In 2015, Kahn wrote high dose prescriptions for the "Holy Trinity" of drugs to a young woman who paid him personally over $1,000. The young woman filled the prescriptions and died of an overdose two days later. Kahn was also convicted by a jury trial and sentenced to 25 years in prison.[99]

---

[87] Ruan v. United States, 142 S. Ct. 2370 (2022) (vacating and remanding United States v. Kahn, 989 F.3d 806 (10th Cir. 2021) and United States v. Ruan, 966 F.3d 1101 (11th Cir. 2020)).

[88] *Ruan*, 142 S. Ct. at 2375.

[89] *Ruan*, 966 F.3d at 1121.

[90] *Id.* at 1122.

[91] *Id.*

[92] *Id.* at 1129-30.

[93] *Id.* at 1123.

[94] *Id.* at 1119.

[95] United States v. Kahn, 989 F.3d 806, 812 (10th Cir. 2021).

[96] *Id.* at 813.

[97] *Id.*

[98] *Id.*

[99] *Id.* at 813-14.

The petitioners appealed their convictions, arguing that the respective district courts erred in refusing to issue their proposed "good faith" jury instructions.[100] Rejecting the argument that the district court abused its discretion in declining to issue Ruan's jury instruction, the Eleventh Circuit affirmed Ruan's conviction.[101] The Eleventh Circuit agreed with the district court that the proposed jury instruction was an incorrect statement of the law, upholding precedent that established "[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard."[102] The Tenth Circuit also upheld the district court's denial of Kahn's proposed good faith instruction, stating that the "relevant inquiry" is "whether a defendant-practitioner objectively acted within" the scope of his professional practice, "regardless of whether he believed he was doing so."[103] The petitioners appealed, and the Supreme Court granted their petitions for certiorari.[104]

The central issue in *Ruan* concerned the requisite mens rea for the unauthorized prescribing of controlled substances under federal law.[105] The Supreme Court held that prosecutors must prove beyond a reasonable doubt that doctors knowingly or intentionally prescribed controlled substances in an unauthorized manner, vacating the courts of appeals' rulings.[106] In other words, the Supreme Court heightened the standard of proof that the government must establish to convict physicians who prescribe inordinate amounts of pain medication.[107] The Court rejected an objective standard, reasoning that it would "turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself."[108] According to the Court, an objective standard implicates negligence in determining criminal liability which has long been rejected.[109] The Court further relied on criminal law's longstanding scienter requirement,[110] which means the

---

[100] Ruan v. United States, 142 S. Ct. 2370, 2375-76 (2022).

[101] United States v. Ruan, 966 F.3d 1101 (11th Cir. 2020).

[102] *Id.* at 1166.

[103] *Kahn*, 989 F.3d at 825.

[104] *Ruan*, 142 S. Ct. at 2377.

[105] *Id.* at 2375.

[106] *Id*.

[107] Ann W. Latner, *Supreme Court Raises Bar for Convicting Doctors of Controlled Substances Act Violations*, MPR THE RIGHT DOSE OF INFORMATION (Sept. 6. 2022), https://www.empr.com/home/features/supreme-court-raises-bar-for-convicting-doctors-of-controlled-substances-act-violations/?utm_source=newsletter&utm_medium=email&utm_campaign=NWLTR_MPR_TOPT_091122_RM&hmEmail=UoyOwIr7j1pYMRYE31cDBobFgIvZ%2BFiA&sha256email=a27694757718643faa37a5cbdb6e07aab51ce07bc131135d8a69e678fee9887f&hmSubId=&NID=.

[108] Ruan, 142 S. Ct. at 2381.

[109] *Id.*

[110] *Id.* at 2376-77.

"degree of knowledge necessary to make a person criminally responsible for his or her actions."[111] This scienter requirement is essential to separate wrongful conduct from "otherwise innocent conduct."[112]

However, the *Ruan* Court did not expressly clarify the test for an effective prescription. The issue remains for courts to determine whether the defendant had (1) not prescribed for a "legitimate medical purpose" and/or (2) departed from the "usual course of professional practice" is to be applied in the conjunctive or disjunctive.[113] On remand, the Tenth Circuit overruled its prior holding that the government could meet its burden of proof by satisfying either prong of the test.[114] The Tenth Circuit now holds that government must prove that a defendant-practitioner knowingly issued a prescription without a legitimate medical purpose and that he issued a prescription not in the usual course of professional practice.[115]

E. The Void-for-Vagueness Doctrine

The inconsistency among courts in interpreting the requirements of a valid prescription raises vagueness concerns. A law which is ambiguous as to informing an individual of the illegality of their conduct risks violating an individual's due process rights.[116] The void-for-vagueness doctrine "guards against arbitrary or discriminatory law enforcement by insisting that a statute provide standards to govern the actions of police officers, prosecutors, juries, and judges."[117] The most important component of the vagueness doctrine is its requirement that "a legislature establish minimal guidelines" to prevent "a standardless sweep that allows [enforcers] to pursue their personal predilections."[118] If a prosecutor can selectively enforce the law by implementing his own standards, then the law is likely unconstitutionally vague.

II. ANALYSIS

The existing criminal guidelines for prosecutions of healthcare professionals who prescribe controlled substances are unconstitutionally vague. It is unclear how the "without a legitimate medical purpose" and "outside the usual course of professional practice" standards should be measured and what degree of compliance is necessary for lawful medical

---

[111] *Id.* at 2377.

[112] *Id.*

[113] Gillespie, *supra* note 76, at 299.

[114] United States v. Kahn, 58 F.4th 1308, 1316 (10th Cir. 2023).

[115] *Id.*

[116] Johnson v. United States, 135 S. Ct. 2551, 2556 (2015) ("The Government violates [the due process] guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement.").

[117] Sessions v. Dimaya, 138 S. Ct. 1204, 1212 (2018).

[118] Kolender v. Lawson, 416 U.S. 352, 358 (1983).

practice. Due to the inconsistent application of the law by lower courts and the Supreme Court's failure to provide a clear test for effective prescription, the current legal approaches regulating opioids are inadequate and unjust for both prescribers and individuals harmed by overprescribing.

A. Ambiguities in Federal Laws Creating Inconsistencies in Courts

The vague, inconsistent, and overly-lenient standards of the CSA have generated issues for law enforcement and have made prescribers hesitant to provide legitimate pain management, while simultaneously allowing overprescribing physicians to avoid accountability. Because neither the CSA nor its accompanying regulations define "usual course of professional practice" or "legitimate medical purpose," courts have struggled to clarify this language uniformly in a manner that can be effectively applied.[119] The CSA and its accompanying regulation fail to provide a clear standard to which medical professionals can conform their prescribing practices, infringing on prescribers' constitutional rights under the vagueness doctrine.[120]

Despite the Supreme Court's recognition that these ambiguous standards create a "gray zone," making it difficult to distinguish between issuing invalid prescriptions and issuing valid ones,[121] the Court has never interpreted these concepts in the context of prescribing controlled substances. For example, the Court in *Moore* did not address the requirements the government must prove to convict a practitioner under the CSA because the defendant stipulated that he knowingly departed from the usual course of professional practice.[122] The Court's conclusion in *Moore* relied in part on the Narcotic Addict Treatment Act of 1974 (NATA) in which the Court noted that Congress "sought to 'cure'" the difficulty in prosecuting physicians under the CSA "because of the intricate and nearly impossible burden of establishing what is beyond 'the course of professional practice' for criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian."[123] Recognizing this issue, NATA promulgated an independent set of explicit requirements that a physician must meet to prescribe narcotics for maintenance or detoxification treatment for patients addicted to drugs. While NATA provides some guidance on "legitimate medical practice" for physicians treating patients already addicted to drugs, the phrase has not been defined in other contexts.[124]

---

[119] Rebecca A. Delfino, *The Prescription Abuse Prevention Act: A New Federal Statute to Criminalize Overprescribing Opioids*, 39 YALE L. & POL'Y REV. 347, 386-87 (2021).

[120] *See supra* notes 116-18 and accompanying text (introducing the vagueness doctrine).

[121] Ruan v. United States, 142 S. Ct. 2370, 2378 (2022).

[122] United States v. Moore, 423 U.S. 122, 126 (1975).

[123] *Id.* at 139 n.16 (quoting S. Rep. No. 93-192, at 14 (1973)).

[124] Delfino, *supra* note 119, at 388.

Subsequently, the Supreme Court analyzed the "legitimate medical purpose" language of the CSA in *Gonzales v. Oregon*.[125] In *Gonzales*, the Court acknowledged that the CSA does not define "legitimate medical purpose" and held that the CSA does not confer the United States Attorney General the power to define or limit the phrase.[126] The Court recognized that "Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood,"[127] but the statute itself "manifests no intent to regulate the practice of medicine generally."[128] Beyond finding that the CSA does not authorize the Attorney General to declare that physician-assisted suicide is not a legitimate medical purpose, the *Gonzales* Court did not attempt to define or clarify the meaning of "legitimate medical purpose" as used in the CSA.

In *Ruan*, the Supreme Court addressed the requisite mens rea for a conviction of distributing a controlled substance in an unauthorized manner under the CSA,[129] reaching the narrow conclusion that the "knowingly" or "intentionally" mens rea applies to the authorization clause. The Court emphasized that the language defining an authorized prescription is "ambiguous," "written in generalities," and "susceptible to more precise definition and open to varying constructions,"[130] yet it did not define authorization nor clarify whether the "knowingly" or "intentionally" mens rea applies to "usual course of professional practice" or "legitimate medical purpose," or both. The Court's lack of clarification illustrates the need for Congress to provide clear standards for prosecutors, healthcare professionals, and jurors.

Given the CSA and its accompanying regulation's lack of instruction on "usual course of professional practice" and "legitimate medical purpose" and the relevant case law's vague attempt to interpret the phrases, the lower courts have struggled with defining these concepts in the context of prescribing controlled substances. Specifically, the circuit courts have inconsistently determined the elements of a valid prescription — that is, whether the valid prescription requirements of "legitimate medical purpose" and "usual course of professional practice" are conjunctive or disjunctive.[131]

1. "Usual Course of Professional Practice"

Under a disjunctive analysis, prescribers can be convicted if the procedures used were inconsistent with those generally recognized throughout the United States, even if the prescriptions were issued for a legitimate

---

[125] 546 U.S. 243 (2006).
[126] *Id.* at 274-75.
[127] *Id.* at 270.
[128] *Id.*
[129] Ruan v. United States, 142 S. Ct. 2370, 2375 (2022).
[130] *Id.* at 2377.
[131] Gillespie, *supra* note 76, at 293.

medical purpose. To evaluate whether the practitioner acted within his "usual course of professional practice," most courts rely solely on an objective standard to analyze the practitioner's conduct in comparison to the generally recognized and accepted standard of medical practice in the United States.[132] In doing so, the courts do not consider whether the medication successfully treated or alleviated the patient's pain. Rather, this standard focuses exclusively on the procedures employed by the practitioner in prescribing the controlled substances. Absent any tie to legitimate medical purpose, this standard is indeterminate as to both the degree of compliance necessary before a prescribing practice becomes unlawful and how the standard should be measured. As a result, the standard offers no avenue for consistent enforcement under the existing federal law.

When a law or rule is unclear and has multiple possible interpretations, known as dual indeterminacy, it activates the constitutional protections provided by the vagueness doctrine.[133] Because criminal statutes that lack a reasonably determinate standard are susceptible to arbitrary and discriminatory enforcement,[134] due process of law requires that the language of a criminal statute is "sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties."[135] An independent objective analysis of "usual course of professional practice" is vulnerable to various definitions of which reasonable minds could disagree,[136] and courts have not uniformly established what

---

[132] *See* United States v. Hurwitz, 459 F.3d 463, 478 (4th Cir. 2006) ("[A]llowing criminal liability to turn on whether the defendant-doctor compiled with his own idiosyncratic view of proper medical practices is inconsistent with the Supreme Court's decision in *Moore*."); United States v. Norris, 780 F.2d 1207, 1212 (5th Cir. 1986) (rejecting the defendant's argument that the word "his," as used in the valid prescription regulation, refers to the doctor's own standards of medical practice, upon reasoning that "[o]ne person's treatment methods do not alone constitute a medical practice."); United States v. Feingold, 454 F.3d 1001, 1011 n.3 (9th Cir. 2006) (noting that the phrase "professional practice" implicitly refers to a "reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."); United States v. Merrill, 513 F.3d 1293, 1310 (11th Cir.) (emphasizing that "[t]he appropriate focus is not on the subjective intent of the doctor," but rather on "whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States.").

[133] *See* Johnson v. United States, 576 U.S. 591, 598 (2015) ("By combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony, the residual clause produces more unpredictability and arbitrariness than the Due Process Clause tolerates."); s*ee also supra* notes 116-18 and accompanying text (introducing the vagueness doctrine).

[134] Connally v. Gen. Const. Co., 269 U.S. 385, 391 (1926).

[135] *Id.*

[136] *See* United States v. Singh, 54 F.3d 1182, 1187 (4th Cir. 1995) (noting that there are no specific guidelines concerning what is required to support a

is required to support a finding that a physician-defendant "acted outside the usual course of professional practice." The expert testimony in Dr. Kahn's trial is illustrative of this point. In evaluating the sufficiency of Dr. Kahn's medical practice, the expert witness heavily utilized the Federation of State Medical Boards Model Guidelines, which analyzes whether there was (1) inadequate monitoring, (2) inadequate attention to informed consent, (3) unjustified dosage increases, (4) excessive reliance on opioids, and (5) failure to make use of available tools for risk mitigation.[137] According to the expert witness, a single deviation from these standards do not render a doctor outside the usual course of practice.[138] Instead, the guidelines look for a general "impression" of a practitioner's compliance.[139] Nevertheless, the recommended guidelines do not indicate how little monitoring or attention to informed consent is "inadequate" nor how many dosage increases are "unjustified."

Moreover, it is unclear which standards control those "generally recognized throughout the United States." Professional medical organizations, federal and state advisory guidelines, state medical boards, and physicians themselves all advocate for various standards for treating pain.[140]

---

conviction that the defendant acted outside the usual course of professional practice and that courts must engage in a case-by-case analysis of the evidence).

[137] Brief for Petitioner at 49, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 21-5261), 2021 WL 6118301.

[138] *Id.*

[139] *Id.*

[140] *See, e.g.*, *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, 10 SAMHSA 1 (2017); Deborah Dowell et al., *CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022*, 71 MORBIDITY & MORTALITY WKLY REP. 1 (Nov. 4, 2022), https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm (providing recommendations for clinicians practicing in pain management, including those prescribing opioids); *Safe Opioid Prescribing*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.hhs.gov/opioids/prevention/safe-opioid-prescribing/index.html (Dec. 16, 2022) (listing resources for the responsible and effective use of opioids in the treatment of pain for medical professionals). For a comprehensive list of state-controlled substances prescribing regulations and guidelines, see Corey Davis, *State-by-State Summary of Opioid Prescribing Regulations and Guidelines*, https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/appendix-b-state-by-state-summary.pdf. Further, the American Medical Association (AMA) has adopted several resolutions criticizing the CDC guidelines as to the maximum recommended opioid dose. Pat Anson, *AMA 'Inappropriate Use' of CDC Guideline Should Stop*, PAIN NEWS NETWORK (Nov. 14, 2018), https://perma.cc/W6QE-XVZY. Barbara McAnemy, the president of the AMA, shared a story of her patient to whom she prescribed opioids for managing the pain of metastatic prostate cancer. Julia MacDonald, *"Do No Harm of Injustice to Them": Indicting and Convicting Physicians for Controlled Substance Distribution in the Age of the Opioid Crisis*, MAINE L. REV. 197, 221-22 (2020). Dr. McAnemy's patient was denied his prescriptions from

Even if the appropriate standard is derived from physicians' conduct, the standard for the "usual course of practice" fails to consider the different approaches by doctors practicing pain management within the medical profession.[141] While medical doctors employ an allopathic approach in practicing medicine, osteopathic doctors focus on a holistic approach.[142] Alternatively, palliative care doctors strive for maximum comfort for their patient who has been diagnosed with an irreversibly deteriorating to terminal condition and for whom curative treatment is no longer feasible.[143] Further, in analyzing unlawful prescribing cases, judges, medical experts, and even prosecutors have different opinions on what constitutes criminal behavior.[144] Unless identifiable standards are uniformly imposed, a physician does not have "'fair notice' of the conduct" that declares a prescription unlawful.[145]

By focusing solely on the manner in which the prescription was issued, the "usual course of professional practice" standard fails to consider the specific needs of an individual patient.[146] It merely compares the prescriber's conduct to a reasonable prescriber's practice without assessing whether the prescription actually helped manage the patient's pain. When the prosecution charges only the "usual course of professional practice" prong, the defendant's intent or the medical efficaciousness of the

---

his pharmacy which followed the CDC guidelines. *Id.* Three days later, the patient attempted suicide. *Id.*

[141] *See* Bob Tedeschi, *A 'Civil War' Over Painkillers Rips Apart the Medical Community*, PBS (Jan. 21, 2017), https://www.pbs.org/newshour/health/painkillers-controversy-doctors (noting there is a "civil war" in the medical community, as one group believes the primary goal of pain treatment is reducing opioid prescribing while the other group focuses on the disability, the human suffering, and the expense of chronic pain).

[142] *MD (Allopathic) vs. DO (Osteopathic) Medicine*, BYU, https://ppa.byu.edu/md-allopathic-vs-do-osteopathic-medicine (last visited Mar. 31, 2023).

[143] Linda Farber Post & Nancy Neveloff Dubler, *Palliative Care: A Bioethical Definition, Principles, and Clinical Guidelines*, 13 BIOETHICS F. 17, 18 (1997), https://pubmed.ncbi.nlm.nih.gov/11655235/.

[144] Brief for Physicians Against Abuse as Amici Curiae Supporting Petitioner, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410), 2022 WL 478202.

[145] Papachristou v. Jacksonville, 405 U.S. 156, 162 (1972).

[146] Researchers have suggested that particular features of the prescription itself can be modified to reduce harm. For example, the greater the number of days for which a prescription is written and the higher the dosages, the greater the risk of associated harm. BONNIE ET AL., *supra* note 10. The simplicity of this study is rebuked by the lack of consensus on the number of days after which risk increases. The CDC's Guideline for Prescribing Opioids for Chronic Pain encourages prescribers to provide the "lowest effective dosage" and prescribe "no greater quantity than needed for the expected duration of pain severe enough to require opioids," and suggests that three days or less will generally suffice. *Id.* Some states, such as Maine and Massachusetts, have enacted legislation that limits the dosage amount of opioids prescribed for the treatment of noncancer pain. *Id.*

prescriptions are irrelevant.[147] Thus, under the CSA, a physician may face criminal charges if a court finds their behavior to be unreasonable, regardless of whether they genuinely believed their patients were in legitimate pain and the prescribed medication was for legitimate medical purposes.

Not only does a "reasonableness" analysis equate criminal liability to civil medical malpractice liability or negligence, but a reasonableness requirement is not typically a level of culpability in criminal prosecutions.[148] Numerous circuits that have held that a physician is acting in the course of professional practice only when the physician prescribes medicine in accordance with a standard of medical practice "generally recognized and accepted in the United States."[149] No circuit, however, has explained how the accepted standard of medical practice differentiates between criminal and civil liability.

In the absence of a subjective element, the federal standards of practice utilized in unlawful prescribing prosecutions to determine the usual course of professional practice set a perilous precedent for criminal liability. The Supreme Court has long enforced the presumption that criminal liability requires knowledge of the facts that distinguish lawful conduct from unlawful conduct.[150] As the Supreme Court emphasized in *Ruan*, it is standard that courts interpret criminal statutes to require the defendant to possess a culpable mental state, irrespective of whether the statute lacks an express mens rea element.[151] Under a disjunctive objective analysis of "usual course," prosecutors were not required to prove that the defendant possessed any mens rea. Rather, this prong focuses on the methods in which the physician prescribed the medication and compares this conduct to the established standard of medical practice in the United States.

If criminal liability is imposed for regulatory violations absent conscious wrongdoing, the law risks discouraging innocent and socially-beneficial prescribing. A lack of access to prescription opioids to treat

---

[147] United States v. Naum, 832 F. App'x 137, 142 (2020) ("Because the issue of whether [the defendant's] treatment was for a legitimate medical purpose was not an element in this case, [the defendant's] contention that he acted with a legitimate medical purpose was not a viable defense. In fact, there was no dispute at trial that [the defendant's] patients suffered from addiction and required treatment."); United States v. Ruan, 966 F.3d 1101, 1139 (11th Cir. 2020) ("And even if [the testifying patient] felt that she benefitted from the medications [the defendant] prescribed, a reasonable jury could nonetheless conclude that the manner in which [the defendant] prescribed them was outside the usual course of professional practice.").

[148] Arthur Anderson LLP v. United States, 544 U.S. 696, 706 (2005).

[149] United States v. Merrill, 513 F.3d 1923, 1306 (2008). *See also* United States v. Feingold, 454 F.3d 1001, 1011 n.3 (2006); United States v. Norris, 780 F.2d 1207, 1209 (1986); United States v. Hurwitz, 459 F.3d 463, 480 (4th Cir. 2006); United States v. Vamos, 797 F.2d 1146, 1153 (1986); United States v. Smith, 573 F.3d 639, 647-48 (8th Cir. 2009).

[150] Ruan v. United States, 142 S. Ct. 2370, 2377 (2022).

[151] *Id.*

legitimate pain has led to horrific adverse consequences, including overdoses on illicit substances and suicide.[152] Requiring the government to prove only a departure from the usual course of professional practice allows doctors — who intended no harm and who prescribed medication that successfully aided their patients — to be criminally prosecuted for failing to abide by a standard of care that is both evolving and ambiguous. This outcome only exacerbates the opioid crisis by deterring doctors from prescribing medication for legitimate medical purposes and inhibiting effective enforcement.

2. "Legitimate Medical Purpose"

The courts' interpretation of the "legitimate medical purpose" prong is equally as inconsistent and unclear as the standard for "usual course of professional practice." Indeed, the Supreme Court has noted that "'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense."[153] Prominent criminal defense attorney, Harvey Silvergate, shared this concern in the Wall Street Journal, where he called for legislators and prosecutors to either "clarify the currently indecipherable line between treating pain and unlawfully feeding drug addicts' habits, or get out of the business of policing and terrorizing physicians."[154]

The "legitimate medical purpose" analysis inquiries into the subjective intent of the physician. An independent subjective analysis wrongfully permits a defendant-physician to rely solely on his own views of adequate medical practice in prescribing highly addictive drugs rather than the widely accepted medical standards.[155] Further, reliance on "legitimate medical purpose" alone without offering a precise definition is subject to arbitrary and inconsistent results because jurors, who possess little to no medical expertise, are tasked with determining the validity of a practitioner's prescribing practices.

Additionally, a subjective standard without an objective counterpart encourages willful ignorance, which permits physicians to continue prescribing by deliberately overlooking facts that, if known, would require the physician to alter his prescribing. For example, a physician could

---

[152] M.R. Larochelle et al., *Comparative Effectiveness of Tapering or Abrupt Discontinuation vs. No Dosage Change for Opioid Overdose for Suicide Patients Receiving Stable Long-Term Opioid Therapy*, 8 [J]AMA 5 (2022); A. Agnoli et al., *Association of Dose Tapering with Overdose or Mental Health Crisis Among Patients Prescribed Long-Term Opioids*, 5 [J]AMA 326, 411-19 (2021).

[153] Gonzales v. Oregon, 546 U.S. 243, 258 (2006).

[154] Harvey Silvergate, *When Treating Pain Brings a Criminal Indictment*, WALL STREET J. (June 12, 2015), https://perma.cc/U66Y-GFLS.

[155] *See* United States v. Vamos, 797 F.2d 1146, 1153 (1986) ("[A subjective standard] permit[s] a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States.").

deliberately neglect to perform a medical evaluation of a patient or inquire into a patient's medical history prior to issuing opioids — despite obvious signs of opioid abuse or misuse — yet escape criminal prosecution by claiming that he had no actual knowledge of the red flags and therefore believed the prescription was for a legitimate medical purpose.

Further, the *Moore* Court's discussion of the circumstances under which doctors could be prosecuted under the CSA suggests that an objective inquiry is required. The Court held that "registered physicians can be prosecuted under § 841 when their activities fall outside the *usual course of professional practice*."[156] Moreover, the Court also noted that, when enacting the CSA, Congress intended to "confine authorized medical practice within *accepted limits*,"[157] and that physicians "who go beyond *approved practice* remain subject to serious criminal penalties."[158] Concurrently, the CSA also indicates that a subjective standard is relevant to a practitioner's role in determining a prescription's validity: "the *practitioner*, acting in the usual course of professional practice, *determines* there is a legitimate medical purpose for the issuance of the new prescription."[159] Therefore, a solution combining both an objective and subjective component arguably has a valid basis in the existing CSA.

B. The States' Inability to Combat the National Opioid Crisis

At the state level, prosecutions for overprescribing are unpredictable and lack a cohesive approach. While most states also regulate the manufacturing, distribution, and prescribing of controlled substances, a consistent standard among the states does not exist. For example, a physician convicted of overprescribing opioids in Florida may face up to twenty years in prison, substantial fines, civil financial penalties, and a loss of his medical license.[160] However, if that physician was just one state over in Alabama, he would not be criminally prosecuted at all under Alabama's controlled substances laws.[161]

The idea of federalism promotes diversity among the states and defers to the individual states to act in their own best interests regarding criminal law and the practice of medicine. Although regulation of health and safety is "primarily, and historically, a matter of local concern," the Supreme Court has confirmed the federal government's power to set uniform

---

[156] United States v. Moore, 423 U.S. 122, 124 (1975).

[157] *Id.* at 142.

[158] *Id.* at 144.

[159] 21 U.S.C. § 802(56)(C) (emphasis added).

[160] FLA. STAT. § 893.13.

[161] In *State v. Hankins*, the Alabama Court of Criminal Appeals upheld the trial court's order dismissing an indictment alleging a doctor unlawfully distributed and trafficked drugs. 155 So.3d 1043, 1048 (2013). The court concluded as a matter of law that a licensed prescriber cannot be charged with the unlawful distribution of a controlled substance or drug trafficking. *Id.*

national standards regarding medical practice.[162] Therefore, given the magnitude of the opioid crisis and its effects on the nation as a whole in conjunction with the inadequacy of state laws as a response to the opioid epidemic, a consistent national statute is appropriate.

The need for a uniform, national response to curtail the opioid epidemic is also evidenced by the United States' vulnerability to subsequent epidemics involving other prescription drugs.[163] For example, researchers have expressed concern that benzodiazepines, a class of sedative medications that slow down brain activity and the nervous system, are being overprescribed.[164] Benzodiazepines are addictive and are especially dangerous when used in conjunction with other drugs.[165] Data shows that in 2015, roughly 23% of opioid overdose deaths involved benzodiazepines.[166]

Despite the fact that 50 million Americans suffer from chronic pain and 19.6 million suffer from high-impact chronic pain,[167] the vague scope of the CSA and the regulations has deterred physicians from prescribing opioids to patients with a legitimate need for pain relief.[168] A clear, uniform effective prescription requirement is critical for ensuring that patients have access to appropriate medical care while ensuring that controlled substances are not abused or diverted for non-medical purposes. Ultimately, the solution should balance the need to ensure that prescriptions are issued only for legitimate medical purposes with the need to grant physicians the flexibility necessary to provide appropriate medical care to their patients.

III. PROPOSED SOLUTION

A uniform federal statute is the appropriate solution to the widespread opioid crisis given its sweeping detrimental effects, the erratic federal standards governing overprescribing prosecutions, and the states' inability to consistently combat opioid abuse. While a minority of the circuits explicitly require the government to prove that a defendant-practitioner prescribed a controlled substances for both an illegitimate medical purpose and acted outside the usual course of professional practice, there is no guarantee that other circuits will follow as the Supreme Court did not

---

[162] Gonzales v. Oregon, 546 U.S. 243, 270 (2006).

[163] Deweerdt, *supra* note 8, at 12.

[164] *Id.*

[165] *Id.*

[166] *Id.* The U.S. Food and Drug Administration (FDA) issued a "Black Box" warning, which is its strongest warning, to its drug labeling of prescription opioids and benzodiazepines. The FDA further advised health care professionals to prescribe opioids together with benzodiazepines only when alternative treatment options are insufficient to relieve the patient's pain.

[167] James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults--United States, 2016*, MORBIDITY & MORTALITY WKLY REP. (Sept. 14, 2018), https://perma.cc/KA8X-BDNH.

[168] Delfino, *supra* note 119, at 401.

address this issue. Further, no circuit has articulated identifiable standards for practitioners to determine what constitutes a legitimate medical purpose within the usual course of professional practice. This paper presents a proposed federal statute below to remedy the vague language of the existing CSA and effectuate resolving the opioid crisis, which includes both a subjective and an objective element with precise definitions. Unlike the existing CSA which broadly regulates all individuals, The Tracking and Regulation of Used Substances and Treatment (TRUST) Act is narrowly tailored to regulate the prescribing practices of physicians who have issued opioids in the absence of a legitimate medical rationale and have exceeded the bounds of established medical practice.

A. Proposed Federal Criminal Statute: The Tracking and Regulation of Used Substances and Treatment (TRUST) Act

(a) An authorized prescribing practitioner who acted knowingly or intentionally in prescribing, manufacturing, distributing, or dispensing a controlled substance classified in Controlled Substances Act, 84 Stat. 1242, 21 U.S.C. § 801 et. seq., for no legitimate medical purpose, and such actions were objectively outside the usual scope of professional practice, is subject to criminal liability under this section.

(b) "Authorized" requires obtaining a registration with the Drug Enforcement Administration permitting the lawful manufacturing, distributing, dispensing, or possessing of controlled substances under the CSA.

(c) "Legitimate medical purpose" is defined as a treatment regimen or program generally recognized and accepted in the field of medical science as being safe and effective in the diagnosis, treatment, prevention, or alleviation of the specific medical condition and aimed to promote the patient's health under all relevant circumstances.

(d) "Outside the usual scope of professional practice" refers to a prescribing practitioner who acted inconsistent with the generally recognized and accepted prevailing medical standards as established by prescribing practitioners in the United States in manufacturing, distributing, or dispensing, or possessing with the intent to manufacture, distribute, or dispense a controlled substance classified in Controlled Substances Act, 84 Stat. 1242, 21 U.S.C. § 801 et. seq.

(1) Such prohibited conduct includes without limitation failing to complete a medical history and physical examination prior to any treatment and documenting such medical record; failing to develop an individualized treatment plan for each patient that states objectives to be used to determine treatment success; and failing to change treatment for patients with signs or symptoms of substance abuse.

(e) "Prescribing practitioner" is defined as:

(1) a doctor of medicine or osteopathy, dentist, veterinarian, or hospital or other person licensed, registered, or otherwise permitted by the United States or State in which he or she practices to dispense controlled substances in the course of professional practice.

B. Explanation of Proposed Statute

The Tracking and Regulation of Used Substances and Treatment (TRUST) Act would serve as an oversight of controlled substances to ensure that opioids are safely prescribed to patients with legitimate pain needs and that, when used as directed, the drugs provide health benefits that clearly outweigh their harms. In doing so, the TRUST Act seeks to punish health care providers who egregiously overprescribe controlled substances while protecting merely negligent prescribers from criminal liability. Most significantly, a statute like the TRUST Act would provide defined standards for physicians to resolve the constitutional infringements and confusion created by the existing CSA.

As proposed in the statute, the government has the burden of proof in showing that (1) the defendant knowingly or intentionally prescribed a patient controlled substances with no legitimate medical purpose, and (2) the defendant was acting outside the usual scope of recognized and accepted medical standards in prescribing the controlled substances. The first element is subjective and requires the court to evaluate whether the drugs were prescribed for what the defendant-physician believed to be a legitimate medical purpose. Other motives, such as to obtain notoriety, status, sexual favors, and money are not legitimate medical purposes. The second element is objective and considers whether the drugs were dispensed in the usual course of the defendant's professional conduct as a registered prescriber. The physician's prescribing practice is measured according to the standard of medical practice as generally established by prescribing practitioners. Prescribers should assess a patients' suitability for an opioid prescription and regularly monitor the patient throughout the course of treatment. The prescriber should also discuss with the patient the risks of opioid use, including the risks of abuse and addition.

By implementing both a subjective and an objective element, the TRUST Act resolves many of the issues involved in prosecutions for opioid prescriptions under the CSA. First, this test satisfies the longstanding scienter requirement for criminal convictions by requiring the government to prove that the defendant knew the prescription was issued for an illegitimate medical purpose at the time of prescribing. Second, this test punishes "pill mill" doctors, such as Dr. Ruan and Dr. Kahn, who knowingly issued opioid prescriptions for illegitimate medical purposes, such as to assist another in the maintenance of a drug habit or for personal profit.[169]

---

[169] *See supra* Section II.B (discussing the facts of *Ruan*).

It prevents a physician-defendant from escaping criminal liability when the prescribing grossly exceeds the safe and ethical bounds of medical practice by merely claiming that he believed the opioid prescription was serving a legitimate medical purpose. Third, this test prevents overzealous prosecutions of prescribers who were honestly seeking to aid their patients but negligently prescribed controlled substances. Under the TRUST Act, mere medical malpractice and negligent care are insufficient for prosecution as permitted by a purely objective standard. Rather, by imposing a subjective element, the Act ensures a conviction does not rest entirely on the general standard of medical practice imposed by a jury that lacks medical expertise.

Finally, this proposed statute recognizes the significance of doctor alienability in treating patients. Medical professionals are not in unanimous agreement as to the correct method of treating patients in pain, and therefore, this statute is crafted to create space for a physician's medical expertise by requiring proof of a subjective ill-intent. Simultaneously, the TRUST Act refrains from over-deterring doctors who prescribe controlled substances for legitimate medical purposes by providing those doctors with clear, consistent guidelines that they can trust. Criminalizing medical care can force doctors to choose between their patients' well-being and criminal liability, which could deter practitioners from providing medical care due to the personal liability.[170] Accordingly, this proposed statute addresses the concern that constraining doctors' ability to treat patients could result in patients turning to other street drugs, such as heroin, which is now often laced with fentanyl and other synthetic painkillers.

The TRUST Act ensures that only medical professionals who are acting in accordance with accepted medical standards are authorized to write prescriptions for highly addictive opioids. Opponents of the conjunctive test argue that it is too strict and could prevent legitimate prescriptions from being issued by qualified practitioners who are not following the exact medical practices of their peers.[171] However, in such instances, the doctor would not be prosecuted under the TRUST Act because the prescription must be written for both an illegitimate medical purpose and outside the usual scope of generally recognized and accepted medical standards in the United States. The conjunctive test refrains unscrupulous practitioners from writing prescription for non-medical purposes, which too often leads to an increase in substance abuse and addiction.

---

[170] Gillespie, *supra* note 76, at 281-82. This was seen after *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022) (overturning Roe v. Wade), in which doctors and institutions have been struggling to compute the line between lawful or personally safe and unlawful or risky conduct. Gillespie, *supra* note 76, at 282.

[171] *See* Stefan G. Kertesz and Adam J. Gordan, *Strict Limits on Opioid Prescribing Risk the 'Inhumane Treatment' of Pain Patients*, STAT NEWS (Feb. 24, 2017), https://www.statnews.com/2017/02/24/opioids-prescribing-limits-pain-patients/ (discussing how strict prescribing guidelines can harm patients in pain).

C. Feasibility of Proposed Statute

As discussed above, because the TRUST Act establishes clearly defined concepts regulating controlled substance prescribing, it effectively criminalizes illegitimate and dangerous prescribing and encourages physicians to issue valid prescriptions according to their medical expertise. However, an issue that remains is whether enacting a statute similar to the one proposed is both feasible and obtainable. A federal law in the United States must pass through the entire legislative process. The TRUST Act would have to be voted on and passed by both the House of Representatives and the Senate.[172] If both the House and the Senate pass the Act, it must be signed by the President to become law.[173]

Recent measures taken by the federal legislature suggest that the TRUST Act is politically feasible.[174] More than 200 bills relating to opioids were presented in the 117th Congress alone.[175] For example, the bipartisan Rural Opioid Abuse Prevention Act, signed into law in December 2022, is aimed at assisting rural communities experiencing opioid overdoses in responding to the opioid crisis.[176] In 2018, Congress passed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act[177] with overwhelmingly bipartisan support in both the House and Senate.[178] It includes more than $3.3 billion in authorized spending over 10 years[179] and focuses

---

[172] United States House of Representatives, *The Legislative Process*, https://www.house.gov/the-house-explained/the-legislative-process.

[173] *Id.*

[174] Congress has recently enacted several laws addressing the opioids crisis, including the Comprehensive Addiction and Recovery Act of 2016 (CARA, P.L. 114-198), the 21st Century Cures Act (P.L. 114-255), the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, P.L. 115-271), the Fentanyl Sanctions Act (Title LXXII of P.L. 116-92), and the Blocking Deadly Fentanyl Imports Act (P.L. 117-81, §6610). *The Opioid Crisis in the United States: A Brief History*, CONG. RSCH. SERV. (Nov. 30, 2022), https://crsreports.congress.gov/product/pdf/IF/IF12260.

[175] CONGRESS.GOV, https://www.congress.gov/search?q=%7B%22source%22%3A%22legislation%22%2C%22search%22%3A%22opioids+%22%7D&pageSize=100&page=3 (last visited Jan. 19, 2023).

[176] *Sen. Ossoff's Bipartisan Bill to Prevent & Treat Opioid Addiction Signed into Law*, (Dec. 20, 2022), https://www.ossoff.senate.gov/press-releases/sen-ossoffs-bipartisan-bill-to-prevent-treat-opioid-addiction-signed-into-law/.

[177] H.R. 6, 115th Cong. (2018).

[178] MaryBeth Musumeci & Jennifer Tolbert, *Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act*, KFF (Oct. 5, 2018), https://www.kff.org/medicaid/issue-brief/federal-legislation-to-address-the-opioid-crisis-medicaid-provisions-in-the-support-act/.

[179] Billy Wynne & Dawn Joyce, *The 660-Page Opioids Bill is Now the Law. Here's What's in It.*, CHCF BLOG (Nov. 1, 2018), https://www.chcf.org/blog/the-660-page-opioids-bill-is-now-the-law-heres-whats-in-it/.

on various issues involved in the opioid crisis, including prevention and enforcement. The SUPPORT Act also requires states to have drug utilization review safety edits for opioid refills and to monitor concurrent prescribing of opioids.[180]

In addition, the recent initiative of both the United States House of Representatives and the United States Senate to introduce and pass bills relating to the opioid crisis suggests that this statute is likely to receive bipartisan support. The opioid crisis is no longer just a public health crisis. Its effects have burdened the economy through lost wages and productivity and increased costs in healthcare, therapy, and addiction treatment.[181] Moreover, opioid legislation is backed by significant public support as a topic of major public health concern in recent years. It should be briefly noted that the TRUST Act could be subject to significant debate caused by pharmaceutical lobbyists who greatly influence Congress and devote millions of dollars annually to doing so.[182] However, medical professionals, advocacy groups, and medical associations may, and often do, lobby lawmakers in support of legislation regulating the prescribing of controlled substances.

CONCLUSION

The ongoing opioid crisis is at the center of five competing public health issues — treating those suffering from painful injuries, reducing the rates of those suffering from opioid addiction, controlling the rising numbers of deaths related to opioid overdoses, punishing prescribers who issue opioids without a purposeful medical rationale, and encouraging prescribers with legitimate reasons to continue to treat patients with prescription opioids. The lack of consistency in the existing criminal guidelines for opioid prosecutions and the Supreme Court's failure to intervene in clarifying the effective prescription regulation highlight the need for a holistic solution that balances the competing issues involved. As the widespread effects of the opioid crisis have expanded beyond the realms of criminal law, and it is now a public health emergency, various coordinated measures are necessary to control the epidemic and ameliorate its malignant effects on society. Therefore, enacting a federal criminal statute is not a comprehensive solution. It is, however, a warranted legislative initiative to reduce the rate of prescription opioid-induced addiction through holding healthcare professionals who overprescribe opioids accountable,

---

[180] Musumeci & Tolbert, *supra* note 178.

[181] *See, e.g.*, *The Economic Impact of the Opioid Epidemic in Northwest Ohio*, UNIV. OF TOLEDO (2022), https://www.utoledo.edu/economic-impact/opioids/ (reporting region's total gross domestic lost to opioid crisis, *inter alia*, number of full-time jobs lost across the region due to opioid epidemic, cost to the area's gross domestic product).

[182] Ashley Duckworth, *Fighting America's Best-Selling Product: An Analysis of and Solution to the Opioid Crisis*, 26 WASH. & LEE J. OF CIV. RIGHTS AND SOC. JUST. 237, 274-75 (2019).

deterring others from overprescribing, and providing clear regulations that foster conscientious opioid prescriptions issued to those suffering from pain. A uniform national statute should instill confidence in patients that they can *trust* their doctors to prescribe only the necessary dosage for legitimate pain management. Simultaneously, a unified standard assures physicians that they are informed of the lawful standards of prescribing controlled substances and can *trust* the justice system to carry out fair prosecutions for unlawful prescribing.

***