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A FELONY A DAY KEEPS THE DOCTOR AWAY

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ABSTRACT

The opioid crisis is a nationwide issue that has resulted in an increase in overdose deaths and a widespread addiction epidemic. The highly addictive qualities of opiates have landed them in the category of a "controlled substance" under the Controlled Substances Act. Both state and federal politicians and law enforcement agencies have grappled with the issue for decades, with little to show for it. Opiates were originally introduced in the medical field to treat acute pain but developed into a medicinal crutch. Subsequently, law enforcement agencies have begun to crack down on the legal, yet technically illegal distribution of opiates from physicians. The statutory construction of the Controlled Substances Act gives licensed physicians authorization to knowingly and intentionally distribute opiates, which would otherwise be illegal. However, as the epidemic has raged on and law enforcement agencies, presidential administrations, and state and local governments have zeroed in on prosecuting physicians, several questions have arisen as to the standard for establishing culpability. Courts have struggled to define several components of the Act, leading to confusion and ambiguity.

In 2022, the Supreme Court, ruled on a larger issue within the landscape of physician-defendant prosecution: the good faith defense. However, the holding not only furthered prosecutorial confusion, but only addressed a niche portion of the larger issue. This Commentary seeks to remedy that failure by both criticizing the Supreme Court's holding and proposing a new statutory

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framework for the Act itself. This framework will focus on defining the ambiguous portions of the Act, such that physicians can avoid prosecution whilst providing the necessary care. Finally, considering the new statutory framework, this Commentary proposes adding the mens rea of "recklessness" to the Act's preexisting statutory requirements.

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INTRODUCTION

The opioid epidemic has wreaked havoc on homes and families across the United States. Law enforcement has sought to regulate the distribution of illegal drugs in the wake of the public health emergency but has faced difficulty in managing one of the larger sources of the medication: licensed physicians. In the 1970s, to combat the drug crisis in America, the federal government passed the Controlled Substances Act ("CSA"),[1] making it unlawful to possess or distribute controlled substances. The CSA also has an "authorization exception" that allows medical professionals to prescribe and distribute the otherwise illegal controlled substances.[2] However, the "authorization exception" did not anticipate that physicians would become one of the largest sources for opioid abuse and distribution in the United States. The persistent and reckless over-prescription of these drugs has led to an increase in physician prosecution, and these lawsuits have given rise to questions regarding burden of proof. The prosecution of several doctors exposed the difficulties of criminally penalizing licensed physicians that are allegedly acting in their professional capacity. Specifically, the case law raised questions about the relevance of the doctor's mental state, and the definition of "course of professional conduct."

This Commentary will analyze whether a court-provided "good faith" jury instruction in cases involving physician prosecution under the CSA is appropriate, and, if so, how this instruction should be provided. This issue arises specifically in the context of a circuit split that has led to a Supreme Court decision on the matter. Additionally, this Commentary argues for the establishment of a more rigid professional standard for doctors, that will both reduce the fear of prosecution and provide more clarity for jurors in the event of an indictment. Finally, in light of establishing a new professional standard, and definition of "legitimate purpose," this Commentary will argue for the modification of the current "knowingly or intentionally" standard, by addition of a "reckless" mens rea, to establish culpability under the CSA.

I. BACKGROUND

Under the Controlled Substances Act, 21 U.S.C. § 841 ("CSA"), it is unlawful for any person to knowingly or intentionally (a) manufacture, distribute, dispense, or possess with intent to manufacture, distribute or

1. The Controlled Substances Act, 21 U.S.C. § 841 (2012).
2. *Id.*

dispense a controlled substance[3] or, (b) to create, distribute, or dispense a counterfeit substance.[4] Prescription opiates are considered Schedule II drugs under the CSA due to the "high potential" for abuse, with use potentially leading to severe psychological or physical dependence.[5]

The use of a "knowingly or intentionally" mens rea standard in cases against physicians under the CSA places a high burden on the prosecution as it requires a demonstration of subjective knowledge or purposeful intent to: consciously overprescribe, prescribe without a legitimate medical purpose, or act outside of the confines of the "modern course of professional conduct."[6] To provide for regulated, lawful prescriptions by physicians, the CSA also has an "authorization exception" [7] that permits authorized individuals to distribute opioids without fear of prosecution.[8] However, this exception requires that medical professionals write prescriptions of controlled substances "for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice."[9] The terms "legitimate medical purpose" and "usual course of professional practice" are not defined within the CSA, and are subsequently up for interpretation by each individual professional. This has, arguably, become the most significant question when prosecuting doctors under the CSA.

In 2020, the Eleventh Circuit Court of Appeals heard *United States v. Ruan*, which involved two doctors charged with violating the Controlled Substances Act by over-prescribing opioids to their patients.[10] The District Court declined to extend the defendant's proposed jury instruction which contained a "good faith" defense for the doctors.[11] In affirming this decision, the Eleventh Circuit emphasized the importance of including an objective standard of good faith for judging the physician's conduct.[12]

3. *Id.*

4. *Drug Scheduling*, U.S. DRUG ENFORCEMENT ADMIN., https://www.dea.gov/drug-information/drug-scheduling (last visited Nov. 26, 2023).

5. *Id.*

6. The Supreme Court has previously held that the "knowingly" *mens rea* requires a showing that the defendant knew of "the facts that make his conduct fit the definition of the offense." Elonis v. United States, 575 U.S. 723, 735 (2001).

7. The Controlled Substances Act, 21 U.S.C § 841 (2012) (quoting 21 C.F.R. § 1306.04(a) (2008)).

8. *See id.*

9. *Id.*

10. United States v. Ruan, 966 F.3d 1101, 1119 (11th Cir. 2020).

11. *See id.* at 1169 (reasoning that the proposed instruction was an incorrect statement of the law, was too subjective, and would confuse the jury in its application).

12. *See id.* at 1167.

In 2021, the Tenth Circuit heard a similar case, *United States v. Khan*, in which it affirmed a physician's convictions under the CSA.[13] The court reasoned that, for the government to prove a case under § 841, the prosecution must prove that a doctor "*either*: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice."[14]

In June 2022, the Supreme Court heard the consolidated appeal of the Tenth and Eleventh Circuit cases in *Ruan v. United States*, the issue on appeal was what level of mens rea applies to the authorization exception of § 841.[15] The Court determined that the CSA, like many criminal statutes, uses the familiar mens rea words "knowingly or intentionally," which ruled out the use of the "good faith" defense.[16]

A. History of the Controlled Substances Act

The regulation of drugs and illicit substances is not a new phenomenon in the United States.[17] In response to the "War on Drugs" initiated by President Nixon in the 1960s, there was a hard push for comprehensive, effective, federal drug reform.[18] This effort resulted in the passage of the Controlled Substances Act.[19] In adopting the CSA, Congress attempted to balance two competing interests: (1) making sure patients were prescribed drugs needed for medical treatment and (2) preventing the "illegal importation, manufacture, distribution," and use of drugs.[20] The CSA separates different substances into "schedules,"

13. United States v. Kahn, 989 F.3d 806, 829 (10th Cir. 2021).

14. *Id.* at 825 (emphasis added).

15. Ruan v. United States, 142 S. Ct. 2370 (2022).

16. The cases were thus remanded to the lower courts to review the instructions from the original cases to determine whether they fit within this standard. *Id.* at 2382.

17. In 1914, Congress passed the Harrison Narcotics Tax Act of 1914 in an attempt to regulate the domestic trade in narcotic drugs. JOANNA R. LAMPE, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 116TH CONGRESS 2 (2019), https://crsreports.congress.gov/product/pdf/R/R45948/1.

18. LISA N. SACCO, DRUG ENFORCEMENT IN THE UNITED STATES: HISTORY, POLICY, AND TRENDS 5 (2014), https://sgp.fas.org/crs/misc/R43749.pdf.

19. *Id.*

20. JOANNA R. LAMPE, THE CONTROLLED SUBSTANCES ACT (CSA): A LEGAL OVERVIEW FOR THE 117TH CONGRESS 1–2 (2021) (quoting 21 U.S.C. § 801(2)), https://www.everycrsreport.com/files/2021-02-05_R45948_947eb3c52b068a17dc7c223301e9d048aef26164.pdf ("The CSA simultaneously aims to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes while also seeking to protect public health from the dangers of controlled substances diverted into or produced for the illicit market." (quoting 21 U.S.C. § 801 (1), (2)). Thus, the CSA aims to protect the public from the dangers of controlled substances while also ensuring access for legitimate purposes. *See id.*

based on the likelihood of abuse, Schedule I being the most addictive and Schedule V the least,[21] with specific regulations based on these classes.[22]

B. United States v. Moore – *Adding Doctors to the Mix*

In 1975, the Supreme Court heard *United States v. Moore*.[23] *Moore* was the foundational decision permitting prosecution of licensed medical professionals for violations of the CSA.[24] The issue before the Court was whether, under the CSA, registered physicians can be prosecuted for dispensing or distributing controlled substances.[25] Defendant Moore, a licensed physician as defined under the authorization exception, was charged with knowingly and unlawfully distributing and dispensing methadone, a Schedule II controlled substance.[26] The indictment covered a five-and-a-half month period in which Moore's practice wrote over 100 prescriptions per day.[27] The record showed that Moore gave his patients only perfunctory examinations,[28] which typically included a request to see the patient's needle marks, and an unsupervised urinalysis, the results of which he frequently ignored.[29] Moore's practice also did not keep accurate records, thus, in some cases the quantity of the prescription was not recorded.[30] The jury determined that Moore's procedures were not within the "usual course of medical practice," and his motivation for prescribing medication under the guise of "treating" his patients was *not* for a "legitimate medical purpose."[31] *Moore* set the standard for juries to deduce which physician decisions were made when acting within the "usual course of professional practice" and for a "legitimate medical purpose."

21. The Controlled Substances Act, 21 U.S.C § 841 (2012).
22. Prescription opioids fall within Schedule II designation. *Id.*
23. 423 U.S. 122, 122 (1975).
24. *See id.* at 144–45.
25. *See id.* at 124.
26. *See id.* at 124–25.
27. *Id.*
28. *Id.* at 126–27.
29. *See id.* (explaining that if a patient made a return visit, which was rare, "no physical examination was performed and the patient again received a prescription for whatever quantity he requested").
30. *Id.* at 127. ("Several patients testified that their use of methadone increased dramatically while they were under [Moore's] care.").
31. *Id.* at 125.

C. Opioid Epidemic

Opioids have a long history in the United States, dating back to the Civil War and the treatment of wounded soldiers.[32] A significant turning point in the history of controlled substances was the introduction of OxyContin, as a "gentler less addictive version of oxycodone," by Purdue Pharma in 1995.[33] OxyContin triggered the first wave of deaths linked to prescription opioids.[34] A second wave of deaths was perpetuated by heroin use, which targeted already susceptible opioid addicts, and finally, a third wave was caused by synthetic opioids like fentanyl.[35]

The opioid crisis has had devastating effects on families across America, resulting in an overwhelming increase in addiction, homelessness, and overdose deaths. Many addicts first start using opioids as part of a medical treatment plan.[36] These treatment plans often stem from a general diagnosis of chronic pain and, evidently, addiction often develops from ordinary, medically warranted procedures.[37] For this reason, physicians generated a large part of the blame for the crisis. [38] In November 2022, the Centers for Disease Control and Prevention introduced prescribing guidelines;[39] the guidelines

32. Becky Little, *How Civil War Medicine Led to America's First Opioid Crisis*, HISTORY (Sept. 13, 2023), https://www.history.com/news/civil-war-medicine-opioid-addiction.

33. *The Origin and Causes of the Opioid Epidemic,* GEORGETOWN BEHAVIORAL HEALTH INST. (Aug. 14, 2018), https://www.georgetownbehavioral.com/blog/origin-and-causes-of-opioid-epidemic.

34. Interview by Karen Feldsher with Howard Koh, Professor of the Practice of Public Health at Stanford University, and member of the Stanford-Lancet Commission on the North American Opioid Crisis (Feb. 9, 2022), https://www.hsph.harvard.edu/news/features/what-led-to-the-opioid-crisis-and-how-to-fix-it/.

35. *Id.*

36. Mayo Clinic Staff, *How Opioid Addiction Occurs,* MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-opioid-addiction-occurs/art-20360372 (last visited Nov. 27, 2023) (describing how short-term pain relief often leads to opioid addiction, which is the cause of the majority of overdose deaths in the United States).

37. *Id.*

38. *See Americans' Attitudes About Prescription Painkiller Abuse*, HARV. T.H. CHAN SCH. OF PUB. HEALTH, STAT, (Mar. 2016), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2016/03/STAT-Harvard-Poll-Mar-2016-Prescription-Painkillers.pdf. According to the poll, thirty-four percent of people questioned believed doctors who inappropriately prescribe painkillers are *mainly* responsible for the growing problem of prescription painkiller abuse. *Id.*

39. Deborah Dowell et al., *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022*, Centers for Disease Control and Prevention (Nov. 4, 2022), https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm#suggestedcitation.

recommend prescribing opioids in a three-day supply or less, except in the case of trauma or major surgery.[40]

The Biden Administration has also invested over $1 billion[41] in communities to address the crisis.[42] Over the course of the COVID-19 pandemic, the United States faced 108,000 overdose deaths in just one year, a thirty-five percent increase.[43] The Biden Administration and smaller government entities continue to generate initiatives to combat the crisis.

1. Prescription Trends with Doctors

Nonmedical use of prescription pain relievers has been the second-most common type of illicit drug use in the United States for more than a decade.[44] Data from the Substance Abuse and Mental Health Services Administration ("SAMHSA") indicates that approximately twenty-five percent of nonmedical opioid users get them from physicians.[45] Moreover, there is wide variation in the standards for prescribing opioids, even among physicians practicing within the same emergency department in the same medical facility.[46]

40. *Id.* When asked whether they agreed or disagreed with these guidelines for treating acute pain, nearly seven in ten Americans agreed. *See Americans' Attitudes About Prescription Painkiller Abuse*, *supra* note 38, at 3.

41. Press Release, U.S. Dep't of Health & Hum. Servs., Biden–Harris Administration Awards More than $1.6 Billion in Funds for Communities Addressing Addiction and Overdose Crises (Sept. 23, 2022).

42. *See id.* (citing *Vital Statistics Rapid Release Provision Drug Overdose Death Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Feb. 15, 2023), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm).

43. *See* Brian Mann, *Biden's Speech Comes with Opioid Epidemic Having Become a Deadly Public Health Crisis,* NPR (Feb. 7, 2023, 4:42 PM), https://www.npr.org/2023/02/07/1155185856/.

44. Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse, The CBHSQ Report: January 12, 2017*. CTR. FOR BEHAV. HEALTH STATI. & QUALITY, SUBSTANCE ABUSE A& MENTAL HEALTH SERVS. ADMIN. (Jan. 12, 2017), https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html (examining sources of misused prescription pain relievers in the United States overall, by demographic subgroups, and by type of user).

45. *See* Steven A. King, *The Opioid Epidemic: Who Is to Blame?* 35 THE PSYCHIATRIC TIMES 14 (2018).

46. *See* Michael L. Barnett, Andrew R. Olenski & Anupam B. Jena, *Opioid-Prescribing Patterns of Emergency Physicians and Risk of Long-Term Use.* 376 NEW ENG. J. OF MED., 663–73 (2017) (examining the extent to which physicians vary in opioid prescribing and the implications of that variation for long-term opioid use and adverse outcomes in patients).

2. The Frequency of Charging Doctors with Violations of the CSA

Between 1995 and 2019, the annual number of criminal cases against physicians charged with opioid-related offenses reported in the U.S. media increased from zero to forty-two.[47] This trend is generally consistent with the rise of the opioid epidemic.[48]

The Department of Justice (DOJ) and the Drug Enforcement Agency (DEA) have implemented various administrative and law enforcement initiatives to address the ongoing crisis. Rather than maintaining one national set of recommendations or guidelines, the DOJ and DEA instead chose to approach the issue regionally, dispatching law enforcement to investigate medical professionals for any instances of overprescribing.[49] The federal government has also implemented Prescription Drug Monitoring Programs ("PDMPs") [50] to address overprescribing and potential misuse amongst patients.[51] Despite both approaches, overprescribing and abuse persist, resulting in more criminal indictments for medical professionals, but little progress addressing the crisis as a whole.

3. The Potential of Under-Prescribing Chronic Pain as a Deterrent Factor

The primary countervailing consideration regarding a federal initiative to combat overprescribing is the potential for under prescribing medication for victims of chronic pain. Johns Hopkins Medicine has defined chronic pain as "long standing pain that persists beyond the usual recovery period or occurs along with a chronic health condition . . . . Chronic pain may be 'on' and 'off' or continuous.[And it] may affect people to the point that they can't work, eat properly, take part in physical activity, or enjoy life."[52] In a 2016 interview, Dr. Howard Fields, an expert

47. Julia B. Berman & Guohua Li, *Characteristics of Criminal Cases Against Physicians Charged with Opioid-Related Offenses Reported in the US News Media, 1995–2019*, 7 INJ. EPIDEMIOL. 50 (2020), https://doi.org/10.1186/s40621-020-00277-8 (examining the epidemiologic patterns of criminal cases against physicians charged with opioid-related offenses reported in the U.S. news media).

48. *See id.* at 4.

49. *See* Whitmore, *supra* note 44.

50. U.S GOV'T ACCOUNTABILITY OFF., GAO-21-22, REPORT TO CONGRESSIONAL COMMITTEES: PRESCRIPTION DRUG MONITORING PROGRAMS, VIEWS ON USEFULNESS AND CHALLENGES OF PROGRAMS (2020), https://www.gao.gov/assets/gao-21-22.pdf.

51. *See id.* ("PDMPs are state-operated electronic databases that track prescriptions that patients receive for opioids or other medications that are at risk for being abused.").

52. *Chronic Pain,* JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/conditions-and-diseases/chronic-pain (last visited, Nov. 14, 2023).

on chronic pain, stated that "many chronic pain patients are actually undertreated for legitimate, life-altering pain, and [those] experiences are being left out of the current conversation about opioids."[53] As many as twenty-five million Americans suffer from daily chronic pain and lack effective non–opioid treatments to manage that pain.[54] Thus, opioid dependency for victims of chronic pain is largely derived from a lack of alternative treatment plans, the urgency of the patient's needs, and the efficacy of the medication for pain management.[55] Doctors find this level of medical ambiguity difficult to navigate, and react by either overprescribing, delaying, or even refusing prescription medication for patients who are in debilitating pain.

Due to the potential for abuse, many physicians have become reluctant to prescribe opioids.[56] This apprehension could be rooted in a fear of prosecution or a fear of perpetuating abuse. A study by the New England Journal of Medicine examined opioid prescriptions from July 2012 to December 2017 and found a twenty-nine percent decrease in the number of providers who started opioid therapy for patients.[57] A number of factors are at play in this figure, but one in particular is worth noting: instead of prescribing opiates for cancer patients, doctors were prescribing an alternative nonopioid medication.[58] Conversely, opiate prescriptions increased among palliative care doctors, who are experts in managing pain, again highlighting the difficulty in addressing the crisis while not hindering access to medication.[59] Critics of the push for prosecution allege that it is irreparably damaging the relationship between doctor and patient, thus exacerbating the struggle to obtain medication for those suffering from chronic pain.[60] Navigating the line

53. Radio Interview by Robin Young with Dr. Howard Fields, Professor of Neurology at the U. of Cal., S.F., Dir. of the WCSF Wheeler Center for the Neurobiology of Addiction, and Founder of the U. of Cal. S.F. Pain Mgmt. Ctr. (February 16, 2016), https://www.wbur.org/hereandnow/2016/02/16/underprescribing-opioids-for-pain.

54. Emily Petrus and Laura Stephenson Carter, *Opioid Addiction and Chronic Pain,* 26 NAT'L INST. OF HEALTH CATALYST 1 (2018).

55. Nora D. Volkow, M.D. and A. Thomas McLellan, Ph. D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies,* 374 NEW ENG. J. OF MED., 1253, 1256 (2016).

56. *See id.*

57. Wenjia Zhu et al., *Initial Opioid Prescriptions among U.S Commercially Insured Patients, 2012—2017,* 380 NEW ENG. J. OF MED., 1043, 1047 (2019).

58. Nat'l Cancer Inst. Staff, *Are Cancer Patients Getting the Opioids They Need to Control Pain?,* NAT'L CANCER INST. (Sept. 16, 2020), https://www.cancer.gov/news-events/cancer-currents-blog/2020/opioids-cancer-pain-oncologists-decreasing-prescriptions.

59. *Id.*

60. *See* Ronald T. Libby, *Treating Doctors as Drug Dealers The DEA's War on Prescription Painkillers,* CATO INST. (June 16, 2005),

between fraudulent pain and genuine suffering has led professionals to err on the side of caution to avoid prosecution. This is another collateral issue that must be addressed in any plans to remedy overprescribing.

II. THE CIRCUIT SPLIT: IS "GOOD FAITH" A WARRANTED DEFENSE?

The definition of good faith varies widely amongst medical professionals. This section will focus on the ways that good faith has been legally defined in the last five to ten years, including interpretations by the Tenth and Eleventh Circuits which the Supreme Court considered in 2022. Additionally, this Part will analyze the potential costs and benefits of each proposed definition, and the effect on federal prosecution.

A. The Eleventh Circuit Interpretation

The Eleventh Circuit heard *Ruan* in July 2020.[61] Doctors Xiulu Ruan ("Ruan") and John Patrick Couch ("Couch") were convicted of conspiring to violate the CSA by dispensing Schedule II drugs, namely fentanyl, outside the usual course of professional practice and without a legitimate medical purpose.[62] The indictment alleged that defendants' medical clinic was essentially a "pill mill."[63] The defendants each made over $3 million from their pharmacy making these fraudulent prescriptions.[64] From January to May 2015, the defendants wrote nearly 300,000 prescriptions for controlled substances, over half of which were Schedule II drugs, the most powerful and dangerous drugs that can be lawfully prescribed.[65]

1. "Good Faith Reasoning"

During the trial, the defendants proposed a jury instruction as the applicable standard for judging a physician's conduct under the CSA.[66]

https://www.cato.org/sites/cato.org/files/pubs/pdf/pa545.pdf (noting that patients must then negotiate between (1) "indicating sufficient pain to doctors to warrant more medication," and (2) avoiding desperation, one of the signs doctors are tasked to look for to identify potential misuse).

61. United States v. Ruan, 966 F.3d 1101, 1119 (11th Cir. 2020).
62. *Id.* at 1120.
63. *Id.*
64. *Id.* at 1122.
65. *Id.*
66. *Id.* at 1165. The instruction stated:

> If a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a legitimate medical purpose and within the usual course of professional practice, and you must return a not guilty verdict for the applicable

The District Court refused to give this instruction for several reasons. The court reasoned that defendant's request was too subjective as it "equate[d] . . . 'good faith' . . . with prescribing 'for a legitimate medical purpose and within the usual course of professional practice.'"[67] Additionally, the court reasoned the language that distinguished the civil standard of care from the criminal standard was unnecessarily confusing to the jury.[68] Ultimately , the court was concerned with the difficulty of applying of the proposed instruction.

The Eleventh Circuit also rejected the "good faith" instruction because whether a physician acts within the usual course of his professional practice must be evaluated based on an objective standard, *not* a subjective standard.[69] Rather than instructing the jury to take the mindset of the physician into consideration, the objective standard required jurors to determine whether the defendant-physician acted outside the usual course of professional practice.[70] Thus, the objective standard provided the jurors with a more rigid framework. This was also simplified because the "framework" was the overall standard of medical care that licensed U.S. practitioners generally recognized and accepted.[71] A comparison of the defendant's course of treatment with that of physicians throughout the country also avoids the problem of jurors

> count. Good faith in this context means good intentions and the honest exercise of professional judgment as to patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a Defendant acted in good faith in dispensing or distributing a Controlled Substance, as charged in the indictment, then you must return a not guilty verdict. The Government must prove, beyond a reasonable doubt, that the decision to dispense or distribute a Controlled Substance fell below a standard of medical practice generally recognized and accepted in the United States before you can return a guilty verdict as to that alleged violation of the Controlled Substances Act. But a Defendant's negligence, failure to meet a standard of care, or medical malpractice, on its own is not enough to convict him.

Id.

The remainder of the instruction stated:

> An unintentional failure to act how a reasonable doctor would have under similar circumstances is, by itself, insufficient to prove that a Defendant dispensed or distributed a Controlled Substance outside the usual course of professional practice and for no legitimate medical purpose. To prove a violation of the Controlled Substances Act in this case, the Government must prove, beyond a reasonable doubt, that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating a pain patient – that the physician, in fact, operated as a drug pusher.

Id.

67. United States v. Ruan, 966 F.3d 1101, 1166 (11th Cir. 2020).
68. *See id.*
69. *Id.*
70. *See id.*
71. *See id.* (quoting United States v. Joseph, 709 F.3d. 1082, 1097 (11th Cir. 2013)).

attempting to infer what the physician *thought* while overprescribing opiates to patients. Finally, the court noted that the CSA itself *mandated* comparison to common and accepted medical practices throughout the United States.[72]

B. The Tenth Circuit Interpretation

In 2021, The Tenth Circuit hear*d Khan*—the facts of which were similar to *Ruan*. The defendants were charged with conspiring to dispense and distribute controlled substances that resulted in death.[73] The Tenth Circuit held that the CSA requires the government to prove that a practitioner (1) subjectively knew that a prescription was not offered for a legitimate medical purpose; or (2) issued a prescription that was *objectively* not in the usual course of professional practice.[74] Both defendants challenged the district court's jury instructions on the good faith defense, but on different grounds.[75] Defendant Nabeel Kahn asserted that the district court erred by expressly limiting its good faith instruction to his brother, Dr. Shakeel Khan ("Dr. Khan"); meanwhile Dr. Khan asserted that the district court erred by instructing the jury that a defendant's "good faith" must be reasonable, permitting the jury to convict him by finding a lesser mens rea than the CSA requires.[76]

The Tenth Circuit affirmed the jury instruction provided by the district court and challenged by Dr. Kahn.[77] However, it reasoned that the good-faith intention of a practitioner is what defines the "scope of professional practice, and thus, the effectiveness of the prescription exception and the lawfulness of the [actual *conduct*]."[78] The court went

72. *Id.*

73. United States v. Kahn, 989 F.3d 806, 813 (10th Cir. 2021).

74. *Id.* at 825.

75. *See id.* at 822.

76. *See id.* at 822–23.

77. *Id.* at 823. The instruction stated:

> The good faith of Defendant Shakeel A. Kahn is a complete defense to the charges…because good faith on the part of Defendant Shakeel Kahn would be inconsistent with knowingly and intentionally distributing and/or dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose, which is an essential part of the charges. "Good faith" connotes an attempt to act in accordance with what a reasonable physician should believe to be proper medical practice. The Good faith defense requires the jury to determine whether Defendant Shakeel Kahn acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice.

Id.

78. *Id.* at 826. ("A controlled substance is prescribed by a physician in the usual course of professional practice, and, therefore, lawfully, if the substance is prescribed by him in good faith, medically treating a patient in accordance with a standard of medical practice

further to state that the relevant inquiry for the first prong of the prosecution's case is *why* a defendant *subjectively* issued that prescription, regardless of whether other practitioners would have done the same.[79] For the second prong, the court stated that a prescription is only considered valid if it is issued "in" the scope of professional practice, thus, the second-prong inquiry is "whether a defendant-practitioner *objectively* acted within that scope, regardless of whether he believed he was."[80] Finally, the court stated that, for this reason, when referencing the usual course of professional practice, federal case law "has rejected a subjective standard of good faith, in favor or an objective one."[81] Thus, a comparison to other medical professionals would not necessarily be required under the Tenth Circuit standard of analysis.[82]

The *Ruan* instruction creates difficulty because it implies that the scope of professional practice is contingent on the subjective mindset of a practitioner and, therefore, fluid. This reasoning might permit overprescription to an addict going through withdrawal, so long as the physician had a "good faith" belief about their conduct. At first glance, this seems simple to prove as medical professionals are expected to act in the best interests of their patients, thus all a defendant would have to prove is that he provided the treatment necessary to ease a patient's pain. This standard would make it incredibly difficult to establish a violation under the CSA, unless there was demonstrable evidence that a medical professional *sought* and *intended* to distribute controlled substances for the illegitimate purpose of personal profit, exacerbating, or even initiating a patient's opioid addiction.

C. The Supreme Court Weighs In

In June 2022, the Supreme Court of the United States granted certiorari from the decision of the Eleventh Circuit and consolidated *Ruan* and *Kahn* to decide what state of mind the Government must prove to convict doctor-defendants under the CSA.[83] Both defendants urged the Court to adopt a subjective good faith standard that would largely shield doctors from liability.[84] The Court determined that, "the Court of Appeals

generally recognized and accepted in the United States." (quoting United States v. Norris, 780 F.2d 1207, 1209 n.2 (5th Cir. 1986)).

79. *See id*.

80. *Id.* (emphasis added).

81. *Id.* at 826 (quoting United States v. Schneider, 704 F.3d 1287, 1303 (10th Cir. 2013)).

82. *See Kahn*, 989 F.3d at 813.

83. Ruan v. United States, 142 S. Ct. 2370, 2375 (2022).

84. *Id.*

in both cases evaluated the jury instructions [relating to mens rea] under an incorrect understanding of § 841's scienter requirements."[85] The Court stated that § 841's "knowingly or intentionally" mens rea standard also applies to the "except as authorized" clause.[86] Thus, once a defendant produces evidence that his or her conduct was "authorized" pursuant to the exception, "the Government must prove beyond a reasonable doubt that the defendant *knowingly* or *intentionally* acted in an unauthorized manner," or for an illegitimate purpose.[87] Thus, the Court held that the subjective intent of the defendant was relevant in determining mens rea because doctors who prescribe opiates in good faith do not meet the required "knowingly or intentionally" standard.[88]

The Supreme Court came to this conclusion by relying on several different considerations. It noted that, where a statute does not specify the culpable mental state, courts have often read the missing language into the statute using "knowledge" or "intent."[89] The crux of the issue in these consolidated cases, however, was whether or not the mental state in the CSA applies to the *exception* granting medical professionals the authority to distribute a controlled substance.[90]

According to the Court, the authorization exception does not contain its *own* mens rea, but rather, falls under the "knowingly or intentionally" standard articulated earlier in the CSA.[91] The Court relies on precedent of similar statutory frameworks to support its conclusion that the authorization provision is a statutory element and should not be treated as requiring a separate level of mens rea.[92] Primarily, the Court references *Liparota v. United States*, where it interpreted a statute that penalized "anyone who 'knowingly uses food stamps in any manner not authorized by' [the] statute."[93] Like the CSA, the *Liparota* statute had an "authorization" clause.[94] The issue in *Liparota* was whether the Government had to prove that the defendant knew he was acting in a manner the statute and regulations did not authorize.[95] In *Liparota,* the Court determined the statute's "knowingly" standard applied to the "not authorized" clause,[96] despite the fact that Congress did not "explicitly and

85. *Id.* at 2382.
86. *Id.* at 2376.
87. *Id.* (emphasis added).
88. *Id.*
89. *See id.* at 2376.
90. *See id* at 2375.
91. *See id.* at 2378.
92. *See id.*
93. *Id.* at 2378 (quoting Liparota v. United States, 471 U.S. 419, 420 (1985)).
94. *Id.*
95. *Id.*
96. *Id.* (citing *Liparota*, 471 U.S. at 419).

unambiguously" state that this mental state should apply to that clause.[97]

The second precedent cited by the Court, *United States v. X-Citement Video*, focused on the applicability of a statute's mens rea to the clause "involving use of a minor."[98] The statute penalized anyone who, "knowingly transports or knowingly receives videos involving the use of a minor engaging in sexually explicit conduct."[99] The Court held that the "knowingly or intentionally" standard also applied to the elemental fact that the media "involve[d] the use of a minor."[100] The Court reasoned that the phrase in question was "the crucial element separating legal innocence from wrongful conduct."[101] In each of these cases, the Court reiterated that a clearly defined statutory mens rea should be applied to subsequent sections of a statute if the elemental factor separates innocent from wrongful conduct.

This reasoning precludes defendants from alleging that a statute's clearly defined mens rea does not apply to the subsequent provisions, which was the defendant's argument in *Ruan*.[102] Additionally, the Court opinion shows that once a defendant proves his or her conduct was "authorized" under the meaning of the CSA, the government must then prove beyond a "reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner."[103]

In his concurrence, Justice Alito, partially joined by Justices Thomas and Barrett[104] discussed the new "hybrid" of an element of an offense and the affirmative defense created by the majority.[105] Justice Alito specifically took issue with the idea that the "good faith" instruction is already implied within the language of the CSA.[106] According to Justice Alito, the CSA contains an exception for prescriptions issued in the course of professional practice, which was further described as "when the physician writes prescriptions 'in good faith.'"[107] Justice Alito goes further to discuss the danger of the ruling, and how "it leaves

97. *Id.* ("[I]f knowingly did not modify the fact of nonauthorization . . . the statute 'would[] criminalize a broad range of apparently innocent conduct.'" (quoting Liparota, 471 U.S. at 426)).

98. *Id.* at 2378 (citing United States v. X-Citement Video, 513 U.S. 64, 68 (1994)).

99. *Id.* (quoting *X-Citement Video*, 513 U.S. at 64) (internal quotations omitted).

100. *Id.* (quoting *X-Citement Video*, 513 U.S. at 64).

101. *Id.* (quoting *X-Citement Video*, 513 U.S. at 73).

102. *Id.* at 2375–76.

103. *Id.* at 2376.

104. *See id.* at 2382 (Alito, J., concurring).

105. *Id.* at 2383 ("The consequences of this innovation are hard to foresee, but the result may well be confusion and disruption. That risk is entirely unnecessary.").

106. *Id.*

107. *Id.* (quoting Linder v. United States, 268 U.S. 5, 17–18 (1925)).

prosecutors, defense attorneys, and lower courts in the dark" regarding how many other affirmative defenses might warrant similar treatment.[108] Justice Alito's concurrence is largely based on textualism, focused on the authorization exception.[109] The majority and concurrence are divided upon whether the "knowingly or intentionally" standard actually *applies* to the introductory phrase of the statute.[110]

Justice Alito further deconstructed the majority by criticizing its interpretation of the so-called "*mens rea* canon."[111] Under the mens rea canon, the Court interprets criminal statutes to require a mens rea for each element of an offense "even where 'the most grammatical reading of the statute' does not support that interpretation.'"[112] Justice Alito criticized the majority for finding that the authorization exception qualifies as an element, because it is not expressly listed as such in the statute.[113] Logistically, he also criticized the holding for its practical implications. According to the majority, if the authorization exception is sufficiently analogous to be considered an element of the offense, it would need to be negated by the government in every prosecution under the CSA.[114] However, in Justice Alito's view, this directly contradicts the requirements set forth in § 885, which states that it is not "necessary for the United States to negative any exemption or exception set forth in [the relevant subchapter] . . . in any . . . indictment."[115] Thus, the authorization exception should absolutely not be considered an element of a violation of the CSA.

To contextualize Justice Alito's divergence, the CSA may be analogized to other statutes with authorization exceptions. For example, Section 229 of the Chemical Weapons Convention Implementation Act of 1998 makes it unlawful for any person to "knowingly . . . develop, produce, otherwise acquire, [or] transfer . . . any chemical weapon."[116] Section 229 *also* has a provision exempting certain individuals and agencies, including members of the Armed Forces and any person "who is authorized by law or by an appropriate officer of the United States."[117] The "authorized personnel" provision here is sufficiently analogous to the

108. *Id.*
109. *See generally id.*
110. *See generally id.*
111. *Id.* at 2383–88.
112. *Id.* at 2384 (quoting Rehaif v. United States, 139 S. Ct. 2191, 2197 (2019)).
113. *Id.* at 2385.
114. *Id.* ("So if lack of authorization were an element, it would be necessary to allege that in every § 841(a)(1) indictment.").
115. 21 U.S.C. § 885.
116. The Chemical Weapons Convention Implementation Act of 1998, 18 U.S.C.A § 229 (West).
117. *Id.*

exception in the CSA. To apply Justice Alito's concurrence from *Ruan*, Section 229 would require the Government to negate the status of an authorized individual or agency every time there is an indictment. For both statutory interpretation and logistical purposes, the majority was incorrect in finding the CSA authorization exception sufficiently analogous to an element of a criminal statute.

III. ARGUMENT

This Commentary takes the position that the Eleventh Circuit's decision to employ an objective mens rea standard is proper while the Tenth Circuit's and Supreme Court's decisions allowing a good faith defense for such prosecutions is both incorrect and harmful to physicians. This Commentary will now propose a new statutory framework for the CSA that includes a lower mens rea and a clearly defined framework for the modern course of professional conduct. These proposals, working together, will protect practicing physicians from prosecution without hindering the goal of decreasing illegal opiate distribution.

As Justice Breyer noted in *Ruan,* "our criminal law seeks to punish the 'vicious will.'"[118] In October 2017, the number of opioid deaths became so severe that the United States declared a public health crisis.[119] Accordingly, in cases involving medical personnel egregiously overprescribing opiates, policy warrants the addition of a mens rea of recklessness. Good faith is inherent in the medical profession and thus, requiring its inclusion in a jury instruction in a criminal prosecution for deviating from the standard of care is confusing. Amending the CSA to employ the "reckless" standard, in conjunction with clearly defining "professional standard," will permit Congress to protect medical professionals and hold accountable those who recklessly overprescribe opioids outside of the bounds of acceptable standards of medicine. Finally, the proposed framework will allow the Eleventh Circuit objective standard to be implemented efficiently and without undue confusion.

Upon entering the profession, medical students around the United States vow to "*avoid harm*."[120] Medical professionals promise this *to the best of their ability*.[121] Thus, a good faith defense is not only redundant,

118. *Ruan*, 142 S. Ct. at 2376 (quoting Morissette v. United States, 342 U.S. 246, 251 (1952)).

119. Press Release, Health and Human Services, HHS Secretary Declares Public Health Emergency to Address National Opioid Crisis (Oct. 26, 2017), https://www.gao.gov/products/gao-18-685r.

120. Stacy Weiner, *The Solemn Truth About Medical Oaths*, AAMC (July 10, 2018), https://www.aamc.org/news/solemn-truth-about-medical-oaths.

121. *See id.*

but would prove difficult in application. This problem is clearly demonstrated by the differences in the subjective standard dictated by the Tenth Circuit and the objective standard proposed by the Eleventh Circuit.

A. Policy

The argument for adding recklessness as a mens rea in § 841 is rooted both in law and policy. The legal argument focuses on the practicality of application, and the relationship between the reckless mens rea and the profession. The policy argument is motivated by the relevant data and statistics stemming from opiate use and how it often arises from legal, medicinal use. In the year 2021 alone, there were 106,699 drug overdoses in the United States.[122] Opioids were involved in 75.4% of these deaths, or approximately 80,411 deaths overall.[123] Further, in 2020, opioid dispensing rates were extremely high, allowing for every single person in 3.6% of U.S. counties to have an opioid prescription.[124] Opioid-use disorders, often called "OUDs", are a subset of substance-use disorders, and now account for the "second most common drug use disorder" in the United States.[125] Additionally, about 27% of long-standing opioid abusers receive these drugs directly by prescription.[126]

Individuals also want to hold doctors accountable for overprescribing opiates. Physicians themselves are criticizing the actions of their peers, specifically blaming those that have become "pill mill" doctors.[127] According to a poll by the Associated Press-NORC Center for Public Affairs Research, 46% of polled individuals think doctors and dentists are significantly to blame for the opioid crisis.[128] These statistics point to general support for tightening restrictions on prescription opioids, and

122. *Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/deaths/index.html (Aug. 22, 2023).

123. *Id.*

124. *U.S. Opioid Dispensing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/rxrate-maps/index.html (Dec. 11, 2023).

125. Kelly K. Dineen and James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?,* 48 AM. J.L. & MED. 7, 10 (2016).

126. *Id.* at 11.

127. Ronald Hirsch, *The Opioid Epidemic: It's Time to Place Blame Where It Belongs*, 114 MO. MED. 82, 82 (Mar. 2017) ("[T]here are also what are known as "pill mill" doctors who set up shop, accept cash as the only payment and are willing to prescribe to anyone for any ailment, real or feigned.").

128. Mike Stobbe & Emily Swanson, *AP-NORC Poll: Many Blame Drug Firms for Opioid Crisis*, AP NEWS (Apr. 25, 2019, 10:55 AM), https://apnews.com/article/united-states-health-new-york-ap-top-news-us-news-103530ad684f4941999e99467121b5d6.

holding rogue and careless physicians responsible for distributing these prescriptions.

B. Reconciling the Supreme Court's Categorization of the Authorization Provision

In *Ruan,* the Supreme Court rationalized the application of the "knowingly" mens rea to the authorization provision by categorizing the provision as an element.[129] This holding provides a dangerous precedent for multi-level statutes with similar provisions. Based on this ruling, specific provisions within statutes can be read as separate components, with different levels of mens rea than what the offense mandates.[130]

C. An Ever-Changing Landscape and Confusion Among Jurors

The importance of a clearly defined and applicable criminal standard is also important for jurors. In cases involving a professional standard, it can be incredibly difficult for a juror to place his or herself in the shoes of someone in a profession they have never practiced. The medical profession is, arguably, one of the most difficult as it is constantly developing new and better treatments, which may affect what is considered "the usual course of professional practice." This problem is illustrated by the rise of physician-assisted suicide. In some states, when terminally ill patients are told they will no longer benefit from care, they have the option to medically terminate.[131] As there are both opponents and supporters for this course of treatment, it becomes incredibly difficult to deduce what would legally fall under a "widely accepted" professional course of conduct.

In 1997, an Oregon statute permitting physician-assisted suicide was criticized by members of Congress, who called on the DEA to prosecute physicians under the CSA for their use of the Schedule II drugs involved in the procedure.[132] However, this attempt went nowhere until the appointment of Attorney General John Ashcroft, who attempted to statutorily crack down on physician-assisted suicide in Oregon by declaring that it was *not* in the "usual course of professional practice," as required by the CSA.[133] In a subsequent Supreme Court case, *Gonzales*

129. *See* Ruan v. United States, 142 S. Ct. 2370, 2377 (2022).
130. *See id.*
131. *States Where Medical Aid in Dying is Authorized*, COMPASSION & CHOICES, https://www.compassionandchoices.org/resource/states-or-territories-where-medical-aid-in-dying-is-authorized (last visited Dec. 13, 2023).
132. *See* Gonzales v. Oregon, 546 U.S. 243, 249, 250 (2006).
133. *Id.* at 254, 256.

v. Oregon,[134] the Court reasoned that the text and structure of the CSA demonstrate that Congress did not intend to provide the Oregon attorney general with the power to effect a radical shift in authority from the states to the federal government with respect to defining general standards of medical practice in every locality.[135] The holding of *Gonzalez* emphasized the idea that regulating professional standards is an incredibly difficult task, which is highly fluid amongst many different jurisdictions.[136]

D. The Solution

1. Adopting the Eleventh Circuit Standard of Objectivity

As previously mentioned, one of the major difficulties in navigating defendant–physician prosecution under the CSA has been determining how to judge a defendant's conduct.[137] In his concurrence, Justice Alito, highlights the redundancy of a subjective judgment of good faith, as it is implied within the language of the CSA that doctors act in good faith when prescribing a controlled substance for a "legitimate medical purpose" in the "course of professional conduct."[138] Allowing doctors to escape liability because they believed that their course of treatment was what the patient needed is an incredibly overbroad standard. This standard would effectively allow physicians to escape liability if they saw a patient claiming to be in pain while masking an addiction, all because the doctor had a subjective good faith belief that the pain was genuine.[139] Addressing this same issue from the patient perspective, a higher

134. *Id.* The issue before the Court was whether the Attorney General had the power to determine what was statutorily defined as "a legitimate medical purpose," in the "course of professional practice"— the Court said no.

135. *See id.* at 259.

136. *See id.* at 275.

137. *See supra* Part II.

138. Ruan v. United States, 142 S. Ct. 2370, 2383 (2022) (Alito, J., concurring) (quoting Linder v. United States, 268 U.S. 5, 17–18 (1925)).

139. *See* Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States' Failed Protection of Legitimate Opioid Prescription Under the Controlled Substances Act and South Australia's Alternative Regulatory Approach,* 47 COLUM. J. TRANSNAT'L. L. 210, 224–25 (2008).

> Consequently, even if a patient lied and did not actually experience the pain he alleged, so long as the physician believed the pain was authentic, he issued the narcotic prescription for a legitimate medical purpose. Given science's present inability to measure pain, a subjective inquiry is valuable because it encourages physicians to treat pain complaints as valid, despite the attendant risk that some patients may lie to procure drugs for illegal purposes.

Id.

criminal standard for physician liability could result in increased opioid prescriptions, or act as a disincentive to pursue other courses of treatment. Consequently, the patient, who is in a vulnerable position, is likely to place significant trust in physicians to pursue treatment that will balance efficacy and safety. Moreover, the shield of liability imposed by the subjective standard may truly open the doors to rises in addiction, as feigning pain could facilitate a prescription based on this limited subjective belief by the physician.

Further, objectivity is frequently utilized by both the physician and patient during appointments for pain.[140] On the one hand, patients, if they have the resources, often pursue multiple physicians to get a "second opinion," regarding a diagnosis or a recommended treatment plan.[141] In pursuing second opinions, patients themselves are employing objectivity by those most educated in the medical field, so why can't physicians do the same?

2. Mandatory Education in the Medical Profession

An updated statute must also include a requirement that doctors remain up-to-date on commonly accepted treatment plans that include opiates, and any new methods to identify and address addiction amongst patients. This requirement would enforce federal guidelines imposed by the Center for Disease Control for *mandatory* training courses on evaluating the type of pain that requires an opioid prescription. These training courses would likely mimic similar, albeit local, guidelines for continuing-education requirements for professionals such as lawyers. Fostering a continuous cycle of education for a landscape as dense and scientifically transformative as the medical profession will only further facilitate the generation of alternative treatment plans to avoid resorting to opiate use.

A recurring problem in the fight against the opioid crisis is the lack of mandatory, uniform guidelines. This is not a criticism of local guidelines, but rather a message of support for a more consistent

140. *See* Xiaohan Xu & Yuguang Huang, *Objective Pain Assessment: A Key for the Management of Chronic Pain*, 9 F1000Rsch. 3 (2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6979466/pdf/f1000research-9-22472.pdf (discussing the development of neuroimaging and electrophysiological techniques improving the objective assessment of pain intensity).

141. Kathy Katella, *Can a Second Opinion Make a Difference?* YALE MED. (Jan. 15, 2020), https://www.yalemedicine.org/news/second-opinions. Dr. Anees Chagpar, MBA, MPH, is a breast surgeon and one of many Yale Medicine specialists who provide second opinions on a regular basis. According to Dr, Chagpar, getting second opinions is "just like with any major decision – buying a house or a car or going to college – it's not a bad idea to go to a couple of places to be sure you know what you're getting and why." *Id.*

framework across the country. Suggestions and recommendations can arguably result in a tendency for physicians to use *too much* discretion when determining courses of treatment for their patients. "[M]any physicians regularly ignore federal guidelines, prescribing large quantities of powerful opioid medications even when better treatment options are available."[142] Mandating an informed, research-based national guideline framework for physicians to follow will alleviate this issue, and provide extra protection to doctors if their prescription rates are questioned. Moreover, these federal guidelines would remain a minimum standard for physicians to follow. This is not to say that state and local jurisdictions are precluded from imposing more stringent standards on physicians within the jurisdiction.

3. Mandated Second Opinions For Opiate Prescriptions

Next, the new statutory definition of the professional standard should require a doctor to receive a second opinion from a third-party physician within the same or substantially similar practice area. Second opinions would be encouraged when an initial suggestion for opiate treatment is made. However, the second opinion will be mandated when a physician suggests a prescription dosage above a certain amount, and/or, on more than one occasion. This doctor must remain professionally independent from the initial prescribing physician to ensure maximum objectivity. A second opinion is not a course of action that is unique in the medical field. Various other fields encourage professionals to consult with their peers and superiors to achieve the best result for their employers or clients, and to avoid potential malpractice. For example, attorneys are encouraged to consult with members of their firms when faced with concerns about their compliance with the Rules of Professional Conduct.[143] Although this example is much less burdensome than this proposed mandate, it remains an important point to demonstrate that second opinions are not a foreign idea to professional practices. Moreover, larger firms often hire their own in-house counsel to

142. Brian Mann, *Doctors and Dentists Still Flooding the U.S with Opioid Prescriptions*, NAT'L PUB. RADIO (July 17, 2020, 8:27 AM), https://www.npr.org/2020/07/17/887590699/doctors-and-dentists-still-flooding-u-s-with-opioid-prescriptions ("Despite widespread devastation caused by America's opioid epidemic, an investigation by NPR found that doctors and other health care providers still prescribe highly addictive pain medications at rates widely considered unsafe.").

143. Richard D. Hendlin, *The Ethical Implications of Lawyers Informally Consulting Other Lawyers for Ethics Advice,* FOR THE RECORD (Nov. 17, 2020), https://blawg401.com/the-ethical-implications-of-lawyers-informally-consulting-other-lawyers-for-ethics-advice/.

provide advice in the face of potential ethics issues.[144] This proposal benefits patients and doctors. First, if the independent physician agrees with the diagnosis and treatment plan of the original doctor, the patient will have more confidence in the treatment plan. Additionally, by receiving approval on a treatment plan by an independent physician, the prescribing doctor will demonstrate that this treatment plan likely has a greater chance of falling within the "usual course of professional conduct."

In the event that the second opinion returns a different conclusion, both original doctor and patient may choose to pursue an additional opinion, or pursue one of the proposed courses of treatment. The purpose of the second opinion is to minimize any rash decisions on the part of both patient and doctor and prevent any dependance on an opiate-based treatment without consideration of alternative medicine. Additionally, an inconsistent second opinion will illuminate any probability that the original doctor's conduct is falling outside the of the commonly accepted "professional standard."

Next, as demonstrated by state guidelines, the new federal guidelines will include a refill threshold based on either the quantity of the prescription, or the frequency in which the patient is refilling the prescription, that triggers medial review for competence before charging. By limiting both the amount given to patients at once, and the ability to seek more opiates, doctors will be able to evaluate the necessity of the prescription for pain and spot potential abuse before it leads to intense addiction. Time limits on prescriptions are fairly common nationwide, with twenty-three states and the District of Columbia[145] enacting statutes with different limitations.[146] In 2021, for the seventh year in a row,[147] Alabama experienced a decrease in the number of opioid prescriptions statewide, a statistic that is attributed to an increase in

144. *Id.*

145. Public Health Law Program*, Prescription Drug Time and Dosage Limit Laws,* CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/phlp/docs/menu_prescriptionlimits.pdf (describing state and local dosage time limits for physicians prescribing or dispensing controlled substances.)

146. *Id.* For example, the Missouri statute mandates supply limits for Schedule II Controlled Substances to a thirty-day supply. *Id.* (quoting MO. ANN. STAT. § 195.080 (1987)). Even more stringent is California, with a statute mandating that "a practitioner . . . may dispense directly to an ultimate user a controlled substance classified Schedule II in an amount *not to exceed* a [seventy-two]-hour supply for the patient." Public Health Law Program*, supra* note 147 (quoting CAL. HEALTH & SAFETY CODE § 11158 (eff. date unclear, 1976—1980)).

147. *See Opioid Prescriptions Decrease for 10th Consecutive Year*, AM. MED. ASS'N (2021), https://end-overdose-epidemic.org/wp-content/uploads/2021/09/IQVIA-opioid-prescription-trends-chart-Sept-2021-FINAL.pdf.

opiate education, drug monitoring programs, and tougher laws.[148] Although these state statutes have demonstrated success in combating the crisis on a local level, it is the lack of uniformity among states that has created difficulties in regulation prompting the need for *mandatory* federal guidelines to set a *minimum* standard for medical professionals to follow.

4. "Red Flag Laws" to Narrow the Definition of "Legitimate Medical Purpose"

Another major issue with the CSA is the lack of defining factors for the term "legitimate medical purpose." As with the "professional standard" dilemma, this vague hyper-discretionary goal for medical prescriptions leaves doctors without proper guidance. It may seem redundant, as the goal of a medical professional should always be alleviating a patient's pain, but a large portion of jurisprudence on prosecuting doctors turns on this terminology, or lack thereof.[149] Rather than further restricting doctors by listing specific instances that *are* "legitimate," the CSA can approach the issue by explaining exactly what *not* to do.[150] The case of *United States v. Moore* displays a perfect example of how these red flag laws should be used.[151] In hindsight, Moore's behavior was so egregious that it begs the question of why criminal liability was ever questioned. However, this exact behavior can be used as a starting point to enumerate exactly what courses of conduct physicians, and their practices, should not engage in, unless they are seeking to invite investigation.

There must also be specific guidelines to follow when patients suffer from chronic pain and terminal illness. Such guidelines would both protect the medical professional from failing to identify potential misuse under the guise of chronic pain and ensure that patients who are genuinely in need are able to access the necessary medicine and care.

148. Ashley Bowerman, *Report: Opioid Prescriptions down in Alabama for 7th consecutive year*, WSFA 12 NEWS, (Sept. 21, 2021, 11:03 PM), https://www.wsfa.com/2021/09/22/report-opioid-prescriptions-down-alabama-7th-consecutive-year/.

149. *See generally* Gonzales v. Oregon, 546 U.S. 243 (2006); Ruan v. United States, 142 S. Ct. 2370 (2022).

150. By enumerating medical "red flags," the new statutory framework would provide doctors with what constitutes problematic behavior, while also facilitating a quick response time for law enforcement when these "flags" are demonstrated. Jacob C. Hanley, *Illegitimate Medical Purpose: Resolving the Fundamental Flaw in Criminal Prosecutions Involving Physicians Charged with Overprescribing Prescription Opioids,* 58 DUQ. L. REV. 229, 230 (2020).

151. *See generally* United States v. Moore, 423 U.S. 122 (1975).

Guidelines could include mandatory check-ins with those frequently using opiates, state or federally sanctioned pain management therapy, and primary access to alternative forms of care.

5. Punishing Physician Deviation From the Proposed Statute with a Lower *Mens Rea*

With the Eleventh Circuit's objective standard of evaluation,[152] and this Commentary's proposed new statutory framework in play, the next step would be adding "recklessly" to the current mens rea of "knowingly" or "intentionally." Since *Moore* opened the door for physician-defendant prosecution under the CSA,[153] state officials and the federal government have increased efforts to hold overprescribing doctors accountable for their actions.[154] A clearly enumerated course of professional conduct will strike a balance between allowing doctors to practice without fear of prosecution, while also facilitating a higher level of accountability among physicians. The current standard for prosecuting medical professionals under the CSA is incredibly high, which adversely allows reckless and careless prescribers to go unpunished. Emphasizing both judicial and medical objectivity in the face the already ambiguous field of medicine is the only way to effectively remedy the tension between the opioid crisis and over-prescription by medical professionals.

IV. CONCLUSION

Effectively combating the opioid crisis is a multifaceted, multi-governmental task that will not be solved overnight. In addressing the issue, it is vital to tighten restrictions on doctors, while simultaneously providing clarity for the more ambiguous portions of the statute which have become the focus of these criminal prosecutions. Physicians deserve the opportunity to continue advocating and treating their patients without fearing federal criminal prosecution, and patients suffering from chronic and unmanageable pain deserve the resources and treatment plans they require to alleviate their conditions.

152. *See supra* Section II,A.

153. *See generally* United States v. Moore, 423 U.S. 122 (1975).

154. *See, e.g.*, *Justice Department Announces Enforcement Action Charging 12 Medical Professionals with Opioid Distribution Offenses*, U.S. DEP'T OF JUST. (May 4, 2022), https://www.justice.gov/opa/pr/justice-department-announces-enforcement-action-charging-12-medical-professionals-opioid; *Doctor Convicted of Illegally Prescribing Opioids to Patients*, U.S. DRUG ENF'T ADMIN. (Nov. 19, 2021), https://www.dea.gov/press-releases/2021/11/19/doctor-convicted-illegally-prescribing-opioids-patients.

The Supreme Court's *Ruan* decision and the role of a "good faith" belief is flawed, but not beyond repair. The implementation of a new statutory framework will minimize much of the confusion regarding a doctor's subjective mindset and their professional course of conduct.