No. 20-1410

In The Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

BRIEF OF *AMICI CURIAE* PROFESSORS OF HEALTH LAW AND POLICY IN SUPPORT OF PETITIONER

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INTEREST OF *AMICI CURIAE*[1]

Amici are professors of health law and policy at American universities. We have no personal interest in the outcome of this case. We have a professional interest in reducing morbidity and mortality related to drugs and ensuring access to appropriate treatment for patients with pain, addiction, and the many other conditions for which prescribed controlled substances are appropriate. Those interests are threatened by medical practitioners' understandable fears of criminal sanction created by the weakened, inconsistent, and unpredictable standards to convict prescribers under Section 841(a)(1) of the Controlled Substances Act (CSA).

SUMMARY OF THE ARGUMENT

Prescribing controlled substances for the benefit of patients is an everyday and essential practice for physicians and other authorized prescribing practitioners.[2] *Gonzales v. Oregon*, 546 U.S. 243, 254 (2006)

[1] Rule 37 statement: The parties were notified and consented to the filing of this brief more than 10 days before its filing. *See* Sup. Ct. R. 37.2(a). No party's counsel authored any of this brief; amicus alone funded its preparation and submission. *See* Sup. Ct. R. 37.6.

[2] Although these cases involve physicians, other practitioners—such as advance practice registered nurses and physician assistants—have prescribing authority under state law and are authorized to prescribe under the Controlled Substances Act to the extent of their state's permissions and in compliance with the Drug Enforcement Agency's requirements of authorization. *See*

(explaining that the inability to prescribe controlled substances would constitute a "severe restriction on medical practice"). Despite dominant public narratives about the harms of prescribed controlled substances, these compounds are neither harmful nor useful absent context. In fact, they are essential to modern medicine;[3] a reality acknowledged by Congress in the initial sentences of the CSA. 21 U.S.C. § 801(1) (many of the controlled substances under the statute's purview "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people"). Indeed, prescribed controlled substances are a critical component of appropriate, ethical, and evidence-based care for patients with a range medical needs and conditions beyond pain and opioid use disorder, from treating patients with severe COVID-19 respiratory failure, Jai Madhok & Frederick G. Mihm, *Rethinking Sedation During Prolonged Mechanical Ventilation for COVID-19 Respiratory Failure*, 131 ANESTHESIA & ANALGESIA 1

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generally, PHILLIP ZHANG & PREETI PATEL, PRACTITIONERS AND PRESCRIPTIVE AUTHORITY (2021), https://www.ncbi.nlm.nih.gov/books/NBK574557/.

[3] For example, every person who has had general surgery or a procedure with sedation (*e.g.*, colonscopy) has received prescribed controlled substances. *See generally*, Richard H. Epstein, et al., *Intraoperative Handoffs Among Anesthesia Providers Increase the Incidence of Documentation Errors for Controlled Drugs*, 43 JOINT COMM'N J. QUALITY & PATIENT SAFETY 392 (2017); Fahima Dossa et al., *Propofol Versus Midazolam with or Without Short-Acting Opioids for Sedation in Colonoscopy: A Systematic Review and Meta-Analysis of Safety, Satisfaction, and Efficiency Outcomes*, 91 GASTROINTESTINAL ENDOSCOPY 1015 (2020).

(2020), to regulating wakefulness for pilots. John A. Caldwell & J. Lynn Caldwell, *Fatigue in Military Aviation: An Overview of U.S. Military-Approved Pharmacological Countermeasures*, 76 AVIATION, SPACE, & ENV'T MED. C39 (2005).

Like all medications, prescribed controlled substances also carry the potential for harm, including the risk that those drugs may be diverted for use by others without medical supervision. Practitioners have professional legal and ethical duties to carefully weigh the potential benefits and harms to their patients, and to prescribe controlled substances in a way that reduces the likelihood of diversion. *See* Kate M. Nicholson & Deborah Hellman, *Opioid Prescribing and the Ethical Duty to Do No Harm*, AMER. J. L. & MED. 297 (2020); Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Health Problems*, 40 L. & PSYCH. REV. 1, 35 (2016). These prescribing decisions are fraught with peril,[4] including legal peril, in ways that prescribing other potentially harmful drugs are not—especially considering the responses to the drug overdose crises in the United States.[5] Over the last decade,

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[4] Daniel Z. Buchman, Anita Ho, & Daniel S. Goldberg, *Investigating Trust, Expertise, and Epistemic Injustice in Chronic Pain*, 14 BIOETHICAL INQUIRY 31 (2017).

[5] The "opioid crisis" is an inaccurate description of the drug use related morbidity and mortality crisis in the U.S., which is a pressing and complex problem with social, cultural, medical, and legal causes. Abundant evidence supports the conclusion that neither prescription opioids nor any class of prescription controlled substances were the only or even a primary driver of overdose

legal and institutional actors have implemented blunt, reactive policies with the singular goal of reducing controlled substances prescriptions. *See*, *e.g.*, Amy Lieberman & Corey Davis, *Laws Limited the Prescribing or Dispensing of Opioids*, NETWORK FOR PUBLIC HEALTH LAW (May 11, 2021), https://www.networkforphl.org/resources/laws-limiting-the-prescribing-or-dispensing-of-opioids/?blm_aid=844744295. As prescribing rates have plummeted during the last decade, the harms to patients in need of care and safe access to medication have significantly increased. Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 KS. L. REV. 101 (2019); Nicholson & Hellman.

CSA Section 841(a)(1) prosecutions carry a significant possibility of federal imprisonment—the most severe of the many legal and quasi-legal remedies available to address problematic prescribing. 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 AMER. J.L. & MED. 1 (2016). Until recently, Section 841(a)'s scienter requirement, which demands a knowing departure from the usual course of professional practice, constrained such prosecutions. But the CSA has been weaponized against practitioners in reaction to the overdose crisis. Federal practitioner

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deaths. *See*, *e.g.*, Nabarum Dasgupta et al., *Opioid Crisis: No Easy Fix to its Social and Economic Determinants*, 108 AMER. J. PUB. HEALTH 2 (2018).

investigations and prosecutions have increased while the standards for conviction under Section 841(a)(1) have steadily eroded. *See*, *e.g.*, NAT'L ASS'N OF ATTORNEYS GENERAL, "FIRST, DO NO HARM": CRIMINAL PROSECUTIONS OF DOCTORS FOR DISTRIBUTING CONTROLLED SUBSTANCES OUTSIDE OF LEGITIMATE MEDICAL NEED (May 4, 2017), https://www.naag.org/attorney-general-journal/criminal-prosecutions-of-doctors-for-distributing-controlled-substances/.

Prosecutorial and judicial statutory reconstruction to more easily convict practitioners is not the cure for drug related morbidity and mortality. *See* Centers for Disease Control and Prevention, National Center for Health Statistics, *Drug Overdose Deaths in the U.S. Top 100,000 Annually* (Nov. 17, 2021), https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2021/20211117.htm (reporting an almost 30% increase in and record high number of overdose deaths between April 2020 and 2021). As we previously explained, and as the petitioners have described in the consolidated cases here, the Tenth and Eleventh Circuits have effectively eliminated Section 841(a)(1)'s *mens rea* requirements as applied to prescribers. *Brief of* Amici Curiae *Professors of Health Law and Policy in Support of Petitioner, Ruan v. United States*, No. 20-1410 (May 7, 2021). While the government must prove *intentional or knowing* distribution of controlled substances for *non-prescribers* under Tenth and Eleventh Circuit precedent, the government may convict an authorized prescriber of felony distribution without proof that they had any knowledge of "all the facts that make

[their] conduct illegal." *McFadden v. United States*, 576 U.S. 186, 194–95 (2015). Practitioners can face decades in prison for nothing more than deviations from accepted medical standards, including mistaken, foolish, negligent, and reckless prescribing (good faith medical error). *See* Dineen & DuBois at 21.

The text and history of the CSA and this Court's relevant precedent all support the conclusion that Section 841(a)(1) was designed to punish practitioners who engage in intentional or knowing illicit drug distribution by using their authorization to prescribe as a subterfuge for diverting drugs. The statute was not intended to remedy poor or even harmful medical decision-making. The Tenth and Eleventh Circuits' constructive rewriting of the CSA as applied to practitioners harms patients with legitimate medical need for controlled substances, forces practitioners to act unethically to protect themselves from legal sanction at the expense of the well-being of the patient, imperils the evolution of patient care, and implicates significant federalism concerns. We respectfully request that this Court clarify the scienter requirements of Section 841(a)(1) and reject the legal exceptionalism embraced by several federal circuits that have determined to apply good faith to the *actus rea* rather than the *mens rea* requirements of the statute. *See*, *e.g.*, *United States v. Khan*, 989 F.3d 806 (10th Cir. 2021). The CSA's reach should only extend to practitioners who knowingly or intentionally (*i.e.*, not with subjective good faith) depart from their controlled substances authorization to prescribe outside the usual course of

professional practice, and thereby transform legitimate prescribing into unlawful distribution. This is the most coherent interpretation of the line between otherwise lawful activity (prescribing as authorized) and criminal distribution under Section 841(a)(1).

ARGUMENT

I. Conviction of Practitioners under Section 841(a)(1) Should Require a Knowing Departure from the Terms of Their Authorization

A. The Statutory Framework and Elements of the Crime

The Controlled Substances Act (CSA) makes it unlawful, "*except as authorized* . . . for any person [to] knowingly or intentionally . . . distribute . . . a controlled substance." 21 U.S.C. § 841(a)(1) (emphasis added). Authorization is attended by certification requirements (such as state practitioner licensure and a valid, DEA-issued certificate of registration (COR) permitting prescribing),[6] as well as practice requirements, including a mandate that authorized practitioners may only distribute controlled substances "in the course of professional practice," 21 U.S.C. § 802(21), by issuing valid prescriptions, *id.* § 829, defined as those "issued for *a legitimate medical purpose*

[6] 21 U.S.C. §§ 822(a) & 823(f); 21 C.F.R. § 1306.03. Authorization also requires conformity with other provisions of the CSA, *id*. § 822(b), and with regulations issued by the Attorney General. *See id*. §§ 821 & 871(b).

by an individual practitioner acting *in the usual course of his professional practice*." 21 C.F.R. § 1306.04(a) (emphases added). The administrative penalties for failure to comply with the authorization requirements include suspension and permanent revocation of the COR. 21 U.S.C. § 824; 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, 389 (2017).[7]

Criminal prosecution under Section 841(a)(1), of course, carries far more serious penalties. To convict a *non-practitioner* defendant, the government must prove that the defendant (1) intentionally or knowingly (2) distributed (3) a controlled substance. *Id*.; *McFadden* at 188-89 (the government is required to "establish that the defendant *knew* he was dealing with a controlled substance" as one of the facts the defendant must know to constitute a crime) (emphasis added).

In *United States v. Moore*, this Court did not address the requirements the government must satisfy to convict *a practitioner* under Section 841(a)(1) because the defendant conceded a knowing departure from the usual course of professional practice at trial. 423 U.S. 122 (1975). The Court reached the narrower conclusion that the federal government's issuance of a COR was not sufficient to shield practitioners from prosecution

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[7] Section 824 also includes a few subsections with *mens rea* requirements, *see* § 824(a)(12)(b); § 824(c)(2)(A), making it even more unlikely that the felony provision at Section 841(a)(1) would not include the same or a higher scienter requirement.

when their prescription(s) fall outside "legitimate channels," such that they are acting "outside the bounds of professional practice" and prescribing not "for legitimate purposes, but primarily for the profits to be derived therefrom." *Id.* at 131-135.[8] This Court has not yet considered "the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug pusher instead of a physician." *Gonzales*, 546 U.S. at 269 (internal quotations omitted).

Since *Moore*, the federal circuit courts have inconsistently defined the elements of the crime in prescriber prosecutions. *Compare, e.g.*, *United States v. Ruan*, 966 F.3d 1101, 1136 (11th Cir. 2020) ("[i]n the medical context, drug distribution in violation of § 841(a)(1) requires proof that either 1) the prescription was not for a 'legitimate medical purpose' *or* 2) the prescription was not made in the 'usual course of professional practice' "); *with United States v. Kohli*, 847 F.3d 483, 486 (7th Cir. 2017) (the government must prove that the defendant (1) knowingly caused to be dispensed the controlled substance alleged; (2) did so by intentionally prescribing the controlled substance outside the usual course of professional medical practice, and not for a legitimate medical purpose; and (3) knew that the substance was some kind of a controlled substance).

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[8] *Moore* was decided when the only unilateral federal mechanism to stop a practitioner from prescribing was Section 841 prosecution. The CSA was later amended to allow the DEA to deny, suspend, or revoke a COR if continued registration would be inconsistent with the public interest.

Even with differences as to Section 841(a)(1)'s specific elements, there had been some consensus that the government must prove that the defendant knowingly departed from "usual course of professional practice," or, at a minimum, acted without a "legitimate medical purpose," which serves as a proxy of sorts for the practitioner's knowing departure from the usual course of professional practice.[9] *See*, *e.g.*, Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 CHAMPION 40 (2019). The Tenth and Eleventh Circuits, however, have eviscerated that tenuous consensus by eliminating the scienter requirement altogether and, thus, permitting conviction for prescriptions not written in the usual course of professional practice. *Ruan* at 1136; *Khan* at 825 (the government must prove "that a practitioner-defendant either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; *or* (2) issued a prescription that was objectively not in the usual course of professional practice") (emphasis added). By writing the *mens rea* out of the statute, a good faith medical prescribing error is criminalized, which conflates civil and criminal liability. *See*, *e.g.*, Diane E. Hoffmann, *Treating Pain Verses 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).

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[9] The regulation at 21 C.F.R. § 1306.04(a) might be understood as providing context to Section 841(a)(1) by using "legitimate medical purpose" as a short-hand for subjective good faith to treat a patient in the "course of professional practice."

B. The Scienter Requirement

"The existence of a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence," *Dennis v. United States*, 341 U.S. 494 (1951), and there is a strong presumption in favor of reading in a *mens rea* requirement, even when not statutorily defined. *Staples v. United States*, 511 U.S. 600 (1994). Congress explicitly included a minimum scienter requirement of knowledge in the text of Section 841(a)(1). Interpreting the statute consistent with "ordinary English usage," *Flores-Figueroa v. United States*, 556 U.S. 646, 652 (2009), the government must prove three material elements under Section 841(a)(1) beyond a reasonable doubt: that the defendant (1) knowingly (2) distributed (3) a controlled substance. *McFadden* at 188-189.

These material elements are the same whether the defendant is a practitioner or a layperson. In the case of a practitioner, however, because prescribing is an authorized activity, the government must meet the distribution requirement by proving a practitioner acted outside their authorization. Thus, in practitioner cases, the government must prove that the defendant (1) knowingly (2) acted without authorization (and, thus, unlawfully distributed) (3) a controlled substance. The word knowingly applies to the verb(s) (here, distribute) and the object of the verb(s) (here, controlled substance) in the statute. *McFadden* at 191; *Liparota v. United States*, 471 U.S. 419 (1985). The second element (acted without authorization) can only be met if the defendant acted outside the course of

professional practice, 21 U.S.C. § 802 (21), *and* did so *knowingly*. *See*, *e.g.*, *United States v. X–Citement Video, Inc*., 513 U.S. 64, 79 (1994) (Stephens, J., concurring) ("courts ordinarily read a phrase in a criminal statute that introduces the elements of a crime with the word "knowingly" as applied to each element").

The Tenth and Eleventh Circuits' elimination of the knowledge requirement for the *actus rea* of distribution (prescribing outside the scope of authorization in the case of practitioners) creates a two-tiered system in which prosecutors are only required to prove knowledge of distribution when prosecuting laypersons. The assertion that the government may succeed against practitioners by either proving that they "(1) subjectively knew a prescription was issued not for a legitimate medical purpose; *or* (2) issued a prescription that was objectively not in the usual course of professional practice," as the Tenth Circuit held in *Kahn* is a perversion of the criminal statute. Such a reading, in fact, severs the *mens rea* (subjective knowledge) from the *actus rea* (objective departure from the usual course of practice) and permits conviction if either is proven instead of reading them together.

Construing the CSA to permit the criminalization of carelessness or negligence also conflicts with this Court's long history of interpreting criminal statutes to include a *mens rea* requirement for each element to avoid criminalizing apparently innocent conduct. *See Staples* at 610; *Liparata* at 426 (requiring knowledge that the possession of food stamps was unauthorized); *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"). Because practitioners frequently prescribe controlled substances knowingly under their authorization, the scienter requirement is critical in separating accidental or negligent conduct from knowing distribution. Without knowledge of the departure from authorized prescribing, a practitioner "may well lack the intent needed to make his behavior wrongful." *Rehaif* at 2197.

Finally, the nature and purpose of the CSA also supports the conclusion that Congress only intended to criminalize drug trafficking as traditionally understood, that is, to prosecute practitioners who use their status as a subterfuge to engage in drug dealing for personal gain. In *Moore*, this Court carefully examined the CSA's legislative history and concluded that Section 841 only applied to transactions that fell outside legitimate distribution chains and that criminality turned on the nature of the transaction. *Moore* at 132-138; *see also Gonzales* at 250. The defendant's knowledge that she is prescribing outside of her authorization is central to the nature of the transaction. As such, the government must prove the practitioner acted intentionally or knowingly (*i.e.*, other than in good faith) to secure a conviction. Any other construction, including the spurious objective good faith standard, is just another road to criminalizing prescribing without the requisite *mens rea* showing. *See*, *e.g.*, Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701 (2009).

II. Eliminating the *Mens Rea* Requirement from 841(a)(1) Stifles Innovation, Harms Patients, and Compromises Practitioners' Ethical Integrity

In the absence of a *mens rea* requirement, the national standards of practice used in Section 841(a)(1) prosecutions to determine the usual course of professional practice is a dangerous precedent for criminal liability. Standard of care inquiries in civil matters evaluate the reasonableness of practitioner treatment decisions and measure prevailing customs, with tolerance for "respectable minority" approaches, including innovative medical practices. Sandra H. Johnson, *Customary Standards of Care*, 43 HASTINGS CTR. REP. 6, 9-10 (2013). In civil matters, liability does not implicate more than reputational and pecuniary interests. On the other hand, using one component of a civil standard to determine criminal liability will further fuel practitioners' reasonable fears of the kinds of legal scrutiny that can end not only practitioners' careers but deprive them of basic liberties. Dineen & DuBois. In self-interest, practitioners are incentivized to avoid innovation and the care of patients with unique or complex needs. Instead of comporting with the ethical duties to maximize their patients' well-being, practitioners over-comply with perceived legal norms to avoid any possible legal entanglement at those patients' expense. *Id.*; Dineen, *Definitions Matter*.

The fear of criminal scrutiny, including the deterrent effect of investigations alone, motivates practitioners to avoid prescribing controlled substances as

well as the care of the patients who might benefit from them. Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973 (2009); *see also* 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* (Oct. 25, 2021), https://www.researchsquare.com/article/rs-991531/v1 (conducting qualitative interviews with prescribers who repeatedly identified the fear of the DEA as motivating patient avoidance). According to Michael Barnes,

> DOJ raids and searches . . . interrupt the delivery of health care, put patients' lives at risk, and unjustly destroy careers and livelihoods. They also create confusion and fear among professionals serving or considering serving similar patient populations. A reluctance to practice and prescribe controlled medications when medically necessary is especially troublesome given rising rates of suicide, the availability of increasingly lethal black-market alternatives, and in the case of OUD, the federal objective of increasing, rather than decreasing, prescribing.

Michael C. Barnes, *A More Sensible Surge: Ending DOJ's Indiscriminate Raids of Healthcare Providers*, 8 LEG. & POLICY BRIEF 7, 21 (2019).

Fear of scrutiny also contributes to the avoidance of patients with opioid addiction, for whom prescribed

controlled substances are both the gold standard of medical care and drastically under-utilized. NAT'L ACADEMIES OF SCIENCES, MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES (2019). As the National Academies of Sciences explained, "the DEA's approach can be 'threatening,' and some . . . providers feel that they are unfairly scrutinized . . . [and] recent aggressive enforcement strategies[,] . . . including increases in raiding, auditing, and launching criminal investigations . . . perpetuate the fear of such surveillance." *Id.* at 120-121. It is ironic that practitioner prosecutions under Section 841(a)(1) may further drive avoidance of patients with addiction given that an express purpose of the CSA was to increase access to addiction care, an area devastated by decades of Harrison Narcotic Act enforcement against prescribers, which created a century long separation of addiction care from medicine and pushed people with substance use disorders from doctors to drug dealers. *See*, *e.g.*, Evan D. Anderson, Jason Sloan, & Leo Beletsky, *Intensive Care for Pain as an Overdose Prevention Tool: Legal Considerations and Policy Imperatives*, 5 U. PA. L. & PUB. AFF. 63, 98 (2019). Even today, most people with addiction face stigma, discrimination, and a lack access to evidence-based care. Kelly K. Dineen & Elizabeth Pendo, *Substance Use Disorder Discrimination and the Cares Act: Using Disability Law to Inform Part 2 Rulemaking*, 52 ARIZ. ST. L.J. 1143 (2020).

Focused policy efforts to curb all prescribing in response to the overdose crises has further turned practitioners away from patients in need. Dineen,

Definitions Matter at 1001-1011 (describing the serious harms and deaths from suicide and the shift to illicit drugs after prescribers abandoned patients, abruptly stopped prescribing, or rapidly tapered patients' opioids out of fear of legal scrutiny). One of the most influential was the CDC Guideline for Prescribing Opioids for Chronic Pain. Deborah Dowell et al., 65 MMWR RECOMM. REP. 1 (2016). These recommendations and others were accorded the force of legal mandates and entities from insurance companies to provider groups, adjusted recommended prescribing parameters further downward to ensure compliance. Dineen, *Definitions Matter*. Practitioners followed suit, many of whom abandoned their ethical duties to patients and made medical decisions out of self-protection rather than in their patients' best interests, including by abruptly discontinuing and involuntarily tapering patients from opioids. *Id*.; 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); Amelia L. Persico et al., *Opioid Taper Practices Among Clinicians*, 14 J. PAIN RES. 3353, 3357 (2021) ("we found that motivation for tapering opioids was strongly influenced by CDC guidelines and insurance regulations *rather than medical reasons or patient specific factors*") (emphasis added).

Patients suffered needlessly and even died. This situation was so dire that both the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention issued warnings about unwarranted

discontinuations and resulting suicides. Christine Vestal, *Rapid Opioid Cutoff is Risky Too, Feds Warn*, PEW (May 21, 2019) https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/05/21/rapid-opioid-cutoff-is-risky-too-feds-warn. Today, many practitioners categorically refuse to treat patients with chronic pain, while others simply stopped medically indicated prescribing. 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% of prescribers stopped prescribing altogether, without regard for patient needs).

Dr. Lynn Webster explained the ethical dilemma and the harms that can result from the legal pressure to reduce even helpful medications. Reflecting on his patient Jack, who died by suicide after Webster decreased Jack's daily medication dose out of fear of legal scrutiny, Webster said,

> I had to ask myself if my concern for my freedom and licensure had led to this tragedy. This was a moral dilemma . . . I could have continued to prescribe a high dose of opioids, but if he had died . . . the medical examiner might have said the death was an unintentional overdose . . . [he] might have even intentionally overdosed and no one would know. Deaths from opioids have become red flags for investigations. By contrast, Jack's death by suicide was not widely recognized by anyone beyond his family and me. I was tormented by the thought that he might have died because I was unable to help him.

Lynn Webster, *Pain and Suicide: The Other Side of the Opioid Story*, 15 PAIN MED. 345 (2014).

Patients with pain, addiction, or both desperately need appropriate care and treatment. If practitioners are held strictly liable under Section 841(a)(1), patient abandonment will become ever more common as practitioners act to avoid scrutiny. Progress in medical care in these areas can only recover if the regulation of medical practice is returned to the province of the states except in narrow circumstances.

III. Any Construction of the CSA that Criminalizes Medical Error Improperly Intrudes on the States' Power to Regulate the Practice of Medicine

Any construction of Section 841(a)(1) that permits the federal government to criminalize good faith medical errors raises alarming federalism implications. The states that have primary authority to regulate the practice of medicine under their reserved Tenth Amendment police powers. *See*, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1925) ("[D]irect control of medical practice in the states is beyond the power of the federal government."); *Barsky v. Bd. of Regents*, 347 U.S. 442, 449 (1954) ("The state's [broad power to establish and enforce standards of conduct within its borders relative to health] extends naturally to the regulation of all professions concerned with health."); *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (The regulation of health and

safety is "primarily, and historically, a matter of local concern[.]"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (espousing that establishing "standards of reasonable medical care" is a "quintessentially state-law" function).

The preservation of a proper balance between federal and state powers is central to our constitutional design and the protection of fundamental liberties. As this Court has explained:

> This federalist structure of joint sovereigns preserves to the people numerous advantages. It assures a decentralized government that will be more sensitive to the diverse needs of a heterogenous society; it increases opportunity for citizen involvement in democratic processes; it allows for more innovation and experimentation in government; and it makes government more responsive. . . . Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.

Gregory v. Ashcroft, 501 U.S. 452, 458 (1991).

Consequently, the federal-state balance of power cannot be dramatically reconstrued by either judicial supposition or a federal law enforcement agency's interpretation of a statute that runs afoul of its plain text. *Raygor v. Regents of University of Minnesota*, 534

U.S. 533, 543 (2002) ("When Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute."). The federal government has no right to interfere with a state's authority to regulate medical practice without "a clear indication that Congress intended that result." *Solid Waste Agency of Northern Cook County v. United States Corps of Engineers*, 531 U.S. 159, 172 (2001); *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000) ("[I]n the field of health care, a subject of traditional state regulation, there is no . . . preemption without clear manifestation of congressional purpose.").

In cases involving "Congressional regulation of core state functions," the clear statement canon has been characterized as a "super-strong rule" of statutory construction that carries weightier force than ordinary preemption. William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules as Constitutional Lawmaking*, 45 Vand. L. Rev. 593, 623-24 (1992); *see also Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 208–09 (1998) ("[A]bsent an unmistakably clear expression of intent . . . we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted).

The rule of lenity, a "time-honored interpretive guideline," also applies when Courts construe an ambiguous criminal statute. *United States v. Kozminski*, 487 U.S. 931, 952 (1988). Under the rule, when

choosing between two constructions of a crime, the statute shall be construed in favor of the defendant. *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221-22 (1952) ("We should not derive criminal outlawry from some ambiguous implication"). The relevant provision of the CSA at issue here, however, is unambiguous.

CSA Section 841(a)(1) cannot be interpreted as criminalizing good faith medical mistakes under pertinent precedent because the statute lacks any suggestion that Congress intended to delegate to the Department of Justice (DOJ) breathtaking authority over the practice of medicine. Instead, Congress explicitly left to the states the authority to regulate the medical professions. *See* 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided."). This Court has long recognized that the state's protection of "the health of its citizens . . . is at the core of its police power," *Sporhase v. Neb. ex rel. Douglas*, 458 U.S. 941, 956 (1982), and has expressly rejected the notion that the CSA grants either DOJ or DEA the broad authority to regulate the practice of medicine:

> [t]he [CSA] and our case law amply support the conclusion that Congress regulates medical practice *insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and*

> *trafficking as conventionally understood*. Beyond this, however, *the statute manifests no intent to regulate the practice of medicine generally*. The silence is understandable given the structure and limitations of federalism, which allow the [s]tates "[]great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.[]"

Gonzales, 546 U.S. at 269-70 (emphases added).

Not only does Congress know how to explicitly delegate the authority to regulate controlled substance prescribing to a federal agency, it has done so in one—and only one—narrow category: opioid use disorder (OUD) treatment. *Id*. at 271 (holding that 42 U.S.C. § 290bb-2a is the only arena in which Congress has set federal medical standards and "indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute"); *see also* Anderson et al. at 98 ("Despite the longstanding norm of federal noninterference in medicine, . . . the federal government can regulate medical practice if it makes its intention to do so clear and unambiguous."). And even then, Congress expressly delegated the authority to set federal medical standards regarding OUD treatment to the Department of Health and Human Services (HHS) and not a federal law enforcement agency. 42 U.S.C. § 290bb-2a ("The Secretary of Health and Human Services, after consultation with the Attorney General . . . shall determine

the appropriate methods of professional practice in the medical treatment of the narcotic addiction. . . .").

Federal law enforcement agencies are unqualified to determine whether drugs "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1). Congress, therefore, did not even leave it to DEA to perform one of its core CSA functions—the scheduling of controlled substances—without health care agency oversight and evaluation. *See id*. § 811(b) ("The Attorney General shall, before initiating proceedings . . . [to schedule or reschedule a drug] . . . request from the [HHS] Secretary a scientific and medical evaluation, . . . The recommendations of the Secretary to the Attorney General shall be binding . . . as to such scientific and medical matters.").

Furthermore, this Court has expressly held that DOJ cannot criminally prosecute OUD prescribers under CSA Section 841(a)(1) unless they sell "drugs, not for legitimate purposes but 'primarily for the profits to be derived therefrom' " and are acting outside the usual course of professional practice such that their behavior is akin to that of a "large-scale [drug] pusher, not as a physician." *Moore* at 345. Congress's refusal to permit a federal agency to regulate the practice of medicine beyond illegal trafficking is further evidenced by the Narcotic Addict Treatment Act (1974) (NATA), which amended the CSA to permit HHS to regulate OUD treatment. NATA's legislative history demonstrates that the Senate Judiciary Committee carefully

weighed the states' long-standing authority to regulate "the general practice of medicine" against "the specialized circumstances within the purview of the bill [e.g., OUD treatment], which entail inordinate *risks of diversion and unethical profiteering*." S. Rep. No. 93-192, at 13 (1973). The Committee report further explains that the purpose of the NATA amendments was to "reaffirm the commitment Congress made to the nation when it passed the [CSA] by . . . facilitating the prosecution of those who engage in the criminal distribution of legitimate narcotic drugs *for profit*." *Id*. at 15. In sum, the CSA permits the federal prosecution of prescribers who operate as drug traffickers as traditionally understood and, thereby, knowingly or intentionally engage in prescribing conduct that exceeds the bounds of professional practice. Congress never intended to delegate to law enforcement the authority to regulate the practice of medicine by criminalizing good faith medical mistakes. *See* 21 U.S.C. § 903.

The CSA also *depends on state law* to determine which medical professionals constitute "practitioners" acting "in the course of professional practice" and are, therefore, presumptively eligible for federal controlled substance registration. 21 U.S.C. § 823(f) provides that "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances *under the laws of the State in which he practices*") (emphasis added); *id*. § 802(21) (defining "practitioner" to include "a physician . . . licensed . . .

by the United States *or the jurisdiction in which he practices* . . . to . . . dispense . . . a controlled substance in the course of professional practice") (emphasis added). The CSA further mandates that DOJ defer to state medical licensing authorities before denying, suspending, or revoking a state-licensed prescriber's registration. *Id*. § 823(f)(1) (explaining that the Attorney General may deny, suspend, or revoke a state-licensed prescriber's registration if doing so is in "the public interest" and that the first of the five factors that the Attorney General must consider in making such a determination is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority"). In a 1998 letter to the House Judiciary Committee Chairman, Attorney General Janet Reno explained that the CSA was not "intended to displace the states as the primary regulators of the medical profession or to override a state's determination as to what constitutes legitimate medical practice." *Oregon v. Ashcroft*, 368 F.3d 1118, 1123 (2004).

Consistent with Congress's long-standing policy of leaving the regulation of medical practice to the states was its refusal to enact the Pain Relief Promotion Act (PRPA), which would have made illicit the controlled substances used in physician-assisted suicide and, thus, delegated to the DEA the authority to regulate medicine. Pointing to the DEA's lack of requisite medical and scientific expertise, Congress rejected PRPA. S. Rep. No. 106-299, at 61 (2000) ("[T]his poorly written, poorly thought-out statute would wreak havoc on States' traditional police authority to regulate their

own doctors—an authority they have enjoyed for more than 200 years. . . . *In our view, the DEA is not qualified to handle investigations into allegation [sic] of the misuse of pain management drugs*.") (emphasis added).

Congress has refused to extend the right to interfere with the states' regulation of medical practice even to those federal agencies with significant scientific and medical expertise. The Food Drug and Cosmetics Act (FDCA) expressly provides that it should not "be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device . . . within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396; *see also United States v. Regenerative Sci.*, *LLC*, 878 F. Supp. 2d 248, 255 (D.D.C. 2012). This express limitation of the FDCA is of significant practical import. If the FDCA pre-empted the regulation of medical practice, prescribers would be stripped of their traditional right to prescribe Food and Drug Administration (FDA) approved drugs "off-label," that is, for non-approved uses to benefit their patients. This Court has expressly endorsed the off-label practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (off-label use is an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). The United States Congress has taken precisely the same view:

> In general, the FDA has no authority to regulate how physicians prescribe approved drugs in the context of their medical practice.

> Physicians prescribing off-label uses of approved drugs is not within the jurisdiction of the FDA.

H.R. Rep. No. 105-310, at 60 (1997).

The Social Security Amendments of 1954 also make clear federal non-interference with the states' health-related police powers, providing that "[n]othing in this title shall be construed as authorizing the Commissioner of Social Security . . . to interfere in any way with the practice of medicine. . . ." 42 U.S.C. § 416. The federal Medicare statute, the Fertility Success Rate and Certification Act of 1992, and the Drug Addiction Treatment Act of 2000 each included similar expansive and express prohibitions on federal interference with the practice of medicine. 42 U.S.C. § 1395 ("Nothing in [the Medicare statute] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine."); 42 U.S.C. § 263a-2(i)(1) ("[HHS] may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine"); 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

Congress's long-standing and express prohibition on federal interference with state authority to regulate the medical professions is grounded in the uncontroversial notion that it is the states that are the

laboratories of inventive "social and economic experiments" in our dual sovereignty system of government. *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Permitting state heterogeneity in medical practice bolsters medical innovation and benefits public health. *Gregory*, 501 U.S. at 458 (explaining that the very purpose of the clear statement rule is to preserve a "federalist structure of joint sovereigns . . . that will be more sensitive to the diverse needs of a heterogeneous society" and that "increases opportunity for citizen involvement in democratic processes; [and] allows for more innovation and experimentation in government"). Medical innovation is necessarily wrought from medical practitioners' discretion to deploy their specialized training and expertise to pioneer new treatment approaches that may improve patients' well-being. This is likely why there is not a single federal statute that indicates that Congress intended to permit a federal law enforcement agency to criminalize good faith yet mistaken attempts to revolutionize medical practice. *United States v. Lopez*, 514 U.S. 549, 583 (1995) (Kennedy, J., concurring) (cautioning against "foreclos[ing] the States from experimenting in an area to which States lay claim by right of history and expertise").

IV. Under the Eleventh Circuit's Construction of Section 841(a), the Standard the Government had to Satisfy to Convict Dr. Ruan of Felony Distribution was Lower than the Applicable State Standard for Civil Malpractice Liability

In closing, it is worth noting that the petitioner's characterization of the Eleventh Circuit's construction of Section 841(a)(1) as "invit[ing] juries to convict doctors of drug dealing based on nothing worse than simple malpractice" is overly generous. Ruan Pet. 3. In fact, it is far easier for the government to convict a practitioner for felony criminal distribution under the CSA in the absence of a scienter requirement than it is for plaintiffs to succeed in civil malpractice actions based on the exact same prescribing conduct for at least two reasons.

First, plaintiffs in state civil malpractice actions are required to prove that they were harmed due to their prescriber's negligence. *See*, *e.g.*, Ala. Code. § 6-5-542(2) ("A breach of the standard of care is the failure by a health care provider to comply with the standard of care, which failure proximately causes personal injury or wrongful death. This definition applies to all actions for injuries or damages or wrongful death whether in contract or tort and whether based on intentional or unintentional conduct."). Under Section 841(a)(1), by contrast, the government does not have to prove that the prescriber's conduct harmed even a single patient. In fact, the government can convict a prescriber for felony distribution under the CSA even

where it is undisputed that the prescriber's conduct improved or enhanced a patient's health outcomes.

Second, proving a departure from the "usual course of professional practice" in a Section 841(a)(1) prosecution is far easier than proving a departure from the standard of care in a state malpractice action because CSA cases revolve around the national standard of practice and lack any standards of expertise about the same or similar specialty, training, or resources. *See*, *e.g.*, *United States v. Merrill*, 513 F.3d 1293 (11th Cir. 2008). In fact, the experts that testify on departures from the usual course of professional practice in CSA cases would not be allowed to testify at all in a most state malpractice actions.[10]

The majority of the government's experts on which the jury relied to determine whether Dr. Ruan's prescribing practices fell outside the "usual course of his professional practice" are unqualified to testify in civil malpractice actions in the State of Alabama, where Dr. Ruan practiced, due to their lack of expertise and experience in Dr. Ruan's practice specialty. The Alabama Medical Liability Act mandates that, "[i]n any action for injury or damages . . . against a health care provider for breach of the standard of care, the plaintiff shall have the burden of proving by substantial

[10] Although not the case in Alabama, roughly half of the states also require an affidavit of merit from a qualified expert that there are reasonable grounds to believe the defendant was negligent. NAT'L CONFERENCE OF STATE LEGISLATURES, MEDICAL LIABILITY/MALPRACTICE MERIT AFFIDAVITS AND EXPERT WITNESSES (Aug. 11, 2021) (cataloging standards for affidavits of merit and expert witnesses).

evidence that the health care provider failed to exercise such reasonable care, skill, and diligence as *other similarly situated health care providers in the same general line of practice ordinarily have and exercise in a like case*." Ala. Code. § 6-5-548(a) (emphasis added). When a malpractice action is brought against a board-certified specialist, admissible expert testimony is limited to state-licensed practitioners who, among other things, are "trained and experienced in the same specialty," "certified by an appropriate American board in the same specialty," and have "practiced in th[at] specialty during the year preceding the date that the alleged breach of the standard of care occurred." Ala. Code. § 6-5-548(c). Any Alabama plaintiff that brought a civil malpractice action against Dr. Ruan, a "board-certified interventional pain specialist," for the prescribing conduct at issue in the instant case would have been limited to experts that satisfied these criteria. Ruan Pet. 5.

At least two of the government's three experts who provided crucial testimony at Dr. Ruan's criminal trial, however, do not come remotely close to satisfying these requirements. Dr. Greenburg, for instance, not only admitted under oath that he is not board-certified in pain management and, therefore, could not have been qualified as an expert in a medical malpractice case against Dr. Ruan in Alabama (where he is not licensed to practice medicine), he conceded that his lack of such certification and expertise also would have disqualified him from testifying against board-certified pain management practitioners in

medical malpractice actions in his home state of Arizona (where he is licensed to practice medicine). Tr. 889; 902-903; *see also* Ariz. Rev. Stat. Ann. § 12-2604 (providing that where a party offers expert testimony against a board-certified practitioner, said expert must be board-certified in the same specialty).

The government also provided expert testimony from Dr. Aultman, a Mississippi licensed hospitalist (*e.g.*, a practice specialty that treats only acutely ill hospitalized patients rather than outpatients with persistent pain or opioid use disorder). Tr. 4439-4445. Dr. Aultman testified that she has never had: (1) any formal training in pain management; (2) any board-certification in pain management; or (3) any residency or fellowship in pain management. Tr. 4441. Consequently, neither Drs. Greenburg nor Aultman would have been qualified to testify as experts in a malpractice case against Dr. Ruan in Alabama. As a result, a medical malpractice plaintiff is always required to prove more elements (causation and damages) and often mandated to proffer substantially more qualified expert witnesses to succeed on a civil malpractice claim than the government needs to prove to secure a felony criminal conviction for the exact same prescribing conduct under the Eleventh Circuit's current construction of Section 841(a).

CONCLUSION

For the foregoing reasons, this Court should reverse the judgments of the courts of appeal.

Respectfully Submitted,

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