NO. 20-1410

In the Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF AMICI CURIAE STEPHEN J. ZIEGLER, LYNN R. WEBSTER, MICHAEL A. BARNES, AND THE CENTER FOR U.S. POLICY IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICI CURIAE

Amici conduct research, teach, and provide consultation on matters relating to pain treatment, addiction, and drug policy.[1]

Stephen J. Ziegler, Ph.D., J.D., is a former Mayday Pain Scholar and Pain Policy Fellow and has focused on the medico-legal barriers to chronic pain and access to essential medicines for over twenty (20) years. Dr. Ziegler has published over thirty–five (35) articles, provides peer review for medical and social science journals, was the founder of a nonprofit policy think tank that focused on the evaluation and improvement of drug policies, and is a professor emeritus, associate, from Purdue University. He has training and experience as a social scientist, attorney, and as a law enforcement officer at the local and federal levels. Dr. Ziegler was an assistant prosecutor, defense attorney, and federal task force officer for the Drug Enforcement Administration at the U.S. Department of Justice.

Lynn R. Webster, M.D., is a senior fellow at the Center for U.S. Policy, former Mayday Pain and Policy Fellow, and a physician who is board certified in anesthesiology, pain medicine, and addiction medicine. He lectures extensively and has authored more

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[1] Written consent to the filing of this *Amicus* brief has been provided by counsel of record for both parties. S. Ct. Rules 37.2 (a), 37.3(a). Pursuant to S. Ct. Rule 37.6, counsel of record for *Amici* nor the parties authored this brief in whole or in part, nor did any party or counsel make a monetary contribution intended to fund its preparation or submission.

than three hundred (300) scientific publications. He has also conducted hundreds of clinical trials with a major emphasis on analgesics and studying the abuse potential of drugs. Dr. Webster is a senior editor of the peer-reviewed journal *Pain Medicine* and a past president of the American Academy of Pain Medicine (AAPM). He is the author of *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of Us* (Oxford University Press) and co–producer of a documentary with the same title.

Michael C. Barnes, J.D., is Chairman of the Center for U.S. Policy, a not-for-profit organization advancing solutions to the nation's substance misuse crisis. He is also Principal Attorney at Sequel Legal, where he practices health and drug law and policy. Mr. Barnes's research and analysis have been published in more than fifteen (15) legal, policy, and medical journals. He is a member of the advisory board for the Rx Drug Abuse & Heroin Summit, the National Sheriffs' Association's Drug Enforcement Committee, and the editorial board for the Journal of Opioid Management. Mr. Barnes was a political appointee under President George W. Bush, having served as confidential counsel in the White House Office of National Drug Control Policy.

INTRODUCTION

Our nation continues to face two (2) intertwined crises: 1) substance use disorder alongside an increase in fatal poisonings and, 2) the under–treatment of pain. While illicit opioids are driving the nation's overdose rate and are distinct from prescription opioids that are used to treat pain and opioid use disorder, *See*, Puja Seth, Rose A. Rudd, & Tamara M. Haegerich, *Quantifying the Epidemic of Prescription Opioid Overdose Deaths*, Am J Public Health 2018, 108:500–2, opioid prescribing has been influenced by a variety of factors including the availability and affordability of health insurance and treatment. Prescription opioids occupy an important role in medical care including the treatment of pain stemming from surgery, accidents, or in the treatment of disease. The challenge is how to ensure appropriate access to prescription opioids and other controlled medications in accordance with the recognition by Congress of their legitimacy, 21 U.S.C. § 801, while simultaneously preventing their misuse and diversion from the closed–loop system that starts at the point of manufacture and ends with dispensing. See, Kelley 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).

There are multiple ways that controlled prescription medications can be diverted, and unfortunately some health care professionals have contributed to the problem through medical error, negligence, recklessness, or even with the criminal intent to prescribe

for illicit profit. But when we consider, a) the small number of prescribers who purposely intend to act as illicit drug traffickers and, b) the enormous resources dedicated to enforcing the Controlled Substances Act, it is reasonable to expect that prescribers who lack criminal intent will also be caught up in the government's use of the criminal justice system to reduce diversion. *See*, Stephen J. Ziegler & Nicholas P. Lovrich, Jr., *Pain Relief, Prescription Drugs, and Prosecution: A Four-State Survey of Chief Prosecutors*, Journal of Law, Medicine & Ethics, 31 (1), 75-100 (2003).

Law enforcement can play an important role in a nation's drug control policy. For example, they can help stem the tide against the importation and trafficking of illicit substances like counterfeit fentanyl, a drug that is responsible for the majority of poisonings each year. *See*, *e.g.*, *Department of Justice Announces DEA Seizures of Historic Amounts of Deadly Fentanyl-Laced Fake Pills in Public Safety Surge to Protect U.S. Communities* (U.S. Department of Justice Press Release, 21–944, September 30, 2021, available at: https://bit.ly/32rVF2r). But when it comes to prescription medications, law enforcement is hampered by their limited knowledge regarding medical practice and the fact that they view the problem and its solution through the singular lens of enforcement, not public health. Consequently, healthcare practitioners are at high risk of being investigated and criminally prosecuted for illicit drug trafficking, irrespective of whether the prescribing stemmed from medical error, negligence, recklessness, or the purposeful intent to commit a criminal act:

> The DEA has teams of investigators specialized in finding negligence when writing perilous prescription, which can cause a harmful addiction or potential overdose. The DEA will investigate the doctors who conduct this kind of practice and continue to combat the opioid crisis. Special Agent in Charge Clyde E. Shelley, Jr., DEA Dallas Field Division.
>
> The Department of Justice will use every available tool to stop doctors who fail to uphold their legal obligation to prescribe controlled substances properly. Assistant Attorney General Jody Hunt.

Department of Justice, Civil Division. Department of Justice Press Release, 19-511, May 19, 2019 (available at: https://bit.ly/3qOSmfY).

The negative impact of these enforcement efforts is not simply damage to a prescriber's reputation, livelihood, or their loss of liberty stemming from a wrongful conviction based on the DEA's "finding of negligence when writing perilous prescriptions." It is also about the millions of people who need and use controlled medicines responsibly but who face significant barriers to access because of the government's efforts to reduce diversion. These barriers have resulted in a variety of unintended negative consequences, such as, but not limited to, increases in substance use disorder, drug poisonings, and suicide. *See*, Lynn R. Webster, *Pain and Suicide: the Other Side of the Opioid Story*, Pain Med. 2014;15(3):345-346, and Stephen J. Ziegler, *The Proliferation of Dosage Thresholds in Opioid Prescribing Policies and Their Potential to Increase Pain and Opioid-Related Mortality*, Pain Medicine 16 (10), 1851-1856 (2015).

SUMMARY OF THE ARGUMENT

The overarching issue and common thread throughout this case concerns the question of intent. *Amici* argue that Dr. Ruan's conviction, along with other similar cases involving prescribers, are unlawful for three (3) essential reasons. First, the Federal Government's use of the standard of care as a proxy for the Controlled Substances Act (CSA) requirement that the prescription be issued for a "legitimate medical purpose in the usual course of practice," increases the risk of wrongful conviction because it effectively modifies or removes the *mens rea* requirement contained in 21 U.S.C. § 841(a)(1) and enables conviction for merely violating the standard of care without regard to mental state. Second, the "knowingly or intentionally" *mens rea* requirement in the statute applies not only to the intent to write or dispense the prescription, but to all remaining material elements, including the defendant's knowledge that the prescription was illegal at the time it was made. Third, the good faith defense goes to the issue of intent and consists of both a subjective and an objective standard and asks whether the defendant's subjective belief was objectively reasonable.

ARGUMENT

I. THE FEDERAL GOVERNMENT'S CURRENT USE OF THE STANDARD OF CARE AS A PROXY FOR THE CSA REQUIREMENT THAT THE PRESCRIPTION BE ISSUED FOR A "LEGITIMATE MEDICAL PURPOSE IN THE USUAL COURSE OF PRACTICE," INCREASES THE RISK OF WRONGFUL CONVICTION BECAUSE IT EFFECTIVELY MODIFIES OR REMOVES THE *MENS REA* REQUIREMENT CONTAINED IN 21 U.S.C. § 841(a)(1) AND ENABLES CONVICTION FOR MERELY VIOLATING THE STANDARD OF CARE WITHOUT REGARD TO MENTAL STATE.

A. The Requirement of *Mens Rea*, *Actus Reus*, and Concurrence in Criminal Law.

A crime generally consists of a wrongful act (*actus reus*), a mental state (*mens rea*), and concurrence between the act and the *mens rea* where the mental state actuates the wrongful act. in general, mental states consist of four (4) alternatives: intention (or purpose), knowingly, reckless, or the least blameworthy, negligence. In most criminal matters, "some form of mental state is a prerequisite for guilt," unless strict liability is involved which is liability without regard to mental state. See, Wayne R. LaFave, *Criminal Law*, 3rd ed. (2000), 446, 453 (citing MPC), 474, 568, 611-612.

B. The Legal Basis for Prescriber Prosecutions.

The prosecution of healthcare professionals in the context of controlled medicines is informed in large part by three (3) primary sources of legal authority relevant to the instant case: the Controlled Substances Act of 1970 (21 U.S.C. § 841(a)(1)), the Code of Federal Regulations (§ 1306.04 (a)), and *United States v. Moore* (1975), and its progeny.

In 1970, Congress passed, and President Nixon signed the CSA, an act that consolidated a variety of federal drug laws for the ostensible purpose of preventing drug abuse and punishing those who engaged in unlawful drug trafficking. The statute provided criminal and civil penalties, a drug classification scheme, and registration provisions for healthcare professionals who prescribe drugs (registrants), sanctions for administrative violations, including the suspension or revocation of prescribing privileges. 21 U.S.C. § 801 *et seq*. (1970) (*See also*, Congressional Research Service, *The Controlled Substances Act (CSA): A Legal Overview for the 117th Congress* (2/5/21). Specifically, section 841 of the act states:

§ 841. Prohibited acts A

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

Shortly after the CSA became law, the Department of Justice through its Attorney General, published a regulation relating to the dispensing of controlled substances by prescription.

21 C.F.R. § 1306.04(a).
Purpose of Issue of Prescription

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[2]

C. How the Federal Government's Current Use of the Standard of Care as a Proxy for the CSA Requirement That the Prescription Be Issued for a "Legitimate Medical Purpose in the Usual Course of Practice," Increases the Risk of Wrongful Conviction.

It is unlawful to dispense "controlled substances without a valid prescription" (*Gonzales v. Oregon*, 546

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[2] Purpose of Issue of Prescription was first published in the C.F.R. on Apr. 24, 1971, at 36 FR 7799 as 306.04 (a); renumbered as 1306.04 at 38 FR 26609, Sept. 24, 1973.

U.S. 243 (2006), citing *United States v. Moore* (1975), and 21 U.S.C. § 841(a)(1)). The definition of what constitutes a "valid prescription" can be found in two (2) places in the CSA:

§ 829. Prescriptions

(e) Controlled substances dispensed by means of the Internet

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice . . .

§ 830. Regulation of listed chemicals and certain machines

(b) Reports to Attorney General

(3) Mail order reporting—(A) As used in this paragraph:

(ii) The term "valid prescription" means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

Section 829 makes reference to prescriptions that are "issued for a legitimate medical purpose in the usual course of professional practice, and Section 830 states the two (2) phrases in the conjunctive: "issued for a legitimate medical purpose . . . and acting in the usual course of the practitioner's professional practice. Both of these phrases also appear in 21 C.F.R.

§ 1306.04(a). However, these twin phrases do not appear in 21 U.S.C. § 841, their meaning is not defined in the statute or regulation, and the Court in *Gonzales* recognized "that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense." *Gonzales*, at 258. The two-part phrase can be found in other parts of the CSA, and while never appearing in the disjunctive, they can appear in the absence of each other as they do in section 831, and 801: 1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose . . . [emphasis added]. 21 U.S.C. § 801.

Taken together, the statute and regulation indicate that it is unlawful for a person, knowingly or intentionally, to dispense a controlled substance unless the dispensing is authorized by the CSA. In order for the dispensing to be authorized, it must be a valid prescription, and a valid prescription is one issued for a legitimate medical purpose in the usual course of practice. But as the *Gonzales* Court asks: "Who decides whether a particular activity is in 'the course of professional practice' or done for 'a legitimate purpose?'" *Gonzales*, at 258 The Court's inquiry also raises two (2) additional questions: how do they decide, and what standards do they use? The CSA is of no help in that regard, and neither is 21 C.F.R. § 1306.04(a).

But according to the government, the answers to all four (4) questions can be found through circular reasoning and expert testimony concerning the medical standard of care or practice (a complex and an evolving standard, distinct from clinical practice guidelines). See, Peter Moffett and Gregory Moore, *The*

Standard of Care: Legal History and Definitions: The Bad and Good News, West J Emerg Med. 2011;12 (1):109-112.

First, if the jury finds that the prescription was outside the standard of care, then the controlled substance was not dispensed for a legitimate medical purpose in the usual course of professional practice, and consequently not a valid prescription. If the prescription was not valid, it would violate 21 C.F.R. § 1306.04(a) and section 841 of the CSA, and the defendant could be convicted as a drug trafficker. In essence, the government has, without notice and opportunity for comment, defined the phrase "legitimate medical purpose in the usual course of professional practice," to mean a prescription that is issued outside the standard of care. But Congress did not declare that the standard of care is a mere proxy for the two–part phrase contained in the CSA, or that violations of best practices amount to a violation of the standard of care, or that if a jury found that the prescription was outside of this standard, a prescriber could be convicted of drug trafficking. Moreover, the CSA does not contain the phrase "standard of care" or the equivalent "standard of medical practice," let alone define it. Consequently, if the jury ultimately believes the government's experts that the prescription falls outside the standard of care, the government need only prove that the defendant intended to write the prescription, not that he knew that the prescription was unlawful at the time it was written. This, however, is not the law in the Ninth Circuit.

In *United States v Feingold*, 454 F.3d 1001 (9th Cir. 2006), the court held that in addition to the government proving that the defendant distributed con-

trolled substances "outside the usual course of professional practice and without a legitimate medical purpose," the jury is also required to "make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional." *Feingold*, at 1008. The court in *Feingold* was correct and recognized a critical distinction between issuing a prescription later found to be invalid and issuing a prescription the defendant knew was invalid at the time it was issued. To limit the statute's *mens rea* to only the defendant's intent to prescribe would enable a jury to convict a defendant for negligent prescribing because the crucial issue for the jury would simply be whether the prescription was outside the standard of care, without regard to the defendant's mental state to commit a criminal act. Such a limitation would effectively modify the statute's *mens rea* requirement and replace it with strict liability, liability without regard to mental state.

It is not that the standard of care has no place in a criminal trial; it is just that the critical inquiry has become whether the prescription was outside the standard of care, not whether the defendant was engaging "in illicit drug dealing." *Gonzales*, at 269-70. Standard of care testimony can be relevant in a section 841 prosecution, but for the limited purpose of providing a baseline to educate the jury about a range of what constitutes acceptable medical practice and to perhaps provide evidence to show that the defendant was acting as a drug trafficker, not a physician. See, Kelley K. Dineen & James M. DuBois (2016), *supra.*, Douglas J. Behr, *Prescription Drug Control Under the Federal Controlled Substances Act:*

a Web of Administrative, Civil, and Criminal Law Controls. Wash Univ J Urban Contemp. Law. 1994; 45:41–119, and U.S. Department of Health and Human Services, *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations* (Final Report, May 9, 2019).

Moreover, outside of the criminal context, violations of the standard of care can also be relevant in tort claims, administrative actions before state regulatory boards, or in actions involving the suspension or revocation of a registrant's ability to prescribe controlled substances. *See*, Michael C. Barnes, Taylor J. Kelly, & Christopher M. Piemonte, *Demanding Better: A Case for Increased Funding and Involvement of State Medical Boards in Response to America's Drug Abuse Crisis*, J Med Reg, 106 (3): 6–21 (2020); John J. Mulrooney & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333 (2017); Dineen & Dubois (2016), and Behr (1994), *supra*. For example, in the case of Dr. Roth, the physician was subject to administrative sanctions regarding his prescribing of pain medication. *In re Roth*, 60 Fed. Reg. 62262, 62263, 62267 (1995). However, unlike a criminal matter before a jury, the trier of fact was an administrative law judge with training and experience on the specific topic. Mulrooney & Legel, *supra*. Although Dr. Roth ultimately prevailed, *Amici* have little doubt that had Dr. Roth been charged with section 841 in a criminal court, the outcome would likely have been different, because despite the higher standard of proof in a criminal trial, his fate would have been in the hands of a lay jury without any such training, and unlike an admin-

istrative court, he could have faced a lengthy prison term, not merely suspension or revocation of his license to prescribe. True, a civil court jury in a malpractice action must determine whether the physician's actions were outside a standard of care, but only if there was a duty to the patient, a breach of that duty, a causal link between the breach and the injury, and resulting damages. *See*, Dineen & Dubois, *supra*. Moreover, like an administrative matter, the penalties in a civil matter are primarily financial, would not result in a loss of liberty, and are often covered by professional liability insurance.

D. The Standard of Care: Challenges for Both Juries and Prescribers.

But the standard of care is not only challenging for juries, its evolving nature and inherent conflicts pose challenges to practitioners as well because the medical judgment of how to treat opioid use disorder and chronic pain with opioids is not an exact science and unavailable or inadequate health insurance coverage influences whether optimal therapies may be started, adjusted, or continued with an individual patient. *See*, U.S. Department of Health and Human Services. *Pain Management Best Practices Inter-Agency Task Force Report, supra*, and Michael E. Schatman, *the Role of the Health Insurance Industry in Perpetuating Suboptimal Pain Management*. Pain Med. 2011;12(3):415-426. Furthermore, risks with medications and interventions exist in all areas of medicine, not only in the provision of opioids or other controlled medicines. The injunction to "do no harm" is fraught with peril not only in the choices of treatments that are available and their attendant risks versus benefit, but also in the choice to do nothing. Significant harm

can and does occur with inadequate treatment of pain and other conditions that may require controlled medicines, whether by action or inaction. *See*, L.R. Webster, *supra.*

For example, although opioids are not considered optimal for a condition known as fibromyalgia, clinical treatment guidelines do indicate that prescription opioids may be justified for severe fibromyalgia, particularly when combined with other recommended therapeutics. *See*, Don L. Goldenberg, Daniel J. Clauw, Roy E. Palmer, & Andrew G. Clair, *Opioid Use in Fibromyalgia: A Cautionary Tale*, Mayo Clin Proc. 91 (5):640-648 (2016). However, the reality is, up to sixty percent (60%) of fibromyalgia patients are prescribed opioids. Yet despite the complexities associated with care, and the recognition among the professional community in clinical guidelines that opioids may be justified, government experts can step outside the bounds of an established medical standard by claiming that legitimate medicine precludes an opioid analgesic ever being prescribed to people with fibromyalgia (or migraine, opioid-use disorder, and other specific conditions).

Urine drug tests (UDTs) are another example of the complexities associated with guidelines and using UDTs to monitor a patient's adherence to the treatment regimen. Guidelines and sometimes state laws require UDT monitoring in opioid-treated patients, and to forego this testing may be considered a deviation from the standard of care. Yet different types of tests have varying degrees of accuracy, and if a patient lacks insurance or cannot afford a co–payment, (estimated at Two Hundred Eleven Dollars ($211) to Three Hundred Sixty–Three Dollars ($363) per test), a UDT

may be prohibitive. See, Deborah Dowell, Tamara M. Haegerich, & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain-United States, 2016*, JAMA. 2016;315(15):1624-1645. This poses a dilemma for the health care practitioner. Legal pressures demand a UDT, but patients may have to forego other essentials in order to afford the urine test. The point is, decisions that lie outside the standard of care are not necessarily matters for prosecutorial action; they are often the result of a lack of resources, the absence of affordable healthcare, the lack of specialists, and the reality that pain and complex conditions are treated by general practitioners with the limited tools and resources available to them and the patients they treat. Unfortunately, best practices guidelines (which are themselves evolving and are distinct from the standard of care), *See, Moffett & Moore* (2011), *supra.*, have been used to place health care providers under investigation or on trial without adequate consideration of the aforementioned limitations. Guidelines are by definition advisory; it matters what organization issues them, and the quality of the evidence to support those recommendations. Clinical practice is inherently difficult and following guidelines and best practices is never a guarantee of an accurate assessment or treatment. Consequently, given the government's law enforcement approach to the public health crisis involving substance misuse and drug poisoning deaths, many practitioners are turning away patients out of fear that treating them with opioids could risk their licenses, livelihoods, and liberty.

In the end, risks are present in every treatment scenario. Differences within the medical community

and among experts hired by the government reveal the myriad realities and challenges of how chronic pain and opioid use disorder is actually treated and the minefield that all practitioners must navigate. The standard of care is not a proxy for the CSA's requirements, nor should it be used as a mechanism to ease the prosecution's path to conviction for violations of a standard without proving the defendant's purposeful intent to engage in illicit drug trafficking.

II. THE FEDERAL GOVERNMENT'S FAILURE TO PROVE THE REQUISITE MENTAL STATE IN 21 U.S.C. § 841 AND ITS APPLICATION TO ALL REMAINING ELEMENTS OF THE STATUTE, INCLUDING THE DEFENDANT'S KNOWLEDGE OF ILLEGALITY AT THE TIME THE PRESCRIPTION WAS WRITTEN, IS CONTRARY TO THIS COURT'S PRIOR HOLDINGS.

Aside from the government's use of the standard of care as the basis of criminal liability without statutory, regulatory, or congressional authorization to do so, the government has also failed to prove the requisite mental state and its application to all remaining elements of the statute, contrary to this Court's holdings in *Liaparota v. United States*, 471 U.S. 419 (1984), and *Flores-Figueroa v. United States*, 556 U.S. 646 (2009).

in *Liaparota v. United States* (1984), a sandwich shop owner was indicted for food stamp fraud in violation of 7 U.S.C. § 2024(b)(1) which states: "[W]hoever knowingly uses, transfers, acquires, alters, or possesses coupons . . . in any manner not authorized by this chapter or the regulations issued pursuant to this chapter shall . . . be guilty of a felony" (*Liaparota*, at 420, n. 1).

The issue before the Court was whether "the Government must prove" the defendant knew he was acting contrary to the statute or regulation. *Liaparota*, at 421. The Court ultimately held that absent an "indication of contrary purpose in the language or legislative history of the statute," the aforementioned statute "requires a showing that the defendant knew his conduct to be unauthorized by statute or regulations," *Liaparota*, at 425. While Congress had not "explicitly and unambiguously indicate[d] whether *mens rea* [was] required," the Court found it appropriate to apply the rule of lenity to ensure "that criminal statutes will provide fair warning concerning conduct rendered illegal and strikes the appropriate balance between the legislature, the prosecutor, and the court in defining criminal liability." *Liaparota*, at 426-427.

In *Flores-Figueroa v. United States* (2009), the defendant was charged with aggravated identify theft in violation of 18 U.S.C. § 1028A(a)(1), a federal statute that imposes increased penalties if "the offender '*knowingly* transfers, possesses, or uses, without lawful authority, a means of identification of another person'" [emphasis in original]. *Flores-Figueroa*, at 648. The Court held, relying in part on English grammar, that when a statute contains a knowing requirement, that knowing mental state applies "to all subsequently listed elements of the crime." *Flores-Figueroa*, at 650. Remarkably, the Court noted the government's concession "that the offender likely must know that he is transferring . . . *something*[3] *without lawful authority*,"[4] and that "courts ordinarily read a phrase in a criminal

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[3] Emphasis in original at 648.

[4] Emphasis added. *Id.*

statute that introduces the elements of a crime with the word 'knowingly' as applying that word to each element." *Flores-Figueroa*, at 652. Here, the jury instructions in Ruan did not require, as they do in the Ninth circuit, that the jury must not only "make a finding of intent . . . with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional." *United States v. Feingold*, 454 F.3d 1001, 1008 (2006). This latter phrase is critical.

But the necessity of proving the defendant's mental state beyond the intent to write the prescription does not end there. *Flores-Figueroa* tells us that the government is also required to prove the statute's knowing requirement in regard to all subsequently listed material elements of the statute and regulations. Although section 841 does not list all of the elements, the trial court's jury instructions must do so, namely, that the prescription was issued for a legitimate medical purpose in the usual course of medical practice. Accordingly, taken together, *Liaparota* and *Flores-Figueroa* would require that the prosecution prove beyond a reasonable doubt that at the precise time the prescription was written, the defendant knew that the prescription was not for a legitimate medical purpose in the usual course of professional practice. The government's efforts to limit the *mens rea* to merely the intent to write the prescription, a prescription later found by a jury to be outside the standard of care, is not a trivial matter, for as this Court observed in *Morissette v. United States*, 342 U.S. 246, 263 (1951), "The purpose and obvious effect of doing away with the requirement of a guilty intent is to ease the prosecution's path to conviction [and] to strip the

defendant of such benefit as he derived at common law from innocence of evil purpose." *Amici* believe, as the Ninth Circuit and Seventh Circuits have recognized, the government must prove that the defendant knew at the time the prescription was issued that he was acting contrary to section 841 and 21 C.F.R. § 1306.04(a). *Feingold*, *supra*; *United States v. Chube*, 538 F.3d 693, 698 (7th Cir. 2008); See, also, Deborah Hellman, Prosecuting Physicians for Trusting Patients, 16 Geo. Mason L. Rev. 3 (2009), at 712-715; 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 (2020); Katherine Goodman, *Prosecution of Physicians as Drug Traffickers: The United States' Failed Protection of Legitimate Opioid Prescription under the Controlled Substances Act and South Australia's Alternative Regulatory Approach*, 47 Colum. J. Transnat'l L. 210 (2008).

III. GOOD FAITH GOES TO THE ISSUE OF INTENT AND CONSISTS OF BOTH A SUBJECTIVE AND AN OBJECTIVE STANDARD AND ASKS WHETHER THE DEFENDANT'S SUBJECTIVE BELIEF THAT HIS PRESCRIBING WAS LAWFUL WAS OBJECTIVELY REASONABLE.

The Court in *Unites States v. Moore* (1975), recognized that even if the prescription was not within the usual course of professional practice, a jury could consider a good faith defense if the defendant made an honest effort to comply with "an accepted standard of medical practice":

> The jury was instructed that Dr. Moore could not be convicted if he merely made "an honest effort" to prescribe for detoxification

> in compliance with an accepted standard of medical practice. The trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice. He instructed the jury that 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." [emphasis added].

Moore, *infra* at 142, n. 20.

Here, the trial court's jury instructions in Ruan linked good faith with the usual course of practice phrase:

> A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States [emphasis added].

Ruan v. United States, *Petitioners Brief in Support of Certiorari*, Appendix p. 105a.

Although there is a split among the circuits about whether a good faith defense exists, and if so, whether it consists of a subjective or objective standard, good faith has both subjective and objective components.

In *United States v. Hurwitz*, 459 F 3rd 463 (2006), the defendant physician was convicted for violations of the CSA relating to his prescribing. On appeal, the defendant argued that the trial court had erroneously denied his request for a jury instruction that used a subjective standard. The federal appeals court held that a good faith instruction is possible in a § 841 prosecution, but the standard is objective, not subjective, because to hold otherwise would permit the defendant "to decide for himself what constitutes proper medical treatment." *Hurwitz*, at 478. However, in Judge Widener's dissent, he disagreed that it was entirely an objective standard because "the act in question is not in dispute, it is the intent of the actor into which inquiry is made." *Hurwitz*, at 483.

On the one hand, a pure subjective standard would enable any defendant to claim that he believed that his prescribing was lawful. Alternatively, a purely objective standard would completely negate the existence of a good faith defense if, as the trial court's instructions in Ruan indicated, good faith depended on whether the prescription was ultimately found to be for a legitimate medical purpose within the usual course of practice. If such were the case, a good faith defense would have no purpose if the prescription was found to be valid.

There is support in the CSA for a subjective standard that recognizes the role that the individual practitioner has in determining the prescription's validity. For example, in the context of filling new prescriptions, the CSA recognizes the subjective opinion of the practitioner in determining the legitimacy of the prescription: "the practitioner, acting in the usual course of professional practice, determines there

is a legitimate medical purpose for the issuance of the new prescription" [emphasis added]. 21 U.S.C. § 802(56)(C).

Consequently, good faith in the context of intent and whether the defendant had knowledge of the illegality of his act, (*i.e.*, whether he knew it was not for a legitimate medical purpose in the usual course of practice), has both a subjective and objective component. Good faith is determined by analyzing whether the defendant believed that his prescription was lawful (subjective), and whether such a belief by the practitioner was reasonable (objective). See, Stephen J. Ziegler, *Pain, Patients, and Prosecution: Who is Deceiving Whom?* Pain Medicine, 8 (5), 445-446. (2007). By taking a subjective-objective approach, the defendant cannot merely claim that he believed the prescription was lawful, nor would good faith rest upon whether the prescription was "in accordance with the standard of medical practice generally recognized and accepted in the United States." Rather, good faith is somewhere in between the two extremes and depends upon the reasonableness of the defendant's subjective beliefs.

IV. Impact on the United States Healthcare System.

It is not merely the reputation, livelihoods, and liberty of physicians that are at risk under the real threat of wrongful conviction stemming from the government's use of an alleged violation of the standard of care as tantamount to illicit drug dealing. Rather, the Ruan case and others like it are also about the millions of people who are suffering in pain from surgery, from chronic conditions, those who are terminally ill, or who have opioid use disorder and need access to essential medicines. When people with medical needs cannot access essential medicines through their healthcare providers, they often resort to harmful, even deadly, alternatives. The treatment of pain, the prevention and treatment of opioid use disorder, preventing suicides, poisonings, and deaths from illicit opioids like heroin and counterfeit fentanyl, all pose significant challenges to public health, policymakers, our healthcare system, and everyday people.

Remarkably, a decade after 21 U.S.C. § 841 became law and the Attorney General published 21 C.F.R. § 1306.04(a), Stephen Stone, associate chief counsel of the Drug Enforcement Administration was arguably correct when he wrote about one part of the two–part phrase in the CSA:

> Acts of prescribing or dispensing of controlled substances which are done within the course of the registrant's professional practice are, for purposes of the Controlled Substances Act, lawful. It matters not that such acts might constitute terrible medicine or malpractice. They may reflect the grossest

> form of medical misconduct or negligence They are nevertheless legal.

Stephen E. Stone, *The Investigation and Prosecution of Professional Practice Cases under the Controlled Substances Act*. Drug Enforcement, 10:1, Spring 1983, 21-28.

Yet decades later, the government is now using alleged violations of the standard of care, which can result from medical error, negligence, or recklessness, as the basis for criminal liability, an application that was never specifically authorized by Congress or the CSA. To be clear, prescribers with knowledge of the prescription's illegality, should have their prescribing privileges revoked and be subject to criminal prosecution. But the hundreds of thousands of physicians and other healthcare professionals with the authority to prescribe essential medicines to treat pain or opioid use disorder who lack the requisite criminal intent and evil purpose, should not have to face the government's enormous resources and risk imprisonment for conduct that amounts to medical error, negligence, or at most, recklessness. Such matters are best addressed administratively by state licensing boards, in civil actions, and the Federal Government's existing administrative framework for registrants, not the federal criminal courts.

CONCLUSION

For the forgoing reasons, this Court should reverse the judgments of the lower court.

Respectfully submitted,

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