Ruan v. United States: "Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care

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Introduction

The Supreme Court's decision in the consolidated cases of *Ruan v. United States* and *Khan v. United States*[1] is a narrow but important decision that both emphasizes the role of scienter in separating innocent from criminal conduct and constrains federal law enforcement's ability to invade medical care under the Controlled Substances Act (CSA).[2] Section 841(a)(1) of the CSA is the general drug distribution provision under which prescribing practitioners and lay people alike are prosecuted. That section makes it unlawful "*except as authorized* . . . for any person [to] knowingly or intentionally . . . distribute . . . a controlled substance."[3] The *Ruan* decision corrected years of conflicting and eroding standards for what the government must prove to secure a conviction in 841(a)(1) prosecutions against doctors or other

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

[2] Comprehensive Drug Abuse & Prevention & Control Act, 21 U.S.C. § 801 et seq. (1970).

[3] 21 U.S.C. § 841(a)(1) (emphasis added). Section 841(a) also includes unlawful dispensing or manufacturing or possession with intent to manufacture, distribute, or dispense any controlled substance or counterfeit substance. Prescribers are charged with distribution or dispensation under 841(a)(1), and a circuit split remains even after *Ruan* on the issue of whether they should be charged with distribution or dispensation. I use the language of distribution for simplicity because both petitioners were charged with distribution, and it does not change any of my assertions in this essay.

prescribing practitioners.[4] By holding that the requisite mental state (the *mens rea*, guilty mind, or scienter requirement) of "knowingly or intentionally" in the statutory text also applies to the "except as authorized" clause, the Court held that the government must prove not only that doctors acted outside the limits of their federal authorization to prescribe controlled substances, but also that they did so knowingly or intentionally.[5] In other words, prescribers can no longer be convicted under Section 841 for innovative, mistaken, negligent, or less-than-careful prescribing.

Despite the legal importance of this case, it didn't garner a lot of attention early on, and, when it did, the serious legal and policy issues were overshadowed by "bad doctor" narratives. To be clear, my claim is not that Drs. Ruan and Khan aren't bad doctors—I don't know, and I am not weighing in on that issue. And, of course, prescribing practitioners are sometimes imperfect in ways that should not merit a felony conviction. For example, they can be careful and still be mistaken, careless, and even negligent or "bad" in the sense of lacking competence or being compromised by their own impairment.[6] There are ample legal and quasi-legal remedies to address each of these problems, in context. Criminalizing all of them, rather than just the truly corrupt prescribers, wasn't and isn't the answer.

To be fair, given their positions of power, doctors are among the least sympathetic of all the victims of the profound injustices of the

[4] The defendants in both *Ruan* and *Khan* were physicians, but I refer to prescribing practitioners as well. Lawyers too often don't understand that other professionals prescribe, including advanced practice registered nurses (APRN) and physician assistants, in accord with their certificates of authorization from the Drug Enforcement Agency. See, e.g., 21 C.F.R. § 1301; Phillip Zhang & Preeti Patel, Practitioners and Prescriptive Authority (2021), https://bit.ly/3A5qabV. Even counsel for the government seemed confused. During oral arguments, he stated that nurse practitioners, one type of APRN, aren't authorized, when in fact they enjoy the ability to prescribe at least some classes of controlled substances in every state. Tr. of Oral Arg. at 48, Ruan v. United States, 142 S. Ct. 2370 (2022) (Nos. 20-1410 & 21-5261), https://bit.ly/3dnBUhS (Mr. Feigin describing a hypothetical type of doctor who should be subject to section 841 as one who, among other things, "trusts nurse practitioners, who aren't DEA registrants, aren't allowed to do this, don't have medical licenses, to do most of the prescribing").

[5] Ruan, 142 S. Ct. at 2376.

[6] Kelly K. Dineen & James M. DuBois, Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?, 42 Am. J.L. &. Med. 1 (2016) (reviewing existing literature and suggesting a framework for misprescribers as careless, corrupt, and compromised by impairment).

War on Drugs.[7] The discourse surrounding the drug overdose crises[8] didn't exactly recruit a long list of champions for doctors accused of abusing their power to distribute drugs. Commentators initially focused on the particular facts—as presented by the government and framed by the circuit court opinions—to dismiss the defendants as corrupt "pill pushers," deserving of the harshest penalties available. A lot of media outlets still call *Ruan* & *Khan* the "pill mill" cases.[9] Most major medical organizations chose not to write amicus briefs despite multiple requests—even though the issue has implications for virtually every physician—for reasons that I can only guess included the risk of being viewed as advocating for "bad doctors." In briefs and at oral arguments, the government relied heavily on arguments based in indignation.[10] Implicitly government's counsel advanced the idea that doctors who had the benefit of the public trust and enjoyed a position of power had betrayed the social contract and shouldn't have the benefit of the typical principles of criminal law.[11] He also essentially argued that no matter what the standards were, those cases aren't "close calls"—the government only brought cases

[7] See, e.g., Deborah Small, The War on Drugs Is a War on Racial Justice, Soc. Res. 896–903 (2001); Brian D. Earp et al., Racial Justice Requires Ending the War on Drugs, 21 Am. J. Bioethics 4, 4–19 (2021).

[8] I avoid the term "opioid crisis" because it's inaccurate and perpetuates the use of the opioid heuristic. The overdose crises are multilayered and worsened by prohibition. See Nabarum Dasgupta et al., Opioid Crisis: No Easy Fix to Its Social and Economic Determinants, 108 Am. J. Pub. Health 2 (2018); Leo Beletsky & Corey S. Davis, Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited, 46 Int'l J. Drug Pol'y 156–59 (2017).

[9] For example, Bloomberg Law, SCOTUSBlog, the New York Times, and others all refer to the cases this way.

[10] Indignation is a visceral bias that can drive irrational decisionmaking, especially when combined with feelings of betrayal and when shared by groups. See, e.g., Kelly K. Dineen, Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems, 40 L. & Psych Rev. 1, 44–45 (2016) (synthesizing work by Cass Sunstein and applying it to pain treatment).

[11] At oral arguments, government's counsel offered a list of examples that really described careless, mistaken, and negligent doctors—including "egotistical doctors" who think they are "doing right by" their patients and an "absentee doctor"—as the types of defendants that should be convicted. Tr. of Oral Arg., *supra* note 4, at 45–48. He also suggested this is a rare type of case where doctors should be criminally punished for carelessness. *Id.* at 59.

against the really "bad doctors" and so inconsistency across circuits was practically inconsequential.[12]

This argument wasn't terribly surprising. We have been conditioned over the last century and certainly over the past decade to blame doctors who prescribe controlled substances for a hefty share of drug-related social harms. Their part in prescription opioid-related harms is particularly salient, and over the last 15 years we have imbued opioids with their own almost magical power of destruction. We continue to throw around terms like "overprescribing" and "misprescribing" without definition and let them serve as a heuristic for a wide range of behaviors,[13] all in a contextual void.[14] Stories of doctors' prosecutions elicit more cheers than concerns—in part because we believe they are "bad doctors" and in part because they provide a (false) reassurance that something is being done about the "opioid crisis." But truth is stranger than fiction and usually more complex.

This essay is an attempt to disentangle some of that complexity and proceeds in four parts. First, I share a few of my nursing experiences working with patients who took prescribed opioids and try to shed some light on the complexity of their care. I also describe the difficulties that arise from criminalizing care. In part II, I provide an overview of the federal criminalization of controlled substances prescribing over the past century, including Section 841(a)(1) prosecutions. I then review the conflicts that led the Court to take up the *Ruan* case and review the opinion in more detail in part III. I conclude by describing the relevance of *Ruan* for patients in need of care and their providers and summarizing the importance of the *Ruan* holding.

[12] *Id.* at 69–70.

[13] In an era of vigorous legal action aimed at misprescribing, not one jurisdiction had bothered to define the prescribing problems they sought to remedy. To that end, I offered a taxonomy that could help policymakers better attend to context and create a kind of cognitive-forcing strategy for bias correction. The taxonomy included inadvertent overprescribing, qualitative overprescribing, quantitative overprescribing, multi-class misprescribing, corrupt prescribing, and underprescribing. Kelly K. Dineen, Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm, 67 U. Kan. L. Rev. 101, 961–1011 (2019).

[14] A series of my past law review articles have addressed these issues in depth. See Dineen & DuBois, *supra* note 6; Dineen, Addressing Prescription Opioid Abuse Concerns in Context, *supra* note 10 (applying behavioral economics to opioid policy and prescribing decisions and introducing the opioid heuristic); Dineen, Definitions Matter, *supra* note 13.

I. The Complexity of the Clinical Picture and the Perils of Criminalizing Care

I have a window into the difficult tradeoffs involved in taking care of patients with chronic or persistent pain (CPP)—not just from reading studies from my comfortable perch in the ivory tower, but firsthand from working as nurse in the late 1990s and early 2000s. I worked primarily for a neurosurgeon with a subspecialty in caring for patients with CPP syndromes refractory to medical care (a fancy way of saying treatments from many other doctors hadn't helped). Dr. Jaimie Henderson was and is an excellent physician—conscientious and empathetic, board certified and fellowship trained, a prolific scholar and thought leader in functional neurosurgery.[15] I would trust him with my life, as many have and still do, to this day.

Our patients' histories were always lengthy, complex, and riddled with trauma (much of it inflicted by the very medical systems they turned to for help). They had learned the hard way that practitioners often viewed them with more suspicion and skepticism than trust,[16] a problem amplified because many of our patients were also poor and disenfranchised in other ways.[17] As desperate for relief as most of them were by the time we met them, almost all of them were more desperate to be taken seriously and to be told the truth about the limits of medicine.[18]

I was their primary point of contact and a sort of medical gatekeeper.[19] I triaged their questions and concerns, programmed their medical devices, helped coordinate the timing and any changes

[15] Dr. Henderson is now at Stanford University, https://stanford.io/3JIInjA. I shared this essay with him and received his permission to publish it via email, which is on file with the author.

[16] See generally Megan Crowley-Matoka & Gala True, No One Wants to Be the Candy Man, 27 Cultural Anthropology 4 689–712, 701 (2012) ("[C]linicians offer[ed] up expressions of frustration, anger, and even disgust in vivid terms: 'Ugh, pain patients—I hate those back pain guys. I just want to turn and run when I see one coming.' And 'What a waste, the kind of energy they spend trying to get their meds—makes me sick.'").

[17] See, e.g., Liesa De Ruddere & Kenneth D. Craig, Understanding Stigma and Chronic Pain: A-State-of-the-Art Review, 157 Pain 8, 1607–10 (2016).

[18] See, e.g., Kelly K. Dineen, Moral Disengagement of Medical Providers: Another Clue to the Continued Neglect of Treatable Pain?, 13 Houston J. Health L. & Pol'y 2 (2013).

[19] See generally Elizabeth Chiarello, Medical versus Fiscal Gatekeeping: Navigating Professional Contingencies at the Pharmacy Counter, 42 J.L. Med. & Ethics 4, 518–34 (2014).

to their prescriptions—including long-term opioid therapy—and reviewed opioid treatment agreements with them.[20] It was the decade of pain and the era of Oxycontin, and some patients were on doses that are mostly unheard of today, but it was absolutely the standard of care for some people with CPP at the time.[21] For many of them, that medication was what allowed them to return to the activities of their daily lives. For a handful, access to those medications was problematic, and in hindsight the way we dealt with those issues was far from ideal.

I'd say we both had a lot of concern for these patients and were unusually comfortable with the complexity and uncertainty involved in taking care of patients with CPP. Our colleagues, like many providers,[22] often didn't understand how "we could stand taking care of these patients" and viewed us as outliers, a kind of association stigma. This paled in comparison to the way the patients themselves were and are still treated, too frequently dismissed as hysterical, difficult, noncompliant, or as "druggies."[23] I still regard patients with CPP as among the most marginalized and mistreated groups of patients in health care.

Only later did it dawn on me that there was another highly stigmatized group I had not regarded at all—those who use drugs or have substance use disorder (SUD). They were so marginalized that we simply didn't see them as our problem, except insofar as it concerned making sure they didn't "take advantage" of us again.[24] Contrary to common presumptions, most people with CPP do not have SUD, but

[20] These agreements spell out the terms under which the prescriber agrees to treat them. These exist to protect the provider from legal scrutiny, but evidence to support their use as a clinical tool is weak at best. See, e.g., Tuesday M. McAuliffe Staehler & Laura C. Palombi, Beneficial Opioid Management Strategies: A Review of the Evidence for the Use of Opioid Treatment Agreements, 41 Substance Abuse 2, 208–15 (2020).

[21] See, e.g., G.M. Aronoff, Opioids in Chronic Pain Management: Is There a Significant Risk of Addiction?, 4 Current Rev. Pain 112–21 (2000); M. Glajchen, Chronic Pain: Treatment Barriers and Strategies for Clinical Practice, 14 J. Am. Bd. Family Practice 3 (2001).

[22] See Dineen, Moral Disengagement, *supra* note 18.

[23] *Id.* The very use of terms (for someone who uses drugs or has a SUD) as a terrible insult illustrates the pervasive stigma that still exists. For a collection of first-person narratives from people with CPP and SUD, see Kelly K. Dineen & Daniel Goldberg (Symposium Editors), Living in Pain in the Midst of the Opioid Crisis, 8 Narrative Inquiry in Bioethics 3 (Winter 2018).

[24] Here again, indignation is a powerful driver of our decisions.

certainly some do.[25] And a subset of this group is those with opioid use disorder (OUD).[26] People with either or both conditions are deserving of appropriate, individualized, and compassionate health care, which may include prescribed controlled substances.[27]

I'm not proud of how I treated people who I discovered were using drugs other than as prescribed. When concerns were brought to our attention, our response was typical of how many providers respond even today, such as telling them they need to find a new doctor and dismissing them from the practice.[28] I personally don't recall having serious conversations about whether they may have had a SUD. I am reluctant to admit that the most effort I put into helping someone who had misused prescriptions was looking up drug treatment centers in the phone book for them. This is especially heartbreaking because, even at that time, there existed broadly effective treatments for OUD, although I can't say I was aware of them. Today, treatment with medication for OUD (MOUD) is lifesaving and more effective than those available for most other serious medical conditions.[29] Yet fewer than half of the people who would benefit from MOUD succeed in accessing it,[30] in part because

[25] In 2020, 14.5 percent of the population had a past-year SUD, with alcohol use disorder accounting for the largest share. SAMHSA, Key Substance Use and Mental Health Indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (2021), https://bit.ly/3QdkAuB.

[26] The incidence of opioid addiction among those with SUD has been estimated at about 3.5 percent, with a greater percentage having mild or moderate OUD. See Joseph A. Boscarino et al., Opioid-Use Disorder among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates, 6 Substance Abuse & Rehabilitation 83 (2015); see also Nora D. Volkow et al., Prevention and Treatment of Opioid Misuse and Addiction: A Review, 76 JAMA Psychiatry 2, 208–16 (2019).

[27] See, e.g., Micheal E. Schatman et al., No Zero Sum in Opioids for Chronic Pain: Neurostimulation and the Goal of Opioid Sparing, Not Opioid Eradication, 14 J. Pain Res. 1809–12 (2021). The gold standard of care for OUD is prescribed opioid medications. See, e.g., Nat'l Acad. of Sci., Eng'g, & Med., Medications for Opioid Use Disorder Save Lives (2019).

[28] See, e.g., Daniel G. Tobin et al., Responding to Unsafe Opioid Use: Abandon the Drug, Not the Patient, 36 J. Gen. Internal Med. 790–91 (2021) (describing a study in which 78 percent of primary care doctors had dismissed a patient for violating a controlled substances treatment agreement).

[29] See, e.g., Nat'l Acad., *supra* note 27.

[30] *Id.*

some health care providers still do not regard these patients as their responsibility.[31]

We could and should have done better by these patients, not just individually but as institutions and communities. I am also disappointed in the systems and structures that failed to educate us about addiction and model appropriate care and treatment. We simply didn't see addiction as within our scope or within the realm of health care as conventionally understood. I now know that laws related to controlled substances prescriptions and addiction treatment, especially criminal laws, are foundational to mutually reinforcing structural, institutional, and individual discrimination against people who use or are perceived as using drugs—including people with CPP and SUD.

A. Prescribing Decisions Are Fraught with Peril

Deciding what, when, how much, and to whom to prescribe controlled substances is one of the most fraught decisions practitioners make in the regular practice of medicine. All medicines carry both promise and peril for the patients to whom they are prescribed. Making the best judgments about when that balance tips in favor of issuing the prescription is rarely completely straightforward. When it comes to controlled substances, that calculation is especially knotty. It's the only area of medicine that borders criminal law so acutely and with so much variability about what separates lawful provider conduct from unlawful, criminal conduct. Prescribing controlled substances is uniquely personally risky to practitioners in a way that all other medical decisionmaking is not. And viewed in hindsight, imperfect but well-meaning decisions can be easily framed as malicious and criminal by law enforcement and other Monday-morning quarterbacks.[32]

When there isn't a bright line between lawful and unlawful conduct, claims ring hollow that only really "bad doctors" are at risk of criminal prosecution.

[31] See, e.g., Alexander C. Tsai et al., Stigma as a Fundamental Hindrance to the United States Opioid Overdose Crisis Response, PLoS Med 16(11): e1002969 (2019); Kelly K. Dineen & Elizabeth Pendo, Substance Use Disorder Discrimination and the CARES Act: Using Disability Law to Guide Part 2 Rulemaking, 52 Ariz. St. L.J. 1143–65 (Winter 2020).

[32] See generally Dineen & DuBois, *supra* note 6.

I offer just one example here of a patient, "Jane," that I think is illustrative. Jane had CPP, with a long history of back injuries and surgeries prior to coming into our care. About a year into the relationship, Dr. Henderson surgically placed a totally implanted, programmable and refillable pump that delivered highly concentrated opioid medication in small volumes into the cerebral spinal fluid space near her spine. Part of my job was refilling and programming those pumps in clinic. This required a small procedure in which I used a sterile, specially designed needle to access a port under the skin and empty any remaining volume of medicine. I then refilled the pump with 20ccs (4 teaspoons) of new medication and reprogrammed the pump to allow it to calculate how long that new volume would last given the concentration and dose. Jane's visits were uneventful for some time, and it seemed like the pump was really helping her pain.

Sometime over the next year, things changed. Over the course of three or four refills, I noted greater and greater discrepancies between the left-over amount I expected and what was actually remaining in the pump (that is, each time there was more liquid medication missing by a factor of a few more ccs). Dr. Henderson and I discussed the issue multiple times, and we also reached out to the device manufacturer, who had no other reports of similar irregularities although minor discrepancies were commonplace. A drug screen was not useful in this case because the pump was still delivering opioids. It wasn't impossible that the steadily increasing discrepancies were a chance pattern of normal variability. We also spent a lot of time talking to the patient about it. At the time, nothing else was amiss. She had been a model patient for years. I was more suspicious than Dr. Henderson, but I also knew it would require some medical skill and access to long needles to somehow access the medication. I was also less compassionate and more indignant, a product of the moralistic and punitive culture that criminalizes people who use drugs.

Weighing the options, I agreed with Dr. Henderson that in the absence of proof, we should trust the patient and continue her care. Dr. Henderson even replaced the pump in hopes that would solve the problem. When I saw the patient post-op, her wound had not fully healed, which was unusual, and the discrepancy was worse rather than better. But we went ahead and refilled and programmed the pump and talked to her again, openly sharing our concerns about diversion and giving her the opportunity to "confess"—as

if she were a suspect and not a patient who may have developed a SUD. She denied any issues and despite our growing concerns, we erred on the side of trusting the patient.

Shortly thereafter, she returned with a seriously infected wound over the pump, leaving me with little doubt that she was accessing the pump and Dr. Henderson with little choice but removal after a course of antibiotics. The device company's analysis of that pump confirmed my suspicions. It found multiple breaches in the core of the access port caused by garden-variety hypodermic needles. The patient eventually admitted that a nurse relative had been extracting tiny amounts of the highly concentrated opioid medication for diversion. I don't know if I ever knew any additional details. I am not sure I cared. My reaction was indignant, smug satisfaction at having been correct rather than concerned for my patient's well-being. After a post-operative follow up, she was discharged from our care. I honestly don't recall if any referrals were made. I viewed Jane as detracting from the "good" patients with CPP, and I bought right into the misguided narratives and false binaries that distinguished patients with CPP as more deserving than people with SUD.

These kinds of absolutes and false binaries are part of what drive some in law enforcement to unfairly scrutinize prescribers. But false binaries, by definition, lack nuance and context. I can now imagine a description of Jane's case in the hands of law enforcement with the benefit of hindsight. It would probably focus on how we refilled that pump for months on end despite repeated "warning signs." We, especially Dr. Henderson, would certainly be accused of missing warning signs, maybe even of being what the government called the "egotistical doctor" who blindly believes he is just doing right by his patient—too caring for our own good.[33] They would have a field day with the pump replacement and certainly find some doctor—under the nonrigorous standards for expert testimony in these cases—to say that he had departed from the usual course of professional practice. They could make a convincing case, especially to the uninitiated (such as a jury), and if this happened a few years later, as the country fell under the moral panic of the overdose crisis, it could have been a travesty for everyone involved.

[33] See Tr. of Oral Arg., *supra* note 4.

At worst, we may have been a little slow to push the issue and a little naïve. Everything that transpired with Jane was in an honest, careful effort to treat her with respect and dignity and maintain a plan of care that helped her function. That she lied to us is not unexpected—she knew diversion is criminal behavior and viewed as deeply shameful to boot. She also knew she would lose her doctor because we, like most practices that treated people with CPP, didn't treat SUD. If the tables were turned, I would have lied to my providers too. That we were fooled, that we erred on the side of trusting a long-term patient, should not be criminal either. And even if we had made actual errors that had harmed her, those should be handled by the myriad state-based regimes better designed to address patterns of less-than-careful medical decisions.[34] Perhaps equally unjust is that there would be no legal scrutiny if we had been a substantial factor in harms from withdrawal or self-harm if we had discharged her after our first suspicions. Doctors are almost never held accountable for withholding care when it comes to opioids.[35] Jane's story is an example of what might be construed as nonnegligent (she arguably suffered no harm *caused* by the prescribing) but potentially criminal prescribing, at least under the standards in some circuits immediately before *Ruan*.

B. Criminalizing Care Causes Harm

Criminalizing medical care and the patients that need that care is state-sanctioned stigma. It can force doctors to choose between their patients' well-being and their own most basic freedoms. The power of legal entanglement or the threat thereof—especially within the criminal legal system—to push practitioners away from providing medically indicated but personally risky care has been particularly

[34] Although it is outside the scope of this essay and the *Ruan* decision did not address it, there are well written and compelling federalism arguments to exclude federal law enforcement from medical care. See, e.g., Br. of Cato Institute as Amicus Curiae Supporting Petitioner, Ruan v. United States, 142 S. Ct. 2370 (2022) (Nos. 20-1410 & 21-5261) (citing to other authorities); Br. of Professors of Health Law & Policy as Amici Curiae Supporting Petitioner at Sec. III, Ruan v. United States, 142 S. Ct. 2370 (2022) (Nos. 20-1410 & 21-5261) (Dec. 23, 2021); Br. of Professors of Health Law & Policy as Amici Curiae Supporting Pet. for Writ of Cert. at Sec. IV, Ruan v. United States, 142 S. Ct. 2370 (2022) (Nos. 20-1410) (May 7, 2021).

[35] See, e.g., Lynn Webster, Pain and Suicide: The Other Side of the Opioid Story, 15 Pain Med. 345 (2014).

salient in the immediate aftermath of *Dobbs v. Jackson Women's Health*,[36] with scores of reported delays and patient abandonments, even in emergencies, as practitioners and institutions struggle to understand the line between lawful or personally safe and unlawful or risky conduct.[37] Even mistaken beliefs about what the law sanctions can create powerful behavioral incentives for practitioners.[38] In the context of abortion, in some states practitioners have few assurances they won't face legal entanglement for appropriate care.[39] Practitioners who chose to keep treating patients associated with opioids and other controlled substances—such as people with CPP, SUD, or both—also operate in murky territory where good and ethical medical decisions may be at odds with legal risks to the provider.[40] They also do so in an environment of promised or actualized enhanced surveillance, including from prescription drug monitoring

[36] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022) (overturning Roe v. Wade).

[37] See, e.g., Carrie Feibel, Because of Texas Abortion Law, Her Wanted Pregnancy Became a Medical Nightmare, NPR (July 26, 2022), https://n.pr/3JIKq7g (detailing the delays in performing an abortion for a woman who was 18 weeks pregnant whose water had broken and infection was progressing with a nonviable pregnancy); Caroline Kitchner, The Texas Abortion Ban Has a Medical Exception. But Some Doctors Worry It's Too Narrow to Use, The Lily (Oct. 21, 2021), https://bit.ly/3dmZLP2 (discussing the availability of surgical care for ectopic pregnancies under the abortion ban in Texas (SB 8) and the fears of legal scrutiny under that law among practitioners).

[38] This is certainly true in some of the reporting about delays in providing emergency surgical treatment for ectopic pregnancies, which probably aren't prohibited under even the strictest state law. For an excellent discussion of the way doctors behave in response to even inaccurate claims about the law, see Sandra H. Johnson, Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously, 53 St. Louis U. L.J. 973 (2009).

[39] There may be some cold comfort of a narrow federal protection for medically indicated stabilizing emergency treatment under The Emergency Medical Treatment and Active Labor Act (EMTALA). See, e.g., U.S. Dep't of Justice, News: Justice Department Sues Idaho to Protect Reproductive Rights, August 2, 2022, https://bit.ly/3bLWo3E (describing a request for declaratory judgment against Idaho under EMTALA); Greer Donley & Kimberly Chernoby, How to Save Women's Lives after Roe, The Atlantic (June 13, 2022), https://bit.ly/3BWJU3Q (explaining how EMTALA could be used to prevent states from criminalizing emergency reproductive health care).

[40] Kate M. Nicholson & Deborah Hellman, Opioid Prescribing and the Ethical Duty to Do No Harm, Am. J.L. & Med. 297 (2020).

programs (PDMPs), of both their professional actions and their patients' confidential care.[41]

It is ultimately practitioners and patients who are casualties of laws and policies carved out of deeply entrenched moral, political, social, and religious ideologies. Law is simply too blunt an instrument to adequately manage the nuanced and constantly evolving nature of medicine. And when it tries to target broader social disputes at the bedside by invading the doctor-patient relationship, the law almost always ends up inducing substantial harms. These are often billed as "unintended consequences."[42] But the harms of overregulation and legal overdeterrence—whether (1) pregnant people with ectopic pregnancies are forced to wait until they are near death from a ruptured fallopian tube, or (2) the legal separation of addiction treatment from all the rest of medicine renders people with SUD invisible to doctors and untreated, or (3) the individuals with CPP who functioned well for years on long-term opioid therapy turn to riskier illicit drugs or become suicidal when doctors abruptly stop prescribing opioids in reaction to poorly conceived opioid policies—are almost always foreseeable, foreseen, and represent, at a minimum, an implicit choice about who and what matters more to society.

II. The History of Federal Controlled Substances Laws that Criminalize Prescribing

In an environment of overregulation, fears of criminal prosecution drive doctors away from patients, leading to more suffering and death among those most in need of medical care. This effect has been openly acknowledged for at least a century in the context of controlled substances prescribing, and yet policymakers continue to enact and enforce laws that induce harm.[43]

[41] For a chilling account of the combined reach, inaccuracy, and discriminatory nature of prescription drug monitoring programs, see Jennifer D. Oliva, Dosing Discrimination: Regulating PDMP Risk Scores, 110 Calif. L. Rev. 47–115 (2022).

[42] Alex Broom et al., The Administration of Harm: From Unintended Consequences to Harm by Design, Crit. Soc. Pol'y (Apr. 7, 2022), https://bit.ly/3p69pIi.

[43] The scope of this essay only allows me to include some of those federal criminal laws that directly bear on prescribing conduct.

A. The Harrison Narcotic Tax Act

The federal government began inserting itself into the doctor-patient relationship after the enactment of the Harrison Narcotic Tax Act in 1914.[44] The law created tracking, registration, recordkeeping, and taxing requirements for individuals and entities involved in the narcotics supply chain, with an exception for patients who possessed drugs prescribed to them "in *good faith* by a physician . . . registered under this Act."[45] The act also expressly allowed doctors to dispense or distribute narcotics to patients "*in the course of his professional practice only*."[46] It was a general intent statute with a maximum fine of $2,000 and not more than five years in prison.[47] The act was aimed at the narcotics supply chain, not patients, who at the time of its enactment were viewed as

> "sufferers" or "patients" . . . [who] could and did get relief from any reputable medical practitioner, and there is not the slightest suggestion that Congress intended to change this beyond cutting off the disreputable "pushers" who were thriving outside the medical profession and along its peripheries.[48]

However, the law enforcement agency—here, the Treasury Department who would also soon be charged with enforcing the prohibition of alcohol—had other plans. Treasury officials quickly tried to play doctor and set clinical parameters on the meaning of "the course of professional practice" and "good faith" in the law, despite their utter incompetence to do so.[49] For example, they declared in 1915 guidance that when treating anyone with SUD, doctors' "prescriptions should show the good faith of the physician in the legitimate practice of his profession *by a decreasing dosage or reduction of the quantity* prescribed from time to time."[50] They also began sending in undercover agents and others to pretend to be a patient in serious pain or with addiction

[44] Harrison Narcotic Tax Act, Pub. L. 223, Stat. 785 (1914) (later codified at 26 U.S.C. § 4701 et seq.).

[45] *Id.* at § 8 (emphasis added).

[46] *Id.* at § 2(a) (emphasis added).

[47] *Id.* at § 9.

[48] Rufus G. King, The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick, 62 Yale L.J. 5, 736–49, 737 (1953), https://bit.ly/3bGycjh.

[49] *Id.*

[50] Br. of Cato Institute, *supra* note 34 (citing to other authorities).

in an effort to "fool" the doctor into prescribing—later using the fact that the "patient" wasn't really suffering as proof that prescribing wasn't in good faith.[51] This practice remains pervasive today and the undercover patients appear with well-developed and documented medical histories consistent with CPP and SUD. This strategy is often effective in securing a conviction. I have written elsewhere how unjust this practice is because prescribers, as mere humans, aren't lie detectors.[52] Moreover, the practice undermines the orientation of mutual, relational trust so foundational to provider-patient relationships.[53]

In short order, federal courts across the country also got involved in the practice of medicine. In a series of cases the courts declared that prescribing opioids to people with SUD was not the "legitimate practice of medicine,"[54] for example, the Supreme Court's decision in *Webb v. United States* in 1919.[55] In the era of prohibition and punitive treatment, other powerful forces hopped on the bandwagon. The American Medical Association eventually issued a resolution in 1920 against the medical treatment of addiction with regular doses of opioids.[56] And in 1919, the Court reversed a lower court's dismissal of a prescribing case, describing the doctor as prescribing to a known "dope fiend" and "not for the treatment of any disease."[57] Emboldened by their judicial victories and prohibitionist orientations, and in concert with the moral panic over the "dope menace" across the country,[58] law enforcement began interpreting the act to prohibit doctors altogether from prescribing regular doses of opioids as a treatment for addiction, regardless of

[51] See, e.g., King, *supra* note 48, at 735–36 (describing the indictment of Dr. Linder based on prescribing a small dose of morphine to an "addict-stool pigeon who was working for the agents").

[52] It also may work only one way. Dr. Ruan refused to prescribe to people who turned out to be undercover agents multiple times, but the district court excluded that evidence on the grounds it wasn't relevant. Petition for Certiorari at n.3, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410).

[53] See Dineen & DuBois, *supra* note 6.

[54] *Id.* See also King, *supra* note 48, at 737–39 (describing the Treasury Department's actions and court decisions in Harrison Act cases against doctors, including Supreme Court opinions from 1919 to 1925).

[55] 249 U.S. 96 (1919).

[56] Institute of Medicine, Federal Regulation of Methadone Treatment, Nat'l Acad. Press (1995).

[57] United States v. Doremus, 249 U.S. 86, 90 (1919).

[58] King, *supra* note 48, at 737–38.

the circumstances or evidence of effectiveness. By 1925, it was widely known that doctors were abandoning patients out of reasonable fears of prosecution, and, in *Linder v. United States,* the Supreme Court tried to walk back its previous sweeping statements in Harrison Act cases.[59] The Court urged that its language about prescribing should be understood as applying only to cases with facts indicating the prescriber did not act in good faith in the usual course of professional practice (i.e., as applying only to "bad doctors"). In somewhat of an acknowledgment of the harms of driving doctors out of the business of caring for people with SUD, and perhaps the dawning knowledge that the law had in many ways created the illicit drug market,[60] the Court wrote:

> [The act] says nothing of "addicts" and *does not undertake to prescribe methods for their medical treatment*. They are diseased and proper subjects for such treatment, and we cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purpose solely because he has dispensed to one of them, in the ordinary course and in good faith . . . for relief of conditions incident to addiction.[61]

But it was too late.[62] Prosecutions continued, and prescribers were left to choose between facing criminal prosecution for helping people with SUD and CPP or remaining safely avoidant. Medicine in the main decided that these patients simply weren't worth the risk. This attitude lingered for decades, and it's still pervasive. In the 1950s, the American Bar Association and the American Medical Association Joint Committee on Narcotic Drugs noted that

> the physician has no way of knowing before he attempts to treat, and/or prescribe drugs to an addict, whether his activities will be condemned or condoned. He does not have any criteria or standards to guide him in dealing with drug addicts, since what constitutes *bona fide* medical practice and good faith depends upon the facts and circumstances of each case.[63]

[59] 268 U.S. 5 (1925).

[60] Thomas M. Quinn & Gerald T. McLaughlin, The Evolution of Federal Drug Control Legislation, 22 Cath. U. L. Rev. 586 (1972).

[61] Linder, 268 U.S. at 18 (emphasis added).

[62] King, *supra* note 48, at 747–48.

[63] Morris Ploscowe, Interim and Final Reports of the Joint Committee of the American Bar Association and the American Medical Association on Narcotic Drugs, Appendix A (1950).

Through the 1960s, federal law enforcement continued to advise prescribers based on the language of *Webb* rather than *Linder*.[64] As enforced, the law solidified the ideas that doctors are criminally blameworthy for addiction and thus risk their very liberty in prescribing opioids to anyone, especially those with SUD. People who use drugs became almost the sole province of law enforcement as well as the poster children for anti-immigration and white-supremacist goals dressed up as drug policy.[65] Criminalization of the people who use drugs—which is highly racialized[66] and includes people who have CPP and SUD—made clarion that they are different, deviant, and defective, unworthy of compassion and appropriate medical care.

B. The Controlled Substances Act

The Harrison Act was widely viewed as "an unenlightened approach to a social problem."[67] The CSA of 1970 repealed the Harrison Act and a multitude of dispersed drug control laws and replaced them with a centralized statute enforced by the Department of Justice governing all narcotic and "dangerous drugs."[68] Leading up to its passage, concerns remained about the Harrison Act's overdeterrence of prescribing and its role in ending the medical treatment of SUD. The House hearings transcript includes the statement that "out of fear of prosecution many physicians refuse to use narcotics in the treatment of [people with SUD]. . . . In most instances they shun addicts as patients."[69] The legislative history does not otherwise provide

[64] Quinn & McLaughlin, *supra* note 60.

[65] See, e.g., andre douglas pond cummings & Steven A. Ramirez, Roadmap for Anti-Racism: First Unwind the War on Drugs Now, 96 Tulane L. Rev. 3 (2022); Doris M. Provine, Race and Inequality in the War on Drugs, 7 Ann. Rev. L. Soc. Sci. 1, 41–60 (2011).

[66] See, e.g., Br. of the Cato Institute and the ACLU of Pa. as Amici Curiae in Support of Appellees, United States v. Safehouse, 985 F.3d 225 (3d. Cir. 2021) (No. 20-1422) (July 6, 2020), https://bit.ly/3vTMrIg.

[67] Quinn & McLaughlin, *supra* note 60, at 597.

[68] The CSA places each controlled substance into one of five schedules based on currently accepted medical use and potential for abuse. Schedule I drugs have no currently accepted medical purpose and a high potential for abuse. Schedules II through V drugs all have a currently accepted medical use with varying potential for abuse, ranging from Schedule II (highest abuse potential) to Schedule V (lowest). 21 C.F.R. § 1308. See, e.g., Dineen & DuBois, *supra* note 6. There are serious questions about the utility and accuracy of this classification system.

[69] House Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4580-4581 (1970).

a lot of background on the issue of prescribing. While the 1970 version of the CSA reflected an awareness of the need for rehabilitation rather than only repression and retribution in drug policy,[70] there remained a strong push for prohibitionist, supply-sided restrictions in much of the law and especially among law enforcement.

A few years later, Congress would eventually create extensive regulatory regimes for the treatment of OUDs with MOUDs—first for methadone administration,[71] and later for buprenorphine prescribing,[72] both of which have been regularly updated. The law also vested Health and Human Services, rather than a law enforcement agency, with the power to set the standards. This is the only instance in which Congress has placed in the hands of a federal agency the responsibility for setting standards for nuanced clinical care, which is contrary to important principles of federalism that properly place the regulation of medical practice solidly within the police powers of the states.[73] It also represents one of many examples of drug exceptionalism and addiction exceptionalism in the law. These regimes are burdensome, segregate care, involve excessive surveillance of providers and patients, continue to impede innovation and appropriate care of people with SUD, and further deter providers from assuming the risks.[74] Those prescribers who submit themselves to these enhanced OUD treatment regimens to provide appropriate, life-saving care to people with OUD also bear the risk of prosecution under Section 841(a)(1).[75]

[70] See Quinn & McLaughlin, *supra* note 60.

[71] Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281 (May 14, 1974).

[72] Drug Addiction Treatment Act of 2000, https://bit.ly/3QuI4ew.

[73] For an excellent explanation of the federalism concerns, see Br. of Professors of Health Law & Policy and Br. of Cato Institute, *supra* note 34.

[74] A comprehensive review of the regulation of opioid treatment programs and other medications for addiction is outside the scope of this essay. See, e.g., Ellen Weber, Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance, 13 J. Health Care L. & Pol'y 1, 49–76 (2010).

[75] See, e.g., United States v. Naum, 832 Fed. App'x 137 (4th Cir. 2020) (unpublished). Naum's petition for cert was granted and the case remanded for further consideration after the *Ruan* decision. Dr. Naum may have acted carelessly and out of compliance with the detailed regulatory requirements for buprenorphine prescribing, for which there are good administrative remedies. Yet he hardly met the standard of a corrupt prescriber—among other things, he enjoyed no real financial gain and his patients were actually helped rather than harmed.

Over the years, the CSA has been amended repeatedly, and, until very recently, generally in furtherance of punitive and retributionist rather than rehabilitative goals. The *Ruan* case focused specifically on one provision of the CSA: the felony drug distribution provision in Section 841(a)(1) under which prescribers are often prosecuted, which carries significantly stiffer penalties than the Harrison Act. The text of Section 841(a)(1) remains unchanged from 1970 as does the primary regulation that governs "effective prescribing." However, the standards for convicting prescribers thereunder have morphed over time in circular and conflicting ways that sometimes borrow from the ghosts of the Harrison Act more than the text of the CSA. This has complicated rather than clarified the standards for conviction.

*C. Section 841(a)(1) and Pre-*Ruan *Supreme Court Opinions*

Section 841(a)(1) makes it unlawful "*except as authorized* . . . for any person [to] *knowingly or intentionally* . . . distribute [] or dispense . . . a controlled substance."[76] For layperson prosecutions, the language is relatively straightforward—prosecutors must prove the defendant (1) knowingly or intentionally (2) distributed (3) a controlled substance. For a range of people to whom the "except as authorized" clause applies—including manufacturers, pharmacies, pharmacists, veterinarians, researchers, and others,[77] it is more complicated, especially because Congress did not provide much guidance. This essay and the *Ruan* case focus on what the government must prove to convict a prescriber under 841(a)(1). That depends, in large part, on what "as authorized" means. If practitioners act safely within the boundaries of "authorization," their conduct is lawful. The harder question to answer is where the boundary sits between less-than-careful prescribing or noncompliance with the CSA's technical requirements and unlawful felonious behavior punishable under 841(a)(1). The petitioners argued, as did most of the amici, that the line is set by the scienter of knowledge or intent explicit in the statutory text.

[76] 21 U.S.C. § 841(a)(1) (emphasis added).

[77] Entities such as manufacturers, pharmacies, and professionals such as pharmacists, researchers, veterinarians, etc. all have specific registration, recordkeeping, and reporting requirements and also fall under the "except as authorized" clause of 841(a)(1), but they are outside the scope of this essay. See 21 C.F.R. §§ 1300–1321.

1. When Is a Prescriber Authorized?

Acting "as authorized" requires compliance with registration mandates,[78] controlled substance prescription content and rules based on the drug's scheduling (technical requirements),[79] and the regulatory requirement of an "effective prescription."[80] Once a practitioner is licensed by the state to practice medicine (or another profession with prescriptive authority under state law),[81] she must apply for a certificate of registration (COR) from the Drug Enforcement Administration (DEA).[82] Practitioners with a COR possess a DEA number and are among those "authorized by this chapter" to dispense a "controlled substance *in the course of professional practice*"[83] and in "conformity with the other provisions of this title."[84] Those provisions include the central regulation defining an "effective" prescription,[85] which the attorney general promulgated without comment from practitioners in 1971.[86] An effective prescription is one "issued for a *legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice*."[87] Practitioners do not violate Section 841(a)(1) if they are otherwise authorized and issue prescriptions for a legitimate medical purpose in the usual course of professional practice.

Discerning the limits and consequences for noncompliance has proved more elusive. In part, this is because there are a range of less-than-ideal prescribing behaviors for which prescribers should not be criminally culpable. It's quite easy to violate the technical requirements for prescriptions.[88] This could be something as simple as

[78] 21 C.F.R. § 1301.

[79] 21 C.F.R. § 1306. Violations of technical requirements, such as lax records or missing dates, are usually spotlighted in these cases as well.

[80] 21 C.F.R. § 1306.04.

[81] 21 C.F.R. § 1306.03.

[82] 21 U.S.C. §§ 822(a) & 823(f); 21 C.F.R. § 1301.

[83] 21 U.S.C. § 802(21) (emphasis added).

[84] 21 U.S.C. § 822(b).

[85] 21 C.F.R. § 1306.04.

[86] 36 Fed. Reg. 7776 (1971).

[87] 21 C.F.R. § 1306.04(a) (emphasis added).

[88] Once when Dr. Henderson was leaving the country for 10 days, I asked him to "pre-sign" a few prescriptions in case I failed to account for the regular timeline of opioid prescription renewals for one or more of our established patients. He did so

omitting some information or forgetting to sign a prescription. In the administrative realm, those who depart from the federal authorization (including the technical requirements) may face administrative sanctions, up to and including the denial, suspension, or revocation of the COR. [89] There are also myriad state civil, administrative, and lesser criminal remedies for inappropriate prescribing.[90] Section 841(a)(1) should be reserved for the most egregious behavior, especially considering the severity of the penalties. However, the federal courts have struggled in the 50 years since the CSA's enactment to elucidate clearly and consistently exactly what the government must prove to secure a conviction against a prescriber under Section 841(a)(1).

2. The Standards before the Overdose Crises

Prior to *Ruan*, only once had the Court addressed prescriber prosecutions under Section 841(a)(1)—in a 1975 case, *United States v. Moore*.[91] The question was whether a prescriber could *ever* be subject to 841(a)(1) because Dr. Moore had already admitted that he did not act for legitimate medical purposes.[92] The Court concluded that where a prescriber was acting "outside the bounds of professional practice" and prescribing not "for legitimate purposes, but primarily for the profits to be derived therefrom," he may be prosecuted under Section 841.[93] The Court did not reach the standards for judging whether and when a prescriber's conduct had shifted from legitimate to "illegitimate channels" but did note that the CSA fails to "unambiguously spell out" such standards.[94] In 2006, in *Gonzales v. Oregon*, the Court noted

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with strict parameters that I would email him the details first and not deliver them to patients without his approval, which I did. We found out soon after that this was a violation of the CSA and didn't repeat it. But this kind of action has been used as a basis for felony conviction and a good example of why scienter is so important. See, e.g., United States v. Joseph, 709 F.3d 1082 (11th Cir. 2013).

[89] This wasn't added until 1984. 21 U.S.C. § 823(f)(1); 21 C.F.R. §§ 1301.35–1301.37.

[90] See, e.g., Dineen & Dubois, *supra* note 6.

[91] 423 U.S. 122 (1975).

[92] At the time of *Moore*, the DEA did not have authority to revoke or suspend a practitioner's COR. That was added in 1984. Absent the reach of 841(a)(1), the only remedies for misprescribing were found in state law. The DEA had no way to stop a practitioner from prescribing unless the state medical board acted first. See Gonzales v. Oregon, 546 U.S. 243, 261–62 (2006) (explaining the addition of the 1984 amendments).

[93] 423 U.S. at 135.

[94] *Id.* at 140.

that it had never considered "the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug pusher instead of a physician."[95]

The jury instructions from *Moore*, which the Supreme Court did not disturb, echoed the Harrison Act and became a model for future prescriber prosecutions. There, the jury was instructed

> that it had to find beyond a reasonable doubt that a physician, who *knowingly or intentionally*, did dispense or distribute [a controlled substance] by prescription, did so *other than in good faith* . . . in the *usual course of a professional practice and* in accordance with a standard of medical practice generally recognized and accepted in the United States.[96]

In the three decades following *Moore*, prescriber prosecutions proceeded across the country, and although there was variation in several of the standards, there was a sort of shaky consensus.[97] In general, and in line with the language of *Moore*, the government had to prove that the prescriber (1) acted outside their authorization, judged by a departure from prescribing for a legitimate medical purpose in the usual course of professional practice, and (2) did so knowingly or intentionally.[98] Initially, courts read this in the conjunctive—requiring *both* a departure from the usual course and no legitimate medical purpose.[99] Expert testimony is almost always used to establish the contours of the "usual course of professional practice." The usual course is judged by something of a watered down, national standard of care—prosecutors can show a departure from the usual course of professional practice far more easily

[95] Gonzales, 546 U.S. at 269 (internal quotations omitted).

[96] Moore, 423 U.S. at 149 (emphasis added).

[97] This is the term we used in our amici brief on the petition. See Br. of Profs. of Health Law & Policy Supporting Cert, *supra* note 34.

[98] Dineen & DuBois, *supra* note 6. See also Ronald W. Chapman II, Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic, 43 Champion 40 (2019).

[99] See, e.g., United States v. Varma, 691 F.2d 460, 462 (10th Cir. 1982) (the prosecution must show defendant "acted intentionally or knowingly and . . . prescribed the drug without a legitimate medical purpose *and* outside the usual course of professional practice") (emphasis added).

than establishing the actual standard of care in a malpractice case.[100] Therefore, also requiring the prosecutor to prove that there was no legitimate medical purpose (or that the defendant acted outside the "bounds of medical practice")[101] was necessary to save from criminal liability a well-meaning provider who had been careless with a prescription (putting them outside the usual course) but had issued it for her patient's legitimate medical needs.[102]

Second, courts allowed some type of good-faith defense for prescribers. Those were eventually described as falling into one of two camps. Some circuits, including the First, Seventh, and Ninth, adopted a subjective good-faith defense standard.[103] The subjective good-faith defense negated the *mens rea* showing of knowledge or intent by allowing the defendant to assert she intended to and honestly believed she was prescribing in the usual course of professional practice. Other circuits, including the Second, Fourth, and Sixth,[104] adopted an objective good-faith defense, which allowed a defendant to assert she honestly believed she had prescribed in the usual course of professional practice, but *only* if the belief was objectively reasonable. This reasonable belief standard rightly drew concern as a dressed-up negligence test that effectively criminalized standard-of-care departures.[105] Inserting the objectively reasonable standard into the good-faith defense circumvented, in some ways, what the jury already was charged with—judging the credibility of the evidence.

[100] For a direct comparison of those differences in Alabama, See Br. of Profs. of Health Law & Policy Supporting Petitioners at Sec. IV, *supra* note 34. See also Br. of Profs. of Health Law & Policy Supporting Cert at n.3, *supra* note 34.

[101] Some courts used this phrase instead of legitimate medical purpose. See, e.g., United States v. Schneider, 704 F.3d 1287, 1295–96 (10th Cir. 2013).

[102] See Petition for Certiorari, Naum v. United States, 832 Fed. App'x 137 (4th Cir. 2020), cert granted and remanded, 2022 U.S. LEXIS 3230 (U.S. June 30, 2022) (No. 20-1480); Chapman, *supra* note 98; John J. Mulrooney II & Katherine E. Legel, Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters, 101 Marq. L. Rev. 333, 425–26 (2017).

[103] United States v. Sabean, 885 F.3d 27 (1st Cir. 2018); United States v. Rosenberg, 585 F.3d 355, 357 (7th Cir. 2009); United States v. Feingold, 454 F.3d 1001 (9th Cir. 2006).

[104] United States v. Volkman, 797 F.3d 377, 387 (6th Cir. 2015); United States v. Hurwitz, 459 F.3d 463, 479 (4th Cir. 2006); United States v. Vamos, 797 F.2d 1146 (2d Cir. 1986).

[105] Deborah Hellman, Prosecuting Doctors for Trusting Patients, 16 Geo. Mason L. Rev. 3 (2009); Diane E. Hoffmann, Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies, 1 St. Louis U. J. Health L. & Pol'y 231(2008).

It removed from their purview the ability to acquit a defendant they judged as credible but whose honest intention and belief that they had prescribed in the usual course was misguided or silly.

Overall, courts generally also expressed concern about maintaining a boundary between criminal and other prescribing conduct, such as negligent or mistaken prescribing, which they expressed in various ways.[106] But these standards began to erode after the early 2000s with a sharp uptick in the last several years, corresponding suspiciously with the growing awareness of the overdose crises.

III. The Conflicting Standards during the Overdose Crises and the *Ruan* Case

Section 841(a)(1)(a) prosecutions were long riddled with uncertainty as applied to people otherwise authorized to prescribe, dispense, distribute, and administer controlled substances. Shifting tides and enhanced concerns about prescribers' role in increased drug-related morbidity and mortality also induced legal actors to create and amend many prescription controlled substances laws. Law enforcement also used the tools at their disposal,[107] including the CSA, especially as Congress appropriated more resources to scrutinize prescribers.[108] In tandem, the standards in some circuits slowly shifted to the point that deviation from behavior akin to standard of care was sufficient for conviction, without regard to the prescriber's mental state. This was achieved by eliminating the legitimate medical purpose element, hollowing out the good-faith defense, and applying the *mens rea* requirement to the simple act of issuing a prescription—all of which is innocent conduct that is part of the everyday practice of medicine. Those courts had transformed a serious federal felony, with the potential for life in prison and fines up to a million dollars, into a strict liability offense—effectively

[106] Br. of Profs. of Health Law & Policy Supporting Cert at Sec. I.C., *supra* note 34.

[107] 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. Reg. 3 (2020) ("[I]nvestigating and prosecuting prescribers . . . 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.").

[108] See, e.g., Dineen, Definitions Matter, *supra* note 13.

criminalizing careless, mistaken, or even careful but innovative prescribing.

At the same time, patients associated with opioids, including people with CPP and OUD, were suffering. The supply-side-only, misaligned legal "solutions" that focused almost exclusively on prescription opioids alone had left people desperately in need of care, mistreated, undertreated, and abandoned.[109] Practitioners were not only concerned about the risks of prescription opioids for their patients; they were also worried about being blamed, about their prescription patterns standing out, and about institutional and legal scrutiny of their practices.[110] Patients who had done well on long-term opioid therapy found themselves involuntarily tapered, cut off altogether,[111] further stigmatized,[112] or without a doctor willing to care for them. Too many of these patients died by suicide or after overdosing on illicit opioids,[113] eventually leading the Food and Drug Administration and the Centers for Disease Control and Prevention to issue warnings.[114] Many people with OUD could not access care, in part because practitioners weren't willing to incur the heightened scrutiny or navigate the regulatory complexities involved in prescribing medications for OUD.[115] Past was prologue and, like the

[109] *Id.*

[110] See, e.g., Cara L. Sedney et al., "The DEA Would Come in and Destroy You": A Qualitative Study of Fear and Unintended Consequences Emerging from Restrictive Opioid Prescribing Policies in West Virginia, 17 Substance Abuse Treatment, Prevention, & Pol'y 1 (2022) (conducting qualitative interviews with prescribers who repeatedly identified the fear of the DEA as motivating patient avoidance).

[111] See, e.g., Jackie Yenerall & Melinda B. Buntin, Prescriber Responses to a Pain Clinic Law: Cease or Modify?, 206 Drug & Alcohol Dep. 107591 (2020) (after state law changes, 24 percent of prescribers stopped prescribing altogether, without regard for patient needs); Amelia L. Persico et al., Opioid Taper Practices Among Clinicians, 14 J. Pain Res. 3353, 3357 (2021) (describing the CDC guidelines as prompting tapering).

[112] See, e.g., Allyn Benintendi et al., "I Felt Like I Had a Scarlet Letter": Recurring Experiences of Structural Stigma Surrounding Opioid Tapers among Patients with Chronic, Non-Cancer Pain, 222 Drug & Alcohol Dependence (2021).

[113] Beth D. Darnall et al., International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Opioid Tapering, 20 Pain Med. 429 (2019).

[114] See, e.g., Christine Vestal, Rapid Opioid Cutoff Is Risky Too, Feds Warn, PEW (May 21, 2019), https://bit.ly/3dmK6zh.

[115] Nat'l Acad., *supra* note 27.

Harrison Act in the 1920s, the law had succeeded in driving patients out of the medical system and into harm's way.

In tandem, it became far easier to convict a prescriber under Section 841(a)(1) even though the statute hadn't changed. By 2021, there was a long list of circuit splits such that *where* a prescriber-defendant was tried, rather than the prescribing conduct, determined whether she would be convicted or acquitted. In the amicus brief we filed in an effort to persuade the Court to hear *Ruan*, we detailed a non-exhaustive list of existing circuit splits in Section 841(a)(1) prescriber prosecutions. These included (1) whether the government must prove a practitioner departed from a legitimate medical purpose;[116] (2) whether the lack of a legitimate medical purpose is an element that must be included in the indictment;[117] (3) the availability and form of the good-faith defense;[118] (4) the relationship between good faith and *mens rea*;[119] (5) whether the jury must actually be instructed on the *mens rea*;[120] and (6) whether a prescriber may be convicted of dispensing, distributing, or both.[121] By the time the Court granted certiorari in *Ruan*, several circuits had successfully converted the drug distribution felony into a strict liability offense, but *only* when the defendant was a prescriber. The circuit courts did this in surprisingly confusing, conflicting, and overlapping ways that are hard to sort out—in part because of courts' reliance on good faith from the Harrison Act and in part because of the complexities of defining acting "as authorized." What the changes have in common, and what the *Ruan* decision corrects, is that most of the circuits

[116] Petition for Certiorari, Naum v. United States, *supra* note 102; Petition for Certiorari, Henson v. United States, 9 F.4th 1258 (10th Cir. 2021), cert granted and remanded (U.S. June 30, 2022) (No.19-3062) (also including a question of whether a willful blindness instruction was harmless error).

[117] Julia 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).

[118] Petition for Certiorari, Ruan v. United States, 142 S. Ct. 2370 (2022) (No. 20-1410).

[119] United States v. Khan, 989 F.3d 806 (10th Cir. 2021) (concluding that objective good faith does not negate *mens rea* but simply explains the course of professional practice); but see, e.g., United States. v. Godofsky, 943 F.3d 1011, 1021 (6th Cir. 2019) ("Reasonable [good faith] conduct or beliefs, if proven, would necessarily prevent the jury from finding that he had a knowing or intentional *mens rea*.").

[120] Petition for Certiorari, Dixon v. United States, 141 S. Ct. 137 (2020) (No. 19-1313).

[121] Petition for Certiorari, Faithful v. United States, 141 S. Ct. 1742 (2021) (No. 20-7204).

had either (1) eliminated *any* scienter requirement or (2) lessened the scienter requirement to one of something akin to recklessness or negligence.[122] They did this in multiple ways.

A. Reading the Effective Prescribing Regulation as Disjunctive

Most circuits had switched to reading the effective prescription regulation in the disjunctive—meaning the government was required to prove that the defendant had *either* (1) departed from the "usual course of professional practice" *or* (2) not prescribed "for a legitimate medical purpose."[123] This was problematic in several ways. First, a departure from the usual course is very easy to prove;[124] moreover, some circuits required only proof of unreasonableness in usual-course departures leading prosecutors to favor that option over legitimate medical purpose departures, which required subjective knowledge.[125] Second, the "usual course" is a moving target. Although courts refer to this as an "objective standard" because it is based on expert testimony about "reasonable" prescriber practices, the acceptable standards of care are made up of a range of options from the almost out-of-date to the innovative.[126] These differences are tolerable in the civil context because of the rigorous expert testimony standards and because it is just one of several elements required for liability to attach, including for patient harm caused by acting outside the standard of care. Even then, the standards for treating people with conditions like CPP are especially complicated. They are subject to wildly divergent views, conflicting evidence of effectiveness, and policies and laws that encourage "reasonable" doctors to adopt practices that aren't in patients' best interests. And they are open to interpretations that are far from objective—a dangerous benchmark for criminal liability.

[122] See, e.g., Model Penal Code, § 2.02.

[123] Only the Ninth Circuit, in *United States v. Feingold*, has affirmatively stated that both showings are required. 454 F.3d 1001 (9th Cir. 2006). See also Naum, 832 Fed. App'x 137; Henson, 9 F.4th 1258. For an example of the reasoning for a disjunctive reading, see United States v. Nelson, 383 F.3d 1227, 1232 (10th Cir. 2004) (overruling precedent and concluding that neither *Moore* nor the effective prescription regulation required a showing of both).

[124] See briefs cited, *supra* note 34.

[125] See, e.g., Khan, 989 F.3d 806.

[126] See, e.g., Sandra H. Johnson, Customary Standards of Care, 43 Hastings Ctr. Rep. 6, 9–10 (2013).

Third, while "legitimate medical purpose" is a regulatory rather than statutory term, it has been understood by both Congress[127] and the Court as an essential component of effective prescribing.[128] The disjunctive reading is also a classic example of the professional arrogance that can infect some lawyers (here some prosecutors and judges) when it comes to the nuances of medicine. In this context, except for the Ninth Circuit, there has been widespread endorsement that the usual course of professional practice and a legitimate medical purpose are simply two ways of saying the same thing.[129] Practitioners do not see it the same way.[130] Imagine a doctor who is overworked and even careless; as a result she accidently provides a new prescription at 20 days rather than 30 days a few times and neglects to make detailed notes in the patients' records. Her patients truly benefit from the prescriptions, which they take as prescribed. In this instance, a provider would have a legitimate medical purpose but would not have acted in the usual course of professional practice—behavior that is better remedied outside the criminal system. Now, if the scienter requirement of knowledge or intent is preserved, either as an element or with a subjective good-faith defense, the defendant here would probably not be convicted.

When paired with a weak objective good-faith defense, the disjunctive reading is more troublesome. In those situations, the defendant could argue she intended and believed she was practicing in

[127] When Congress amended the CSA to account for both mail order and internet prescribing in recent decades, it included new statutory provisions that include "legitimate medical purpose" in the definition of a valid prescription. For mail order prescriptions, a valid prescription is "issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice." 21 U.S.C. § 830(b)(3)(A)(ii) (2000). For internet prescriptions, among other things, a valid prescription is one "issued for a legitimate medical purpose in the usual course of professional practice." 21 U.S.C. § 829(e)(2)(A) (2008).

[128] Gonzales, 546 U.S. at 257 (describing C.F.R. § 1306.04 as a parroting regulation). Justice Antonin Scalia explained in his dissent that Section 1306.04 "gives added content to the text of the statute [§ 829]," such that a legitimate medical purpose is implicit in the requirements for an effective prescription. *Id.* at 279 (Scalia, J., dissenting) (citing Moore, 423 U.S. at 137 n.13 (1975)).

[129] That perception was aided greatly with active conflation by the DEA in guidance and policy. See Chapman, *supra* note 98.

[130] See, e.g., Mulrooney & Legel, *supra* note 102.

the usual course of professional practice. However, her belief would have to be reasonable, as judged again against the weak quasi-standard-of-care testimony allowed in these prosecutions. This is the very definition of circular reasoning: creating a situation in which the defendant can only be saved by convincing a jury it was reasonable to think she was behaving in ways the experts have already said are not reasonable.

Preserving or restoring a conjunctive reading is a work-around for the ways in which the objective good-faith defense weakens scienter. In the example above, the doctor's legitimate medical purpose could save her from the consequences of criminalized carelessness. This was the focus of the petition for cert in *Naum,* in which the doctor had taken on the treatment of people with OUD, including buprenorphine prescribing in hard hit and underserved West Virginia. He earned very little money and overstretched himself in the process. His patients benefited from the treatment—in fact, it's likely his prescriptions saved multiple lives. Nonetheless, it was true that he didn't act in the usual course of professional practice—he was careless in not adhering to the many regulatory requirements for OUD treatment and over-relied on a nurse. The Fourth Circuit allowed Naum an objective good-faith defense, but the jury didn't see his proffered belief as reasonable, and he was convicted. A conjunctive reading could have saved him, as he certainly had a legitimate medical purpose. While the *Ruan* Court did not weigh in on the specific conjunctive/disjunctive question, it was a question presented in the *Khan* petition as well. The Court's ultimate clarification of both scienter and to what elements it applies should provide reassurance.

B. Hollowing Out the Objective Good-Faith Defense

The issues that ultimately caught the Court's attention were the treatment by the Tenth and Eleventh Circuits, in *Khan* and *Ruan* respectively, concerning the objective good-faith defense (which was particularly dangerous because it was coupled with a disjunctive reading of the effective prescription regulation).[131] In both cases, the circuits had arrived at the conclusion that the objective good-faith defense was only available to defendants who already practiced within the usual course of practice. Intent didn't matter.

[131] Khan, 989 F.3d at 825–26.

The Eleventh Circuit in *Ruan* upheld the district court's jury instructions that collapsed good faith into standard of care, saying:

> A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully *if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice* generally recognized and accepted in the United States. The defendants in this case maintain at all times they acted in good faith and in accordance with [the] standard of medical practice generally recognized and accepted in the United States in treating patients. . . . Thus *a medical doctor has violated Section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice*.[132]

The district court, in issuing those instructions, had rejected the defendant's proposed instructions as too subjective. Those said:

> Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance *with what he reasonably believed to be proper medical practice*.[133]

The Eleventh Circuit agreed with the district court that those instructions were simply "too subjective." They endorsed the standard that would rest conviction on a simple showing that the prescriber's actions were not in the usual course of professional practice. The panel asserted that a good-faith defense was only available to defendants when their "conduct *also was in accordance with the standards of medical practice* recognized in the United States."[134] They had transformed Section 841(a)(1) into a strict liability offense such that even a mistake in prescribing was felonious.

The Tenth Circuit also created a strict liability offense for usual course departures in 2021, in *United States v. Khan*, by reconstructing the mechanism of the good-faith defense as having nothing to do with the culpable mental states. The court expressly stated,

[132] Petition for Certiorari, *supra* note 52, at 12 (emphasis added).

[133] *Id*. at 11 (emphasis added).

[134] *Id.* at 14 (emphasis added).

"[u]nlike other criminal offenses, good faith does not go to mens rea for § 841 offenses involving practitioners" and "the only relevant inquiry . . . is whether a defendant-practitioner objectively acted within [quasi-standard of care], regardless of whether he believed he was doing so."[135] In their estimation, knowledge only went *to the act* of writing a prescription—a standard met unless the prescriber did so in their sleep. Together, the Fourth, Tenth, and Eleventh Circuits had rewritten the CSA as applied to practitioners, grounding criminal liability in a mere departure from accepted medical practice.

C. It's the Scienter

Each of these issues was essentially about scienter in prescribing cases—both what it was and to what elements it applied. This was the focus of most of the briefs after the Court granted certiorari as well as of the Court's opinion. Viewed in that light and with the freedom to ask the Court for major clarifications, it seemed appropriate to explain that the circuits had managed to take a relatively straightforward statute and complicate it beyond recognition such that the elements of the crime for prescribers were no longer obvious. The boundary between innocent and unlawful conduct was clear as mud. In short, before *Ruan*, the defendants could not have knowledge of "all of the facts that make [their] conduct illegal."[136]

A culpable mental state requirement for criminal offenses is the default in the U.S. criminal legal system, and its existence grows in importance with the severity of the punishment.[137] The Court will also read in a *mens rea* requirement in a statutory void.[138] But there is no void here—knowledge or intent appear in the statute and interpreting the statute consistent with ordinary English usage means that the scienter requirement is one of knowledge or intent, just as it is for laypersons. The government, appealing to the "bad doctors" narrative again, asked the Court to ignore those words (but only when prescribers were defendants) in favor of a quasi-scienter which they struggled to articulate at oral argument. This left the justices

[135] Khan, 989 F.3d at 825–26.

[136] McFadden v. United States, 576 U.S. 186, 194–95 (2015).

[137] Dennis v. United States, 341 U.S. 494 (1951).

[138] Staples v. United States, 511 U.S. 600 (1994).

puzzled by the "no objectively honest effort" *mens rea* offered, which isn't a traditional mental state, and also because inserting reasonableness leads one back to a strict liability offense.[139]

In our amicus brief we argued that the government must prove beyond a reasonable doubt three material elements under Section 841(a)(1), whether prosecuting a layperson or a prescriber: that the defendant (1) knowingly (2) distributed (3) a controlled substance. Of course, prescribing controlled substances is part of everyday practice. Every time a doctor wrote a controlled substance prescription, she would be committing a crime if prescribing alone were enough for distribution. Proving a knowing departure from the authorization is what transforms conduct from innocent (regular prescribing) to unlawful (distribution).[140] Treating this as an element of the offense, rather than an affirmative defense, is the most straightforward reading of the statute. Holding that the *mens rea* applies to departures from authorization also is in line with several of the Court's previous cases that emphasize the role of scienter in separating innocent from criminal conduct.[141] The Court agreed, framing the question before them as "the state of mind that the government must prove to convict these doctors of violating the statute."[142]

[139] For example, at oral arguments, Justice Neil Gorsuch pushed the government's counsel on the implications of eliminating a *mens rea* for prescribers in the following exchange: "Justice Gorsuch: Just assume hypothetically [that the government brings a case against a doctor where their behavior is a close call] and that the jury believes that it's not legitimate medical purpose under your regulations. Even though it's an extremely close case, that individual stands, under the government's view, unable to shield himself behind any *mens rea* requirement and is subject to essentially a regulatory crime encompassing 20 years to maybe life in prison. Mr. Feigin: Well, Your Honor, I think— I think it's – Justice Gorsuch: I think the answer has to be yes, isn't it? Mr. Feigin: Your Honor, I think the answer is going to be yes." Tr. of Oral Arg., *supra* note 4, at 71–72.

[140] United States v. X-Citement Video, Inc., 513 U.S. 64, 79 (1994) ("[C]ourts ordinarily read a phrase in a criminal statute that introduces the elements of a crime with the word 'knowingly' as applied to each element.").

[141] See, e.g., Rehaif v. United States, 139 S. Ct. 2191, 2196 (2019) ("The cases in which we have emphasized scienter's importance in separating wrongful from innocent acts are legion."); Liparota v. United States, 471 U.S. 419, 426 (1985) (requiring knowledge that the possession of food stamps was unauthorized).

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

IV. The *Ruan* Decision and Conclusion

In an opinion written by Justice Stephen Breyer, the Court held that the statute's knowingly or intentionally *mens rea* applies to the "except as authorized" clause, such that the government must prove that a doctor or practitioner defendant *knowingly* acted outside the limits of their federal authorization to prescribe controlled substances or *intended* to do so.[143] The Court treats the knowing departure from authorization as an element of the offense, based on the importance of the vicious will in criminal offenses, the long-standing presumption of scienter, and the importance of setting a clear boundary between innocent and criminal conduct.

Procedurally, however, the Court did not treat a knowing departure as an element that must be pled in the indictment because of Section 855 of the CSA, which states that the government does not need to:

> "negative"—i.e., refute—"any exemption or exception . . . in any complaint, information, indictment, or other pleading." This means that, in a prosecution under the Controlled Substances Act, the Government need not refer to a lack of authorization (or any other exemption or exception) in the criminal indictment . . . and that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit," not upon the prosecution.[144]

The Court interpreted Section 885 to hold that the defendant retains the burden of production in raising the issue of authorization to prescribe controlled substances. Once raised, the government must prove beyond a reasonable doubt that the prescriber (subjectively) knew or intended to act outside her authorization (retaining the burden of persuasion).

In a concurring opinion by Justice Samuel Alito, joined in full by Justice Clarence Thomas and in part by Justice Amy Coney Barrett, the justices read Section 885 to preclude treating a departure from authorization as an element. They would treat it, instead, as an exception that would form the basis of an affirmative defense for which the defense would retain the burden of proving. The concurring

[143] *Id.* at 2375–76.

[144] *Id.* at 2379.

justices also argued that an authorization departure could not be an element because "except as authorized" preceded the words "knowingly or intentionally" in the statute, and basic grammar prohibits the adverbs of knowingly and intentionally from modifying the preceding clause.[145] This would make it far easier to convict a prescriber than a layperson and impose a different scienter requirement.

After *Ruan*, the government must prove not only that the prescriber did not act as authorized, but that she did so knowingly or intentionally. The decision should go a long way toward confining Section 841(a)(1) prosecutions to the corrupt among the "bad doctors" who knowingly used their authorization as a subterfuge for drug dealing as conventionally understood, a position that accords with the Court's previous treatment in *Moore*. It represents a victory for prescribing practitioners, who faced the threat of criminal investigation and prosecution for almost any prescribing behavior, including mistaken or careless controlled substances prescribing, whether their patients suffered any harm at all. While there is much work remaining to rationalize controlled substances prescribing law and policy, I hope *Ruan* will allow practitioners to fear criminal scrutiny a bit less and be slightly more willing to provide care that they believe is in their patient's interest such that patients with CPP, SUD, or both reap some benefit.

[145] This was the subject of some humorous back and forth between Justices Alito and Breyer about their grammar teachers in oral arguments. Tr. of Oral Arg., *supra* note 4, at 24.