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 THE CATO INSTITUTE AS *AMICUS CURIAE* SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether physicians alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under Section 841(a)(1) without regard to whether, in good faith, they "reasonably believed" or "subjectively intended" that their prescriptions fall within that course of professional practice.

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INTEREST OF *AMICUS CURIAE*[1]

The Cato Institute was established in 1977 as a nonpartisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government. Cato's Robert A. Levy Center for Constitutional Studies was established in 1989 to promote the principles of limited constitutional government that are the foundation of liberty. Toward those ends, Cato has participated as amicus curiae in numerous cases before federal courts. Cato also works to defend individual rights through publications, lectures, conferences, public appearances, and the annual Cato Supreme Court Review, and files amicus briefs.

This case interests Cato because the federal government cannot and should not criminalize good faith, legitimate medical practice. Misguided prescription-drug regulation upsets federalism and denies care to patients in desperate need.

SUMMARY OF ARGUMENT

Dr. Xiulu Ruan is currently facing 21 years in prison due to the Eleventh Circuit's unique strict liability regime for interpreting the Controlled Substances Act (CSA). After a lengthy jury trial in which various medical experts disagreed with each other over proper medical procedures—as doctors inevitably do—a jury was asked to render a verdict without consideration as to whether Dr. Ruan

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[1] Rule 37 statement: All parties were timely notified of and consented to the filing of this brief. No part of this brief was authored by any party's counsel, and no person or entity other than *amicus* funded its preparation or submission.

prescribed controlled substances in good faith. This amounts to, in essence, the federal regulation of the practice of medicine under a strict liability standard. If the CSA were really meant to work that way, Congress would presumably have said so.

But that is not how the CSA is supposed to work, as over a hundred years of case law tells us. The CSA—and its predecessor the Harrison Narcotics Act of 1914—were designed to exist within a framework that "presum[es] and rel[ies] upon a functioning medical profession regulating under the States' police powers." *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006). Respecting the states' police powers means not turning good-faith medical disputes—of the kind that civil courts and state licensing boards hear every day—into federal crimes. Federal jurisdiction under the CSA begins when a doctor has abandoned the subjective belief of practicing medicine and becomes a mere drug dealer. Until that occurs, it is a dispute over the practice of medicine that is properly adjudicated under state law.

That was understood from the very moment the federal government got involved in regulating controlled substances. The cases heard by this Court between 1916 and 1925—all arising from the prosecution of doctors—demonstrate that the practicing-medicine-in-good-faith defense was simply assumed to be part of the Harrison Act. It was even assumed to be part of the law by Treasury officials before this Court ever heard a case arising under the Act. That assumption came from a due appreciation of federalism, something that is no less warranted today.

Finally, both the strict liability standard that the Eleventh Circuit applied here and the objective standard requested by the government undermine federalism and are functionally unworkable in a constitutionally permissible way. Despite the contrary assertions of the DEA and the CDC, there is no definition of "overprescribing" sufficiently coherent in this context to avoid the specter of unconstitutional vagueness in the context of criminal prosecutions.

The Court should vacate Dr. Ruan's conviction and restore appropriate constitutional limits to the CSA.

ARGUMENT

I. THE GOOD-FAITH DEFENSE FOR DOCTORS ACCUSED OF MISPRESCRIBING CONTROLLED SUBSTANCES HAS BEEN PART OF FEDERAL LAW FOR OVER 100 YEARS

The Harrison Narcotics Act of 1914 was a tax and registration act that regulated opiates and cocaine. *United States v. Jin Fuey Moy*, 241 U.S. 394, 399–401 (1916). The Act created a registration requirement for those authorized to dispense opiates, and it contained an explicit exemption for medical practice: "Nothing contained in this section shall apply . . . to the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this Act in the course of his professional practice only[.]" Harrison Act § 2(a), 38 Stat. 785. It was assumed from the beginning that the Act included a good-faith defense for doctors accused of misprescribing opiates.

As a tax law, the Harrison Act was enforced by the Treasury Department. Initial guidance issued by the department on May 11, 1915—before this Court heard any challenge to the Act—assumed a good-faith defense was inherent in the law:

> In cases of treatment of addicts these prescriptions should show the good faith of the physician in the legitimate practice of his profession by a decreasing dosage or reduction of the quantity prescribed from time to time[.]

Public Health Reports (1896-1970), Vol. 31, No. 19, at 1205 (May 12, 1916).[2] The theme here is a recurring one: There's no doubt a good-faith defense exists; the dispute was whether certain prescribing practices furnish sufficient circumstantial evidence of "bad faith."

When it heard the first challenge to the Act—a challenge to its constitutionality and scope—this Court took it as seemingly obvious that the medical exception included a good-faith defense. As Justice Holmes wrote for the Court, Dr. Jin Fuey Moy was accused of writing a "prescription for the morphine sulphate, and that he did not issue it in good faith, but knew that the drug was not given for medicinal purposes[.]" *Jin Fuey Moy*, 241 U.S. at 399. Later in the opinion, Justice Holmes again invokes the good-faith defense in delineating the scope of the Act: "There is a proviso that the section shall not apply to any employee of a registered person and certain others, with qualifications, or to the possession of any of

[2] Available at https://bit.ly/3J9XTEH.

the drugs which have been prescribed in good faith by a physician registered under the act." *Id.* at 400.

In the aftermath of Dr. Jin Fuey Moy's case, Treasury Department agents began interpreting the Act as prohibiting doctors from prescribing opiates to compulsive users for the purpose of "maintaining" their addiction. Rufus King, *The Drug Hang-up: America's Fifty-Year Folly* 32–50 (1972). A virtual war on opiate-prescribing doctors was inaugurated, and eventually "[s]ome 20,000 doctors were charged with violating the Harrison Act[.]" Johann Hari, *Chasing the Scream: The First and Last Days of the War on Drugs* 38 (2015). During that time many "horrified juries refused to convict, because they could see the doctors were only treating the sick the best they could." *Id.*

Yet in the subsequent cases heard by this Court, the question whether a good-faith defense was available was never seriously challenged. The question instead was whether prescribing maintenance doses to compulsive opiate users qualified as a medical purpose "in the course of professional practice" under the statute. In *Webb v. United States*, the Court held maintenance doses did not qualify as a medical purpose. 249 U.S. 96, 99 (1919). Yet the Court was also explicit in stating that Dr. Webb and his co-defendant were not issuing prescriptions in good faith: "It was the intent of Webb and Goldbaum that morphine should thus be furnished to the habitual users thereof by Goldbaum and *without any physician's prescription issued in the course of a good faith attempt* to cure the morphine habit." *Id.* at 98 (emphasis added). The Court, in a medically dubious *ipse dixit*, took it as literally beyond discussion that a maintenance dose prescribed to a compulsive user had no legitimate

medical function and thus the good-faith defense was unavailable. *Id.* at 99–100 ("to call such an order for the use of morphine a physician's prescription would be so plain a perversion of meaning that no discussion of the subject is required").

Prosecutions of doctors continued. Yet doctors were never categorically stripped of the good-faith defense but were instead simply precluded from arguing that providing maintenance doses could be categorized as good faith. In *United States v. Behrman*, some members of the Court began dissenting from the idea that a good-faith defense could not encompass the prescribing of maintenance doses and seemed uneasy with the idea of the justices second-guessing the professional judgment of medical doctors. And, again, no justice disagreed that the good-faith defense was available, but only whether the concept of "good faith" permitted a court to exclude from that defense entire categories of conduct as a matter of law. As Justice Holmes wrote in dissent, joined by Justices McReynolds and Brandeis:

> In view of the allegation that I have quoted and the absence of any charge to the contrary, it must be assumed that he gave them in the regular course of his practice and in good faith.
>
> …
>
> It seems to me impossible to construe the statute as tacitly making such acts, however foolish, crimes, by saying that what is in form a prescription and is given honestly in the course of a doctor's practice, and therefore, so far as the words of the statute go, is allowed in terms, is not within the words, is not a prescription

> and is not given in the course of practice, if the Court deems the doctor's faith in his patient manifestly unwarranted. It seems to me wrong to construe the statute as creating a crime in this way without a word of warning.

United States v. Behrman, 258 U.S. 280, 290 (1922) (Holmes, J., dissenting).

Three years later, however, Justice Holmes's dissenting opinion in *Behrman* became the law in *Linder v. United States*. 268 U.S. 5 (1925). In *Linder*, the trial court gave jury instructions believed to be in line with the decision in *Behrman*. The instructions allowed for a good-faith defense but did not allow that defense to be raised if Dr. Linder "knew that this woman was addicted to the use of narcotics, and if he dispensed these drugs to her for the purpose of catering to her appetite or satisfying her cravings for the drug[.]" *Id.* at 16. The trial court's instructions continued:

> If, on the other hand, you believe from the testimony that the defendant believed in good faith this woman was suffering from cancer or ulcer of the stomach, and administered the drug for the purpose of relieving her pain, or if you entertain a reasonable doubt upon that question, you must give the defendant the benefit of the doubt and find him not guilty.

Id. These jury instructions—which were found deficient as regards the good-faith defense—were nevertheless more favorable to the defendant than those in Dr. Ruan's trial.

In the *Linder* decision, the Court eventually arrived at the standard that should inform this Court's opinion in this case as well:

> The opinion cannot be accepted as authority for holding that a physician who acts *bona fide* and according to fair medical standards may never give an addict moderate amounts of drugs for self-administration in order to relieve conditions incident to addiction. Enforcement of the tax demands no such drastic rule, and if the Act had such scope, it would certainly encounter grave constitutional difficulties.
>
> …
>
> Federal power is delegated, and its prescribed limits must not be transcended even though the end seems desirable. The unfortunate condition of the recipient certainly created no reasonable probability that she would sell or otherwise dispose of the few tablets intrusted [sic] to her, and we cannot say that, by so dispensing them, the doctor necessarily transcended the limits of that professional conduct *with which Congress never intended to interfere.*

Id. at 22–23 (emphasis added).

The *Linder* Court's regard for comity-based constitutional constraints is notable, and every bit as relevant today. Although the scope of congressional powers has changed drastically since 1925, the states still regulate their medical practitioners as part of their police powers and that was fully understood by the Congresses that passed both the Harrison Act and the Controlled Substances Act.

II. THE ELEVENTH CIRCUIT'S EXPANSIVE INTERPRETATION OF THE CSA PREVENTS STATES FROM EXERCISING THEIR SUPERIOR JUDGMENT OVER REGULATION WITHIN THEIR BORDERS

States regulate the practice of medicine under their general police power to protect the health, safety, and welfare of state citizens. U.S. Const. amend. X; *Slaughter-House Cases*, 83 U.S. 36, 62 (1872) (describing the police power as extending "to the protection of the lives, limbs, health, comfort, and quiet of all persons. . . . within the State"); *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824) (finding "health laws of every description" form "a portion of that immense mass of legislation, not surrendered to the general government"). "The doctor-patient relationship is an area that falls squarely within the states' traditional police powers [and] the federal government may not force the states to regulate that relationship to advance federal policy." *Conant v. Walters*, 309 F.3d 629, 647 (9th Cir. 2002), *cert. denied*, 540 U.S. 946 (2003). Accordingly, when Congress passed the Controlled Substances Act to regulate certain drugs, it took care to preserve the historical delegation of power between the federal government and the states. 21 U.S.C. 13 § 801 *et seq*; *Gonzales,* 546 U.S. at 269–70 (finding the CSA manifests no intent to regulate the practice of medicine beyond illicit drug dealing and trafficking).

State-level regulation allows for policies tailored to local conditions and enables experimentation in response to pain management and addiction. Good faith, legitimate medical practice may look much different in West Virginia than it does in Hawaii. As

do lawyers, doctors often disagree in good faith, and including particularly those who practice in distinct geographic regions and with often much different patient demographics. Ensuring appropriate space for states to define the ambit of "legitimate medical practice" within which doctors may not be convicted for good-faith acts under the CSA is critical for millions of vulnerable patients.

Over 100 years ago, in first interpreting the Harrison Narcotics Act, this Court was concerned that Congress might have reached too far—under the taxing power—to regulate every person who possessed opioids. In reading the statute as being limited with respect to doctors and others in the medical field, the Court took it as obvious that Congress would not stretch its powers to a possibly unconstitutional degree without clearly saying so:

> Only words from which there is no escape could warrant the conclusion that Congress meant to strain its powers almost if not quite to the breaking point in order to make the probably very large proportion of citizens who have some preparation of opium in their possession criminal[.]

Jin Fuey Moy, 241 U.S. at 402. Moreover, "cautioning against the conclusion that the CSA effectively displaces the States' general regulation of medical practice is the Act's pre-emption provision, which indicates that, absent a positive conflict, none of the Act's provisions should be 'construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which

would otherwise be within the authority of the State.'" *Gonzales*, 546 U.S. at 270–71 (citing 21 U.S.C. § 903).

Until recently, federal courts generally agreed that 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. Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 Champion 40 (2019).[3] But the Eleventh Circuit constructively eliminates "knowingly" or "intentionally" from the burden of proof, expanding the CSA's criminal penalty to many more prescribing practices than the CSA intended.

This upsets the balance of power between states and the federal government over medical practice. Critically, it also prevents states from exercising their superior judgment over patient care within their borders. The DEA lacks the institutional competence to assess what legitimate medical practice looks like in fifty diverse states. *See generally*, Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. Kan. L. Rev. 961 (2019) [hereinafter "Dineen, *Definitions Matter*"]. A heavy-handed, monolithic approach denies care to patients in need and prevents doctors from pursuing effective harm-reduction.

[3] Available at https://bit.ly/32iATCP.

A. Section 841(a)(1) Regulates a Narrow Scope of Conduct

"The Controlled Substances Act . . . 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 . . . the statute manifests no intent to regulate the practice of medicine." *Gonzales,* 546 U.S. at 269–70. "Conventionally understood" drug dealing and trafficking means "[selling] drugs, 'primarily for the profits to be derived therefrom' and . . . 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.'" *United States v. Moore*, 423 U.S. 122, 135 (1975) (citations omitted). Federal courts have consistently held that a deviation from the standard of care is not sufficient to meet the *mens rea* requirement under the Controlled Substances Act. *See, e.g.*, *United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006). Instead, providers must depart further from being even a "bad doctor" to "a 'pusher' whose conduct is without a legitimate medical justification." *Id*. The key question for whether a physician may be prosecuted under the CSA, then, is whether she acted as a doctor or intentionally abandoned that role in favor of becoming a drug trafficker. Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 St. Louis U.J. Health L. & Pol'y 231, 235 (2008) [hereinafter "Hoffmann, *Treating Pain*"]. Thus, physicians may not be convicted under the CSA simply for prescribing in ways that violate professional standards

or for negligently allowing patients to misuse or divert their medications. *Id.*

But by effectively denying a good-faith defense under the CSA, the Eleventh Circuit criminalizes prescribing practices far beyond "illicit drug dealing and trafficking as conventionally understood." 546 U.S. at 270. This Court has recognized that "obviously, direct control of medical practice in the States is beyond the power of the Federal Government." *Linder*, 268 U.S. at 18. The CSA itself provides that "[n]othing 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." 21 U.S.C. § 823(g)(2)(H)(i). Further, the House Report accompanying the CSA states that the law "provides for control by the Justice Department of problems related to drug abuse through registration . . . of [those] in the legitimate distribution chain, and making transactions outside the legitimate distribution chain illegal." 38 H.R. Rep. No. 91-1444, pt. 1 at 1, 3 (1970). If prescribing directly to patients with pain issues is not in the "legitimate distribution chain," it is hard to imagine what could be.

This Court relies on the clear-statement canon for cases involving "congressional regulation of core state functions" to prevent excessively broad statutory constructions like the Eleventh Circuit's. William N. Eskridge, Jr. & Philip P. Frickey, *Quasi-Constitutional Law: Clear Statement Rules as Constitutional Lawmaking*, 45 Vand. L. Rev. 593, 623–24 (1992); *Raygor v. Regents of Univ. of Minn.*, 534 U.S. 533, 543 (2002) (finding that 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). Thus, any construction of the CSA that would permit the federal government to intrude on a state's right to regulate medical malpractice and deviations from the standard of care must be grounded in "a clear indication that Congress intended that result." *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs*, 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."); *Gonzales,* 546 U.S. at 272 ("When Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute."). In the absence of any indication in statutory text that the CSA criminalizes practices outside of "conventionally understood" trafficking and drug dealing, much less a clear statement to this effect, the Eleventh Circuit erred in finding that the CSA criminalizes good-faith prescriptions of controlled substances.

B. Without a Scienter Requirement, the CSA Effectively Regulates the Practice of Medicine

Most state statutes and courts define medical practice as (1) the diagnosis of disease, condition, or injury; and (2) prescribing, administering, or providing treatment. Cynthia Marietta & Amy L. McGuire, *Direct-to-Consumer Genetic Testing: Is It the Practice*

of Medicine?, 37 J.L. Med. & Ethics 369, 371 (2009). A state's regulation of medical practice includes defining the scope of "legitimate medical purpose," licensing practitioners, and imposing penalties for conduct such as deviations from the standard of care and aiding in the unauthorized practice of medicine. Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look at Medical Licensure Boards,* 3 Health Matrix 309, 326–30 (1993); Nadia N. Sawicki*, Character, Competence, and the Principles of Medical Discipline*, 13 J. Health Care L. & Pol'y 285, 290 (2010).

An effective good-faith defense, alongside consideration of whether a practice falls within a state's definition of "legitimate medical purpose," is needed to preserve the distinction between malpractice and "conventionally understood" drug dealing and trafficking. *Gonzales,* 546 U.S. at 270. Identifying the importance of this distinction, most circuits offer some version of good-faith defense. The First Circuit held that "a sincere effort to act in accordance with proper medical practice, even if flawed, could not undergird a guilty verdict" under the CSA. *United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018). "Because good faith is a defense to criminal charges under Section 841(a) but not to civil liability for medical malpractice, 'inclusion of a good faith instruction is . . . a plain-spoken method of explaining to the jury a critical difference between the two standards.'" *Id.* (quoting *United States v. Smith*, 573 F.3d 639, 650 (8th Cir. 2009); *see also United States v. Kohli*, 847 F.3d 483, 489 (7th Cir. 2017); *Feingold*, 454 F.3d at 1006. Likewise, the Second, Fourth, and Sixth Circuits held that a good-faith defense is "necessary" because, without

it, a physician might be convicted "for a gross mistake or malpractice," instead of "as a 'drug pusher.'" *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *see also United States v. Hurwitz*, 459 F.3d 463, 479–82 (4th Cir. 2006); *United States v. Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981). Though it did not address what instruction the CSA requires, this Court in *Moore* took no issue with lower court's jury instruction 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. . ." *Moore,* 423 U.S. at 138. But the Eleventh Circuit's holding collapses the meaning of drug dealing and trafficking into noncompliance with the standard of care.

C. Patients Benefit from State Control Over Medical Practices

The CSA was ostensibly enacted to prevent harm from drug abuse and dependence, but courts can create a public-health crisis under it when they criminalize good-faith, legitimate medical practice. Approximately twenty million people in the United States live with "high-impact chronic pain" which impedes "life or work activities on most days or every day." James Dahlhamer et al., *Prevalence of Chronic Pain and High Impact Chronic Pain Among Adults*, 67 Morbidity & Mortality Wkly. Rpt. 1001, 1002 (2018). Prescription opioids are essential for many of these patients to function. *Id.* But "sixty to seventy percent of all [chronic pain] patients do not receive adequate pain relief." Rima J. Oken, *Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain*, 23 Cardozo L. Rev. 1917, 1917 (2002).

Fear of prosecution is the primary reason physicians deny patients the treatment they need. Meredith Lawrence, *How the CDC Guidelines Killed My Husband,* 8 Narrative Inquiry in Bioethics 219, 219–21 (2018). When the CDC issued new prescribing guidelines for opioids in 2016, for example, many practitioners unwillingly and inappropriately tapered medications without adequate consideration for the patient's well-being, causing so much suffering and death that the Food and Drug Administration and the CDC issued warnings. Christine Vestal, "Rapid Opioid Cutoff is Risky Too, Feds Warn," *Pew: Stateline*, May 15, 2019. This fear "compromise[s] access to treatment for individuals with legitimate medical needs . . . [creating] a chilling effect on prescribers, . . . who are decreasing and altogether ceasing their prescribing out of fear." 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 (2020).

Regulators disproportionately focus on preventing illegitimate diversion of opioids at the expense of the human harms associated with insufficient access to medication. Criminalizing prescribing practice beyond "conventionally understood" trafficking leads to widespread mortality, morbidity, and suicidality. *Moore*, 423 U.S. at 342; Dineen, *Definitions Matter*, at 969–75 (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). When regulators cut the prescription opioid supply, persons with chronic pain and substance-use

disorders often turn to dangerous illicit drugs like illicitly manufactured fentanyl, cocaine, and methamphetamines. Dineen, *Definitions Matter*, at 969. Many people with substance-use disorder today lack access to evidence-based care entirely, precluding effective harm-reduction measures from taking place. 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, 1148 (2020).

This Court should limit DEA's enforcement authority to the narrow conditions specifically contemplated by the CSA. Strict court review in this area will ensure that enforcement doesn't compromise federalism and that patients face no more obstacles to receiving the care they need.

III. WITHOUT A SUBJECTIVE GOOD-FAITH COMPONENT, PRESCRIBING PHYSICIANS DON'T KNOW WHEN THEIR CONDUCT IS AT RISK OF PUNISHMENT UNDER THE STATUTE

Subjecting medical doctors to the penalties of Section 841(a)(1) of the Controlled Substances Act even when they make a good-faith effort to issue prescriptions only for "legitimate medical purpose . . . in the usual course of [their] professional practice," 21 C.F.R. § 1306.04(a), prevents medical doctors from knowing when their conduct is at risk of punishment under the statute. Unless the terms of a criminal statute are "sufficiently explicit to inform those who are subject to it what conduct on their part will render them liable to its penalties," that law violates due process of law. *Connally v. Gen. Constr. Co.*, 269 U.S.

385, 391 (1926). Medical doctors, like all persons, must be "free to steer between lawful and unlawful conduct[.]" *Grayned v. City of Rockford*, 408 U.S. 104, 108–09 (1972). Trapping "the innocent by not providing fair warning" is the opposite of due process. *See id.*

Moreover, without a reasonably determinate standard, criminal statutes promote arbitrary and discriminatory enforcement. *Kolender v. Lawson*, 461 U.S. 352, 357–58 (1983). Criminal statutes must "establish minimal guidelines to govern law enforcement." *Id.* They must not create "a standardless sweep that allows policemen, prosecutors, and juries to pursue their personal predilections." *Id.* (cleaned up).

Here, the Eleventh Circuit's interpretation of the CSA both traps innocent doctors and does not sufficiently impede arbitrary enforcement. The correct course of action, then, is to reject and Eleventh Circuit's view and apply a good-faith defense under the CSA for medical practitioners prescribing controlled substances.

A. There Is No One Discernable "Usual Course of Their Professional Practice" to which Practitioners Can Conform Their Conduct

There is no objective standard for prescribing opioids. To be sure, the concept of fair notice embodied in the void for vagueness doctrine does not require actual notice that a defendant's actions violate the law, but rather "that a defendant have *constructive* notice that his act is criminal; that is, that the defendant *could* have found out whether his conduct

was prohibited by the statute." John F. Decker, *Addressing Vagueness, Ambiguity, and Other Uncertainty in American Criminal Laws*, 80 Denv. U. L. Rev. 241, 248 (2002) (emphasis in original). However, medical views on when to prescribe opioids vary too much by context, are subject to too much debate, and federal and state standards are too ambiguous to permit prescribing doctors to discover what Section 841(a)(1) of the CSA requires of them. *See* Hoffmann, *Treating Pain*, at 291.

Federal standards for what qualifies as inappropriate prescribing of opioids are either too ambiguous to provide clarity for medical practitioners or are inconsistent. For example, a 2016 CDC Guideline for prescribing opioids for chronic pain "does not define inappropriate prescribing at all." Dineen, *Definitions Matter*, at 961–62 (citing Deborah Dowell et al., Ctrs. for Disease Control & Prevention, *CDC Guideline for Prescribing Opioid for Chronic Pain-United States*, 65 Morbidity & Mortality Wkly. Rpt., Recommendations & Rpts. 1, 3 (2016)).[4] While the Drug Enforcement Administration's Practitioner Manual lists criteria of what it sees as indicative of "inappropriate prescribing," much of the patterns it lists provide little to no clarity for medical professionals. Dineen, *Definitions Matter*, at 986–87. The first criterion the Manual mentions is whether a practitioner is prescribing an "inordinately large quantity of controlled substances[.]" Off. of Diversion Control, Drug Enforcement Admin., *Practitioner's Manual* 30 (2006).[5] But "'inordinate' amounts depend

[4] Available at https://bit.ly/3H0tC9t.

[5] Available at https://bit.ly/3H4gcJv.

upon context and prescriber specialty." Dineen, *Definitions Matter*, at 987. And while the FDA focuses on "careless prescribing," the FDA does not define that term—a term that itself connotes a negligence standard that is inappropriate in criminal law. *Id.* at 987–88 (citing Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Agency's Approval of Dsuvia and the FDA's Future Consideration of New Opioids (Nov. 2, 2018)).[6] Guidelines that medical doctors might glean from other agencies are often inconsistent or unhelpful as well. *Id.* Furthermore, asking doctors to "glean" standards from outside sources to try to determine the boundaries of criminal conduct is not how criminal law should work.

Medical practitioners providing insufficient prescriptions for patients in pain because of fear of prosecution is further evidence that a purely objective standard in this context is unhelpful. *See id.* at 992–94. Certainly, there are additional factors at play for why medical doctors are withholding opioid prescriptions from patients in need, but there is growing documentation that "many physicians believe that the risk of incurring sanctions is too high for them to continue prescribing opioids." George Comerci et al., *Controlling the Swing of the Opioid Pendulum*, 378 New Eng. J. Med. 691, 691–93 (2018). Indeed, there are reports that medical doctors frequently "avoid opioid analgesics even in cases when it contradicted their view of what would provide the best care for their patients[.]" "Not Allowed to Be Compassionate," *Human Rights Watch*, 3–4 (Dec. 18,

[6] Available at https://bit.ly/3snXMiT.

2018).[7] All of this suggests that medical practitioners do not understand how to navigate any supposed objective standard for treating patients with opioids.

Whereas an objective metric lacks the clarity necessary to guide the conduct of medical practitioners, recognizing some form of a good-faith defense radically minimizes that problem. For example, under a purely subjective construction of a good-faith defense—which the First, Seventh, and Ninth Circuits have all recognized—medical doctors must only honestly attempt to prescribe controlled substances in the best interest of their patients to avoid federal criminal sanction. *Sabean*, 885 F.3d at 45; *Kohli*, 847 F.3d at 490–91; *Feingold*, 454 F.3d at 1008. Obviously, medical practitioners—with decades of schooling and training as well as strict ethical rules within the profession—can be expected to do that much.

Moreover, even under a "reasonable belief" standard, doctors are given much greater notice of the requirements of federal law. Several federal circuits interpret the CSA essentially to require medical doctors to prescribe controlled substances "in accordance with what [they] *reasonably* believe[] to be proper medical practice." *Hurwitz*, 459 F.3d at 478–482 (emphasis added); *accord Wexler*, 522 F.3d at 205–06; *United States v. Godofsky*, 943 F.3d 1011, 1022, 1027 (6th Cir. 2019). Under this approach, prescribing doctors must sincerely attempt "to conduct [themselves] in accordance with a standard of medical practice generally recognized and accepted in

[7] Available at https://bit.ly/3pgFWME.

the country." Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 Geo. Mason L. Rev. 701, 710 (2009) [hereinafter "Hellman, *Prosecuting Doctors*"] (quoting Jury Instructions at 49, *United States v. Hurwitz* (E.D. Va. Apr. 17, 2007) (No. 1:03CR467). This standard is certainly more nebulous than a purely subjective approach. *See id.* at 708–11. But at least medical doctors would only be required by federal law to attempt to conform to the constantly evolving and highly contextual standards of medical practice recognized in the country and not be locked away for simply prescribing opioids in a situation that a few fellow practitioners—in other words, expert witnesses—believe was unwarranted.

B. An Objective Standard Turns the Vague Requirements of Section 841(a)(1) into a Strict Liability Crime for Doctors

It is common for doctors who sincerely believe they are practicing good medicine to disagree with one another. Sincere belief, however, is not a defense under Section 841(a)(1) in the Eleventh Circuit, making it functionally a strict liability crime. Criminal juries are thus being asked to decide good-faith medical disputes under vague standards, and guilty verdicts can mean decades in prison, even for doctors with the most benign motives.

Strict liability crimes "contradict[] the most basic principles of modern criminal law." Laurie L. Levenson, *Good Faith Defenses: Reshaping Strict Liability Crimes*, 78 Cornell L. Rev. 401, 401 (1993). Thus, insofar as strict liability crimes are permissible, courts should be reticent to "discover" them, especially where, as here, there are so many

indications that the Eleventh Circuit is misreading the CSA.

But even worse than a strict liability crime that comes from the misreading of a statute is a strict liability crime based on vague and indeterminable standards. If strict liability crimes are to exist, the standards should be clear enough that someone will know when they have crossed a legal line.

Certainly physicians, like all persons, must "knowingly or intentionally" distribute a controlled substance to be convicted under the CSA. 21 U.S.C. § 841(a)(1). Of course, that is itself hardly a meaningful scienter requirement for medical doctors who are registered under the Act because they may do what is generally forbidden "to the extent [that it is] authorized by their registration." *Id.* § 822(b).

But criminal statutes without a scienter requirement are more likely to be void for vagueness, because under such statutes defendants are more likely to be convicted for simple mistakes. *Gonzales v. Carhart*, 550 U.S. 124, 149 (2007). Just as with vague objective standards, "strict liability crimes pose a considerable risk that the criminal law will be misused." Paul J. Larkin, Jr., *Strict Liability Offenses, Incarceration, and the Cruel and Unusual Punishments Clause*, 37 Harv. J.L. & Pub. Pol'y 1065, 1091 (2014). As such, this Court consistently strives to construe criminal statutes so as not to impose strict liability. *Id.* at 1086 (citing *Flores-Figueroa v. United States*, 556 U.S. 646, 657 (2009); *United States v. X-Citement Video, Inc.*, 513 U.S. 64, 78 (1994); *Staples v. United States*, 511 U.S. 600 (1994); *Liparota v. United States*, 471 U.S. 419, 433 (1985); *United States*

v. U.S. Gypsum Co., 438 U.S. 422, 435–36 (1978); *Morissette v. United States*, 342 U.S. 246 (1952)). It should continue that practice here.

CONCLUSION

This Court should reject the Eleventh's Circuit's holding and rationale and affirm that physicians may not be convicted under Section 841(a)(1) for prescribing controlled substances outside the usual course of professional practice when they either "reasonably believed" or "subjectively intended" that their prescriptions fall within that course of professional practice.

Respectfully submitted,

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