Paving a Path to Justice: Examining the Implications of the *Ruan v. United States* Decision on the Opioid Crisis [Ruan v. United States, 142 S. Ct. 2370 (2022)]

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The Controlled Substances Act places stringent restrictions on prescribing controlled substances, such as opiates, and subjects doctors to criminal prosecution for violating those restrictions. In Ruan v. United States, however, the Court held that a doctor does not violate the Controlled Substances Act unless the government can prove he knew his conduct fell outside an exception for prescriptions authorized under related regulations. These exceptions allow doctors to prescribe controlled substances following their professional discretion.

In short, this decision is vital for both healthcare providers and patients who rely on prescriptions for controlled substances to relieve pain. For healthcare providers, the holding provides much-needed clarity about when they may prescribe controlled substances without fear of criminal prosecution. This clarity will help them continue providing needed care to patients without unnecessarily burdening themselves with worry about the threat of criminal prosecution. For patients, the decision means they can continue relying on their doctor's prescription for a controlled substance to relieve pain without fear their doctor may be criminally prosecuted.

I. INTRODUCTION

The United States opioid epidemic is one of the country's most pressing public health issues, with powerful and long-lasting consequences for individuals, families, and communities.[1] Courts and lawmakers nationwide are weighing in on this crisis by examining legal tools for prosecuting those involved or holding them liable.[2] The Controlled

1. *Understanding the Opioid Overdose Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/opioids/basics/epidemic.html [https://perma.cc/U277-ZGP5] (last visited Sept. 30, 2023); *see generally* Jennifer Lyden & Ingrid A. Binswanger, *The United States Opioid Epidemic*, 43 SEMINS. PERINATOLOGY 123 (2019) (discussing the United States ("U.S.") opioid epidemic as a national crisis, with rising overdoses linked to heroin and illicitly made fentanyl).

2. *See generally* SEAN E. GOODISON, MICHAEL J. D. VERMEER, JEREMY D. BARNUM, DULANI WOODS, & BRIAN A. JACKSON, RAND CORP., LAW ENFORCEMENT EFFORTS TO FIGHT THE OPIOID CRISIS: CONVENING POLICE LEADERS, MULTIDISCIPLINARY PARTNERS, AND RESEARCHERS TO

Substances Act ("CSA") places stringent restrictions on prescribing controlled substances, such as opiates, and subjects doctors to criminal prosecution for violating those restrictions.[3] The legal ramifications of medical professionals' responsibilities in diagnosing and treating pain and opioid addiction have presented countless challenges to patients and healthcare providers.[4]

That said, the Supreme Court's recent decision in *Ruan v. United States* recasts how legal responsibility will be understood in this ongoing battle against opioids.[5] The Court held that a doctor violates the CSA only if the government can prove he knew his conduct fell outside an exception for prescriptions authorized under related regulations—exceptions that let doctors prescribe controlled substances following their professional discretion.[6]

The implications of the clarified decision going forward are significant as it has two main benefits: (1) it protects doctors who act in good faith, and (2) it makes sure patients receive necessary pain relief.[7] The Court held that doctors can prescribe controlled substances under the CSA if they believed their prescription practices were lawful and acted in good faith—the government bears the burden of proving beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized way.[8] This safeguard protects doctors making professional judgments when prescribing controlled substances and prevents false convictions based on government disagreements with medical assessments.[9] It also provides

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IDENTIFY PROMISING PRACTICES AND TO INFORM A RESEARCH AGENDA (2019). The National Institute for Justice (NIJ), in collaboration with RAND Corporation and the Police Executive Research Forum (PERF) organized a two-day event in September 2018. The event aimed to gather experts in public safety and public health to identify effective strategies and prioritize research for combating the opioid crisis). *See also* Brian Krans, *More 'Pill Mill' Doctors Prosecuted Amid Opioid Epidemic*, HEALTHLINE (Oct. 16, 2019), https://www.healthline.com/health-news/pill-mill-doctors-prosecuted-amid-opioid-epidemic.

3. Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801–971.

4. *See generally* Jacob Sullum, *America's War on Pain Pills Is Killing Addicts and Leaving Patients in Agony*, REASON, Apr. 2018, https://reason.com/2018/03/08/americas-war-on-pain-pills-is/ (discussing the history of the war on opioids and the patient fallout left in its wake); *see also* Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' 'Bad Law' Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 999–1000 (2009) (explaining the fear of criminal scrutiny, including how the "penalties of the process" drive some practitioners away from the patients most in need of care).

5. *See* Ruan v. United States, 142 S. Ct. 2370 (2022).

6. *See id.* at 2375; 21 U.S.C § 841(a)(1) (individuals with state licensure for medical practice or any other prescriptive authority are permitted to dispense controlled substances upon obtaining a Certificate of Registration (COR) from the Attorney General and Drug Enforcement Administration ("DEA")); 21 U.S.C. §§ 822(a); § 823(f)); 21 C.F.R. § 1306.03 (1997).

7. *See Ruan*, 142 S. Ct. at 2375; *see also* 21 C.F.R. § 1306.04(a) (2020).

8. *Ruan*, 142 S. Ct. at 2376; *see also* § 1306.04(a).

9. *See* Christine Vestal, *Rapid Opioid Cutoff Is Risky Too, Feds Warn*, STATELINE (May 21, 2019, 12:00 AM), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/05/21/rapid-opioid-cutoff-is-risky-too-feds-warn [https://perma.cc/C35L-FWWK] (explaining that while some changes in medication occurred moderately, many practitioners involuntarily and inappropriately

critical protection, allowing doctors to keep prescribing controlled substances in good faith without worrying about being convicted based on the government's subjective interpretation of applicable regulations.[10] In addition, this decision will reassure patients who rely on controlled substance prescriptions to manage their pain. The ruling also helps clarify how healthcare providers should approach the management of opioid use disorder ("OUD") within controlled substances regulations and criminal law.[11]

II. BACKGROUND

A. Case Description

The Drug Enforcement Administration's ("DEA") "Operation Pilluted," which began in May 2015, led to the raid of two pain clinics in Mobile, Alabama, directed by physicians Dr. Xiulu Ruan and Dr. Shakeel Kahn.[12] This operation was part of a nationwide fifteen-month

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tapered doses without considering patients' welfare, resulting in death and agony that spurred warnings from both the Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC")); *see also* Jackie Yenerall & Melinda B. Buntin, *Prescriber Responses to a Pain Clinic Law: Cease or Modify?*, 206 DRUG & ALCOHOL DEPENDENCE 1, 2 (2020) (discussing how twenty-four percent of practitioners categorically refused to treat patients and stopped prescribing altogether, without regard for patient care following state law changes).

10. *See* Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm,* 67 U. KAN. L. REV. 961, 1001–11 (2019) (explaining the hasty retreat from treating chronic pain with opioids and the desertion of many patients in need as the opioid crisis became widely reported creating intense focus on prescription opioids for long-term pain management and the 'unsavory' physicians who prescribed them). Subsequently, legislators put into action new regulations, enforcement measures, and administrative advice. *Id.* at 971–73. After the CDC established strict recommendations to limit opioid prescribing—which was accorded the force of legal mandate—federal agencies, state regulatory agencies and legislatures, insurance companies, and provider groups pushed their own regulations further downward in order to adhere to the CDC's mandates. *Id.* at 968, 975–76. *See* John J. Coleman, *Monitoring Prescriptions, Third Party Healthcare Payers, Prescription Benefit Managers, and Private Sector Policy Options*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN HISTORY, POLICY, AND TREATMENT 39 (John F. Peppin, John J. Coleman, Kelly K. Dineen & Adam J. Ruggles eds., 2018).

11. *See* Michael C. Barnes, Taylor J. Kelly, & Christopher M. Piemonte, *Demanding Better: A Case for Increased Funding and Involvement of State Medical Boards in Response to America's Drug Abuse Crisis*, 106 J. MED. REGUL. 3, 8 (2020) (discussing how the investigation and prosecution of prescribing physicians "has compromised access to treatment for individuals with legitimate medical needs. Enforcement efforts have created a chilling effect on prescribers . . . who are decreasing and altogether ceasing their prescribing out of fear of investigation and prosecution"). The DEA's tactics can be intimidating to many physicians, and many physicians believe they are treated unfairly. NAT'L ACADS. OF SCIS., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES 120–121 (Alan I. Leshner & Michelle Mancher eds., 2019). The agency has taken drastic steps recently such as increasing raids, audits, and criminal investigations which only add to the apprehension caused by their surveillance activities. *Id.* at 121.

12. Amber Stegall, *Operation Pilluted Nets 280 Individuals, 20 Doctors and Pharmacists in 4-State Drug Bust,* WAFB (May 20, 2015, 9:53 PM), https://www.wafb.com/story/29117188/operation-pilluted-nets-280-individuals-20-doctors-and-pharmacists-in-4-state-drug-bust/; *see generally* Khary K. Rigg, Samantha J. March, & James A. Inciardi, *Prescription Drug Abuse & Diversion: Role of the Pain*

investigation into illegal prescribing practices and diversion crimes involving pill mills, pharmacies, doctors, pharmacists, nurse practitioners, and physician assistants—resulting in 280 arrests.[13]

Because of Operation Pilluted, Dr. Xiulu Ruan and Dr. Shakeel Kahn, licensed medical practitioners authorized to prescribe controlled substances, were charged with violating 21 U.S.C. § 841.[14] Section 841 explicitly prohibits anyone from knowingly or intentionally manufacturing, distributing, or dispensing illegal drugs except as authorized by a licensed medical practitioner under a two-prong test which requires: (1) that the doctor's actions were for a "legitimate medical purpose;" and (2) "[within the] usual course of his professional practice."[15]

At the core of Dr. Ruan and Dr. Kahn's separate district court trials was whether they could be convicted of distributing controlled substances without the mens rea stated in Section 841.[16] Although the district courts allowed mentioning "good faith" in the jury instructions, they reminded the respective juries that a violation of 21 U.S.C. § 841 occurred if a doctor did not meet either requirement of the two-prong test.[17] Both defendants objected to the jury instructions regarding mens rea issued at their trials, yet both were ultimately found guilty of illegally prescribing medication.[18]

Following their convictions, Drs. Ruan and Kahn filed appeals with the Tenth and Eleventh Circuits, challenging their convictions on the grounds the district court erred in denying their proposed jury instruction about a "good faith" defense.[19] The circuit court of appeals determined the district court had not abused its discretion by refusing to present the defendants' suggested "good faith" instruction to the jury.[20] It also affirmed it accurately explained criminal violations under the CSA.[21]

Drs. Ruan and Kahn then filed a Petition for a Writ of Certiorari with the Supreme Court, consolidating their cases.[22] Their case is the first time the Supreme Court has addressed a medical provider's violations of 21 U.S.C. § 841 in nearly five decades.[23] The issue before the Supreme Court

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Clinic, 40 J. DRUG ISSUES 681 (2010) (discussing the misuse and diversion of prescription drugs, including "pill mills," South Florida clinics' role in the illegal trade of painkillers, drug policies on the United States-Mexican border, and increasing deaths from opioids).

13. Stegall, *supra* note 12; *see generally* Rigg et al., *supra* note 12.
14. *Ruan*, 142 S. Ct. at 2375.
15. *Id.* (quoting 21 CFR § 1306.04(a) (2020)).
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.* at 2376.
20. *Id.*
21. *Id.*
22. *Id.*
23. *See United States v. Moore, 423 U.S. 122, 124, 138–39 (1975) (*The judge "instructed the jury that it had to find 'beyond a reasonable doubt that a physician, who knowingly or intentionally, did

in *Ruan* was whether a doctor alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under 21 U.S.C. § 841(a)(1) even if they, in good faith, reasonably believed or subjectively knew their prescriptions fell within the usual course of professional practice.[24]

B. Legal Background

1. The Controlled Substances Act

The CSA is a federal law that regulates the manufacture, distribution, and possession of certain drugs in the United States.[25] The CSA classifies drugs into five categories, or schedules, based on their potential for abuse and medicinal value.[26] Schedule I drugs have the highest potential for abuse and no accepted legitimate medical use.[27] Schedule V drugs have the lowest potential for abuse and the most accepted medical use.[28] In sum, the manufacturing, distributing, or possessing drugs not listed in the five schedules is illegal under the CSA.[29] Even still, the CSA includes several exceptions, including an exception for prescriptions written by authorized doctors.[30] This exception allows doctors to prescribe drugs in Schedules II–V for legitimate medical purposes.[31]

The CSA lets the federal government crackdown on drug trafficking and distribution networks outside those exceptions.[32] It also enables the government to impose strict regulations on prescription drugs, including

dispense or distribute [methadone] by prescription, did so *other than in good faith* for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.'" (emphasis added) (internal citations omitted)); *see* Julia B. MacDonald, *"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, 213–16 (2020) (discussing whether legitimate medical purpose is an element that must be included in indictments); *see* Ronald W. Chapman II, Nat'l Ass'n of Crim. Def. Laws., *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, THE CHAMPION MAG., Sept.–Oct. 2019, at 40 (discussing how legitimate medical purpose serves as a dividing line between criminality and prescribing negligence). *But see, e.g.*, United States v. Nelson, 383 F.3d 1227, 1231 (10th Cir. 2004) ("It is difficult to imagine the circumstances in which a practitioner could have prescribed controlled substances within the usual course of medical practice but without a legitimate medical purpose.").

24. *Ruan*, 142 S. Ct. at 2375–76.

25. *See* CSA, 21 U.S.C. § 821; *Controlled Substance Schedules*, U.S. DRUG ENF'T ADMIN.: DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/schedules/index.html [https://perma.cc/SXK4-CXVB] (last visited Sept. 30, 2023).

26. § 812(b).

27. § 812(b)(1).

28. § 812(b)(5).

29. § 841(a).

30. §§ 829(a)–(f).

31. *Id.*

32. Trafficking provisions impose penalties for the illicit production, distribution, and possession of controlled substances outside the legal registration system. *See* §§ 841–865.

doctor oversight and patient registration requirements.[33] Although the CSA helps law enforcement, it has been controversial since its enactment in 1970, with critics arguing it impedes research into potentially beneficial new drugs and fuels the War on Drugs.[34] Still, supporters argue the CSA is necessary to protect public health and safety.[35]

In that regard, doctors who violate the CSA by prescribing illegal drugs can face felony charges.[36] The punishments for felonies are typically reserved for intentional wrongdoing.[37] Therefore, courts presume that Congress intended defendants to have a guilty state of mind when interpreting and enforcing criminal statutes.[38] To secure a conviction against a doctor charged with CSA violations, the government must show the individual knew their actions were illegal.[39] This presumption of a guilty state of mind is known as the mens rea requirement.[40]

2. The Opioid Pandemic

The United States Centers for Disease Control and Prevention ("CDC") declared the opioid epidemic doctor-driven, so law enforcement began addressing doctors excessively prescribing drugs such as painkillers.[41] As a result, most Americans commonly believe that our present "opioid crisis" started around 1990 with the inception of OxyContin.[42] The accepted explanation is that deceptive marketing spurred

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33. The Act serves two primary purposes: safeguarding the public against the risks associated with controlled substances while also guaranteeing access to these substances for legitimate use—accomplished by imposing registration requirements and reporting obligations, which are designed to thwart the diversion and misuse of controlled substances. *See* §§ 821–832.

34. Sullum, *supra* note 4; Johnson, *supra* note 4 at 1014 (explaining that "[d]octors do not trust the law or the legal system to be fair, predictable, or appropriate as it applies to medical practice").

35. *See generally* Jacob Gross & Debra B. Gordon, *The Strengths and Weaknesses of Current US Policy to Address Pain*, 109 AM. J. PUB. HEALTH 66 (2019) (addressing pain as a public health concern that requires comprehensive policies at national and local levels and discussing the objective as the need to strike a delicate balance between inadequate and ineffective pain treatment while also acknowledging the unintended consequences of escalating opioid use that harms public well-being).

36. *The Controlled Substances Act*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/csa [https://perma.cc/NVC8-AZNP] (last visited Sept. 30, 2023).

37. Ruan v. United States, 142 S. Ct. 2370, 2382 (2022).

38. *Id.*

39. *Id.*

40. *See id.* at 2377.

41. Robert Lowes, *CDC Issues Opioid Guidelines for 'Doctor-Driven' Epidemic*, MEDSCAPE MED. NEWS (Mar. 15, 2016), https://www.medscape.com/viewarticle/860452; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 1; *Law Enforcement Looks to Research to Help Fight the Opioid Crisis,* NAT'L INST. OF JUST. (Nov. 25, 2019), https://nij.ojp.gov/topics/articles/law-enforcement-looks-research-help-fight-opioid-crisis [https://perma.cc/WV37-X8MQ].

42. *See* Sullum, supra note 4 ("Contrary to the impression left by most press coverage of the issue, opioid-related deaths do not usually involve drug-naive patients who accidentally get hooked while being treated for pain. Instead, they usually involve people with histories of substance abuse and psychological problems who use multiple drugs, not just opioids."); see *also* Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain*

careless prescribing, leading to unfathomable opioid-related deaths and extreme patient dependency—dire circumstances President Donald Trump labeled a health disaster.[43] But the rise in opioid overdose deaths can be charted in "three distinct waves."[44] While the first wave did begin in the 1990s with increased prescription opioids, the second wave started in 2010 with an increase in heroin overdose deaths, followed by a third wave in 2013 with increased overdose deaths caused mainly by the illicitly manufactured synthetic opioid fentanyl.[45]

To reduce the growing rate of drug overdose in America, local, state, and federal agencies seek these 'pill mills' that supply opioids without proper authorization or prescription oversight.[46] Pill mills are distinguished from legitimate pain specialists by their patient volume, the number of prescriptions they write, and limited medical screenings.[47] These shady pill mills mostly rely on cash payments only.[48] Besides criminal prosecutions, the United States government also sues the doctors who run pill mills for defrauding federal healthcare programs like Medicare and Medicaid.[49]

Simultaneously, though the medical field acknowledges the issues with pill mills, doctors express anxiety that criminalizing medical cases could result in a "chilling effect" in which well-intentioned doctors may be reluctant to prescribe medication for legitimate patient needs.[50] Additionally, pain specialists criticize the CDC's 2016 prescription guidelines, asserting that it seems to ask "physicians to make prescribing choices based on public health concerns . . . rather than the most appropriate course of therapy for the individual patient."[51] Adversaries also argue that the prevailing notion of attributing addiction and mortality to pain management has led to strict measures on prescription opioids, hurting the

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Adequately While Avoiding Legal Sanction?, 42 A. J. L. & MED. 1, 21 (2016); Lyden & Binswanger, *supra* note 1; CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 1.

43. Joanna Walters, *America's Opioid Crisis: How Prescription Drugs Sparked a National Trauma*, THE GUARDIAN (Oct. 25, 2017, 12:00 AM), https://www.theguardian.com/us-news/2017/oct/25/americas-opioid-crisis-how-prescription-drugs-sparked-a-national-trauma; Krans, *supra* note 2 (stating that the CDC says the opioid epidemic is "doctor driven"). *But see* RACHEL N. LIPARI & ARTHUR HUGHES, THE SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., HOW PEOPLE OBTAIN THE PRESCRIPTION PAIN RELIEVERS THEY MISUSE Fig.1 (Jan. 12, 2017), https://www.samhsa.gov/data/sites/default/files/report_2686/ShortReport-2686.html [https://perma.cc/W4SW-M4QA].

44. CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 1.

45. *Id.*

46. Krans, *supra* note 2.

47. *Id.*

48. *Id.*

49. *Id.*

50. *See generally* Sullum, *supra* note 4 (discussing the history of the war on opioids and the patient fallout left in its wake); Johnson, *supra* note 4, at 1013–14.

51. Joseph V. Pergolizzi Jr., Robert B. Raffa, Gianpietro Zampogna, Frank Breve, Robert Colucci, William K. Schmidt & Jo Ann LeQuang, *Comments and Suggestions from Pain Specialists Regarding the CDC's Proposed Opioid Guidelines*, 16 PAIN PRAC. 794, 798 (2016).

well-being of susceptible individuals coping with persistent pain and those receiving end-of-life assistance.[52]

III. COURT'S DECISION

A. To Convict Doctors Under the Controlled Substances Act, Proof of Subjective Intent to Do Wrong is Necessary

In *Ruan*, the Supreme Court addressed a challenge to jury instructions in prosecuting doctors for allegedly prescribing drugs contrary to medical practice guidelines established by the CSA.[53] The guidelines allow registered doctors to act within their professional scope to dispense controlled substances only for legitimate medicinal purposes.[54] There was an intense debate over whether a doctor's intent should be subjectively considered when prescribing medication under the guidelines.[55] Individuals charged and other supporters of this viewpoint argued for the long-standing legal presumption of mens rea involved in criminal offenses.[56] The government opposed this sentiment, arguing for an objective standard per the act, which "does not permit a physician to simply decide for himself that any manner or volume of drug distribution is 'medicine.'"[57] The government also contended that because the phrase "except as authorized" preceded "knowingly" in the CSA, there is no need for a mens rea requirement for any exceptions[58] and that the CSA's exception for authorized prescriptions is not an element of the crime.[59] Therefore, the government argued it was an affirmative defense—like insanity or entrapment—and one the defendant must prove to defeat charges.[60] But in a critical part of the opinion, the Court found that the statutory exception was "sufficiently like an element . . . to warrant similar legal treatment."[61] The Court explained that an exception in a criminal statute that functions similarly to an element of the crime should be treated

52. Sullum, *supra* note 4; Johnson, *supra* note 4, at 982–83.
53. Ruan v. United States, 142 S. Ct. 2370, 2375 (2022).
54. *Id.* at 2375, 2388; U.S. DRUG ENF'T ADMIN., *supra* note 36.
55. *Ruan*, 142 S. Ct. at 2376.
56. *Id.*; Brief for Professors of Health Law & Policy as Amicus Curiae Supporting Petitioner at 7–11, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410).
57. Abbe R. Gluck, *Amid Overdose Crisis, Court Will Weigh Physician Intent in "Pill Mill" Prosecutions and More Under the Controlled Substances Act*, SCOTUSBLOG (Feb. 28, 2022, 10:02 AM), https://www.scotusblog.com/2022/02/amid-overdose-crisis-court-will-weigh-physician-intent-in-pill-mill-prosecutions-and-more-under-the-controlled-substances-act/ [https://perma.cc/B9RA-E9LQ].
58. *Id.*
59. *Ruan*, 142 S. Ct. at 2379.
60. *See id.* at 2379–80.
61. *Id.* at 2380.

like an element—with the government rather than the defendant—bearing the burden of proof.[62] Therefore, the Court found the "knowingly or intentionally" mens rea standard applied to the "except as authorized" clause of 21 U.S.C. § 841.[63]

As a result, the Court concluded that previous cases upholding the convictions of doctors for dispensing controlled substances without authorization were based on an erroneous interpretation of the knowledge requirement in § 841.[64] This knowledge requirement means that in a Section 841 prosecution in which a defendant met his burden of production under 21 U.S.C. § 885, the government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized way.[65]

On that basis, the Court ruled for the petitioning doctors' position, with Justice Stephen Breyer authoring an opinion that quickly dismissed arguments based on semantic reasoning—strongly emphasizing a criminal culpability requirement when determining guilty parties.[66] He underscored the legal footing this mens rea distinction relies on, which has been long-standing in common law.[67] Defendants who present evidence of being "authorized" to dispense controlled substances are often doctors who prescribe drugs through valid prescriptions.[68] Justice Breyer explained that typically, we do not consider such dispensations inherently illegitimate, "we expect, and indeed usually want, doctors to prescribe the medications that their patients need."[69] He emphasized that when prosecuting under Section 841, the misconduct of a doctor is determined based on the issuance of an "unauthorized" prescription rather than the act of dispensing itself, and that "authorization plays a 'crucial' role in separating innocent conduct from wrongful conduct."[70] The cases were remanded on that basis so juries could access updated instructions under the new criteria.[71]

In contrast, in the concurrence, Justice Alito's stance differs vastly from that of his colleagues; though arriving at a similar conclusion, he believes it is unnecessary to presume mens rea or place on the government any burden relating to whether an exception exists.[72] Justice Alito questioned the legitimacy of the majority's use of the mens rea cannon when

62. *Id.* at 2380–81.
63. *Id.* at 2382.
64. *Id.*
65. *Id.* at 2380–81.
66. *Id.* at 2376–77.
67. *Id.* at 2377.
68. *Id.*
69. *Id.*
70. *See id.* at 2382 (quoting United States v. X-Citement Video, Inc., 513 U.S. 64, 73 (1994)).
71. *Id.*
72. *Id.* at 2383–84 (Alito, J., concurring).

its use "allows courts to ignore obvious congressional intent . . . it is Congress that has the power to define the elements of criminal offenses, not the federal courts."[73] Unlike the majority opinion, Justice Alito based his analysis on long-standing precedent from existing alcohol and narcotics laws.[74] He drew on the Harrison Narcotics Act of 1914 to support an evaluation standard requiring defendants to affirmatively show their "good faith" when dispensing medicine to receive a legal exception.[75] Justice Alito argued that should they fall short of this benchmark, it is incumbent on the government's evidence alone—under only a preponderance of the evidence standard, not a beyond reasonable doubt standard—to disprove such individuals of authorization defenses.[76]

IV. COMMENTARY

In its unanimous decision, the Court affirmed long-standing criminal law presumptions requiring mens rea and upheld doctor discretion in an emotional victory for medical professionals and chronic pain patients.[77] This pivotal ruling carries great weight amid the ongoing opioid epidemic in America. It protects healthcare providers who prescribe necessary treatments to improve their patients' well-being, alleviating concerns surrounding potential legal repercussions.[78] Strikingly, both parties agreed the standard of proof should consider subjective perspectives when determining whether medical professionals have contravened the CSA.[79]

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73. *Id.* at 2385 n.* (second footnote on page).

74. *Id.* at 2388.

75. *Id.* at 2383.

76. *Id.* at 2387.

77. *Id.*; Bret Kelman, *Doctors Rush to Use Supreme Court Ruling to Escape Opioid Charges*, KFF HEALTH NEWS, (Sept. 19, 2022), https://kffhealthnews.org/news/article/opioid-prescribing-doctors-use-supreme-court-ruling-to-escape-charges/ [https://perma.cc/XL8F-A4NP]; Alexander Lekhtman, *Win for Pain Patients as SCOTUS Cuts DEA's Power to Persecute Prescribers*, FILTER (June 28, 2022), https://filtermag.org/supreme-court-pain-dea/ [https://perma.cc/H7EF-V39X]; *see also* Jacob Sullum, *SCOTUS Rules that Doctors Who Write Prescriptions in Good Faith Can't Be Convicted of Drug Trafficking*, REASON (June 27, 2022), https://reason.com/2022/06/27/scotus-rules-that-doctors-who-write-prescriptions-in-good-faith-cant-be-convicted-of-drug-trafficking ("The unanimous decision will rein in prosecutions that have long had a chilling effect on pain treatment.").

78. *See generally* Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants,* 108 AMER. J. PUB. HEALTH 182 (2018). Making decisions regarding the prescription of controlled substances is one of the most difficult tasks within medicine, particularly in light of today's opioid crisis. *Id.* at 182–83. Despite this, research indicates opioids are not solely responsible for, nor even a major contributor to, current overdose epidemics. *Id.* at 183–84.

79. *See Ruan*, 142 S. Ct. at 2382.

A. Moving Forward in Good Faith

The implications of the decision requiring mens rea going forward are significant.[80] In Justice Alito's remarks about mens rea, he delved into the meaning of good faith, noting its stricter nature than the common distinction separating negligence from malpractice.[81] He explained that acting in good faith as a doctor does not always involve acting like a good doctor but adhering to objective guidelines within professional medical practice.[82] He wrote to act in good faith: "'as a physician' does not invariably mean acting as a *good* physician, as an objective understanding of the 'in the course of professional practice' standard would suggest."[83] Despite a doctor's careless or even reckless errors in prescribing medicine, they are still technically "acting as a doctor—[they are] simply acting as a *bad doctor*."[84]

To that end, this decision applies well beyond the CSA and challenges how many other exceptions or affirmative defenses in other statutes may require the same treatment. The intersection of complex regulatory frameworks and criminal law, as observed in cases like *Ruan*, can create perplexity and vagueness. That said, this intricacy could result in individuals being indicted for violating regulations they are unaware of and exacerbate the trend of over-criminalization. Criminal law also exacerbates this problem, as it is often used to enforce complex regulatory schemes. Thus, a law that criminalizes a doctor for making a mistake in interpreting a regulation or relying on their clinical judgment can discourage activities beneficial to society and is unjust.

Doctors and other healthcare providers have long been plagued by regulatory crimes that involve highly technical rules and exceptions, turning on complex questions of intent and medical judgment.[85] These regulatory crimes can threaten life-altering consequences for anyone who gets it wrong—so they can often intimidate doctors from using their medical judgment when treating patients.[86]

For healthcare providers, the decision provides much-needed clarity about when they may prescribe controlled substances without fear of

80. Kelman, *supra* note 77. Within three months of the *Ruan* decision, the case was referenced in no less than fifteen current prosecutions across ten states. *Id.* With the decision serving as a catalyst, doctors have cited it in motions for acquittals, new trials, plea reversals, and post-conviction appeals. *Id.* Additionally, other defendants opted to postpone their cases to take advantage of the new precedent.

81. *Ruan*, 142 S. Ct. at 2383 (Alito, J., concurring).

82. *Id.* at 2389.

83. *Id.*

84. *Id.*

85. *Id.* at 2377–78 (majority opinion).

86. *See id.* at 2376. For example, Dr. Ruan was sentenced to "over 20 years in prison and ordered . . . to pay millions of dollars in restitution and forfeiture" and Dr. Kahn was "sentenced to 25 years in prison." *Id.* at 2375–76.

criminal prosecution. This clarification also provides an essential safeguard for doctors acting in good faith and within the bounds of their professional judgment when prescribing controlled substances.[87] It ensures these doctors cannot be convicted based on the government's subjective interpretation of applicable regulations or because the government simply disagrees with their medical judgment. Given doctors and other healthcare providers' vital role in our society, we need them to use their best judgment to help those in need without fear of punishment for making a mistake. Yet this is different when the same doctor knowingly enables addiction and recreational abuse through prescriptions.[88]

B. Hope For Chronic Pain Patients

At the same time, for patients, this decision means they can continue relying on their doctor's prescription for a controlled substance to relieve pain without fear their doctor may be criminally prosecuted. This opportunity to continue to depend on their doctor's ability and willingness to prescribe pain medications is critical, as many chronic pain patients cannot find doctors willing to prescribe opioids because of the government's crackdown on prescription opioids.[89] Opioid-related deaths are often misunderstood, involving people with drug abuse and psychological issues misusing multiple drugs, not just opioids.[90] Policies that do not distinguish between drug abusers and non-abusers can cause harm by denying essential pain medication to those who need it.[91] These policies oversimplify and neglect the complex problem of overdose, forcing patients into pain or dangerous drugs like heroin and fentanyl.[92] The ramifications of the decreased prescription of opioids by primary care doctors have been alarming, resulting in a lack of access to necessary

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87. *See id.* at 2380.

88. *Id.* at 2379.

89. Sullum, *supra* note 4 (explaining the relationship between the increase in opioid prescriptions and opioid overdose deaths is "not quite as straightforward as it might seem. Opioid prescriptions, measured by [morphine milligram equivalents] per capita, fell by nearly a fifth from 2010 to 2015, while deaths involving these drugs continued to rise"); Johnson, *supra* note 4, at 1000–01.

90. Sullum, *supra* note 4 ("Although some people who now obtain opioids indirectly may have had prescriptions at some point, [the results of the 2014 data analysis from the National Survey on Drug Use and Health (NSDUH)] undercut the notion that nonmedical users typically start as bona fide patients.").

91. *Id.* (The CDC guidelines appear to ask "physicians to make prescribing choices based on public health concerns . . . rather than the most appropriate course of therapy for the individual patient . . . [encouraging] prescribers [to] forego the use of [extended release/long acting] opioids in patients who could possibly benefit from them . . . essentially punish[ing] the chronic pain patient for offenses committed by drug abusers.").

92. *Id.* ("To the extent that the crackdown on prescription analgesics has made them more expensive and harder to get, it has pushed opioid users toward more dangerous drugs. That helps explain why total opioid-related fatalities more than tripled from 2002 to 2016, even as illegal use of pain pills declined."); Barnes, *supra* note 10.

medication for long-term users.[93] This lack of access has left patients abandoned by their healthcare providers to decide between a subpar existence or ending their life altogether.[94] Thankfully, the *Ruan* decision has provided a glimmer of hope for these individuals.

V. CONCLUSION

The *Ruan* decision clarifies the interaction between controlled substance regulations and criminal law. Criminal law can be a blunt and heavy weapon that must be wielded with great caution when policing those who provide valuable public services—lest they be intimidated from using their educated judgment and innovation to help those in need. The decision safeguards doctors acting in good faith and exercising their professional judgment from wrongful convictions based on the government's subjective interpretation of relevant regulations about prescribing controlled substances.

This decision significantly affects medical treatment for individuals suffering from opioid use disorder and those requiring prescription medication for pain management. It clarifies how healthcare providers and patients should navigate the interface between controlled substances regulations and criminal law. By clarifying that healthcare providers can be charged under the CSA if they violate exceptions granted by related regulations and are aware or should have known about unauthorized prescription practices, the decision sets a higher standard for convicting doctors. Prosecutors must now prove the prescription was medically unjustified and that the prescriber knew it was unjustified.

The ruling challenges the Department of Justice's pursuit of criminal charges against prescribers who played a part in the opioid epidemic. Previously, lower courts neglected to consider a prescriber's intent, leaving doctors charged with improper prescriptions without a defense based on good faith. Doctors may argue good faith in defense, but acquittal is not guaranteed. Defendants guilty of running genuine pill mills will still face conviction, though a potential second trial may be required.

That said, the Supreme Court's lifeline aims to offer relief to a specific group of defendants who dispensed with their hearts instead of their minds. By distinguishing between an unethical doctor and a licensed medical practitioner who behaves like a drug peddler instead of a healthcare provider, the Supreme Court aims to protect doctors who prescribe opioids in good faith but with inferior skills and knowledge.

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93. Sullum, *supra* note 4; Yenerall & Buntin, *supra* note 9, at 3.
94. Sullum, *supra* note 4; Yenerall & Buntin, *supra* note 9, at 13; Vestal, *supra* note 9.

The decision carries importance beyond *Ruan's* relevant context of prescribing opioids. For example, consider the case of a hospital doctor providing lifesaving medical care to patients facing threats of criminal prosecution for her clinical decision-making. Fearful of being wrong and facing trouble, she may avoid exercising her best judgment. This scenario would have disastrous consequences for patients who depend on her for help. In regulating professionals using criminal law, we must be cautious to avoid stifling innovation and discouraging people from helping others due to the fear of punishment.