RUAN'S HIPPOCRATIC HEGEMONY: PHYSICIAN IDIOSYNCRASY SHOULD NOT DETERMINE CRIMINALITY

Abstract: This Note advocates for congressional and state action to remedy the Supreme Court's flawed 2022 decision in *Ruan v. United States*. This approach includes a modified return to the objective good faith defense established by the Controlled Substances Act of 1970 (CSA) and *United States v. Moore*, the 1975 seminal case that established that physicians could be prosecuted under 21 U.S.C. § 841. *Ruan* requires that the government show a defendant physician subjectively knew their conduct in issuing controlled substances was unlawful. This permits the substitution of an individual physician's conception of acceptable medical practice in place of a generally agreed upon standard when a jury decides whether the physician prescribed in good faith. The *Ruan* decision is inconsistent with the text and intent of the CSA and the objective good faith defense standard established in *Moore*. Further, it is incongruous with the Supreme Court's 2006 decision in *Gonzales v. Oregon*, which delegated authority to the states, not individual physicians, to determine the bounds of acceptable medical practice. Additionally, *Ruan* had the unintended consequence of exacerbating a treatment disparity between low-level drug couriers and physicians charged under the CSA. This Note argues that a comprehensive, uniform amendment to the CSA, state prescribing statutes, and federal agency prescribing guidelines clearly defining what constitutes lawful prescribing would fulfill the *Ruan* Court's aims and maintain consistency with the CSA and the Supreme Court's prior holdings. Simultaneously, it would prevent the inequity between drug couriers and physicians from intensifying.

INTRODUCTION

Imagine you are a recent medical school graduate: you are most likely white,[1] from a high-income background, and will soon be making sizable

[1] *See* John Daniszewski, *Why We Will Lowercase White*, ASSOCIATED PRESS (July 20, 2020), https://blog.ap.org/announcements/why-we-will-lowercase-white [https://perma.cc/NXZ4-KHNA] (elaborating on the rationales behind keeping the term "white" lowercase in Associated Press-published works). The term "white" is lowercase in this Note for two key reasons discussed by the Associated Press: (1) unlike the term "Black," there is not a sufficient collective identity and shared history for the term "white" to justify its capitalization, and (2) the capitalization of "white" has the unintentional effect of giving legitimacy to white supremacists who adopted that capitalization for their purposes. *Id.* It should be noted, however, that some scholars argue that "white" should be capitalized because the lowercase "white" allows "white people . . . the comfort of [a] racial invisibility" and capitalizing it "can underscore the existence of an unjust racial power imbalance." Nell Irvin Painter, Opinion, *Why 'White' Should Be Capitalized, Too*, WASH. POST (July 22, 2020), https://www.

amounts of money.[2] The Hippocratic Oath (the Oath), on which you swore, rings heavily in your ears and will serve as an ethical guidepost for your career.[3] In swearing by it, you pledged to treat your patients to the best of your ability, to abstain from committing any injustice to them, and to be greatly punished should you violate any of your vows.[4] Nonetheless, after discovering the lucrative industry of pill milling, your word and your wallet are not enough to keep away the temptation to break the Oath.[5]

Soon, you have established a well-oiled pilling machine, whereby dozens of patients per day pay cash for a very brief appointment lacking proper physical examination or testing to obtain a fraudulent opioid prescription.[6] Because that is not nearly enough to satisfy your greed, you create faux patients, write fraudu-

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washingtonpost.com/opinions/2020/07/22/why-white-should-be-capitalized/ [https://perma.cc/3QAC-8KTW].

[2] *See Diversity in Medicine: Facts and Figures 2019*, ASS'N AM. MED. COLLS., aamc.org/data-reports/workforce/interactive-data/figure-18-percentage-all-active-physicians-race/ethnicity-2018 [https://perma.cc/F9E2-TC2J] (showing, by way of pie chart, that roughly 56% of active physicians are white, while less than half of that figure are Asian, Hispanic, and "Black or African American" combined); JAY YOUNGCLAUS & LINDSAY ROSKOVENSKY, ASS'N OF AM. MED. COLLS., AN UPDATED LOOK AT THE ECONOMIC DIVERSITY OF U.S. MEDICAL STUDENTS 2 (2018), https://www.aamc.org/media/9596/download?attachment [https://perma.cc/8732-G5CL] (stipulating that over the last three decades, roughly seventy-five percent of enrolled medical students were from the two highest household-income distributions); *How Much Does a Physician Make?*, U.S. NEWS & WORLD REP., https://money.usnews.com/careers/best-jobs/physician/salary [https://perma.cc/24GX-WGJN] (noting that physicians earned a median income of $208,000 in 2021, which was ranked number six in "Best Paying Jobs" according to U.S. News and World Report).

[3] *See* Brendan LoPuzzo, 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*, 47 HOFSTRA L. REV. 1397, 1397 (2019) (stating that the majority of medical school graduates swear by a modern version of the Hippocratic Oath (the Oath) before practicing medicine); Lisa R. Hasday, *The Hippocratic Oath as Literary Text: A Dialogue Between Law and Medicine*, 2 YALE J. HEALTH POL'Y L. & ETHICS 299, 300 (2002) (defining the Oath as a "code of medical ethics" sworn by those entering the medical practice).

[4] *See* Hasday, *supra* note 3, at 299 (providing a full textual recitation of the Oath). The historical origins of the Oath are based around the principle of "medicine [as] the science of healing, not of doing harm." *Id.* at 301 (footnote omitted). The modern version of the Oath still demands a higher ethical standard for medical practitioners, which demarcates them from those practicing alternative medicine. *Id.* at 302.

[5] *See* Karly Newcomb, *Defying "Do No Harm": Doctors Are Fueling the Opioid Crisis with Limited Criminal Repercussions*, 11 CRIM. L. PRAC. 59, 59–60 (2021) (noting that some pill mill doctors make up to $20-30,000 per day, with some reaching $750,000 in only one year of operating a mill). A pill mill is commonly an individual or group of practitioners masked as a pain clinic that issues strong narcotics "inappropriately or for non-medical reasons." Pia Malbran, *What's a Pill Mill?*, CBS NEWS (May 31, 2007), https://www.cbsnews.com/news/whats-a-pill-mill/ [https://perma.cc/TWB8-M6R9].

[6] *See* Adam M. Gershowitz, *Punishing Pill Mill Doctors: Sentencing Disparities in the Opioid Epidemic*, 54 U.C. DAVIS L. REV. 1053, 1056–57 (2020) (describing the makeup of most pill mill operations).

lent prescriptions for said patients, and then conspire with pharmacists and street dealers to sell the opioids to the public.[7] The Oath has long been abandoned.[8]

Over the next few years, you make millions of dollars and illicitly distribute millions of pills, but in the process you attract the attention of the U.S. Attorney's Office, which charges you with the "unlawful distribution of controlled substances" under 21 U.S.C. § 841.[9] Fortunately for you, juries hold a difficult-to-pierce trust of the medical profession, prosecutors carry a heavy burden of proof, and the universal subjective good faith defense established by the Supreme Court in its 2022 *Ruan v. United States* decision has made it far more difficult to prove your criminal mens rea.[10]

Prosecutors must provide significant evidence of egregious misconduct, known as "badges of bad faith," to overcome the jury instruction that what matters is *your* subjective belief, not the belief of reasonable physicians, that you prescribed in accordance with accepted medical practice.[11] Even if prose-

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[7] *See id.* at 1057 (elaborating on further illicit activities of pill mill doctors).

[8] *See* Newcomb, *supra* note 5, at 62 (arguing that pill mill doctors forsake the Oath).

[9] *See* Gershowitz, *supra* note 6, at 1058 (stating that the majority of pill mill doctors were charged under § 841); 21 U.S.C. § 841 (giving power to prosecutors to charge for illicit controlled substance distribution). A scholar chronicled some of the most infamous pill mill cases, noting the following convicted doctors and their illicit financial gain: Dr. Pravin Mehta, assets totaling $13 million; Dr. Richard Evans, $2.4 million; Dr. Andrew Sun, $1 million; Dr. Rodney Moret, $3 million. Gershowitz, *supra* note 6, at 1064, 1067, 1074, 1076. They also listed the number of pills and prescriptions illicitly doled out by some of these doctors: Dr. Noel Blackman, 365,000 oxycodone pills in one year alone; Dr. Richard Evans, 1.6 million pills; Dr. Ernesto Lopez, almost "one million oxycodone pills"; Dr. Andrew Sun, estimated 2.5 million pills. *Id.* at 1065, 1067–68, 1074.

[10] *See* Newcomb, *supra* note 5, at 76–77 (noting jurors' trust of doctors and a prosecutor's secondary task of piercing this trust to obtain a conviction); Adam M. Gershowitz, *The Opioid Doctors: Is Losing Your License a Sufficient Penalty for Dealing Drugs?*, 72 HASTINGS L.J. 871, 874–75 (2021) (stating that prosecutors often decline to charge physicians because of the heavy burden of proof and instead leave their fate to state medical boards); Ruan v. United States, 597 U.S. 450, 468 (2022) (establishing a universal subjective good faith defense standard for physicians charged under § 841); *see also Heath Hyde Gets Doctor's Pill Mill Cases Dismissed*, HEATH HYDE: FED. CRIM. DEF. ATT'Y (Oct. 3, 2022), https://heathhydelawyer.com/pill-mill-cases-dismissed [https://perma.cc/GB88-BWTK] (advertising the services of a federal criminal defense attorney who has utilized the Supreme Court's 2022 *Ruan v. United States* decision to his advantage and obtained dismissals before trial in several pill mill cases).

[11] *See* United States v. Sabean, 885 F.3d 27, 47–48 (1st Cir. 2018) (affirming a conviction on appeal based on a subjective good faith defense jury instruction because the government provided sufficient evidence of egregious misconduct by the defendant physician, referred to as "badges of bad faith"); Government's Response in Opposition re 151 Supplemental Motion for Acquittal & Motion for New Trial at 6–7, United States v. Parasmo, No. 19-CR-1, 2023 WL 1109649 (E.D.N.Y. Jan. 30, 2023), ECF No. 154 (providing substantial evidence of badges of bad faith in motion opposing defendant's motion for retrial or acquittal based on the *Ruan* subjective good faith defense standard); *Ruan*, 597 U.S. at 465, 468 (rejecting jury instructions predicated on the beliefs of other reasonable physicians and approving instructions that focus on the defendant physician's own subjective beliefs).

cutors overcome these hurdles and convict you, you could still fare relatively well at sentencing as a white-collar physician defendant.[12]

Now, envision you are a low-level drug courier: you are likely a foreign citizen and a person of color, from a low-income background, and have few financial prospects on the horizon.[13] With few means to support yourself and your family, you make the difficult decision to become a drug courier.[14] In the drug trade, you are the lowest rung on the organizational ladder with no insight into the business operations or the grander scheme.[15] You may not even be aware of the exact amount or type of drug you are carrying.[16]

For all the risk you have accepted, your pay is likely under $2,000 per day of smuggling.[17] One day, while smuggling heroin across the United States' border, you are apprehended by federal agents, who find more heroin on your person than you knew about.[18]

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[12] *See* Adam M. Gershowitz, *The Myth of the All-Powerful Federal Prosecutor at Sentencing*, 95 ST. JOHN'S L. REV. 581, 619 (2021) (providing historical context that white-collar defendants generally receive more favorable outcomes at sentencing compared to blue-collar defendants); Gershowitz, *supra* note 6, at 1102–03 (stating, via table, that some of the most egregious convicted pill mill doctors received below-guidelines sentences).

[13] *See* SAM TAXY, JULIE SAMUELS & WILLIAM ADAMS, URB. INST., U.S. DEP'T OF JUST., NCJ 248648, DRUG OFFENDERS IN FEDERAL PRISON: ESTIMATES OF CHARACTERISTICS BASED ON LINKED DATA 3 (2015), https://bjs.ojp.gov/content/pub/pdf/dofp12.pdf [https://perma.cc/VR63-PQR9] (stating that, as of October 2015, 76% of federally incarcerated drug offenders were Black, African American, or Hispanic and only 22% were white); Walter I. Gonçalves, Jr., *Banished and Overcriminalized: Critical Race Perspectives of Illegal Entry and Drug Courier Prosecutions*, 10 COLUM. J. RACE & L. 1, 5 n.10 (2020) (suggesting, anecdotally, that the majority of drug couriers "are of low socioeconomic strata, working factory, blue-collar, or other low-paying jobs" and are not U.S. citizens).

[14] *See* United States v. Cordoba-Hincapie, 825 F. Supp. 485, 488 (E.D.N.Y. 1993) (stating that, with no financial means available to provide for herself or her loved ones, the defendant became a drug courier to provide for her family and pay for her hearing loss operation).

[15] *See* Gonçalves, *supra* note 13, at 5 n.10 (describing the limited business knowledge and involvement of drug couriers); DAVID BJERK & CALEB MASON, THE MARKET FOR MULES: RISK AND COMPENSATION OF CROSS-BORDER DRUG COURIERS 26 (2014) (stipulating that drug couriers operate separately from the drug retail organization and have little intention of ascending within the organizational structure); Steven B. Wasserman, *Toward Sentencing Reform for Drug Couriers*, 61 BROOK. L. REV. 643, 651 (1995) (categorizing a drug courier defendant as a "beast of burden" who was hired to transport drugs with no knowledge of the penal dangers to herself or the financial benefits to her employer).

[16] *See Cordoba-Hincapie*, 825 F. Supp. at 488–89 (stating that the defendant falsely believed, based on her employer's claims, that she was carrying cocaine when in reality, she had ingested balloons filled with heroin); United States v. de Velasquez, 28 F.3d 2, 3 (2d Cir. 1994) (noting that the defendant was unaware of an additional amount of heroin hidden in her footwear by her employer).

[17] *See* BJERK & MASON, *supra* note 15, at 26 (providing, via empirical study, the average pay for a drug courier). Drug couriers face a substantial amount of risk; on average, they are sentenced to over three years of incarceration while a substantial number were sentenced based on mandatory minimums. Gonçalves, *supra* note 13, at 55–56.

[18] *Cf.* BJERK & MASON, *supra* note 15, at 1 (noting that about three thousand drug couriers are arrested every year trying to enter the United States from Mexico).

The U.S. Attorney's Office elects to charge you under the same statute as pill mill doctors, Section 841.[19] Here, it is you, not the prosecutor, who faces a steep uphill battle to overcome bias in the courtroom, reduced mens rea protections, and harsher penal outcomes than high-level drug distributors.[20] You cannot rely on a stronger mens rea protection akin to *Ruan*; only physicians can count themselves so fortunate.[21] Instead, consideration of your mens rea can be virtually eliminated from evaluation during trial and at sentencing.[22]

Even with weak circumstantial evidence of your criminal state of mind, the government can prove your guilt through expert testimony that merely describes characteristics shared between you and a common drug courier.[23] In other words, your mens rea can be proven through profiling.[24] If you are convicted, mens rea will still not be on your side.[25] Although you lacked knowledge of the total drug quantity on your person, you will likely be on the hook for every gram.[26]

In *Ruan*, the Supreme Court held that a physician's criminal liability is no longer primarily governed by the reasonable beliefs of their fellow physicians as to what constitutes acceptable medical practice.[27] Now, a physician may escape a conviction if the government fails to disprove that the physician subjectively believed that their prescriptions comported with acceptable medical practice.[28]

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[19] *See* Gershowitz, *supra* note 6, at 1058 (noting that both pill mill doctors and street-level drug offenders can be charged under § 841); United States v. Moore, 423 U.S. 122, 131 (1975) (holding that "any person" may face prosecution under § 841).

[20] *See* Adam Weber, Note, *The Courier Conundrum: The High Costs of Prosecuting Low-Level Drug Couriers and What We Can Do About Them*, 87 FORDHAM L. REV. 1749, 1790 (2019) (comparing penal outcomes between high- and low-level drug distributors); Gonçalves, *supra* note 13, at 48 (noting the courtroom bias that drug couriers face); Jack B. Weinstein & Fred A. Bernstein, *The Denigration of Mens Rea in Drug Sentencing*, 7 FED. SENT'G REP. 121, 121 (1994) (arguing that mens rea is largely disregarded in drug courier sentencings).

[21] *See* Ruan v. United States, 597 U.S. 450, 454 (2022) (narrowing its holding to only grant the subjective good faith defense standard to physicians charged under § 841).

[22] *See* Weinstein & Bernstein, *supra* note 20, at 121–22 (discussing the virtual elimination of mens rea during the sentencing of drug couriers); United States v. Foster, 939 F.2d 445, 449–51, 454–55, 458 (7th Cir. 1991) (nullifying, in essence, the consideration of mens rea in drug courier trials by permitting the use of drug courier profiles to prove a defendant's knowledge).

[23] *See Foster*, 939 F.2d at 454–55, 458 (permitting drug courier profile evidence to prove the defendant's mens rea in a drug courier case); United States v. Solis, 923 F.2d 548, 551 (7th Cir. 1991) (same).

[24] *See* United States v. Ramos-Rodriguez, 809 F.3d 817, 826–27 (5th Cir. 2016) (allowing drug courier profiling as expert testimony to prove knowing mens rea); United States v. Doe, 149 F.3d 634, 637 (7th Cir. 1998) (same).

[25] *See* Weinstein & Bernstein, *supra* note 20, at 121 (arguing that mens rea protections have virtually been eliminated at sentencing in drug courier cases).

[26] *See id.* (noting the stringent quantity-dependent sentencing outcomes in drug courier cases).

[27] Ruan v. United States, 597 U.S. 450, 465–66 (2022).

[28] *See id.* at 454 (holding that the Government must show that a physician knowingly or intentionally issued an unauthorized prescription to obtain a conviction).

Whereas no one drug courier's subjective belief can overcome what others have deemed an illicit act, the same cannot be said for physicians, whose subjective belief may overcome what other doctors agree is unlawful prescribing.[29] This protection is exclusive to physicians and cannot be subverted by expert testimony that the defendant matched the profile of a pill mill doctor.[30] Instead, to obtain a conviction, the government must present significant circumstantial evidence outlining a physician's unlawful conduct to convince a jury that the physician's subjective good faith belief is a falsehood.[31]

Despite the seemingly good intentions of the Supreme Court, *Ruan* has unjustly widened the treatment gap between physicians and drug couriers charged under the CSA.[32] Additionally, the Controlled Substances Act of 1970 (CSA) and the Supreme Court's 1975 decision in *United States v. Moore* already establish an objective, flexible framework through which unlawful physician conduct can be governed without the need for a subjective good faith defense.[33] Armed with this information, this Note argues that the subjective good faith defense established by *Ruan* is an improper solution.[34]

To decrease the unjust disparity between physicians and drug couriers and to fulfill the *Ruan* Court's aims, this Note argues for a uniform statutory amendment to the CSA that mandates an *objective* good faith defense standard for physicians.[35] Additionally, this Note proposes that state statutes and federal agency guidelines can comprehensively outline generally accepted prescribing practices that physicians must make a good faith effort to adhere to.[36]

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[29] *Compare id.* at 454, 465–66 (granting physicians a good faith defense that may overcome a finding that reasonable physicians do not believe it comports with acceptable medical practice), *with* United States v. de Velasquez, 28 F.3d 2, 3, 6 (2d Cir. 1994) (affirming the sentence of the drug courier defendant for the entire drug quantity despite her credible subjective belief that she had no knowledge of part of the quantity).

[30] *See Ruan*, 597 U.S. at 454 (circumscribing its holding narrowly to physicians); United States v. Sabean, 885 F.3d 27, 47 (1st Cir. 2018) (holding that a subjective good faith defense for physicians charged under § 841 must be proven by "badges of bad faith," which are defined as "conduct that is commonly understood to be plainly unprofessional," rather than matching to profiling characteristics).

[31] *See Ruan*, 597 U.S. at 467 (noting that the government may disprove a subjective good faith defense through circumstantial evidence); *Sabean*, 885 F.3d at 47 (holding that a subjective good faith defense for physicians is disproven through "badges of bad faith," or specific instances of unlawful conduct).

[32] *See supra* notes 2–31 and accompanying text (detailing, via hypotheticals, the differences in circumstances between pill mill doctors and drug couriers and the differences in mens rea protections between the two groups under *Ruan*).

[33] *See infra* notes 155–158 and accompanying text (describing the government's argument that an objective good faith defense already exists to protect defendant physicians who make an honest effort to comport with acceptable medical standards).

[34] *See infra* notes 213–226 and accompanying text.

[35] *See infra* notes 227–234 and accompanying text.

[36] *See infra* notes 235–242 and accompanying text.

Part I of this Note first discusses the legislative history and legal standards of Section 841.[37] It then outlines the good faith defense for physicians charged under the statute and the prosecutorial burden that must be met to obtain a conviction.[38]

Part II first considers the justifications for granting physicians a subjective good faith defense.[39] It then presents arguments against the subjective good faith defense and proposes a solution that could replace *Ruan* and simultaneously fulfill the *Ruan* Court's aims.[40] Finally, Part II muses on the policy implications of *Ruan*, outlining the argument that it exacerbates the mens rea treatment disparity between drug couriers and physicians charged under the CSA.[41]

Part III of this Note argues that a subjective good faith defense for physicians is unjust, pointing to its inconsistency with established law and alluding to the policy concerns enumerated in Part II.[42] It then proposes a uniform, comprehensive solution that incorporates federal agency guidelines, state statutory schemes, and a model statute to be implemented into the CSA.[43] Overall, Part III argues that this multi-faceted solution would satisfy the *Ruan* Court's aims, alleviate concerns regarding an objective mens rea standard, and help prevent the inequitable disparity in mens rea treatment between physicians and drug couriers charged under the CSA from escalating.[44]

I. The History of Section 841: How Did We Get Here?

This Part focuses on the history of Section 841 and how it applies to physicians.[45] Section A of this Part recounts the legislative history of the CSA and Section 841.[46] Section B highlights *United States v. Moore*, the 1975 landmark case in which the Supreme Court held that physicians could be charged under Section 841.[47] Section C then discusses the good faith defense and mens rea protections for physicians prior to and following the Supreme Court's 2022 decision in *Ruan v. United States*.[48]

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[37] *See infra* notes 45–74 and accompanying text.
[38] *See infra* notes 76–115 and accompanying text.
[39] *See infra* notes 117–151 and accompanying text.
[40] *See infra* notes 153–179 and accompanying text.
[41] *See infra* notes 180–207 and accompanying text.
[42] *See infra* notes 209–226 and accompanying text.
[43] *See infra* notes 227–242 and accompanying text.
[44] *See infra* notes 209–242 and accompanying text.
[45] *See infra* notes 45–115 and accompanying text.
[46] *See infra* notes 49–60 and accompanying text.
[47] *See infra* notes 62–74 and accompanying text.
[48] *See infra* notes 76–115 and accompanying text.

A. The Controlled Substances Act: Congress Combats Drug Abuse Through Criminal Liability

Congress first attempted to combat drug addiction in the United States with criminal prosecutions through the Harrison Narcotics Act (HNA) of 1914.[49] The HNA made it unlawful to possess or deal several enumerated controlled substances but carved out an exception for those who lawfully registered with their local internal revenue collector.[50]

Physicians were permitted to register under the HNA but were required to keep meticulous records of any drugs they administered or disbursed, including the date, amount of drugs, and the patient's personal information.[51] If a physician failed to comply, they would be subject to a fine of up to $2,000, up to five years of imprisonment, or both.[52]

After decades of additional legislation, drug abuse in the United States remained rampant, which pressured Congress to replace the HNA with a new, comprehensive framework—the CSA—to exert greater control over the production and dissemination of controlled substances.[53] Congress intended for the CSA to combat drug abuse and addiction through more efficient legal enforcement and a measured system to criminally penalize drug offenders.[54]

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[49] Richard C. Boldt, *Drug Policy in Context: Rhetoric and Practice in the United States and the United Kingdom*, 62 S.C. L. REV. 261, 262 (2010).

[50] Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785, 785–86, *repealed by* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2006)). Specifically, Congress enumerated "opium or coca leaves or any compound, manufacture, salt, derivative, or preparation thereof" as prohibited controlled substances. *Id.* The coca plant, originally grown in South America, was transformed into medicines and even implemented into the Coca-Cola syrup, in addition to its more commonly known derivation—cocaine. *A Social History of America's Most Popular Drugs*, PBS, https://www.pbs.org/wgbh/pages/frontline/shows/drugs/buyers/socialhistory.html [https://perma.cc/6P34-4VKC]. Though supported by the army's Surgeon-General for medicinal use in 1886, by 1914 there were hundreds of thousands of Americans addicted to cocaine, likely contributing to Congress's decision to enact the HNA. *Id.* Opium, popularized during the nineteenth century in the form of morphine, was eventually synthesized into the widely addictive substance heroin by the Bayer Company. *Id.*

[51] Harrison Narcotics Act of 1914 ch. 1, § 2, 38 Stat. at 786.

[52] *Id.* at 789.

[53] *See* 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, 1753 (2018) (providing the context behind the passage of the CSA); H.R. REP. NO. 91-1444, at 6 (1970) (noting that drug abuse reaching epidemic levels was the motivation behind the CSA). The CSA is formally titled the "Comprehensive Drug Abuse Prevention and Control Act of 1970," which is now codified at 21 U.S.C. §§ 801–971. *See* McClure, *supra*, at 1753 (noting the modern codification of the CSA). *See generally* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended in 21 U.S.C. §§ 801–971 (2006)) (governing controlled substance prosecutions).

[54] H.R. REP. NO. 91-1444, at 1.

The CSA divided drugs into five schedules, predicated primarily on their medical usefulness and the dangers they posed to users.[55] The majority of opioids—a type of drug commonly prescribed by pill mill doctors—fall under Schedule II.[56] Despite having a present medical utility, Schedule II drugs are marked by a significant danger of abuse or extreme dependence on the substance.[57]

Given the known dangers of controlled substances, the CSA prohibited the knowing or intentional creation, distribution, dissemination, or possession with intent to commit the aforementioned acts, of controlled substances under Section 841(a).[58] An "except as authorized" clause was created, however, for distributors lawfully registered under the CSA.[59]

All current and potential manufacturers or distributors—including physicians—are now required to register with the Attorney General to lawfully create, disseminate, and possess controlled substances pursuant to Section 822(a)–(b).[60] The next Section explores whether those who are lawfully CSA-registered, namely physicians, would be subject to criminal liability under Section 841 or whether the "except as authorized" clause created a per se immunity from prosecution.[61]

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[55] *See* Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 29 (2016) (providing the rationale behind the CSA's drug schedules); 21 U.S.C. § 812(b) (listing the five schedules of drugs). Congress established the Drug Enforcement Administration (DEA) via the CSA in 1973 and granted it authorization to "schedule and regulate controlled substances." 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, 281 (2013). The schedules range from no sanctioned medical use in Schedule I to some accepted medical purpose in Schedules II-V, with diminishing potential for abuse approaching Schedule V. Dineen & DuBois, *supra*, at 29; *see* 21 U.S.C. § 812(b)(1)–(5) (listing the characteristics for drugs in each schedule).

[56] *See* Khary K. Rigg, Samantha J. March & James A. Inciardi, *Prescription Drug Abuse & Diversion: Role of the Pain Clinic*, 40 J. DRUG ISSUES 681, 683 (2010) (providing statistics demonstrating that opioids are commonly distributed by pill mill doctors); Dineen & DuBois, *supra* note 55, at 29 (stating the schedule placement of opioids). Common prescription opioids include Vicodin, OxyContin, and Percocet. Joanna Shepherd, *Combatting the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J.L. & MED. 85, 87 (2014).

[57] 21 U.S.C. § 812(b)(2).

[58] *See id.* § 801(2) (noting Congress's principal findings regarding the dangers of controlled substances); *id.* § 841(a)(1) (making it unlawful "to manufacture, distribute, or dispense, or possess with intent [to commit the aforementioned], a controlled substance").

[59] *See id.* § 841(a)(1) (noting an "except as authorized" clause for individuals authorized under the CSA); *id.* § 822(a)(1)–(2) (granting authorization for registered individuals to deal in controlled substances).

[60] *Id.* § 822(a)–(b).

[61] *See infra* notes 62–74 and accompanying text; *see also* United States v. Moore, 423 U.S. 122, 124, 131 (1975) (stating the primary issue in the case was whether a "per se [exemption]" from § 841(a) prosecutions existed for physicians registered under the CSA).

B. United States v. Moore*: Section 841 Applies to Physicians, Too*

In *Moore*, the Supreme Court set out to decide whether physicians could face prosecution under Section 841(a).[62] The respondent, Dr. Raymond Moore, was a properly licensed and registered physician convicted under Section 841(a)(1) on twenty-two counts of unlawfully distributing and dispensing the controlled substance methadone.[63]

Moore's cash-for-pills scheme involved minimal physical examination of patients, unsupervised drug tests and drug usage, and wholly inaccurate records of drug dispensation.[64] Many of the patients simply used the prescriptions to fuel their addictions, and others re-sold their pills or distributed them to loved ones.[65]

Moore was fined $150,000 and sentenced to up to forty-five years in prison.[66] Moore appealed to the District of Columbia Circuit Court of Appeals, which held that although Moore's conduct was wrongful, he, and other physicians, were exempt from prosecution under Section 841.[67]

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[62] 423 U.S. at 131.

[63] *Id.* at 124–25. Methadone is a highly addictive substance that can be used to treat heroin addiction. *Id.* Moore claimed he was prescribing the substance based on a British physician's detoxification program, to which the government rebutted that it was wholly inconsistent with accepted treatment methodology. *Id.* at 126. Moore argued that the CSA was lenient with regards to medical practice and would permit his conduct as authorized. *Id.* at 138.

[64] *Id.* at 126–27. Moore dispensed over 11,000 prescriptions containing roughly 800,000 methadone pills over a meager five and a half months from August 1971 to February 1972. *Id.* at 126. Given that Moore charged up to $50 for a 150-pill prescription, he enriched himself to the tune of $260,000 in less than half a year. *Id.* Based on a Consumer Price Index Inflation Calculator, Dr. Moore's $260,000 illicit profits from February 1972 would have an equivalent purchasing power exceeding $1,900,000 in February 2024. *CPI Inflation Calculator*, U.S. BUREAU OF LAB. STAT., https://www.bls.gov/data/inflation_calculator.htm [https://perma.cc/T9XE-E5K9].

[65] *Moore*, 423 U.S. at 127.

[66] *Id.* at 125. Based on the Consumer Price Index Inflation Calculator, the Court-imposed $150,000 fine in October 1972 would have an equivalent purchasing power exceeding $1,100,000 in February 2024. *CPI Inflation Calculator*, *supra* note 64 [https://perma.cc/WNJ5-WAJ6]; *see also* Richard D. Lyons, *Licenses Planned for Doctors Urging Methadone*, N.Y. TIMES, Nov. 13, 1972, at 5, https://timesmachine.nytimes.com/timesmachine/1972/11/13/issue.html [https://perma.cc/GFF7-Z6FF] (noting the date of Moore's original conviction was in October 1972). In the wake of Moore's methadone prescription conviction, the FDA approved methadone for the treatment of opioid addiction but required physicians to obtain a specific license to prescribe it. Lyons, *supra*; *see* COMM. ON FED. REGUL. OF METHADONE TREATMENT, INST. OF MED., FEDERAL REGULATION OF METHADONE TREATMENT 93–94 (Richard A. Rettig & Adam Yarmolinsky eds., 1995) (noting the FDA's approval of methadone for opioid addiction treatment in late 1972).

[67] *Moore*, 423 U.S. at 127. The Court of Appeals reasoned that Congress had only intended for the prosecution of physicians to occur under Sections 842 and 843, both of which carried substantially lower penalties than Section 841. *Id.* at 128–29. Penalties under Section 841 would have been up to fifteen years imprisonment, a fine of up to $25,000, or both. *Id.* at 129 n.6. At most, a conviction under Sections 842 or 843 would yield imprisonment up to four years, a fine up to $30,000, or both. *Id.*

On review, the Supreme Court held that any person, including physicians, could be prosecuted under Section 841.[68] The Court reasoned that a physician's CSA registration under Section 822(b) operated as a limited authorization for certain lawful conduct, but not a total immunity against all punishment.[69]

The Court further held that registered physicians could face prosecution under Section 841 if their activities fell "outside the usual course of professional practice."[70] The Court found that Moore's conduct overstepped acceptable limits of professional medical practice.[71] Evidence of insufficient physical exams, inadequate drug testing, lack of precautions against drug abuse and resale, unregulated prescription dosage, prescribing an amount requested by patients, and a cash fee-scale for pills all led the court to conclude that Moore was merely a drug pusher.[72]

The Court reversed the judgment of the District of Columbia Circuit Court of Appeals and affirmed Moore's initial conviction and sentence.[73] Thus, *Moore* established that physicians could violate Section 841 if their conduct, when compared to generally accepted practice, fell outside the bounds of acceptable medical standards.[74] The next Section explores the implementation of mens rea and a good faith defense in Section 841 physician prosecutions.[75]

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[68] *Id.* at 131. The Court looked to the specific text of the statute, which provided that any person could be in violation of the statute. *Id.*; *see* 21 U.S.C. § 841(a) (stating that any person could commit the unlawful conduct prohibited by the statute).

[69] *Moore*, 423 U.S. at 132–33, 138. Under the HNA, street dealers and drug pushing physicians shared criminal penalties. *Id.* at 139. Because Congress's intent in enacting the CSA was to bolster, not diminish, narcotics prosecutions, the Court reasoned that this treatment carried over to the CSA. *Id.* at 132; *see* H.R. REP. NO. 91-1444, at 1 (1970) (stating the intent of the CSA). The Court analogized Moore's case to two physician convictions it upheld during the 1920s pursuant to the HNA. *Id.* at 132. In 1920, in *Jin Fuey Moy v. United States*, the Supreme Court upheld a physician's conviction where there were large amounts of drugs distributed without proper physical examination or proper directions for use and a rising fee system based on the drug quantity prescribed. 254 U.S. 189, 193–95 (1920), *overruled on other grounds by* Funk v. United States, 290 U.S. 371, 387 (1933). Only two years later, in *United States v. Behrman*, the Court reversed the court of appeals and affirmed another defendant physician's original conviction where the physician prescribed controlled substances to a known addict. 258 U.S. 280, 288–89 (1922). The 1975 *Moore* Court reasoned that even in the infancy of narcotics prosecutions, Congress did not intend to grant physicians full immunity via Section 822(b). 423 U.S. at 131–32.

[70] *Moore*, 423 U.S. at 122, 124, 138–40. The *Moore* Court pointed to other provisions in the act, Sections 812, 823, 828, and 844, which all implied limitations on what constituted a physician's acceptable professional practice. *See id.* at 142 (reasoning why physicians could be prosecuted for going outside the limits of acceptable medical practice).

[71] *Id.* at 142–43.

[72] *Id.* The Court rejected Moore's argument that his methadone treatment was permitted by the CSA as proper research or experimentation, reasoning that this logic would allow CSA registrants to circumvent Section 841 entirely by receiving excessive discretion in patient treatment. *Id.* at 143.

[73] *Id.* at 125, 146.

[74] *See id.* at 138–39, 142 n.20, 146 (reversing the Court of Appeals and upholding the original conviction based on a jury instruction that measured Moore's conduct against generally accepted

C. Mens Rea and the Good Faith Defense: How Has Ruan *Changed Things?*

This Section outlines the application of mens rea and the good faith defense in Section 841 physician prosecutions before and after *Ruan*.[76] Subsection 1 provides an analysis of mens rea and the good faith defense, and their importance in Section 841 physician prosecutions.[77] Subsection 2 examines *Ruan* and its impact on the good faith defense and mens rea for physicians charged under Section 841.[78]

1. An Overview of Mens Rea and the Good Faith Defense in Section 841 Physician Prosecutions

Criminal law, in general, aims to punish those who exhibit a nefarious will and commit conscious wrongdoing.[79] Logically, most criminal statutes are intended to penalize those with a culpable state of mind.[80] This state of mind is consistently referenced as "scienter," or the level of knowledge that renders one criminally accountable for their actions.[81]

In Section 841 prosecutions, a defendant is criminally accountable if he or she unlawfully and "knowingly or intentionally" dealt in controlled substances.[82] To successfully prosecute physicians under Section 841, the government is required to prove that the defendant physician (1) "knowingly or intentionally" disseminated "a controlled substance," (2) knew the substance was con-

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medical practice). The Court left the question of whether Moore should be penalized under Section 845, which included a steeper punishment for distributing to those younger than twenty-one years old, up to the lower court on remand. *Id.* at 146.

[75] *See infra* notes 76–115 and accompanying text.

[76] *See infra* notes 77–115 and accompanying text.

[77] *See infra* notes 79–90 and accompanying text.

[78] *See infra* notes 91–115 and accompanying text.

[79] *See* Morissette v. United States, 342 U.S. 246, 251 (1952) (stating the general purpose of criminal law); Elonis v. United States, 575 U.S. 723, 734 (2015) (stipulating the conscious requirement for criminal wrongdoing). Conduct deemed criminal is inherently portrayed as wrongful within the realm of criminal law, which some scholars have argued buoys society's civil order. *See* Sandra G. Mayson, *The Concept of Criminal Law*, 14 CRIM. L. & PHIL. 447, 451–52 (2020) (discussing different scholarly interpretations of the "collective-condemnation concept"). Further, the idea of "collective-condemnation" proffers that society's stigmatization of criminal convicts is a distinct feature that sets criminal law apart from its civil counterpart. *Id.* at 452.

[80] Rehaif v. United States, 139 S. Ct. 2191, 2195 (2019). Criminal statutory codes, such as the Model Penal Code, have endeavored to provide clarity as to what constitutes a criminal offense and the requisite mens rea such that innocent conduct would be insulated from prosecution. *See, e.g.*, MODEL PENAL CODE § 1.02(1)(c)–(d) (AM. L. INST. 2022) (stipulating the intended "purposes . . . [and] principles of construction" for the Model Penal Code).

[81] *See Rehaif*, 139 S. Ct. at 2195 (quoting *Scienter*, BLACK'S LAW DICTIONARY (10th ed. 2014)) (providing a working definition of "scienter").

[82] 21 U.S.C. § 841.

trolled pursuant to the CSA, and (3) that the prescriptions at issue were distributed "outside the usual course of professional practice."[83]

Whether a physician's conduct is unlawful is a question ultimately reserved for the jury.[84] The first part of physician prosecution jury instructions is usually derived from 21 C.F.R § 1306.04(a), which mandates that prescriptions be effectuated with a "legitimate medical purpose" by a physician "acting in the usual course of his professional practice."[85]

If a jury finds that a physician's actions failed to comport with these elements, the physician violates Section 841.[86] A physician can raise a good faith defense, however, which can negate the mens rea for these elements unless the government disproves the defense "beyond a reasonable doubt."[87] The *Moore* Court implicitly based this defense on an objective standard, which permits a jury to infer the requisite mens rea for the crime if the government shows the physician failed to make a good faith effort to adhere to generally accepted medical practice.[88]

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[83] United States v. McIver, 470 F.3d 550, 556 (4th Cir. 2006) (quoting United States v. Moore, 423 U.S. 122, 124 (1975)). Drug courier prosecutions, in contrast, require the government to prove beyond a reasonable doubt that a defendant (1) knew or intended to possess the controlled substance, (2) intended to disburse it, and (3) knew the substance was controlled. *See* United States v. Magana, 118 F.3d 1173, 1199 (7th Cir. 1997) (citing United States v. Jackson, 51 F.3d 646, 655 (7th Cir. 1995)) (stipulating the requirements for a possession with intent to distribute case).

[84] *See* United States v. Lovern, 590 F.3d 1095, 1100 (10th Cir. 2009) (holding that a jury would decide whether physician conduct was within the scope of usual professional practice).

[85] 21 C.F.R § 1306.04(a) (2023). The requirements that a prescription be issued for a "legitimate medical purpose" in "the usual course of . . . professional practice" has been heavily criticized by some scholars, who argue that there is too much ambiguity as to what behavior runs afoul of the law. *See* Julia MacDonald, Comment, *"Do No Harm or Injustice to Them": Indicting and Convicting Physicians for Controlled Substance Distribution in the Age of the Opioid Crisis*, 72 ME. L. REV. 197, 220–21 (2020) (arguing that there is a lack of clarity on the issue of acceptable professional practice); LoPuzzo, *supra* note 3, at 1404 (noting the lack of clear guidelines on acceptable medical practice in prescribing opioids). A scholar detailed a circuit split on whether "legitimate medical purpose" and "the usual course of professional practice" are elements of an unlawful distribution charge that must be included in the Government's indictment. MacDonald, *supra*, at 206–12. In attempting to offer some clarity, in 1978, in *United States v. Rosen*, the Fifth Circuit Court of Appeals enumerated a list of behaviors that violated these elements seen in previous cases from the Second, Third, Fifth, Eighth, Ninth, and Tenth Circuits, and the U.S. Supreme Court. 582 F.2d 1032, 1035–36 (5th Cir. 1978). Some examples of unlawful behavior entailed (1) copious amounts of drugs prescribed, (2) abundant prescriptions doled out, (3) a lack of physical examination, (4) prescribing to known re-sellers, and (5) no link between the controlled substance prescribed and treatment of a patient's condition. *Id.*

[86] Ruan v. United States, 597 U.S. 450, 454 (2022).

[87] United States v. Wexler, 522 F.3d 194, 205 (2d Cir. 2008); *see Ruan*, 597 U.S. at 456 (noting the categorization of good faith as a complete defense).

[88] *See* United States v. Moore, 423 U.S. 122, 138–39, 142 n.20 (creating an objective good faith defense standard by accepting jury instructions that made no mention of the physician's subjective beliefs as to whether they prescribed in good faith); *Wexler*, 522 F.3d at 205–06 (approving a jury instruction that based the *Moore* good faith defense on a "standard of objective reasonableness"); *see also* Brief for the United States at 27, 30, *Ruan*, 597 U.S. 450 (Nos. 20-1410 & 21-5261) (interpreting *Moore* as establishing that when a physician fails to make an "objectively reasonable effort" to under-

Over thirty years after *Moore*, in the 2006 case *Gonzales v. Oregon*, the Supreme Court held that each state would determine what constituted the bounds of acceptable medical practice and that their respective medical communities must have input in Section 822 registration revocations.[89] The next subsection discusses the Court's effort, sixteen years after *Gonzales*, to bolster protections for physicians, reasoning that it was still too difficult to differentiate between lawful and unlawful prescribing.[90]

2. *Ruan* Provides a Subjective Good Faith Defense for All Physicians Charged Under Section 841

In *Ruan*, the Supreme Court endeavored to address a statutory ambiguity surrounding mens rea in Section 841 physician prosecutions.[91] More specifically, the Court proposed that Section 1306.04(a) and the CSA left the issue of unlawful prescribing in a gray area, making it difficult to differentiate it from permissible conduct.[92] To achieve its aims of clarifying the statutory language and imposing a new scienter requirement for physician prosecutions, the Court accepted and consolidated the petitions of Dr. Xiulu Ruan and Dr. Azad Khan.[93]

Ruan and Khan were both convicted of unauthorized controlled substance distribution under Section 841.[94] Ruan's comprehensive criminal scheme in-

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stand or comply with accepted medical practice, they will have the "requisite mens rea to violate Section 841(a)"). It should be noted, however, that some circuit courts approved jury instructions that rejected the objective reasonable physician standard. *See, e.g.*, United States v. Alerre, 430 F.3d 681, 687 (4th Cir. 2005) (affirming jury instruction that mandated jury to not convict if it only found that the defendant physician's conduct failed to reach a reasonable physician's expected standards); United States v. Sabean, 885 F.3d 27, 45, 47–48 (1st Cir. 2018) (affirming conviction based on a subjective good faith defense jury instruction).

[89] 546 U.S. 243, 270 (2006).

[90] *See Ruan*, 597 U.S. at 454 (mandating that a subjective good faith defense and higher burden of proof be applied in § 841 physician prosecutions).

[91] *See id.* at 459 (characterizing the prior statutory language governing physician conduct as ambiguous). This ambiguity was previously recognized by the Fifth Circuit, which in 1981 in *United States v. Harrison*, held that the list of condemned physician conduct it had provided in *Rosen* only three years prior was neither exclusive nor exhaustive. United States v. Harrison, 651 F.2d 353, 355 (5th Cir. July 1981). The Fifth Circuit further held that the list did not provide a minimum threshold for the sum of condemned behaviors that would justify a jury trial on the issue of appropriate medical practice. *Id.* In sum, the Fifth Circuit did not provide a clear demarcation for what constituted an unlawful prescription. *See id.* (leaving significant room for ambiguity in its interpretation of the *Rosen* list).

[92] *Ruan*, 597 U.S. at 458–60.

[93] *Id.* at 457.

[94] Press Release, Acting U.S. Att'y Steve Butler, U.S. Att'y's Off., S. Dist. of Ala., Dr. Couch and Dr. Ruan Sentenced to 240 and 252 Months in Federal Prison for Running Massive Pill Mill (May 26, 2017) [hereinafter Dr. Ruan Press Release], https://www.justice.gov/usao-sdal/pr/dr-couch-and-dr-ruan-sentenced-240-and-252-months-federal-prison-running-massive-pill [https://perma.cc/2WDM-9326] (stating press release information regarding Dr. Xiulu Ruan's conviction in Alabama); Press Release, U.S. Att'y's Off., E. Dist. of Pa., Doctor Sentenced to 24 Months in Prison for Selling Prescriptions of Suboxone and Klonopin (April 9, 2018) [hereinafter Dr. Khan Press Release], https://

volved the misappropriated distribution of two fentanyl drugs while receiving kickbacks or investment returns from both manufacturers, in addition to collecting profits from the pharmacy that he co-owned with another doctor.[95] Khan, on the other hand, was employed at a pill mill clinic where the controlled substances Suboxone and Klonopin were prescribed in abundance for significant cash fees.[96]

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www.justice.gov/usao-edpa/pr/doctor-sentenced-24-months-prison-selling-prescriptions-suboxone-and-klonopin [https://perma.cc/37L4-G8JU] (stating press release information regarding Dr. Azad Khan's conviction in Pennsylvania).

[95] Dr. Ruan Press Release, *supra* note 94. Ruan and his co-defendant, Dr. Couch, jointly ran two pain care clinics and a pharmacy, which were mostly run as profit centers for the two doctors. *Id.* Evidence at trial showed that the doctors became top prescribers of two fentanyl drugs, Subsys and Abstral, while receiving kickbacks from one manufacturer and investing heavily in the other manufacturer's stock. *Id.* Both Subsys and Abstral are drugs comprised of fentanyl, an extreme narcotic that is prescribed to combat cancer-related pain for which ordinary pain medication is insufficient. *Fentanyl (Buccal Mucosa Route, Oromucosal Route, Sublingual Route)*, MAYO CLINIC, https://www.mayoclinic.org/drugs-supplements/fentanyl-buccal-mucosa-route-oromucosal-route-sublingual-route/description/drg-20063888 [https://perma.cc/A3HZ-NNSU] (Feb. 1, 2024). The FDA mandates that any indication be corroborated by significant evidence of efficacy established by appropriate scientific studies. *See* 21 C.F.R. § 201.57(c)(2)(iv) (2023) (providing requirements for drug product indications); *see also* Sunghwan Sohn & Hongfang Liu, *Analysis of Medication and Indication Occurrences in Clinical Notes*, 2014 AM. MED. INFORMATICS ASS'N ANN. SYMP. PROC. 1046, 1046 (defining "indication" in medicine as a legitimate rationale to use a specific medication to treat patients). Despite only being U.S. Food and Drug Association (FDA)-indicated for cancer-related pain, Ruan and Couch prescribed both fentanyl drugs for ordinary bodily pain. Dr. Ruan Press Release, *supra* note 94. Fentanyl drugs pose a significant danger of physiological dependence and withdrawal side effects for people improperly using or withdrawing from the drugs. *Fentanyl (Buccal Mucosa Route, Oromucosal Route, Sublingual Route)*, *supra*. The doctors' pharmacy filled all the fentanyl drug orders, which could cost patients' insurance up to $24,000 every month, and netted three quarters of the profits from the drug reimbursements. Dr. Ruan Press Release, *supra* note 94. Based on this extensive criminal enterprise, Ruan was sentenced to 252 months of incarceration. *Id.*

[96] Dr. Khan Press Release, *supra* note 94. Khan was employed by a co-defendant physician at a pain clinic. *Id.* Evidence and expert testimony at trial showed that (1) "Suboxone and Klonopin should never be prescribed together" unless unquestionably necessary, and that (2) the doctors dispensed both to nearly all patients at the clinic, irrespective of any patient's medical necessity. *Id.* Klonopin, the name brand for the drug clonazepam, is typically used to treat seizure and panic disorders. *Clonazepam (Oral Route)*, MAYO CLINIC, https://www.mayoclinic.org/drugs-supplements/clonazepam-oral-route/description/drg-20072102 [https://perma.cc/EHJ2-9S7X] (Mar. 1, 2024). Suboxone is the brand name for the drug that combines buprenorphine and naloxone and is generally used to treat "opioid (narcotic) dependence or addiction." *Buprenorphine/Naloxone (Oromucosal Route, Sublingual Route)*, MAYO CLINIC, https://www.mayoclinic.org/drugs-supplements/buprenorphine-naloxone-oromucosal-route-sublingual-route/description/drg-20074097 [https://perma.cc/55YU-W389] (Mar. 1, 2024). Using a benzodiazepine, like Klonopin, concurrently with Suboxone can prove extremely dangerous and even fatal. *Side Effects of Mixing Suboxone and Benzos*, AM. ADDICTION CTRS., https://americanaddictioncenters.org/benzodiazepine/mixing [https://perma.cc/BZD4-ARWS] (Jan. 3, 2024). Additionally, Khan and his fellow doctors failed to perform the requisite physician and mental evaluations to prescribe the substances, many patients receiving the drugs testified to re-selling their medication, and the doctors routinely ignored positive illicit drug tests and negative prescribed drug tests. Dr. Khan Press Release, *supra* note 94. Based on this criminal scheme, the Eastern District of Pennsylvania sentenced Khan to two years of incarceration. *Id.*

Khan and Ruan both appealed their convictions on the basis of mens rea.[97] They argued that their respective District Courts erred in denying their request for a jury instruction that would have mandated the government to prove that the doctors subjectively knew they issued unauthorized prescriptions.[98] The District Courts instead used the objective good faith defense standard, whereby the "standard of medical practice generally recognized and accepted in the United States" or the beliefs of a reasonable physician would determine whether the prescriptions were lawful.[99]

Khan and Ruan eventually petitioned the Supreme Court, where their cases were consolidated under the same issue.[100] The Court first considered the relationship between Section 841's "except as authorized" clause and Section 1306.04(a).[101] The Court assumed that prescriptions were only permitted under Section 841 if they comported with the Section 1306.04(a) elements of "legitimate medical purpose" and "usual course of . . . professional practice."[102]

The Court then asked whether Section 841's "knowingly or intentionally" mens rea applied to the "except as authorized" clause of the statute.[103] Worded differently, is it sufficient that a reasonable physician or generally accepted medical practice would deem the physician's prescription unauthorized or is the government required to prove that the physician "*knew or intended*" for it to be unauthorized to obtain a conviction?[104]

The Court held that the mens rea provision applied to the "except as authorized" clause, requiring the government to prove that the defendant physician subjectively knew or intended their prescriptions to be unlawful.[105] The Court reasoned that (1) criminal law should penalize those who are conscious of their wrongdoing, (2) a higher mens rea standard would avoid punishing

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[97] *Ruan*, 597 U.S. at 455–57.

[98] *Id.*

[99] *Id.* at 455–56 (quoting Petition for a Writ of Certiorari at 139a, *Ruan*, 597 U.S. 450 (No. 20-410)). The Ninth Circuit has postulated that widely accepted medical practice entails a qualified group of medical professionals who concur on a particular controlled substance prescription as a viable medical treatment. United States v. Feingold, 454 F.3d 1001, 1011 n.3 (9th Cir. 2006). States vary on their interpretation of a "legitimate medical purpose" for prescriptions, but physicians are generally expected to perform a physical examination, consider a patient's medical past, monitor the success of the treatment plan and adjust as necessary, and properly document all of this information. LoPuzzo, *supra* note 3, at 1405.

[100] *Ruan*, 597 U.S. at 457.

[101] *Id.* at 454.

[102] *Id.* at 454–55 (quoting 21 C.F.R § 1306.04(a) (2021)).

[103] *Id.* at 454–55. The "except as authorized" clause gives physicians the authority to lawfully distribute controlled substances. 21 U.S.C. § 822(b). The Court reasoned that Section 822(b) authorization was a key component in separating the wrongful actions of street dealers and the lawful conduct of doctors. *Ruan*, 597 U.S. at 458–59. Thus, the Court wished to apply a scienter provision to separate a physician's lawful conduct from unlawful acts. *Id.*

[104] *See id.* at 454–55 (posing this question as the key issue in the case).

[105] *Id.* at 468.

innocent conduct, (3) resolving ambiguity in defining an authorized prescription would also avoid punishing innocent conduct, and (4) the severe penalties incurred by violating Section 841 justified a stronger mens rea protection for physicians.[106]

In a practical sense, *Ruan* alters permissible jury instructions for Section 841 physician prosecutions.[107] Previously, juries could be instructed that a physician's good faith defense was predicated on the beliefs of fellow reasonable physicians and generally accepted medical practice.[108] Now, to establish the requisite mens rea for criminal liability post-*Ruan*, a defendant physician invoking the good faith defense will require the government to overcome the jury instruction that the defendant physician subjectively believed their actions comported with acceptable medical practice.[109]

The *Ruan* Court held that the government could still negate the subjective good faith defense and prove the requisite mens rea through objective circumstantial evidence.[110] Although *Ruan* did not provide specific examples of usable evidence, in 2018, in *United States v. Sabean*, the First Circuit Court of Appeals illustrated acceptable evidentiary proof sufficient to obtain a conviction based on a subjective good faith jury instruction.[111]

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[106] *Id.* at 457–61. Both cases were remanded to the courts of appeals below to decide whether the district court jury instructions complied with the new subjective good faith defense standard. *Id.* at 468. Both Ruan's and Khan's convictions were overturned by their respective circuit courts. *See* Nate Raymond, *Doctors' 'Pill Mill' Convictions Partially Tossed After U.S. Supreme Court Ruling*, REUTERS (Jan. 5, 2023), https://www.reuters.com/world/us/doctors-pill-mill-convictions-partially-tossed-after-us-supreme-court-ruling-2023-01-05/ [https://perma.cc/66H6-BJEJ] (discussing the Eleventh Circuit's decision to overturn Ruan's conviction); Jacklyn Wille, *Doctor's 'Pill Mill' Convictions Vacated Under Supreme Court Law*, BLOOMBERG L. (Feb. 3, 2023), https://news.bloomberglaw.com/us-law-week/doctors-pill-mill-convictions-vacated-under-supreme-court-law [https://perma.cc/S3S2-U4YX] (discussing the Tenth Circuit's decision to overturn Khan's conviction).

[107] *See* United States v. Ruan, 56 F.4th 1291, 1298 (11th Cir.) (holding that a § 841 physician prosecution jury instruction must include a subjective version of the good faith jury instruction), *cert. denied*, 144 S. Ct. 377 (2023).

[108] *See Ruan*, 597 U.S. at 456 (noting the now-rejected district court jury instruction in Khan's trial); United States v. Moore, 423 U.S. 122, 138–39 (1975) (providing a good faith jury instruction based on a "standard of medical practice generally recognized and accepted in the United States") (citation omitted).

[109] *See Ruan*, 597 U.S. at 468 (implementing a universal subjective good faith defense for physicians charged under § 841).

[110] *Id.*; *see also* United States v. Parasmo, 19-CR-1, 2023 WL 1109649, at *20 (E.D.N.Y. Jan. 30, 2023) (noting that objective evidence supplied by the Government can prove subjective knowledge of wrongdoing, even after the invocation of the good faith defense).

[111] *See* United States v. Sabean, 885 F.3d 27, 45, 48 (1st Cir. 2018) (affirming a conviction on appeal based on the jury instruction which required the Government to show the requisite mens rea by proving "at a minimum, that the [physician] defendant 'was aware to a high probability the prescription was not given for a legitimate medical purpose in the usual course of professional practice' and that the defendant 'consciously and deliberately avoided learning that fact'") (citation omitted).

In *Sabean*, the court held that certain "badges of bad faith" were probative of the defendant physician's subjective knowledge of his wrongdoing.[112] The court noted that a controlled substance prescription (1) without proper physical examination, (2) issued to a known addict, or (3) involving inadequate record-keeping was proof of bad faith.[113] Additionally, bad faith could be shown through expert testimony and overt evidence of an ulterior motive in prescribing the drugs.[114] Based on the facts presented, which included many of these bad faith badges, the Court held that the jury rationally inferred the defendant physician subjectively knew or intended his prescriptions to be unlawful and upheld his conviction.[115] The next Part explores the overall debate surrounding the subjective good faith defense standard.[116]

II. Good Intentions vs. Alternative Means and Unintended Consequences: Is a Subjective Good Faith Defense Justified?

This Part of the Note analyzes the arguments for and against a subjective good faith defense for physicians.[117] Section A of this Part discusses the arguments for the subjective good faith defense.[118] It notes the murky pre-*Ruan* standards surrounding lawful prescriptions and the Supreme Court's intention to protect innocent physicians and deter a chilling effect that left doctors and pa-

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[112] *Id.* at 47. The First Circuit Court of Appeals defined badges of bad faith as "conduct that is commonly understood to be plainly unprofessional" and used the example of a physician prescribing a controlled substance sans physical examination. *Id.*

[113] *Id.*

[114] *Id.* In the context of Section 841 physician prosecutions, expert testimony would be "from a medical or pharmacological expert." *Id.* at 46. The Court held, however, that such testimony was not necessary to find a defendant guilty and only contributed as a probative finding. *Id.*

[115] *Id.* at 47–48. In 2022, in an Eastern District of New York case, *United States v. Parasmo*, the defendant moved to vacate his conviction under Section 841 or be granted a new trial based on the subjective good faith defense standard established in *Ruan*. Defendant's Supplemental Motion for Acquittal, Motion for New Trial, at 1, United States v. Parasmo, No. 19-CR-1, 2023 WL 1109649 (E.D.N.Y. Jan. 30, 2023), ECF No. 151. The government's response motion offered a plethora of bad faith badges, based on the *Sabean* standard, to prove that the defendant, Parasmo, knew or intended his prescriptions to be unlawful. Government's Response in Opposition re 151 Supplemental Motion for Acquittal & Motion for New Trial, *supra* note 11, at 6–7. Bad faith badges found in *Parasmo* included regularly dispensing opioid prescriptions to patients (1) with a known drug addiction history, (2) who requested early refills after doubtful claims of losing their medication, and (3) whose drug test results showed clear signs of drug misuse and possible secondary distribution. Government's Response in Opposition re 151 Supplemental Motion for Acquittal & Motion for New Trial, *supra* note 11, at 7. Additionally, several patients had experienced drug overdoses or had a pharmacist object to the prescription, while one had just left a drug rehabilitation center. *Id.* Eastern District of New York Judge Joan M. Azrack denied the defendant's motions, demonstrating that evidence of this type of unprofessional conduct would be sufficient to support a conviction post-*Ruan*, at least in this jurisdiction. *See Parasmo*, 2023 WL 1109649, at *24–25 (denying the defendant's motion for acquittal or retrial); *Id.* (addressing subjective good faith evidence based on the *Ruan* standard).

[116] *See infra* notes 117–207 and accompanying text.

[117] *See infra* notes 117–207 and accompanying text.

[118] *See infra* notes 124–151 and accompanying text.

tients alike to suffer.[119] Section B of this Part examines the arguments against the subjective good faith defense.[120] It explains how the *Ruan* decision ran contrary to the CSA and the Supreme Court decisions in *Moore* and *Gonzales*.[121]

Section C proposes a potential alternative solution that would enable a return to an objective good faith defense and still address the *Ruan* concerns.[122] Section D of this Part contemplates the broader impact of the *Ruan* decision, which exacerbated the mens rea treatment disparity between drug couriers and physicians charged under the CSA.[123]

A. Justification for a Subjective Standard: Resolving Critical Ambiguity to Protect Law-Abiding Physicians and Patients

The state of affairs before the *Ruan* decision was handed down presents the strongest argument for a subjective good faith defense.[124] In 2022, the *Ruan* Court mused that the pre-existing statutory language surrounding unauthorized prescriptions was too open to interpretation and did not adequately define what constituted an authorized versus an unauthorized prescription.[125] The Court contended that the statutory language was so amorphous that it required a powerful scienter provision to properly cabin it and mitigate the possibility of overdeterrence.[126]

A significant human toll resulted from this ambiguity, which many used to criticize the state of pre-*Ruan* physician prosecutions.[127] In some cases, a criminal indictment alleging improper prescribing was enough to shut some socially beneficent doctors' doors for good.[128] The *Ruan* Court explicitly intended to protect such socially useful conduct from over-criminalization.[129]

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[119] *See infra* notes 124–151 and accompanying text.
[120] *See infra* notes 153–166 and accompanying text.
[121] *See infra* notes 153–166 and accompanying text.
[122] *See infra* notes 168–179 and accompanying text.
[123] *See infra* notes 180–207 and accompanying text.
[124] *See infra* notes 125–151 and accompanying text.
[125] 597 U.S. 2370, 459 (2022).
[126] *Id.* at 459–60.
[127] *See infra* notes 128–134 and accompanying text (discussing such criticism).
[128] *See* MacDonald, *supra* note 85, at 204 (detailing the case of Dr. Joseph Olivieri, who had treated HIV and AIDS patients for years before being indicted by the U.S. Attorney's Office for improper prescribing).
[129] *See* 597 U.S. at 459 (noting the socially beneficial nature of many physicians' prescribing practices); *see also* Diane E. Hoffmann, *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, 293–94 (2008) (arguing that the dangers of under-prosecution of pill mill physicians are outweighed by the potential costs of unjustifiable physician prosecutions, pointing to the chilling effect on pain treatment).

Other physicians became afraid to prescribe opioids and outright refused to treat patients afflicted with chronic pain for fear of legal repercussions.[130] This fear was compounded by the fact that physicians could not always defend their conduct as a subjective good-faith mistake or as mistaken reliance on others' directions or recommendations.[131] In other words, a physician's subjective intent was often unimportant.[132]

Physicians paralyzed with the fear of prosecution left their patients without the opioids they were dependent on for pain relief and, in some cases, just to function.[133] Worse yet, some noted that patients used dangerous and illegal drugs purchased through illicit channels to supplant their much-needed and now-defunct opioid prescriptions.[134]

Many argue that doctors lacked the guidance to inform their conduct, emphasized by the failures of the Federal Circuit Courts, the CSA, the U.S. Food

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[130] *See* Brianna Ehley, *How the Opioid Crackdown Is Backfiring*, POLITICO (Aug. 28, 2018), https://www.politico.com/story/2018/08/28/how-the-opioid-crackdown-is-backfiring-752183 [https://perma.cc/D3NV-U3LK] (quoting a primary care physician from Oregon who refuses to administer treatment for chronic pain because of the fear of prosecution and noting, via survey, that many prescribers now limit their opioid prescriptions for the same reason); Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 702 (2009) (arguing that criminalizing doctors trusting their patients' requests for pain medication would limit anguishing patients' access to medications and decrease the number of pain treatment physicians). From January 2017 to August 2018, the Department of Justice prosecuted almost 200 physicians for unlawful prescribing. Ehley, *supra*. Doctors' offices may have become a primary target for the war against drugs, leading to increasingly dubious prosecutions of physicians. Hellman, *supra*, at 701, 703.

[131] Ian Lopez, *Pill Mill Ruling Raises Burden for Opioid Cases Against Doctors*, BLOOMBERG L. (June 30, 2022), https://news.bloomberglaw.com/health-law-and-business/pill-mill-ruling-raises-burden-for-opioid-cases-against-doctors [https://perma.cc/EWR6-NCYZ]; *see also Ruan*, 597 U.S. at 468 (settling a good faith defense standard for physicians which would permit a subjective good-faith mistake as a viable defense to a charge of unlawful prescribing).

[132] *See* Lopez, *supra* note 131 (implying that a physician's subjective intent was not always accepted as a defense prior to *Ruan*). A physician's erroneous conduct or judgment may derive from the compassion for and trust of their patients, which may affect whether a conviction would be truly justified. Hellman, *supra* note 130, at 705.

[133] *See* MacDonald, *supra* note 85, at 201 (indicating that many patients of physicians fearing prosecution had their opioid prescriptions lowered or rejected by their physicians); Ehley, *supra* note 130 (mentioning that many patients now have to face frequent, intense pain without the relief they received from lawfully prescribed opioids and how some can no longer function). One such example is Jon Fowlkes, a law enforcement officer who made formal plans to commit suicide because he could no longer live with agonizing back pain after his doctor terminated his opioid prescription. Ehley, *supra* note 130. This was not simply confined to anecdote, however, as a 2005 survey illustrated that fewer than 50% of those afflicted with chronic pain felt their physicians were sufficiently ameliorating their pain. Harvey Silverglate, Opinion, *When Treating Pain Brings a Criminal Indictment*, WALL ST. J. (June 12, 2015), https://www.wsj.com/articles/when-treating-pain-brings-a-criminal-indictment-1434148923 [https://perma.cc/BY37-LC8F].

[134] *See* Jacob James Rich & Robert Capodilupo, *The Fight to Criminalize Opioid Prescribing*, REASON (Feb. 10, 2023), https://reason.com/2023/02/10/the-fight-to-criminalize-opioid-prescribing/ [https://perma.cc/54FA-NPR9] (hypothesizing the potential likelihood of patients turning to the illicit drug market to fill their need for opioids); Ehley, *supra* note 130 (noting, via survey, that some patients used dangerous street drugs to fill the need left by their defunct opioid prescriptions).

and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC) and some states to provide a uniform and legally binding delineation between lawful and unlawful prescriptions.[135]

The CSA originally established the two primary elements of a lawful prescription.[136] The CSA mandated that prescriptions be issued with a "legitimate medical purpose" within "the usual course of professional practice," which is the standard adopted by most states in their respective controlled substance statutes.[137] It did not, however, provide sufficient guidance for how these elements should be adjudicated.[138]

By not taking a mechanical approach, federal courts failed to demarcate a clear line between a physician's lawful and unlawful conduct.[139] In 2018, the First Circuit, in *United States v. Sabean*, mused that no exact formulation existed for the requisite proof that a physician's conduct was unlawful.[140]

The issue is instead left to juries, which must sift through the unclear CSA elements to form borderline medical judgments about whether a defendant physician's conduct was lawful.[141] Harvey Silverglate, a prominent criminal defense attorney, argued that the U.S. Attorney's Offices readily capitalized on this ambiguity in physician prosecutions by forcing doctors to navigate through the murky standards at their own risk of incarceration.[142]

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[135] *See* MacDonald, *supra* note 85, at 220–23 (arguing that the pre-*Ruan* standards for unlawful physician conduct were too unclear and detailing the failures of the Centers for Disease Control and Prevention (CDC) and Federal Courts to establish a clear standard); LoPuzzo, *supra* note 3, at 1404, 1419–20 (noting the lack of clarity pre-*Ruan* and the failures of the CSA, FDA, and CDC in clarifying a proper standard).

[136] LoPuzzo, *supra* note 3, at 1404–05.

[137] John A. Gilbert & Barbara Rowland, *Chapter 10. Practicing Medicine in a Drug Enforcement World*, 27 HEALTH L. HANDBOOK 392, 410–11 (2015).

[138] *See* LoPuzzo, *supra* note 3, at 1404 (noting that the CSA fails to cover who determines what establishes a "legitimate medical purpose").

[139] *See id.* at 1419 (stating that there is no definite rule established by the courts for what is the "usual course of [one's] professional practice"); MacDonald, *supra* note 85, at 222 (observing that some courts have criticized defendants for proffering mechanical approaches to the CSA elements). For example, the Fifth Circuit, in the 1981 case *United States v. Harrison*, rejected a physician's argument that because his conduct did not fall within the Fifth Circuit's prior enumerated condemned physician behavior, his conduct was thus legitimate. 651 F.2d 353, 355 (5th Cir. July 1981).

[140] 885 F.3d 27, 46 (1st Cir. 2018). After reviewing a bevy of circuit court decisions on the Section 1306.04(a) elements, a scholar argued there is no uniform application of the good faith defense among the circuit courts. Hellman, *supra* note 130, at 708.

[141] *See Sabean*, 885 F.3d at 46–47 (expounding on the role of juries in determining whether a physician's conduct was lawful); LoPuzzo, *supra* note 3, at 1419 (same). In fairness, however, jurors are aided by expert testimony on the issues unless the physician's misconduct is so egregious that the prescription clearly lacks any "legitimate medical purpose." Gilbert & Rowland, *supra* note 137, at 401–02.

[142] Silverglate, *supra* note 133.

On their face, federal agency guidelines seem immensely helpful in guiding physicians through the proper methods for prescribing opioids.[143] The FDA and CDC guidelines include recommendations for proper pre-prescription patient examination, treatment plans, long-term management of treatments, and evaluating a patient's adherence and response to a prescribed drug.[144] Neither of these guidelines, however, formally defines what constitutes the lawful prescribing of opioids; they merely offer recommendations without requiring a specific course of action for physicians to follow.[145]

Even among the states, no unified manner exists to delineate lawful opioid prescribing.[146] Although some states have mandated limitations on opioid prescriptions, others have only issued voluntary guidelines that fail to properly establish what constitutes a physician's lawful prescribing conduct.[147]

Many believe *Ruan* provides the necessary protection for physicians to "prescrib[e] in good faith" without fear of criminal repercussions.[148] As a direct result, patients with chronic pain or those needing controlled substances for their ailments can rely on receiving their prescriptions with more certainty.[149]

Although the *Ruan* Court did not delineate specific boundaries for the CSA elements, a subjective good faith defense gives discretion to physicians to administer proper care to their patients, even if it does not necessarily comport

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[143] *See* MacDonald, *supra* note 85, at 221 (providing details of the CDC's helpful recommendations); LoPuzzo, *supra* note 3, at 1420 (noting that the FDA and CDC guidelines have illuminated several components of proper prescribing practices).

[144] LoPuzzo, *supra* note 3, at 1422–24.

[145] *Id.* at 1425. The American Medical Association criticized the CDC guidelines, arguing they should only be considered as guidance and noted that it did not establish proper measurable thresholds for opioid prescriptions. MacDonald, *supra* note 85, at 221.

[146] LoPuzzo, *supra* note 3, at 1420, 1425 (citing Angelo J. Cifaldi & Lisa English Hinkle, *Regulations and Policies Affecting a Physician's Prescribing Authority*, 2016 AHLA SEMINAR PAPERS 2, 9).

[147] *Compare* Bd. of Registration in Dentistry, *Update for Prescribers: New Law Regarding Opioids*, MASS.GOV (Mar. 15, 2016), https://www.mass.gov/news/update-for-prescribers-new-law-regarding-opioids [https://perma.cc/XE5P-J848] (detailing a 2016 Massachusetts state law that limits a physician's supplying of opioids), *and Division of Professions and Occupations (DPO): Opioid Guidelines—Under Review and Pending Update*, COLO. DEP'T REGUL. AGENCIES, https://dpo.colorado.gov/Opioid Guidelines [https://perma.cc/Z3PE-SCKD] (outlining a similar law for Colorado), *with* ARIZ. DEP'T OF HEALTH SERVS., ARIZONA OPIOID PRESCRIBING GUIDELINES 2 (2018), https://www.azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf [https://perma.cc/Q7YS-NPCK] (providing voluntary guidelines for opioid prescribers in Arizona), *and Opioid Prescribing Guidelines*, OHIO ACAD. FAM. PHYSICIANS, https://www.ohioafp.org/public-policy/state-legislative-regulatory-issues/opioid-prescribing-guidelines/ [https://perma.cc/PVN2-PURN] (detailing similar guidelines in Ohio).

[148] Lopez, *supra* note 131; *see also* Brief for Amicus Curiae Due Process Institute in Support of Petitioner at 3–4, Ruan v. United States, 597 U.S. 450 (2022) (No. 20-1410) (contending that the pre-*Ruan* standards did not comport with due process and give fair notice to physicians, enabling them to tailor their conduct to the law).

[149] Lopez, *supra* note 131.

with generally accepted standards of medical practice or the beliefs of a reasonable physician.[150]

Some believe *Ruan*'s added flexibility will save the lives of patients and the livelihoods of doctors prescribing in good faith and caring for their patients to the best of their ability.[151] Nevertheless, as discussed in the next Section, detractors of the subjective good faith defense argue that the subjective standard is unnecessary and unacceptably inconsistent with existing case law and statutory constructions.[152]

B. Opposing a Subjective Standard: Arguments That States and "Reasonable Physicians" Should Govern Lawful Prescribing Practice

An argument against *Ruan*, proffered by the government in its brief for the case, is that no one physician's idiosyncratic practices should govern what constitutes lawful prescribing and acceptable medical practice.[153] This is consistent with the CSA, which provides flexibility for medical practice but requires that physicians act in accordance with "the usual course of . . . professional practice."[154] The government further contended that an objective good faith defense already existed within this analysis, permitting a physician to prove they lacked a guilty state of mind.[155]

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[150] *See* Myles Starr, Meaghan Lee Callaghan & Donald M. Pizzi, *Landmark Supreme Court Ruling Recognizes Opioid Prescriber Good-Faith Defense*, OR MGMT. NEWS (Aug. 4, 2022), https://www.ormanagement.net/Feature/Article/07-22/Landmark-Supreme-Court-Ruling-Recognizes-Opioid-Prescriber-Good-Faith-Defense/67650 [https://perma.cc/2Y7U-XPDS] (predicting the potential impact of *Ruan*); *Ruan*, 597 U.S. at 454–68 (failing to address specific boundaries for legitimate medical purpose and usual course of professional practice anywhere in the Court's majority decision).

[151] Starr et al., *supra* note 150. Additionally, Compassion & Choices, a nonprofit organization that seeks to improve end-of-life care, argued in their amicus brief to the Supreme Court that end-of-life care would be bolstered by ruling in favor of a subjective good faith defense. Brief of Amicus Curiae Compassion & Choices in Support of Petitioners at 2, *Ruan*, 597 U.S. 450 (Nos. 20-1410 & 21-5261). The amicus brief contended that a chilling effect left many end-of-life patients in desperate need of opioids, leading to an increase in pain-related hospital visits. *Id.* at 9.

[152] *See infra* notes 153–167 and accompanying text.

[153] Brief for the United States, *supra* note 88, at 24. Specifically, the government pointed to the comprehensive and deliberate registration scheme that required physicians to comport with accepted medical standards in dispensing controlled substance prescriptions. *Id.* at 29–30; *see also* 21 U.S.C. § 822(b) (authorizing registered physicians to lawfully issue controlled substances); *id.* § 841(a) (only permitting authorized individuals registered under § 822 to lawfully distribute controlled substances).

[154] Brief for the United States, *supra* note 88, at 29–30; *see* 21 C.F.R. § 1306.04(a) (2023) (requiring prescribing physicians to comply with the requirements of "legitimate medical purpose" and "usual course of . . . professional practice"); Gonzales v. Oregon, 546 U.S. 243, 285 (2006) (Scalia, J., dissenting) (noting that "the use of the word 'legitimate' connotes an *objective* standard of 'medicine'").

[155] *See* Brief for the United States, *supra* note 88, at 26–27 (clarifying that a good faith defense already existed under the CSA and its interpretation in the 1975 *United States v. Moore* decision); *see also* Hoffmann, *supra* note 129, at 235, 278 (noting the objective good faith defense for physicians charged under § 841, which existed prior to *Ruan*). In 2006, in *United States v. Hurwitz*, the Fourth Circuit held that the good faith defense inquiry was objective and should be governed by whether the

To do so, all a physician must do is show they made an objectively reasonable good faith effort to comport with accepted medical standards.[156] If, after evaluating the evidence at trial, a jury finds that a defendant physician made an honest effort to follow what has been deemed by other physicians to be accepted medical standards, the defendant physician will avoid criminal liability under Section 841.[157] This differs from the *Ruan* standard, which instructs juries to determine criminal liability based on a physician's subjective beliefs, rather than the reasonable beliefs of fellow physicians or generally accepted standards of medical practice.[158]

The government also made careful note that the defendants and their amici failed to present concrete examples of physicians who were convicted despite acting in good faith.[159] Scholars have agreed that the fears of overcriminalization of innocent conduct are unfounded, as there was never an outbreak of unwarranted physician prosecutions.[160] Additionally, some note that, pre-*Ruan*, high evidentiary burdens led many prosecutors not to charge physicians whose conduct was egregious enough to warrant losing their medical license.[161]

The government further argued that accepted medical standards should be furnished by individual states, not by the mind of an individual practitioner.[162] This was derived from the Supreme Court's own decision in the 2006 case *Gonzales v. Oregon*, in which the Court delegated authority to states to eluci-

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physician genuinely attempted to comport his conduct with generally accepted medical practice. *See* Hellman, *supra* note 130, at 710 (quoting Jury Instructions at 48, United States v. Hurwitz, No. 1:03-CR-467 (E.D. Va. Apr. 17, 2007)) (quoting the approved jury instructions in *Hurwitz*). Further, the Fourth Circuit explicitly rejected a determination of criminal liability based on the physician's own beliefs as to accepted medical practice. United States v. Hurwitz, 459 F.3d 463, 477–78, 480 (4th Cir. 2006).

[156] *See* Brief for the United States, *supra* note 88, at 27 (noting the requirements for a physician to prove they acted in good faith established in *Moore*). The specific jury instructions approved in *Moore* stated that to convict a physician, a jury must find "beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute [a controlled substance] by prescription, did so other than in good faith . . . in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted." United States v. Moore, 423 U.S. 122, 138–39, 142 n.20 (1975) (citation omitted).

[157] Brief for the United States, *supra* note 88, at 27. The Government flipped this scenario, noting that any physician who did not take this small step has treated their limited CSA authorization as a blank check on which to impart their personal beliefs on proper medical practice, thus showing "the requisite mens rea to violate Section 841(a)." *Id.* at 30.

[158] Ruan v. United States, 597 U.S. 450, 465, 467–68 (2022).

[159] *See* Brief for the United States, *supra* note 88, at 41 (observing the lack of foundation for the petitioners' predictions of unjustifiable physician prosecutions).

[160] Gershowitz, *supra* note 10, at 874.

[161] *Id.* at 874–75. Many prosecutors instead defer to state medical boards, which is a civil remedy, to administer a punishment for egregious physician behavior. *Id.* at 875.

[162] Brief for the United States, *supra* note 88, at 40.

date what constituted acceptable medical practice.[163] Similar authority is found in the CSA under Section 823(f), which requires physicians to prescribe in accordance with state laws.[164]

The government attempted to assuage fears of murky and inconsistent state standards by noting the current practices of states and their respective medical boards in providing guidance to prescribing physicians and requiring continued physician education on proper prescribing practices.[165] As mentioned previously in this Note, however, many argue there is no uniform or consistent application across the states and pointed out that in some instances, state guidance is merely voluntary.[166] The next Section discusses a potential solution to this concern.[167]

C. One Potential Alternative to Ruan*: Uniform Standards Provide the Necessary Clarity for an Objective Good Faith Defense*

One potential way to ameliorate the concern of inconsistent standards governing lawful prescribing would begin by implementing a uniform model statute into the CSA.[168] The new CSA statute could be akin to one proffered by a scholar which predicated a defendant physician's good faith defense on whether the physician (a) prescribed lawfully and (b) the physician's practice area validated the treatment plan.[169]

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[163] 546 U.S. 243, 270–71 (2006). The Court in the 2006 case *Gonzales v. Oregon* further clarified that not even the Attorney General, who largely oversees CSA enforcement, could make an individualized decision to bar a specific medical practice as unlawful. *See id.* (rejecting the government's argument that the CSA grants Executive officers authority to prohibit specific medical practices as unlawful).

[164] 21 U.S.C. § 823(f). This is further bolstered by § 822(b), which requires authorized physicians to prescribe "in conformity with the other provisions of" the CSA. *Id.* § 822(b).

[165] *See* Brief for the United States, *supra* note 88, at 23–24 (citing to several state medical board policies in Alabama, Arizona, and Wyoming that provide adequate prescription guidance and continuing education requirements for state-registered physicians).

[166] *See supra* notes 146–147 and accompanying text (outlining the shortcomings of state prescription guidelines).

[167] *See infra* notes 168–179 and accompanying text.

[168] *See* LoPuzzo, *supra* note 3, at 1428–29 (providing a model statute for states to adopt to clarify the CSA elements of "legitimate medical purpose" and "[usual] course of professional practice"). The scholar considered a variety of circuit court decisions, FDA and CDC guidelines, several states' guidelines, and the CSA itself in creating a proposed model statute. *Id.* at 1428–29, 1428 n.274, 1429 nn.275–79.

[169] *Id.* at 1428–29. The statute reads:

> A physician acts in good faith when prescribing opioids for the legitimate medical purpose of treating pain, where he or she: (a) does so legally; and (b) his or her area of practice qualifies use of the chosen course of treatment; and (c) in light of admissible evidence a reasonable physician in the same or similar area of medical practice 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; and (2) prescribed with competence and respect for widely-accepted and established treatment-standards.

Further, (c) a similarly situated reasonable physician could evaluate the defendant physician's treatment plan and determine that it comported with (1) the physician's best effort to administer treatment and (2) generally accepted medical standards.[170] The scholar argues that this statute grants flexibility via the good faith defense and provides specific examples of lawful prescribing by requiring adherence to generally accepted medical standards.[171]

These standards, in turn, could be comprised of a combination of FDA, CDC, and robust mandatory state prescription guidelines already existing in states like New York.[172] The FDA and CDC guidelines provide adequate recommendations for proper prescribing conduct.[173] This includes pre-treatment patient assessment, documentation of prescribed drugs, proper dosages, and constant monitoring to ensure correct drug usage and treatment efficacy.[174]

Adding specific statutory restraints on prescriptions, like New York State's initial supply and refill limitations, would allow physicians to apprise themselves with certainty as to what constitutes lawful prescribing in the state in which they practice.[175] One could argue that even *Ruan* fails to do this, as it only adds a subjective good faith defense and leaves the concept of acceptable medical practice in its already murky state.[176]

Under this hypothetical standard, physician conduct would not be judged based on strict conformity with the enumerated lawful prescribing practices.[177]

Id. (footnotes omitted).

[170] *See id.* (noting the model statute's requirements for establishing a physician's good faith defense).

[171] *Id.* at 1429–30.

[172] *See id.* at 1426–27, 1429 (noting that New York, via statute, has partially defined accepted medical practice for prescribers and referring to physician adherence to the FDA and CDC guidelines).

[173] *See generally* FED. DRUG ADMIN., FDA BLUEPRINT FOR PRESCRIBER EDUCATION FOR EXTENDED-RELEASE AND LONG-ACTING OPIOID ANALGESICS (2016), [https://perma.cc/JB4H-FAMT] (outlining recommendations for the proper prescription of opioids); Deborah Dowell et al., Ctrs. for Disease Control & Prevention, *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States 2022*, MORBIDITY & MORTALITY WKLY. REP., Nov. 4, 2022, https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7103a1-H.pdf [https://perma.cc/X9S6-C8UG] (same).

[174] FED. DRUG ADMIN., *supra* note 173, at 2–4; Dowell et al., *supra* note 173, at 11–12. One could argue the documentation recommended by the FDA and CDC is analogous to the CSA's original recording requirement. *See* H.R. REP. NO. 91-1444, at 4 (1970) (noting the CSA requirement that registered physicians "keep records of schedule I substances; keep records of narcotic drugs in other schedules which they dispense . . . [and] keep records of [controlled drug] transactions"). Though not exactly equivalent, as the CSA explicitly excluded prescriptions from this reporting requirement, it does illustrate Congress's willingness to impose recording requirements on lawful distributors of controlled substances. *See id.* (implying an intent to impose recording requirements).

[175] *See* LoPuzzo, *supra* note 3, at 1426–27 (elaborating on New York's statutory limitations on prescribing practices).

[176] *See* Ruan v. United States, 597 U.S. 450, 454–68 (failing to specifically delineate the line between lawful and unlawful medical practice).

[177] *See* LoPuzzo, *supra* note 3, at 1428–29 (providing a good faith defense for physicians in the model statute); *see also* Gonzales v. Oregon, 546 U.S. 243, 272–73 (2006) (rejecting the argument

Pursuant to the model statute and the government's proffered interpretation of the Supreme Court's 1975 decision in *United States v. Moore*, a physician's mens rea could only be proven if the physician did not make an objective good faith effort to prescribe in accordance with what reasonable physicians would deem accepted medical practice.[178]

Whereas this Section offers a competing approach to physician prosecutions under Section 841, the next Section explores an ever-present policy concern regarding the *Ruan* decision.[179]

D. Ruan *Exacerbates Disparities: A Lesser Mens Rea Standard for Drug Couriers Charged Under the CSA*

A potential policy concern with the new *Ruan* standard is that it widens the mens rea treatment gap between physicians and drug couriers to an unacceptable level.[180] Despite falling under the same criminal statutory scheme for offenses both involving the illicit distribution of controlled substances, these offenders arguably receive substantially different mens rea treatment.[181] Drug couriers charged under the CSA have not been afforded a subjective mens rea protection akin to *Ruan*.[182]

Some have contended that even the objective mens rea standard that should govern drug courier prosecutions can be circumvented by drug courier profile testimony.[183] The Seventh Circuit permits the government to prove a drug courier defendant's mens rea by noting sufficient similarities between the defendant and common "drug courier profile" characteristics.[184]

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that one individual physician's interpretation of appropriate medical practice permits the government to prohibit a use inconsistent with that practice).

[178] *See* LoPuzzo, *supra* note 3, at 1429–30 (noting that a good faith defense exists in the model statute); Brief for the United States, *supra* note 88, at 27, 30 (interpreting *Moore* as only permitting a finding of a criminally liable mens rea where the physician did not make an objectively reasonable good faith effort to comply with accepted medical practice).

[179] *See infra* notes 180–207 and accompanying text (discussing a novel comparison between the mens rea standard for physicians and drug couriers charged under the CSA).

[180] *See infra* notes 181–207 and accompanying text.

[181] *See infra* notes 182, 200–206 and accompanying text (outlining arguments that physicians and drug couriers receive different mens rea treatment); United States v. Moore, 423 U.S. 122, 131 (1975) (holding that any person could be charged under § 841 for unlawfully distributing controlled substances); Gershowitz, *supra* note 6, at 1058 (stating that both pill mill doctors and street drug offenders—including drug couriers—can be charged under the same statute, § 841).

[182] *See* Ruan v. United States, 597 U.S. 450, 454 (2022) (circumscribing a subjective good faith defense holding to CSA-registered physicians).

[183] Mark J. Kadish, *The Drug Courier Profile: In Planes, Trains, and Automobiles; and Now in the Jury Box*, 46 AM. U. L. REV. 747, 750, 768 (1997).

[184] Kadish, *supra* note 183, at 779. Testimony explaining such a profile has been permitted for other uses as well, such as background information justifying reasonable suspicion, to rebut a defendant's own testimony that they could not be a drug dealer because of certain characteristics, to enhance the jury's understanding of drug courier paraphernalia found in the defendant's possession, or to aid

A scholar argues that even if a defendant claims they did not pack the drugs, had no knowledge of their presence, or did not intend to sell them, matching the defendant to these characteristics can help prove both knowledge of the drugs and an intent to disseminate them.[185] The Seventh Circuit has upheld several convictions where mens rea was proven by drug courier profile evidence submitted through expert testimony.[186]

In 1991, in the Seventh Circuit case *United States v. Solis*, the government argued, through expert testimony, that the common use of beepers in the drug trade proved the defendant's intent to disburse cocaine.[187] The defendant,

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the jury in connecting apparently innocuous events and criminal activity. *See* United States v. Sokolow, 490 U.S. 1, 10 (1989) (holding drug courier profile evidence admissible to justify reasonable suspicion); United States v. Beltran-Rios, 878 F.2d 1208, 1212–13 (9th Cir. 1989) (permitting drug courier profile testimony to rebut the defendant's own profile testimony); United States v. Holmes, 751 F.3d 846, 851 (8th Cir. 2014) (allowing drug courier profile testimony to explain significance of drug paraphernalia evidence); United States v. Brown, 7 F.3d 648, 650, 652 (7th Cir. 1993) (same); United States v. Espinosa, 827 F.2d 604, 612–13 (9th Cir. 1987) (permitting drug courier testimony to be used as modus operandi evidence).

[185] Kadish, *supra* note 183, at 750. Common drug courier profile characteristics can include: (1) travel by any mechanized means, (2) traveling alone or with others, (3) being in nearly any age demographic, (4) arriving or departing from a number of major U.S. cities or foreign countries, (5) dressing formally or informally, (6) using cash to cover travel expenses, (7) appearing nervous, and even (8) looking at surroundings. *Id.* at 748–49. A scholar argues that these characteristics are not only overly vast, but also inherently contradictory. *Id.*

[186] *See, e.g.*, United States v. Foster, 939 F.2d 445, 458 (7th Cir. 1991) (upholding conviction based on drug courier profile testimony); United States v. Solis, 923 F.2d 548, 551–52 (7th Cir. 1991) (same). A similar type of testimony, known as "negative profiling evidence," attempts to prove guilt by *contrasting* a defendant's character with a common profile. Commonwealth v. Horne, 66 N.E.3d 633, 636, 638 (Mass. 2017). In 2017, in the Massachusetts Supreme Judicial Court case *Commonwealth v. Horne*, the Commonwealth proffered expert testimony that because the defendant *did not* share the characteristics of an addict—frail, deteriorating physical condition, rotting teeth—he was more likely to have possessed the crack cocaine on his person with intent to distribute. *Id.* The defendant was convicted of cocaine possession "with intent to distribute," partially based on this testimony. *Id.* at 636. The Massachusetts Supreme Judicial Court overturned the defendant's conviction because the lower court's erroneous allowance of the negative profiling testimony "created a substantial risk of a miscarriage of justice." *Id.* at 640.

[187] 923 F.2d at 551. In the Seventh Circuit's 1991 case *United States v. Solis*, the defendant, Dolores DeJesus Solis, was arrested in O'Hare airport by two law enforcement officers. *Id.* at 549. The officers discovered that Solis had several notebooks that contained various beeper numbers. *Id.* A beeper, also known as a pager, is "a small device, usually carried or worn on the body, that vibrates or makes a noise to tell you that someone wants you to phone them." *Beeper*, CAMBRIDGE DICTIONARY, https://dictionary.cambridge.org/us/dictionary/english/beeper [https://perma.cc/L7FC-GGXJ]. Beepers proliferated in the drug trade during the 1980s and onward because they were inexpensive and digital versions could "display[] a caller's return telephone number," which made it easy to facilitate a drug transaction while maintaining a low profile from rival drug dealers and the police. *Street Smart: Drug Dealers Turn on to Beepers*, TIME (Oct. 6, 1986), https://content.time.com/time/subscriber/article/0,33009,962483,00.html [https://perma.cc/B854-4EGE]. This was the basis for a police officer's testimony at Solis's trial, who testified regarding "the use of beepers in the drug trade" and made note "that they permit drug traffickers to be anonymous and mobile." *Solis*, 923 F.2d at 549–50. Although the jury's inability to render a verdict resulted in a mistrial, Solis waived her retrial right and was subsequently convicted via bench trial "based on transcripts and exhibits from the first trial." *Id.* at

Dolores DeJesus Solis, possessed a number of beepers, which the government linked to the same drug courier profile characteristic to prove that Solis was knowingly involved in drug trafficking.[188] The Court of Appeals upheld the conviction, reasoning that drug courier profiles could be used as substantive proof of wrongdoing.[189] Other circuit courts have similarly upheld these profiles as substantive proof of guilt.[190]

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550. The bench trial judge considered the officer's drug profile testimony in rendering a verdict, whose alleged erroneous admission formed the sole basis for Solis's appeal. *Id.*

[188] *Solis*, 923 F.2d at 549–50.

[189] *Id.* at 551. That same year in the Seventh Circuit case *United States v. Foster*, the government successfully argued that the defendant had knowledge he was trafficking cocaine at a Chicago train station because his characteristics and behavior, including the employment of hard-sided suitcases, matched common drug courier profile characteristics. 939 F.2d at 449–51. The Seventh Circuit upheld the defendant's conviction, noting that this characteristic was transformed by expert testimony into substantive proof of wrongdoing. *Id.* at 449–51, 454–55, 458. Even when courts in the Ninth Circuit prohibited the use of "drug *courier* profile evidence," they still permitted "drug *trafficking* profile evidence." *See, e.g.*, United States v. Valencia-Amezcua, 278 F.3d 901, 909 (9th Cir. 2002) (upholding the use of the latter as "probative [evidence] of [the defendant's] guilt"); United States v. Freeman, 498 F.3d 893, 906 (9th Cir. 2007) (condoning the use of profiles in drug trafficking cases); United States v. Rhodes, No. 19-cr-00333, 2022 WL 2764198, at *3 (D. Or. July 15, 2022) (condoning the use of trafficking profiles and differentiating between "drug *courier* profile evidence" and "drug *trafficking* profile evidence"). Although there exists a technical distinction between these two types of evidence, drug trafficking profile evidence is still comprised of "the general practices of criminals" intended "to establish the defendants' modus operandi." *Freeman*, 498 F.3d at 906 (quoting *Valencia-Amezcua*, 278 F.3d at 908–09). Like a drug courier profile may reference the use of beepers as evidence that one is acting as a drug courier, drug trafficking profile testimony similarly employs innocuous behavior as evidence of a defendant's involvement in drug trafficking, such as "frequently us[ing] pagers and public telephones." *See* United States v. Gil, 58 F.3d 1414, 1422 (9th Cir. 1995) (upholding expert testimony that the use of "pagers and public telephones" was evidence that the defendant was a drug trafficker); *see also Solis,* 923 F.2d at 551 (upholding expert testimony that the use of beepers was evidence that the defendant was a drug courier). Particularly troubling is that Ninth Circuit courts endorse the government questioning an expert witness "regarding the intent to distribute narcotics of a typical person in roughly the same situation as the defendant." United States v. Younger, 398 F.3d 1179, 1190 (9th Cir. 2005). This, in essence, is using drug trafficking profile evidence to prove a defendant's subjective intent irrespective of the semantic differences between the two types of drug profile evidence. *See id.* (allowing hypothetical questions on the part of the government to prove the defendant's intent to disseminate controlled substances). Although Ninth Circuit courts tried to dissuade fears of the drug profile evidence being used to prove a defendant's requisite mens rea, the Ninth Circuit Court of Appeals explicitly sanctioned an expert to testify that an individual with the evidence at issue "would, in fact possess the drugs for the purpose of distributing." United States v. Gonzales, 307 F.3d 906, 911–12 (9th Cir. 2002).

[190] *See, e.g.,* United States v. Ramos-Rodriguez, 809 F.3d 817, 826–27 (5th Cir. 2016) (permitting drug courier evidence to establish an inference that the defendant knowingly transported drugs); United States v. Doe, 149 F.3d 634, 637 (7th Cir. 1998) (upholding use of drug courier testimony as probative of the defendant's "intent to possess and distribute heroin"). Many courts have criticized the use of drug courier profiles as actual proof of guilt, yet some still permitted the testimony with a limiting instruction. *See, e.g.*, United States v. Jones, 913 F.2d 174, 177 (4th Cir. 1990) (holding drug courier profile testimony inadmissible as substantive evidence of guilt); United States v. Gomez-Norena, 908 F.2d 497, 501 (9th Cir. 1990) (issuing a limiting instruction as to how the jury may use drug courier profile testimony); United States v. Hernandez-Cuartas, 717 F.2d 552, 555–56 (11th Cir. 1983) (same). Some have argued the efficacy of jury instructions, however, is largely overstated, casting

At the sentencing stage, scholars argue that a drug courier-defendant's "knowing and intentional" mens rea is often disregarded when considering the known amount of drugs on which the sentence is based.[191] The scholars provide examples of drug courier defendants who were sentenced based on the strict quantity of drugs seized, but not the actual known quantity.[192]

In 1994, in *United States v. de Velasquez*, the Second Circuit held that actual knowledge and even mere foreseeability were not requirements for a sentence to include the total drug quantity possessed by a drug courier defendant.[193] Defendant Ana Marin de Velasquez, from Colombia, had knowingly ingested over 600 grams of heroin to be smuggled into the United States.[194] Unbeknownst to de Velasquez, the drug traffickers employing her had placed over 160 additional grams of heroin in her shoes.[195] The District Court includ-

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significant doubt on the idea that a jury would truly disregard the drug courier profile testimony as evidence of a defendant's guilty state of mind. Daniel W. Edwards, *The Man Behind the Curtain: Confronting Expert Testimony*, 1 U. DENV. CRIM. L. REV. 1, 21 (2011). *See generally* Joel D. Lieberman & Jamie Arndt, *Understanding the Limits of Limiting Instructions: Social Psychological Explanations for the Failures of Instructions to Disregard Pretrial Publicity and Other Inadmissible Evidence*, 6 PSYCH. PUB. POL'Y & L. 677, 701–03 (2000) (providing an in-depth analysis on the theories behind the perceived inadequacy of limiting instructions). A scholar argues that the issue remains that such evidence, irrespective of limiting instructions, will be heard by the jury and likely affect the verdict. Kadish, *supra* note 183, at 752.

[191] *See, e.g.*, Weinstein & Bernstein, *supra* note 20, at 121 (discussing the virtual elimination of mens rea in drug courier cases); Fred A. Bernstein, *Discretion Redux—Mandatory Minimums, Federal Judges, and the "Safety Valve" Provision of the 1994 Crime Act*, 20 U. DAYTON L. REV. 765, 775 (1995) (same).

[192] Weinstein & Bernstein, *supra* note 20, at 121; *see also* United States v. Ekwunoh, 12 F.3d 368, 370–71 (2d Cir. 1993) (mandating that the sentence of drug-courier defendant be based on the quantity of heroin provided to her by an undercover agent); United States v. de Velasquez, 28 F.3d 2, 6 (2d Cir. 1994) (affirming sentence of drug courier defendant based on quantity of heroin seized by federal agents); Wasserman, *supra* note 15, at 643–44 (noting the "strict quantity-based sentencing" in drug courier cases).

[193] *de Velasquez*, 28 F.3d at 3. The previous year, in *United States v. Ekwunoh,* the Second Circuit had similarly held that actual knowledge of drug quantity was not necessary for a sentence to incorporate the entire amount. 12 F.3d at 370. Defendant Caroline Ekwunoh was working as a clothing vendor and home attendant and was the sole provider for her three children when she was asked by her boyfriend to meet another drug courier in a New York airport. Bernstein, *supra* note 191, at 775. Unbeknownst to her, the supposed courier was a DEA informant who gave her a case containing far more heroin than Ekwunoh knew about. *Id.* Despite her lack of knowledge, the Second Circuit mandated the Eastern District of New York to sentence her based on the full amount of heroin in her possession. *Id.* Were it not for Congress's "Safety Valve" provision, Ekwunoh would have served the entire time imposed for this sentence. *Id.* at 776–77. Instead, she was released after having served thirty months in prison, deemed "a broken woman" by the district court. *Id.* at 777.

[194] *de Velasquez*, 28 F.3d at 3.

[195] *Id.* When de Velasquez arrived at John F. Kennedy Airport in New York from Colombia, she was arrested by Customs Agents after the discovery of the additional heroin in her shoes. *Id.* She, like many other drug couriers, pled guilty under Section 952(a)—another CSA statute—which makes it illegal to import narcotics into the United States. *Id.*; *see* 21 U.S.C. § 952(a) (criminalizing the importation of controlled substances); Wasserman, *supra* note 15, at 643 (stating that it is common for drug couriers, particularly those with similar factual history to that of de Velasquez, to plead guilty to a

ed the heroin in de Velasquez's shoes in calculating her sentence, which resulted in a sentence of forty-six-months' incarceration.[196]

De Velasquez appealed, arguing that the doctrine of mens rea mandated that the court exclude the heroin in her shoes for lack of actual knowledge or, at the very least, only incorporate it if it was reasonably foreseeable to her that the shoes held additional heroin.[197]

The Second Circuit rejected de Velasquez's arguments and reasoned that a defendant who is knowingly acting as a drug courier should bear the liability of a greater quantity of drugs than they knew of or could reasonably have foreseen.[198] Scholars have noted that this ruling was unprecedented and argued that it effectively rendered intent and state of mind largely irrelevant for drug courier sentencings in the Second Circuit.[199]

In comparing the mens rea treatment of drug couriers and physicians both charged under the CSA, it is arguable that physicians fare much better.[200] Re-

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federal charge). A scholar noted that this specific fact pattern is emblematic of the "typical Second Circuit drug courier prosecution," involving (1) a female defendant from a foreign country (2) "working for an un-apprehended supplier who is operating from abroad," (3) who is then "arrested at Kennedy airport," (4) accepts a guilty plea, and (5) is sentenced based on the quantity of drugs on her person. Wasserman, *supra* note 15, at 643. The guilty plea should be of no surprise to those with knowledge of the justice system, as plea bargains comprise by far the most common adjudication of criminal cases. Alexandra W. Reimelt, Note, *An Unjust Bargain: Plea Bargains and Waiver of the Right to Appeal*, 51 B.C. L. REV. 871, 873 (2010).

[196] *de Velasquez*, 28 F.3d at 3–4. If the heroin in de Velasquez's shoes were exempt from the sentencing calculus, her recommended sentencing range would have been as low as thirty-seven months. *Id.* at 4.

[197] *Id.* at 4.

[198] *Id.* at 6. It should be noted that the Second Circuit affirmed its holding from one year prior in *United States v. Imariagbe* in which it held that "neither due process nor the doctrine of mens rea requires" the defendant to have knowledge of the "total quantity of drugs in [their] possession to be sentenced for the full amount." *de Velasquez,* 28 F.3d at 4 (citing United States v. Imariagbe, 999 F.2d 706, 707 (2d Cir. 1993)). This was not simply an affirmation, however, as the Second Circuit took this one step further in *United States v. de Velasquez* in 1994, holding that the sentence *should* be contingent on the total drug quantity irrespective of mens rea concerns. *Id.*

[199] Weinstein & Bernstein, *supra* note 20, at 121. A variety of courts have upheld or adopted the *de Velasquez* holding, which ascribes strict liability for the total quantity of drugs regardless of the actual known quantity. *See, e.g.*, United States v. Castrillon, 376 F.3d 46, 47 (2d Cir. 2004) (upholding the *de Velasquez* holding in the Second Circuit); United States v. Powell, 249 F. Supp. 3d 617, 626 (E.D.N.Y. 2017) (upholding the *de Velasquez* decision as binding precedent in the Eastern District of New York); People v. Busch, 113 Cal. Rptr. 3d 683, 689 (Ct. App. 2010) (adopting the *de Velasquez* federal standard of strict liability for drug quantities irrespective of the actual known quantity). Only four years after *de Velasquez,* in *United States v. Edwards*, the Seventh Circuit held that a defendant could be sentenced for the entire drug quantity in a conspiracy, despite a lack of explicit knowledge, because his role as a co-conspirator in the drug trade made the total amount reasonably foreseeable. United States v. Edwards, 115 F.3d 1322, 1328 (7th Cir. 1997). Other circuit courts have held similarly. *See, e.g.*, United States v. Lawrence, 918 F.2d 68, 71 (8th Cir. 1990) (upholding a sentence based on the total amount of drugs in a conspiracy); United States v. Evans, No. 93-1769, 1994 WL 399137, at *5 (5th Cir. July 21, 1994) (same).

[200] *See infra* notes 201–206 and accompanying text.

quiring prosecutors to use specific instances of a physician's unlawful conduct to both prove the objective unreasonableness of a physician's prescriptions *and* disprove the physician's subjective good faith in issuing the prescriptions is a much higher burden than in drug courier cases.[201] In drug courier cases, profiling evidence can prove mens rea by mere comparison of common characteristics and behavior.[202] In essence, although a physician's subjective beliefs have the power to overcome objectively unlawful conduct, a drug courier's subjective state of mind regarding their objectively unlawful actions may be rendered entirely irrelevant by profile evidence.[203]

Physicians also arguably fare much better at sentencing than drug couriers.[204] Though drug couriers can be attributed a knowing mens rea at sentencing for drugs of which they had no knowledge, a physician may have the requisite knowledge for the criminal mens rea but still avoid being sentenced for the entire known quantity of drugs.[205] Instead of following the stringent quantity-dependent sentencing of drug courier cases, courts have often departed below sentencing guidelines and prosecutorial recommendations that were based on the known quantity of drugs distributed by physicians.[206]

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[201] *Compare* United States v. Sabean, 885 F.3d 27, 47–48 (1st Cir. 2018) (affirming the conviction of a defendant physician where a multitude of specific instances of unlawful conduct were presented), *with* United States v. Solis, 923 F.2d 548, 551–52 (7th Cir. 1991) (maintaining the conviction of a defendant where the government utilized expert testimony that the defendant's use of beepers was evidence that the defendant was a drug courier).

[202] *Compare* United States v. Foster, 939 F.2d 445, 451, 454, 458 (7th Cir. 1991) (affirming the use of a comparison between the drug courier defendant's innocuous behavior to the same drug courier profile characteristics to convict the defendant), *with* United States v. Parasmo, No. 19-CR-1, 2023 WL 1109649, at * 22–23 (E.D.N.Y. Jan. 30, 2023) (noting that evidence that the defendant physician continued to prescribe controlled substances despite direct knowledge of patient drug abuse and secondary dealing of prescription pills was exactly the type of evidence permitted by *Ruan* to prove the requisite criminal mens rea).

[203] *Compare* Ruan v. United States, 597 U.S. 450, 468 (2022) (giving deference to a physician's subjective state of mind that must be disproven by objective circumstantial evidence), *with Foster*, 939 F.2d at 451, 454, 458 (permitting link between the defendant's perceived behavior and common drug courier profile characteristics to show the defendant was knowingly acting as a drug courier despite the defendant's clear denial of knowledge).

[204] *See infra* notes 205–206 and accompanying text.

[205] *See* United States v. de Velasquez, 28 F.3d 2, 6 (2d Cir. 1994) (attributing knowing mens rea to the defendant for the entire quantity of drugs despite testimony that she had no knowledge of part of the total quantity); Gershowitz, *supra* note 6, at 1065–69 (noting that Dr. Noel Blackman, Dr. Ernesto Lopez, and Dr. Richard Evans were among many convicted physicians sentenced below a prosecutorial recommendation or sentencing guidelines range based on the proven known quantity of drugs distributed).

[206] *See* Gershowitz, *supra* note 6, at 1102–03 (stating, via table, that only ten of the twenty-five most infamous pill mill cases were within the sentencing guidelines, while the other fifteen received below-guidelines sentences). In one instance, despite the presiding judge being outraged by the defendant physician's unlawful behavior, the defendant still received a sentence of only five years of incarceration, below the guidelines range of thirty years to life and the prosecutor's recommendation of eight years. *Id.* at 1068–69.

Though a full comparison of the treatment disparity between drug couriers and physicians in the criminal justice system is beyond the scope of this Note, it bears mentioning that one could argue additional disadvantages for drug couriers and additional advantages for physicians both exist.[207]

The last Part of this Note proposes a solution that will help remedy these policy concerns and satisfy *Ruan* supporters and opponents alike.[208]

III. A MODEST PROPOSAL: A RETURN TO THE OBJECTIVE GOOD FAITH DEFENSE, UNIFORM MODEL STATUTES, AND COMPREHENSIVE GUIDELINES FOR PHYSICIANS

This Part argues for a modified return to an objective good faith defense standard for Section 841 physician prosecutions.[209] Part A contends that the Court's 2022 decision in *United States v. Ruan* is inconsistent with the text and intent of the CSA, conflicts with existing Court precedent, and unacceptably exacerbates the treatment disparity between physicians and drug couriers charged under the CSA.[210]

Part B contends that there is a viable alternative solution that augments the objective good faith defense established by the CSA and the 1975 decision *United States v. Moore* rather than changing the standard entirely to a subjective one, as the Supreme Court did in *Ruan*.[211] More specifically, it asserts that implementing a uniform model statute and comprehensive guidelines on lawful prescribing practices into the pre-existing objective good faith defense framework would satisfy both supporters and opponents of the *Ruan* decision.[212]

A. The Problem with Ruan*: Inconsistency with Prior Law and the Exacerbation of Treatment Disparities*

The CSA does not authorize individual physician discretion to substitute their own idiosyncratic medical judgments over traditionally accepted medical practice.[213] *Ruan*'s subjective good faith defense will, in effect, allow a physi-

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[207] *See, e.g.*, Newcomb, *supra* note 5, at 76–77 (noting the difficult task for prosecutors to overcome jurors' trust of physicians and a high evidentiary burden); Anna Roberts, *(Re)forming the Jury: Detection and Disinfection of Implicit Juror Bias*, 44 CONN. L. REV. 827, 835–37 (2012) (describing juries' implicit and explicit biases that people of color could face at trial). Specifically, defendants of color must essentially overcome a presumption of guilt and the erosion of their constitutional right to remain silent. Roberts, *supra*, at 837.

[208] *See infra* notes 209–242 and accompanying text.

[209] *See infra* notes 210–242 and accompanying text.

[210] *See infra* notes 213–226 and accompanying text.

[211] *See infra* notes 227–242 and accompanying text.

[212] *See infra* notes 227–242 and accompanying text.

[213] *See* Brief for the United States, *supra* note 88, at 30 (arguing that the CSA's registration scheme mandates compliance with accepted medical standards and does not allow for a physician's own personal medical judgment to supersede these standards).

cian to make their own medical judgments irrespective of generally accepted medical practice, provided a jury does not believe their conduct is egregious enough to warrant a finding of bad faith.[214] This is directly contrary to the CSA and the Supreme Court's holding in the 2006 case *Gonzales v. Oregon*, which stipulated that a state's laws should determine acceptable medical practice for physicians.[215]

As mentioned previously in this Note, an indirect consequence of *Ruan* is the exacerbation of disparate mens rea treatment between physicians and drug couriers charged under the CSA.[216] The evidentiary level of proof required to convict physicians under *Ruan* too greatly exceeds the low level of proof required to convict drug couriers.[217] Additionally, a physician's ability to escape criminal liability for a known quantity of drugs via their subjective beliefs while drug couriers may be assigned knowledge for a quantity they did not know of is too unbalanced.[218]

Although it is true that physicians, unlike drug couriers, are responsible for socially beneficial conduct, which the Supreme Court rightfully endeavors to give greater protection to, they still receive more favorable treatment within the objective good faith defense framework.[219] Unlike drug couriers, physicians would still receive authorization to dispense controlled substances and have a defense from criminal liability if a jury found their deviation from acceptable medical practice was objectively in good faith.[220]

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[214] *See* Ruan v. United States, 597 U.S. 450, 468 (2022) (granting physicians facing prosecution under § 841 a subjective good faith defense standard); United States v. Sabean, 885 F.3d 27, 47–48 (1st Cir. 2018) (demonstrating the level of unlawful physician conduct to suffice finding the requisite mens rea to violate § 841 under a subjective good faith defense standard).

[215] *See* 21 U.S.C. § 823(f) (requiring prescribing physicians to comport with state laws governing controlled substance distribution and dispensation); Gonzales v. Oregon, 546 U.S. 243, 270–71 (2006) (holding that states should determine the bounds of acceptable medical practice).

[216] *See supra* notes 201–206 and accompanying text (outlining how physicians have more mens rea protection than drug couriers charged under the CSA).

[217] *Compare Sabean*, 885 F.3d at 47–48 (finding requisite mens rea only where physician's bad faith was shown through egregious instances of conduct), *with* United States v. Foster, 939 F.2d 445, 454–55 (7th Cir. 1991) (permitting mens rea to be shown through drug courier profile testimony), *and* United States v. de Velasquez, 28 F.3d 2, 6 (2d Cir. 1994) (allowing mens rea to be shown through mere possession of drugs).

[218] *See* Gershowitz, *supra* note 6, at 1065–69, 1102–03 (listing various convicted physicians whose sentences did not reflect the known quantity of drugs); *de Velasquez*, 28 F.3d at 6 (holding that a knowing mens rea may be assigned to a drug courier defendant for the total quantity of drugs even if they lacked knowledge of or could not reasonably foresee any part of the quantity).

[219] *See Ruan*, 597 U.S. at 459–60 (noting the Court's imperative to protect a physician's socially beneficial conduct through a greater mens rea provision); Brief for the United States, *supra* note 88, at 27 (outlining the protections afforded to physicians by an objective good faith defense).

[220] *See* Brief for the United States, *supra* note 88, at 27 (stating that the Court's 1975 *United States v. Moore* objective mens rea standard provided a good faith defense for physicians); 21 U.S.C. § 822(b) (issuing authorization for physicians to distribute and dispense controlled substances); *see also* United States v. Moore, 423 U.S. 122, 132–33, 142–43 (1975) (interpreting that § 822(b)'s authorization "was added merely to ensure that [registered] persons engaged in lawful activities could

This exceeds the protections afforded to drug couriers, who must still reckon with the impact of drug courier profile testimony and stringent quantity-dependent sentencing, both of which diminish the importance of their mens rea.[221] Although the mens rea standards between the two groups likely cannot be made entirely equivalent, instituting an objective good faith defense for physicians would still reduce the inequitable disparities between physicians and drug couriers.[222]

In effect, an objective good faith defense for physicians would bring the gap in power of each group's subjective beliefs closer together.[223] Just as one drug courier's claimed state of mind cannot overcome objective evidence of illicit drug quantities, physicians could no longer claim the protection of their idiosyncratic, subjective interpretation of acceptable medical practice in defending their objectively unlawful prescriptions.[224]

Ruan advocates proffer that the chilling effect on patients and physicians was caused by the unclear standards governing lawful physician conduct, which led some physicians to forego patient treatment entirely for fear of prosecution.[225] The next section argues that this Note's suggested counterproposal to *Ruan* mitigates concerns of ambiguity by offering a uniform, legally binding standard that sufficiently informs physicians as to what constitutes lawful prescribing practices.[226]

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not be prosecuted" and further holding that the defendant physician's conduct warranted criminal conviction because it was not in good faith and eclipsed the limits of acceptable medical practice).

[221] *See* Weinstein & Bernstein, *supra* note 20, at 121 (arguing that drug couriers' mens rea has been virtually eliminated at sentencing); Kadish, *supra* note 183, at 751, 779 (noting that "drug courier profile testimony" can suffice as evidence of a guilty state of mind).

[222] *See Ruan*, 597 U.S. at 459 (noting that CSA authorization is the key factor that separates unlawful dispensation of controlled substances from lawful dispensation); 21 U.S.C. § 823 (providing stringent and numerous requirements to become CSA-registered, which substantially limits the range of individuals who may obtain authorization to lawfully distribute controlled substances). Although a comprehensive solution to the drug courier mens rea issues is beyond the scope of this Note, a scholar suggests that courts should closely re-examine the use of drug courier profile evidence and consider the true prejudicial impact of the testimony on verdicts. Kadish, *supra* note 183, at 789–90. Similarly, other scholars have urged the Federal Sentencing Commission to re-embrace the traditional understanding of mens rea in drug courier sentencings. Weinstein & Bernstein, *supra* note 20, at 123.

[223] *See supra* notes 202–203 and accompanying text (discussing the gap in power between a physician's and drug courier's subjective beliefs).

[224] *See* United States v. Foster, 939 F.2d 445, 449, 458 (7th Cir. 1991) (demonstrating how a drug courier's claimed state of mind could not overcome objective evidence of illicit drugs); United States v. de Velasquez, 28 F.3d 2, 3, 6 (2d Cir. 1994) (same); United States v. Moore, 423 U.S. 122, 142–43 (1975) (affirming defendant physician's conviction where his subjective claim of proper medical treatment was wholly inconsistent with objective generally accepted medical practice).

[225] *See supra* notes 124–151 and accompanying text (outlining arguments supporting the *Ruan* subjective good faith defense).

[226] *See infra* notes 227–242 and accompanying text.

B. A Better Alternative to Ruan*: A Comprehensive, Objective Standard that Answers the Ruan Concerns*

This Note's proposed objective good faith defense standard, as derived from the CSA, *Gonzales v. Oregon*, and *United States v. Moore*, will require physicians to show they made an *objectively* reasonable good faith effort to comport with their state's accepted medical practices.[227] This standard would be based on the beliefs of fellow reasonable physicians, or each state's laws and medical community, to decide what constitutes acceptable medical practice, rather than be predicated on the defendant's subjective beliefs.[228]

This would still grant physicians a desired flexibility as juries, not the government, would decide whether the physician's conduct demonstrated a good faith effort to comport with approved medical practice.[229] In particular, the proffered objective good faith defense standard would not criminalize isolated mistakes regarding the CSA elements made in good faith but instead focus on the totality of the physician's conduct.[230]

The new standard would be codified in a uniform, model statute to operate as an amendment to the CSA, like the one specified earlier in this Note.[231] An example statute could read akin to this:

> A physician prescribes controlled substances in good faith for a legitimate medical purpose in the usual course of their professional practice where: (1) they are authorized to do so under the Controlled Substances Act (CSA); (2) they prescribe a drug approved for medical use under the CSA; and (3) a jury could determine, after analysis of admissible evidence and expert testimony, that a reasonable physician would conclude that the defendant physician made an honest

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[227] *See Moore*, 423 U.S. at 138–39, 142 n.20 (implementing an objective good faith defense that requires a physician's showing of an "honest effort" to comport with accepted medical practice); 21 U.S.C. § 823(f) (requiring physicians to comport with state law in prescribing controlled substances); *id.* § 822(b) (ordering authorized physicians to conform with all CSA provisions in issuing prescriptions); Gonzales v. Oregon, 546 U.S. 243, 270–71 (2006) (construing states as the authority to determine accepted medical practice).

[228] *See* Brief for the United States, *supra* note 88, at 35 (explaining how the objective good faith defense standard would operate in practice).

[229] *See* United States v. Lovern, 590 F.3d 1095, 1100 (10th Cir. 2009) (designating juries as the actor to decide whether physician conduct comported with accepted medical practice); *Gonzales*, 546 U.S. at 272–73 (rejecting the government's argument for an inflexible standard, which would permit the Attorney General to prohibit a medical use that was inconsistent with any one individual physician's conception of appropriate medical standards); *Moore*, 423 U.S. 122, 138–39, 142 n.20 (upholding an objective good faith defense based on a flexible honest effort standard, and not rigid compliance with accepted medical practice).

[230] *See* Brief for the United States, *supra* note 88, at 35 (outlining the contours of the objective good faith defense).

[231] *See supra* notes 168–171 and accompanying text (outlining example of a model statute).

> effort to comport with generally accepted medical practice in issuing the prescriptions.[232]

Jury instructions would reflect the third provision of the statute, instructing juries to evaluate the good faith defense based on whether a reasonable physician would find that the defendant made an honest effort to comport with generally accepted medical practice.[233]

Though this statute and the jury instructions would be uniformly applied to all Section 841 physician prosecutions, accepted medical practice would still be governed by each state's individual statutes and medical communities, thus alleviating the concerns espoused in the Court's 2006 *Gonzales v. Oregon* decision of federalism superseding a state's police power.[234]

Under this proposed model, a combination of pre-existing FDA, CDC, and state controlled substance prescription guidelines offers an ideal statutory composition.[235] As mentioned previously in this Note, the FDA and CDC guidelines could provide concrete and comprehensive requirements for patient treatment while individual states could impose further restrictions based on the input of each state's medical community.[236]

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[232] *See* 21 C.F.R. § 1306.04(a) (2023) (issuing required elements of "legitimate medical purpose" and "usual course of . . . professional practice" for lawful prescriptions); 21 U.S.C. § 841(a) (criminalizing any unauthorized distribution or dispensation of controlled substances); *id.* § 822(b) (authorizing registered physicians to distribute controlled substances); *id.* § 812(b) (noting the approved Schedule II–V controlled substances, which all have a currently acceptable medical purpose); *Moore*, 423 U.S. at 138–39, 142 n.20 (instituting objective good faith defense standard for physician prosecutions based on whether a physician made an honest effort to comport with acceptable medical practice); *Lovern*, 590 F.3d at 1100 (holding that juries should determine whether a physician acted in accordance with accepted medical practice); Brief for the United States, *supra* note 88, at 27 (arguing that the *Moore* objective good faith defense standard requires a physician to inform themselves of what constitutes acceptable medical practice and make a good faith honest effort to comport with said practice).

[233] *See Moore*, 423 U.S. at 138–39, 142 n.20 (approving good faith defense jury instructions based on generally accepted medical practice); Ruan v. United States, 597 U.S. 450, 465 (2022) (noting that an objective good faith defense would center on the beliefs of a reasonable physician); Brief for the United States, *supra* note 88, at 35 (noting that an objective good faith defense standard would permit physicians to avoid criminal liability if a doctor makes a good faith effort to comport with accepted medical practice).

[234] *See* 546 U.S. at 270–71 (expressing concern that the federal government should not regulate medical practice, which is a power reserved to the states).

[235] *See* FED. DRUG ADMIN., *supra* note 173, at 2–4 (administering pointed recommendations for proper prescribing practices); Dowell et al., *supra* note 173, at 11–12 (same); N.Y. PUB. HEALTH LAW § 3331 (McKinney 2024) (providing model example of a state statutory provision governing opioid prescriptions).

[236] *See* N.Y. PUB. HEALTH LAW § 3331 (McKinney 2024) (issuing specific statutory limitations on prescriptions); FED. DRUG ADMIN., *supra* note 173, at 2–4 (providing specific recommendations regarding initial patient assessment, initiating treatment, drug dosages, and treatment management); Dowell et al., *supra* note 173, at 11–12 (same). Each of these guidelines offers unique recommendations: the FDA guidelines contain instructions for proper opioid prescribing, which includes specific limitations on usage, prescribing to opioid-tolerant patients, dosing intervals, and any specific interac-

Even if states differ in their individual restrictions, state medical boards can require CSA-authorized physicians to routinely educate themselves on accepted medical practice so they can lawfully prescribe with confidence.[237] Thus, if a physician's conduct revealed that they did not make an honest effort to comport with accepted medical practice, they would have the requisite mens rea to violate Section 841.[238]

Physicians would retain a good faith defense and, unlike the lack of guidance in *Ruan*, would have additional clarity on lawful prescribing practices.[239] The government, as noted in *Ruan*, could still provide objective evidence of a physician's unprofessional and unreasonable conduct at trial to disprove a physician's good-faith defense.[240]

Although the good-faith defense under this proposed standard may offer less protection than the one in *Ruan*, the justification for the greater standard would no longer exist.[241] The feared statutory ambiguity and risk of criminalizing innocent conduct would be greatly diminished, if not eliminated entirely.[242]

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tions with other drugs; the CDC guidelines contain several in-depth non-opioid alternatives for pain management that physicians should consider before issuing an opioid prescription; and the New York statute limits physician prescriptions to Schedule II through V drugs and limits opioid prescriptions for pain management to three months, having determined that to be the general time in which a patient's tissue will fully heal. *See* N.Y. PUB. HEALTH LAW § 3331(McKinney 2024) (enumerating specific controlled substance prescription restrictions); FED. DRUG ADMIN., *supra* note 173, at 7–8 (advising physicians on proper opioid prescribing practices); Dowell et al., *supra* note 173, at 17–19 (providing alternatives to opioid prescriptions for patients afflicted with pain).

[237] *See, e.g.*, ALA. ADMIN. CODE r. 540-x-4.09(8) (2024) (mandating that physicians registered to prescribe controlled substances in Alabama take part in yearly "continuing medical education"); WYO. STAT. ANN. § 33-26-202(b)(xiv) (2023) (requiring same for registered Wyoming physicians). Specifically, the Alabama state medical board's continuing education requirement can include guidance on general proper prescribing practices, discerning when patients are improperly using prescription drugs, or proper prescription practices for patients afflicted with chronic pain. ALA. ADMIN. CODE r. 540-x-4.09(8).

[238] *See* Brief for the United States, *supra* note 88, at 30 (noting that, under an objective good faith defense standard, a physician has the requisite mens rea to infringe § 841 when they fail to make a good faith, honest effort to comport their conduct with accepted medical practice).

[239] *See* Ruan v. United States, 597 U.S. 2370, 454–68 (2022) (chartering a universal subjective good faith defense for physicians but failing to address clear boundaries for what constitutes accepted medical practice).

[240] *See id.* at 467 (outlining permissible evidence to disprove the good faith defense).

[241] *See id.* at 459–60 (justifying a stronger good faith defense by pointing to the statutory ambiguity surrounding unlawful prescribing and risk of criminalizing innocent physician conduct); *supra* notes 227–228 (noting the different standards between this Note's proposed objective good faith defense as compared to *Ruan*'s subjective good faith defense).

[242] *See supra* notes 227–240 and accompanying text (proposing a solution that resolves the statutory ambiguity surrounding § 841 physician prosecutions by clearly defining what constitutes lawful prescribing and accepted medical practice, thus greatly reducing the risk that innocent or legitimate good faith physician conduct could be criminalized).

CONCLUSION

Ruan v. United States was a well-intentioned Supreme Court decision that purported to ameliorate the harms of the CSA's statutory ambiguity regarding lawful prescribing—an ambiguity that paralyzed good doctors with fear, leaving patients to suffer without their necessary prescriptions. To do so, the Court standardized a subjective good faith defense for physicians, requiring the government to prove that an authorized physician charged under Section 841 subjectively knew or intended their prescriptions to be unlawful. It failed to consider, however, viable alternatives to resolving this statutory ambiguity without resorting to the problematic subjective good faith defense. The approach taken by the Court ran contrary to existing Supreme Court decisions in *United States v. Moore* and *Gonzales v. Oregon* in addition to the CSA itself. The Court also neglected a potential policy concern that the mens rea treatment disparity between physicians and drug couriers charged under the CSA would be exacerbated by enacting a subjective good faith defense for physicians.

Instead, an ideal solution could be comprised of an objective good faith defense statute to serve as an amendment to the CSA, a uniform state statutory construction comprised of FDA, CDC, and state prescription guidelines, and the input of each state's medical communities. This comprehensive solution would allow physicians to be properly informed of lawful prescribing practices and treat their patients with confidence. A subjective good faith defense would be unnecessary given the now non-existent statutory ambiguity which had motivated the *Ruan* decision. Simultaneously, an objective good faith defense standard would prevent the mens rea treatment disparity between physicians and drug couriers from worsening. Under this solution, no one individual's subjective, idiosyncratic beliefs could overcome objectively unlawful acts. As this Note has shown, the aims of *Ruan* could be met while remaining consistent with existing law and without heightening inequity in the justice system.

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