No. 20-1410

In The Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For A 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 United States 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 and addiction. Those interests are threatened by the increasingly weakened and varying standards to convict prescribing practitioners under the Controlled Substances Act (CSA).

SUMMARY OF THE ARGUMENT

Controlled substances hold a special place at the intersection of medicine, law, and society. No decisions are as fraught with peril in medicine than whether, how, how much, and for how long to prescribe controlled substances, especially during an opioid crisis.[2] These decisions implicate not just the benefits and risks to the patients to whom drugs are prescribed, but also the risks to third parties who use diverted drugs

[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] We use this term for conciseness, not accuracy. Significant evidence indicates that prescription opioids alone are neither the lone nor primary driver of what are now several overlapping overdose crises. Nabarum Dasgupta et al., *Opioid Crisis: No Easy Fix to its Social and Economic Determinants*, 108 AMER. J. PUB. HEALTH 2 (2018).

without medical supervision. The later consideration is as far as Congress intended federal law enforcement to reach into the regulation of medical practice, an area that falls squarely within the States' police powers.

The Eleventh, Fourth, and Tenth Circuits have recently construed the CSA in a manner that permits the government to convict a prescriber of a felony for nothing more than deviations from accepted medical standards, including behavior akin to mere negligence.[3] These circuits have criminalized prescribing negligence by (1) permitting convictions when prescriptions deviate from accepted medical practices without considering whether the practitioner acted without a legitimate medical purpose (also referred to as "beyond the bounds of medical practice"),[4] and

[3] These are not exactly deviations from the standard of care in the malpractice sense. Arguably, defendants have fewer protections in CSA cases. The CSA requires no harm. The discovery processes and expert witness practices also vary between malpractice and CSA proceedings, in part because of the significant, pertinent differences between the rules of civil and criminal procedure, *see, e.g.*, Jennifer D. Oliva & Valena E. Beety, *Discovering Forensic Fraud*, 112 NW. U. L. REV. 121 (2017) and, in part because of the national standard of acceptable practice for CSA cases. *See, e.g.*, *United States v. Merrill*, 513 F.3d 1293 (11th Cir. 2008). Most states reject a purely national standard and require experts in the same or similar specialty and community. Roughly half require an affidavit of merit from a qualified expert before filing a case. Nat'l Conference of State Legislatures, *Medical Liability/Malpractice Merit Affidavits and Expert Witnesses* (June 24, 2014) (cataloging standards for affidavits of merit and expert witnesses).

[4] Some courts have also added or substituted "beyond the bounds of medical practice," a phrase from *United States v. Moore*, 423 U.S. 122, 140 (1975), for "without a legitimate purpose."

(2) constructively refusing to extend to practitioners a good faith defense. These approaches criminalize mistaken or negligent prescribing for which there are already myriad civil, administrative, and even lesser criminal remedies. *See* Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AMER J.L. & MED. 1, 21 (2016). The constructive rewriting of the CSA as applied to practitioners runs afoul of the text and purpose of the CSA, conflicts with this Court's controlling case law, imperils the evolution of medicine and patient care, and implicates significant federalism concerns. We respectfully request that this Court clarify that the CSA's reach only extends to practitioners who prescribe knowingly or intentionally (*i.e.*, not in good faith) without a medical purpose outside the usual course of professional practice. The questions implicated by the instant petition and those in *United States v. Naum*, No. 20-1480, are what the government must prove to convict a prescribing practitioner under CSA Section 841(a)(1). Consequently, this Court should consolidate the instant petition and *Naum* and grant certiorari in both cases.

United States v. Schneider, 704 F.3d 1287, 1295–96 (10th Cir. 2013).

ARGUMENT

I. Statutory Framework, Purpose, and Conflicting Approaches

A. The Statutes and the Regulation

The Controlled Substances Act (CSA) makes it unlawful, "except as authorized by this subchapter . . . for any person [to] knowingly or intentionally . . . distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a)(1). Practitioners are among those "authorized by this chapter" to dispense a controlled substance once they have received (1) state licensure to practice medicine, or another profession with prescriptive authority, and (2) a certificate of registration (COR) from the Attorney General, acting through the Drug Enforcement Administration (DEA). *Id*. §§ 822(a) & 823(f); 21 C.F.R. § 1306.03. Once licensed (by the state)[5] and registered (by the DEA), practitioners are permitted to distribute, dispense, [and] conduct research with . . . a controlled substance *in the course of professional practice*," 21 U.S.C. § 802(21) (emphasis added) and in "conformity with the other provisions of this title." *Id*. § 822(b). Those provisions include the requirements of valid prescriptions, *id*. § 829, and specific grants of authority to the Attorney General to promulgate and enforce regulations. *Id*. §§ 821 & 871(b). The Attorney General promulgated 21 C.F.R. § 1306.04, the central regulation with which practitioners must conform,

[5] Some states require additional authorization by DEA equivalent state agencies in addition to licensure and a COR is conditioned on the prior satisfaction of both conditions. *See* Dineen & DuBois at n.163.

without comment from practitioners in 1971. 36 Fed. Reg. 7776 (1971). Section 1306.04 explains that an effective, and, therefore, lawful prescription is one "issued for *a legitimate medical purpose* by an individual practitioner acting *in the usual course of his professional practice*." 21 C.F.R. § 1306.04(a) (emphasis added).[6] In summary, a licensed practitioner with a valid COR who issues a prescription for a *legitimate medical purpose in the usual course of professional practice* is "authorized" and not unlawfully prescribing under CSA Section 841(a)(1). This reading comports with *United States v. Moore*, which this Court decided almost 50 years ago. 423 U.S. 122 (1975).

B. *United States v. Moore* and Its Aftermath of Clashing Approaches

In *Moore,* this Court held that prescribing practitioners fall within the reach of CSA Section 841 when their prescription(s) fall outside "legitimate channels," such that they are acting "outside the bounds of professional practice" and prescribing not "for legitimate

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[6] In *Gonzales v. Oregon*, this Court read the language at 21 U.S.C. § 830(b)(3)(A)(ii), added in 2000 and defining a valid prescription as one "issued for a legitimate medical purpose by an individual practitioner . . . acting in the usual course of the practitioner's professional practice," to conclude that 21 C.F.R. § 1306.04 was a parroting regulation. 546 U.S. 243, 257 (2006). In dissent, Justice Scalia explained that Section 1306.04 "gives added content to the text of the statute [§ 829]," *id.* at 279 (Scalia, J., dissenting), such that a legitimate medical purpose is implicit in the requirements for an effective prescription. *Id.* (citing *Moore*, 423 U.S. at 136 n.13).

purposes, but primarily for the profits to be derived therefrom."[7] *Id.* at 131–35. The question presented and underlying egregious behavior of the practitioner in *Moore* allowed the Court to avoid addressing exactly what the government is required to prove to convict practitioners under the CSA beyond establishing that they acted "outside the course of professional practice." The Court did admit, however, that the CSA failed to "unambiguously spell[] out" such requirements. *Id.* at 140. The *Moore* Court did not address the availability and nature of the good faith defense, although it did not take issue with the district court's jury instructions that included a good faith charge.[8] Thirty-one years later, this Court explained 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," a statement that remains true today. *Gonzales v. Oregon*, 546 U.S. 243, 269 (2006) (internal quotes omitted).

In the five decades since *Moore*, the federal courts have taken divergent, conflicting, and, frankly,

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[7] At the time of *Moore*, the DEA lacked the authority to revoke or suspend a practitioner's COR and thus, absent the reach of 841(a)(1), could not stop a practitioner from prescribing unless the state took action first. *See Gonzales*, 546 U.S. at 258 (explaining the addition of the 1984 amendments).

[8] "The judge instructed the jury it had to find beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute methadone by prescription, did so *other than in good faith* for detoxification in the *usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States*." *Moore*, 423 U.S. at 139 (emphases added).

confusing approaches to Section 841(a)'s rudimentary requirements. An alarming number of circuit splits have developed regarding Section 841(a), including: (1) whether the government must prove a practitioner departed from a legitimate medical purpose, Petition for Cert., *Naum v. United States*, *docketed*, 20-4133 (Apr. 22, 2021); (2) the availability and form of the good faith defense, Petition for Cert., *Ruan v. United States*, *docketed*, 17-12653 (Apr. 7, 2021); (3) whether legitimate medical purpose is an element that must be included in the indictment, *see* 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); (4) the relationship between good faith and *mens rea*, *United States v. Khan*, 989 F.3d 806, 812 (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 [defendant] had a knowing or intentional *mens rea*"); (5) whether the jury must be instructed on *mens rea*, Petition for Cert., D*ixon v. United States*, 18-4936, *cert. denied* (June 22, 2020); and (6) whether a prescriber may be convicted of dispensing, distributing, or both, Petition for Cert., *Faithful v. United States*, 18-20671, *cert. denied* (Mar. 29, 2021).

C. The Shaky Consensus

Despite these concerning circuit splits, there were points of general but fragile agreement until recently. First, the government had to prove that the practitioners knowingly or intentionally acted without a legitimate purpose outside the usual course of professional practice to secure a conviction under the CSA. *See* Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 CHAMPION 40 (2019). The legitimate medical purpose showing creates a boundary between criminality and prescribing negligence. Although a few courts have claimed legitimate medical purpose and usual course of professional practice are interchangeable, *see*, *e.g.*, *United States v. Nelson*, 383 F.3d 1227, 1231 (10th Cir. 2004) (explaining that it is "difficult to imagine circumstances in which a practitioner could have prescribed controlled substances within the usual course of medical practice but without a legitimate medical purpose" as well as the reverse), that claim is contrary to common sense and a fair reading of the CSA and 21 C.F.R. § 1306.04. Unlike the *Nelson* court, very few practitioners have trouble distinguishing these. 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) ("The two bases may be . . . co-morbidly present, but that does not support the proposition that the phrases are interchangeable."). Because the standard of care is increasingly used as a proxy for the "usual course" standard, a mistaken or even somewhat

careless prescriber could only be saved from criminal sanction because of her legitimate medical purpose.

Second, courts extended some version of the good faith defense to practitioners, whether measured by a subjective standard, *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), or a so called "objective" standard,[9] *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). The defense is a critical way to distinguish criminal from civil liability. *See, e.g., United States v. McIver*, 470 F.3d 550, 560 (4th Cir. 2006) (good faith is a "plainspoken method of explaining a critical difference between the two standards").

Third, the difference between the standard for civil negligence and that for criminal liability was acknowledged and emphasized by the courts. *See* Dineen & DuBois at 31–34; *Volkman*, 797 F.3d at 387 (practitioner cannot be convicted merely for "carelessness or negligence or foolishness"). There was general agreement that the "standard for criminality is at least two steps beyond that which would satisfy the breach requirement in malpractice: from a mistaken doctor (one breach in otherwise careful practice) to a bad doctor (pattern indicating carelessness) to a criminal doctor

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[9] Objective good faith may be an oxymoron. Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 3 (2009).

(pattern indicating knowledge or intention to violate law)," Dineen & DuBois at 32, although other scholars have been long concerned about the conflation of those standards. *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). Those concerns about conflation have come to fruition in the Fourth, Tenth, and Eleventh Circuits.

II. The Erosion of Standards and the Risks of Harm

What little consistency once existed, however, is waning quickly. Several circuits have substantially eroded the standards for a practitioner's conviction and available defenses under Section 841. There are especially concerning erosive trends in the Fourth, Tenth, and Eleventh Circuits, where courts have endorsed convictions for prescribing "outside the usual course of professional practice." Full stop. Those circuits have eliminated any consideration of legitimate medical purpose and an effective good faith defense.

The *Ruan* Petition details the path of the Eleventh Circuit, which has collapsed the meaning of good faith into compliance with the standard of care over the last decade. Petition at 23–27; *United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020), *petition for cert. pending*, 17-12653 (Apr. 7, 2021). The Fourth Circuit also recently departed from the precedent in *Hurwitz* and eliminated the legitimate medical purpose

requirement. *United States v. Naum*, 832 Fed. App'x 137 (4th Cir. 2020) (unpublished) *petition for cert. pending*, 20-4133 (Apr. 22, 2021) (declaring irrelevant that the prescriptions were for a legitimate medical purpose, the patients' legitimate treatment needs, and the lack of profit motive because departure from the usual course of practice was enough).

The Tenth Circuit had previously required proof that a practitioner acted without a legitimate medical purpose to convict. *United States v. Varma*, 691 F.2d 460, 462 (10th Cir. 1982) (holding that 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). In 2004, however, the Circuit held that a "practitioner has unlawfully distributed a controlled substance if she prescribes the substance either outside the usual course of medical practice *or* without a legitimate medical purpose." *Nelson*, 383 F.3d at 1232 (emphasis added) (explicitly stating that the court was not "bound by the language of *Varma*" and concluding that neither 21 C.F.R. § 1306.04(a) nor *Moore* required more). This year, the Tenth Circuit constructively eliminated the good faith defense and reaffirmed that the government need not show that the defendant acted without a legitimate purpose to convict. *Khan*, 989 F.3d at 825–26 (rejecting a good faith defense as to deviations from the usual course of professional practice, upon which a conviction may be based alone, and stating that "[*u*]*nlike other criminal offenses*, good faith *does not* go to *mens*

rea for § 841 offenses involving practitioners" and that "the *only relevant inquiry* . . . is whether a defendant-practitioner objectively *acted* within that scope, regardless of whether he believed he was doing so") (emphases added). Together, the Fourth, Tenth, and Eleventh Circuits have effectively rewritten the CSA as applied to practitioners, grounding criminal liability in a mere departure from accepted medical practice.

III. Patient Harm is Predictable if the Standard of Care is the Proxy for Criminal Liability

In negligence, standard of care is used to "scrutinize[e] . . . practice and treatment decisions" and measure prevailing custom, with some allowance for "respectable minority" views, Sandra H. Johnson, *Customary Standards of Care*, 43 HASTINGS CTR. REP. 6, 9–10 (2013), but even this can suppress innovation in medicine. *Id*. The dark side of standard of care as a proxy in criminal prescribing cases is that fear of scrutiny pushes practitioners solidly to the "safe middle," at least for the practitioner, where adoption of new practices dies. *Id.*

Even worse, the fear of criminal scrutiny, including the "penalties of the process," Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973 (2009), drives some practitioners away from the patients most in need of care. Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 KS. L.

REV. 101, 1001–11 (2019) (describing the serious harms and deaths from suicide and the shift to illicit drugs after prescribers abandoned patients, abruptly stopped, or rapidly tapered patients' opioids out of fear of legal scrutiny); Michael C. Barnes et al., *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, 6–21, 8 (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.").

The sequala of Harrison Narcotic Act enforcement is illustrative of the harms that follow when the government uses a meat cleaver instead of a scalpel on issues at the intersection of law and medicine. What followed was a century-long segregation of addiction care from medicine, which created a vacuum of care and pushed people with substance use disorders from doctors to drug dealers, Evan D. Anderson et al., *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 a substance use disorder lack access to evidence-based care and continue to face stigma and discrimination in every aspect of their lives. 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). Practitioners

remain unwilling to treat them for fear of scrutiny. Nat'l Academies of Sciences, *Medications for Opioid Use Disorder Save Lives*, 120–21 (2019) ("[T]he 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[.]").

The rush to the middle and outright patient abandonment has already happened in the treatment of individuals with persistent pain. Dineen, *Definitions Matter*. As the news of the opioid crisis proliferated with a laser-like focus on prescription opioids for chronic pain and the "bad" doctors who prescribed them, law and policy actors enacted new restrictions, enforcement, and administrative guidance. *Id*. The Centers for Disease Control and Prevention (CDC) recommendations to limit opioid prescribing were accorded the force of legal mandates and entities from insurance companies to provider groups adjusted recommended prescribing parameters further downward to ensure compliance. *Id*.

While some responded moderately, many practitioners involuntarily and inappropriately tapered medications without consideration for the patient's well-being, causing needless suffering and death to the point that the Food and Drug Administration (FDA) and the CDC issued warnings. 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 prescribing. Jackie Yenerall & Melinda B. Buntin, *Prescriber Responses to a Pain Clinic Law: Cease or Modify?*, 206 DRUG AND ALCOHOL DEP. 107591, 1–4 (2020) (After state law changes, 24% of prescribers stopped prescribing altogether, without regard for patient needs).

Patients with pain, addiction, or both desperately need appropriate care and treatment. Patient abandonment will grow more widespread as practitioners avoid legal scrutiny. Progress in medical care in these areas will be stymied until the regulation of the medical practice is returned to the province of the states except in cases in which a practitioner is acting without a legitimate medical purpose and outside the course of professional practice.

IV. Criminalizing Negligent Prescribing Improperly Intrudes on the States' Power to Regulate Medical Practice

The federal cases that construe Section 841(a)(1) in a manner that criminalizes negligent prescribing raise serious federalism concerns. The regulation of medical practice has long been the purview of the states under their reserved 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 federal-state balance-of-power norms are central to our dual sovereignty structure of government. Those core norms cannot be fundamentally altered by either a federal law enforcement agency's policy decision to target the distribution of specific controlled substances or extra-textual judicial supposition. *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."); *Bond v. United States*, 572 U.S. 844, 857–60 (2014) (refusing to interpret a statute in a way that would upset the usual balance of federal and state powers absent a clear statement from Congress). Instead, any construction of the CSA that would permit the federal government to intrude on a state's right to regulate medical practice must be grounded in "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."); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

The federal courts' application of the clear statement canon in cases involving "Congressional regulation of core state functions" has been characterized as a "super-strong rule" of statutory construction that carries more force than a traditional presumption. 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 to alter the usual constitutional balance . . . we will interpret a statute to preserve rather than destroy the States' substantial sovereign powers.") (quotation marks and citations omitted); *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) ("[W]here federal law is said to bar state action in fields of traditional state regulation, . . . we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") (citation and quotation marks omitted); *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (Congress's authority to preempt state law "in areas traditionally

regulated by the States" is "an extraordinary power in a federalist system" that "we must assume Congress does not exercise lightly.").

The federal courts also apply the rule of lenity, a "time-honored interpretive guideline," when construing an ambiguous criminal statute. *United States v. Kozminski*, 487 U.S. 931, 952 (1988). As this Court has explained:

> when a choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite. We should not derive criminal outlawry from some ambiguous implication.

United States v. Universal C.I.T. Credit Corp., 344 U.S. 218, 221–22 (1952). The CSA, however, is not ambiguous.

CSA Section 841(a)(1) cannot be interpreted as criminalizing negligent prescribing because the statute is bereft of any indication—clear or otherwise—that Congress intended to grant a federal law enforcement agency such sweeping authority over the practice of medicine. In fact, the statutory text makes clear that Congress intended to leave the regulation of medical practice to the states. Consistent with that proposition, this Court has already determined that the CSA does not include a clear statement of Congressional intent for the DOJ or DEA to regulate the practice of medicine beyond illicit drug trafficking and profiteering:

> [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).

Gonzales clarifies that Congress knows how to set federal standards of medical practice in the context of prescribing and has expressly done so in one—and only one—arena: opioid use disorder (OUD) treatment. *Id*. at 271 (holding that 42 U.S.C. § 290bb-2a is the only area 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* Evan D. Anderson et al. at 98. ("Despite the longstanding norm of federal noninterference in medicine, it is clear that the federal government can regulate medical practice if it makes its intention to do so clear and unambiguous."). Congress, of course, did not leave the regulation of OUD treatment standards to law enforcement—it expressly delegated that authority to the Department of Health and Human Services (HHS). 42 U.S.C.

§ 290bb-2a ("The Secretary . . . after consultation with the Attorney General . . . shall determine the appropriate methods of professional practice in the medical treatment.").

Recognizing that federal law enforcement agencies lack the requisite scientific expertise to make medical determinations, Congress did not trust DOJ to perform one of its core functions under the CSA—the scheduling of controlled substances—without health care agency oversight and approval. 21 U.S.C. § 811(b).

Even where the federal government's regulatory authority is at its apex in the context of OUD treatment regulation, this Court has expressly stated 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 so far outside the usual course of professional practice that their behavior is akin to that of a "large-scale [drug] pusher, not as a physician." *Moore*, 423 U.S. at 342–43. The legislative history that attends to the Narcotic Addict Treatment Act (1974) (NATA), which amended the CSA to permit HHS to regulate OUD treatment, is in accord. That record demonstrates that the Senate Judiciary Committee 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) (emphasis added). The Committee also reported that NATA intended 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 (emphasis added). In other words, the purpose of the CSA was to permit the federal prosecution of prescribers who operate as profiteering drug traffickers as traditionally understood and, thus, beyond the bounds of professional practice. The statute was never intended to regulate the practice of medicine by criminalizing good faith medical mistakes or mere deviations from the standard of care. *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.").

Indeed, the CSA states on its face that it is not intended to interfere with the practice of medicine as regulated by the states. CSA Section 903 expressly provides that:

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

Id. § 903. The CSA also *depends on state law* to determine which medical professionals constitute "practitioners" acting "in the course of professional practice" and, thus, are COR eligible. *Id*. § 823(f) provides that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices"); *id*. § 802(21).

The CSA further compels the DOJ to defer to state licensing authorities before the agency may deny, suspend, or revoke 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 that determination is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority"). Consistent with the text and structure of the CSA, Attorney General Janet Reno explained in a 1998 letter to the House Judiciary Committee Chairman 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).

Congress also refused to enact the Pain Relief Promotion Act, which would have outlawed the controlled substances used in physician-assisted suicide and, thereby, permitted a federal law enforcement agency to regulate pain management medicine. 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."). It practically strains credulity to contend that Congress would delegate medical practice regulation to a federal law enforcement agency that has no pertinent medical or scientific expertise whatsoever.

Congress has even proscribed the federal agencies with significant scientific and medical expertise from interfering with state medical practice regulation. The federal Food, Drug, and Cosmetic Act (FDCA) provides that it should not "be construed to limit or interfere with the authority of a health care practitioner to prescribe . . . 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) ("Defendants state[d] that Congress has left the practice of medicine to the States to regulate. FDA does not disagree with these principles."). This express FDCA limitation is of significant practical import. If the FDCA preempted the regulation of medical practice, prescribers would be stripped of their traditional right to use approved drugs "off-label," that is, for non-approved uses to best serve their patients, a practice this Court has expressly endorsed. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (holding that 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 Social Security Amendments of 1954 also make clear that they are not intended to interfere with the states' health-related police powers. 42 U.S.C. § 416 ("Nothing in this title shall be construed as authorizing the Commissioner of Social Security . . . to interfere in any way with the practice of medicine[.]").

These federal statutory "hands-off" approaches to regulating medical practice acknowledge the traditional federal system in which states are the laboratories of inventive "social and economic experiments." *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("Denial of the right to experiment may be fraught with serious consequences. . . . 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."). State heterogeneity in the realm of health policy bolsters medical innovation and benefits public health. *Gregory*, 501 U.S. at 458 (explaining that the 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"). All medical innovations are wrought from the bold decisions of practitioners to deploy their extensive

training and expertise to pioneer new treatment approaches that may save lives, improve patients' health, or reduce their suffering. There is no federal statute that indicates that Congress intended to authorize a federal law enforcement agency to criminalize such good faith yet mistaken attempts to revolutionize medical practice or simply best treat their patients.

CONCLUSION

For the reasons stated in the Petition for Writ of Certiorari and this brief, this Court should grant the Petition.

Respectfully submitted,

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