IN THE

Supreme Court of the United States

XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

BRIEF OF AMICI CURIAE ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS AND JEFFREY A. SINGER, M.D., IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

A physician otherwise authorized to prescribe controlled substances may be convicted of unlawful distribution under 21 U.S.C. § 841(a)(1) if his prescriptions "fall outside the usual course of professional practice." *United States v. Moore*, 423 U.S. 122, 124 (1975). To ensure that physicians are not convicted for merely negligent conduct, however, the federal courts generally permit doctors to advance a "good faith" defense.

The question presented, on which the circuits are deeply divided, is whether a physician 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, he "reasonably believed" or "subjectively intended" that his prescriptions fall within that course of professional practice.

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INTERESTS OF AMICI CURIAE1

Amicus Association of American Physicians and Surgeons ("AAPS") is a national association of physicians. Founded in 1943, AAPS is dedicated to protecting the patient-physician relationship. AAPS has been a litigant in this Court and in other appellate courts. See, e.g., Ass'n of Am. Physicians & Surgs. v. Mathews, 423 U.S. 975 (1975); Ass'n of Am. Physicians & Surgs. v. Tex. Med. Bd., 627 F.3d 547 (5th Cir. 2010);

¹ Amici file this brief with written consent by all the parties, including petitioner who filed blanket consent. Pursuant to Rule 37.6, counsel for amici curiae authored this brief in whole, no counsel for a party authored this brief in whole or in part, and no such counsel or a party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity – other than amici, their counsel, and the members of Amicus AAPS – contributed monetarily to the preparation or submission of this brief.

Ass'n of Am. Physicians & Surgs. v. Clinton, 997 F.2d 898 (D.C. Cir. 1993).

Amicus Jeffrey A. Singer, MD, FACS, is a general surgeon who has been in private practice for 40 years as a specialist in general surgery in the state of Arizona. He is a Fellow of the American College of Surgeons who received his MD from New York Medical College and completed his general surgery postgraduate training at Maricopa County General Hospital in Phoenix. As a surgeon, he often needs to prescribe medication, including opioids, to treat both acute and chronic pain resulting from acute and chronic surgical conditions.

The denial of the petitioner's good faith defense in prescribing medications has a chilling effect on the treatment of pain, an issue in which *Amici* have a strong interest.

SUMMARY OF ARGUMENT

Lengthy incarceration without proving criminal intent is tyrannical. A 21-year imprisonment for medicating pain deters all physicians against fully treating patients who suffer. Undertreatment of pain inevitably results when a robust good faith defense is denied. Dr. Ruan acted in good faith as shown by an unsuccessful undercover sting operation against him, but that evidence and testimony by supportive patients were all withheld from the jury. In addition, the jury was misled that Dr. Ruan could have called anyone he wanted as a witness. He was not allowed to.

Under the Eleventh Circuit decision, nearly any physician who treats pain is at risk of an arbitrary 21year imprisonment based on a small fraction of his prescriptions. By eliminating a bona fide good faith defense, the approach taken by the Eleventh Circuit renders misled juries as the arbiters of what constitutes legitimate medical practice. The Eleventh Circuit decision below even begins its factual analysis with a discussion of how much money the defendant physician made over an extended period of time, which hardly seems relevant and omits the high costs to become a physician. These trials of physicians degenerate into scapegoating and eliciting jealousy.

Mischaracterizing a doctor based on non-representative prescriptions does not make him a drug dealer, or reduce overall abuse of prescriptions. Instead, eliminating a high-volume prescriber has the effect of dispersing that medication among many smaller practices without reducing the potential for misuse. The denial of a bona fide good faith defense by the Eleventh Circuit exacerbates the problem it purports to address. Allowing a robust good faith defense would safeguard legitimate practices and help patients in pain to become productive in their lives.

ARGUMENT

Pain medications are as essential to medical practice as rhetoric is to the practice of law. Imposing lengthy incarcerations without allowing a strong good faith defense violates individual rights and deters legitimate professional practice. Good faith should be recognized as a defense for every physician accused of improper prescribing under federal law.

I. The Presumption of Requiring Proof of Criminal Intent Should Apply Here, Including a "Good Faith" Defense.

In a recent appeal also arising from the Eleventh Circuit, it likewise declined to require proof of full criminal intent in connection with a conviction under a federal gun possession statute. *Rehaif v. United States*, 139 S. Ct. 2191 (2019). This Court reversed, just it should do here to allow a good faith defense before incarcerating a physician for 21 years.

"We normally characterize this interpretive maxim as a presumption in favor of 'scienter,' by which we mean a presumption that criminal statutes require the degree of knowledge sufficient to 'mak[e] a person legally responsible for the consequences of his or her act or omission." *Id.* at 2195 (quoting Black's Law Dictionary 1547 (10th ed. 2014), brackets in decision).

This Court has often invoked that essential presumption when interpreting criminal statutes. "In determining Congress' intent, we start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state regarding 'each of the elements that criminalize innocent conduct." Rehaif, 139 S. Ct. at 2195 (quoting United States v. X-Citement Video, Inc., 513 U.S. 64, 72 (1994)). See also Morissette v. United States, 342 U.S. 246, 256-58 (1952). "We apply the presumption in favor of scienter even when Congress does not specify any scienter in the statutory text." Rehaif, 139 S. Ct. at 2195 (citing Staples v. United States, 511 U.S. 600, 606 (1994)).

"[T]he presumption in favor of a scienter requirement should apply to each of the statutory elements that criminalize otherwise innocent conduct." X-Citement Video, Inc., 513 U.S. at 72; see also Staples, 511 U.S. at 614-15 (1994); Liparota v. United States, 471 U.S. 419, 426 (1985). "[W]here a statute is susceptible of two constructions, by one of

which grave and doubtful constitutional questions arise and by the other of which such questions are avoided, our duty is to adopt the latter." See Jones v. United States, 529 U.S. 848, 857 (2000) (inner quotations and citations omitted). Indeed, it is "incumbent on [courts] to read the statute to eliminate [serious constitutional] doubts so long as such a reading is not plainly contrary to the intent of Congress." X-Citement Video, Inc., 513 U.S. at 78.

Even if Congress intended for physicians to be convicted without proof of criminal intent, that should still not be allowed by courts. "[I]n 2021, we have overwhelming evidence that the legislature intends the simple possession statute to penalize innocent nonconduct, and we have overwhelming legal authority that this violates the due process clauses of the state and federal constitutions." *State v. Blake*, 197 Wash. 2d 170, 188, 481 P.3d 521, 531 (2021).

Yet in its decision below, the Eleventh Circuit begins its characterization of Dr. Ruan not by analyzing his mens rea or even his medical decisionmaking, but by citing how much money he made over nearly a half-decade, which was not extraordinary on an annual basis given the high cost of becoming a physician. United States v. Ruan, 966 F.3d 1101, 1121-22 (11th Cir. 2020). It is typical in these trials of physicians for their costly, extensive training to be left out of the picture, and for cumulative income to be without reference the presented undercompensation for years that preceded it.

Worse, exculpatory evidence is often kept from the jury, as done below:

Two undercover DEA agents posed as patients of Ruan's ... but Ruan never prescribed either patient opioids. The government moved *in limine* to exclude videos of these visits, arguing that they did not show anything illegal and Ruan was merely trying to prove that he practiced 'good medicine.' The district court agreed, so the jury never saw them.

Ruan, 966 F.3d at 1127. Indeed, the trial court excluded evidence of good faith prescribing by Dr. Ruan, and instead limited his ability to call witnesses to merely patients used by the prosecution. *Id.* at 1131. The prosecution wrongly told the jury that Dr. Ruan was allowed to call any witness. *Id.* at 1158.

The Eleventh Circuit has reportedly tended to be pro-prosecution,² but its exclusion of the good faith defense and affirmance of the exclusion of Dr. Ruan's witnesses goes too far. Nothing in the proverbial War on Drugs justifies blocking a good faith defense.

² As one commentator observed in connection with sentencing:

The Eleventh Circuit affirmed upward variances [in sentencing] at a rate of almost 10 times that at which it affirmed downward variances, affirming all but 1 of the 41 upward variances that it reviewed, a relative reversal rate of approximately 2% and reversing 7 of the 34 downward variances that it reviewed, a relative reversal rate of approximately 21%.

Carrie Leonetti, "De Facto Mandatory: A Quantitative Assessment of Reasonableness Review after Booker," 66 DePaul L. Rev. 51, 76 (Fall 2016) (footnotes omitted). Anecdotally, when a district court publicly reprimanded prosecutors for misconduct and applied the Hyde Amendment to reimburse an exonerated defendant, on appeal the Eleventh Circuit reversed in order to hold for the prosecution. *United States v. Shaygan*, 652 F.3d 1297, 1302 (11th Cir. 2011).

Far from helping patients, the elimination of a top prescriber harms them. Dr. Eugene Gosy in the Buffalo area, for example, was criticized in the media for being the top prescriber of controlled substances in New York. Davis & Schulman, "How high the cost for killing pain?" Buffalo News (Mar. 6, 2011).3 But he had completely won one malpractice case and partially prevailed in another. After he was publicized as the top pain prescriber in the state, he was ultimately indicted. In a circuit that allows only a weak, objective good faith defense, the trial court denied Dr. Gosy's motion to dismiss for lack of alleged criminal intent. United States v. Gosy, No. 16-CR-46, 2019 U.S. Dist. LEXIS 31389 (W.D.N.Y. Feb. 27, 2019). Few physicians in the area were willing to treat the patients for pain after Dr. Gosy's highly publicized indictment, and his many patients were stranded without medical care. His patients sent 30,000-plus words in support of him to the sentencing judge after a plea bargain. See Patrick Lakamp, "This man is no monster," Buffalo News (Oct 15, 2020).4

Incarceration of physicians who treat pain does not eliminate the pain and the need to treat it. A robust good faith defense is essential to protect patient access to prescriptions written in good faith.

https://buffalonews.com/news/how-high-the-cost-for-killing-pain-rise-in-addiction-deaths-from-prescription-drugs-is/article 742baefd-335d-5559-8956-94fbc467937f.html (viewed Dec. 25, 2021).

⁴ https://buffalonews.com/news/local/crime-and-courts/this-manis-no-monster-before-gosy-sentencing-patients-urgeleniency/article_42f40762-0e23-11eb-99e0-4f3554f89a5c.html (viewed Dec. 25, 2021).

II. States, Not Juries, Should Determine What Constitutes Proper Medical Practice.

Juries lack the training necessary to delineate the boundaries of medicine and then convict based on it. Yet that is the approach taken by the Eleventh Circuit, contrary to the teachings of this Court in *United States v. Moore*, 423 U.S. 122 (1975), and several other circuits. States, not federal juries, are who should be assessing the boundaries of medical treatment of pain.

Allowing prosecutions of physicians for being the highest prescribers merely ensures, after repetition of that approach, that access by patients to such medications will become exceedingly difficult or impossible. Rather than resort to draconian 21-year prison sentences for frequent prescribers, a more sensible approach would be simply to suspend a DEA registration while providing full due process for the physician and listening to his supportive patients.

By eliminating a meaningful good faith instruction, the Eleventh Circuit irrationally usurps state authority over the regulation of medicine. The approach of federal prosecution of a physician who complied with governing state authority is contrary to federalism and, when denying the defense of good faith, also contravenes due process.

In *Moore*, the Supreme Court upheld the conviction of a physician for prescribing drugs because, unlike here, the federal remedy of revocation of his DEA registration was *not* a viable option. There, unlike here, "[r]egistration was mandatory for practitioners with state licenses" except under inapplicable exceptions. *Id.* at 138 n.15. The *Moore* Court approved of how the trial judge:

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.'

Id. at 138-39 (emphasis added). The *Moore* jury was thus expressly instructed to convict or acquit based on its finding about good faith. *See also United States v. Linder*, 268 U.S. 5, 18 (1925) (acquittal required if the jury found that defendant physician acted "in good faith" in prescribing narcotics).

Most innovative physicians advance medical practice contrary to "generally recognized and accepted" treatments, but that is not the proper test for criminal prosecution. Good faith is. Nothing in the *Moore* precedent or common sense countenances usurping state authority by federal juries.

In *Moore*, the defendant conceded that "he did not observe generally accepted medical practices." *Id.* at 126. The Court observed that:

"[i]n billing his patients he used a 'sliding-fee scale' pegged solely to the quantity prescribed, rather than to the medical services performed. The fees ranged from \$ 15 for a 50-pill prescription to \$ 50 for 150 pills. ... When a patient entered the office he was given only the most perfunctory examination.

Id. Unlike the trial below, the flagrant practices in *Moore* were plainly non-medical in nature. The issue of what constitutes valid medical practice was

essentially conceded in *Moore*, rather than put to a jury.

Other Circuits have long recognized some type of a good faith defense. See, e.g., United States v. Tran Trong Cuong, 18 F.3d 1132, 1137 (4th Cir. 1994). That Circuit approved a jury instruction declaring that if a "doctor dispenses a drug in good faith in medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully." 18 F.3d at 1138 (emphasis added).

That approved jury instruction continued:

Good faith in this context means good intentions in the honest exercise of best professional judgment as to a patient's need. It means the doctor acted in accordance with what *he believed* to be proper medical practice. If you find the defendant acted in good faith in dispensing the drug, then *you must find him not guilty*.

Id. (emphasis added).

The Eleventh Circuit's contrary standard is similar to one corrected by the Court of Appeals of Kansas in the conviction and sentence of Dr. Stan Naramore, for administering large quantities of painkillers to two patients who subsequently died. In Dr. Naramore's case "the jury apparently found, beyond a reasonable doubt, that Dr. Naramore's actions were totally outside appropriate medical practice." *State v. Naramore*, 25 Kan. App. 2d 302, 322 (1998). From that finding the jury concluded that Dr. Naramore had homicidal intent. "Having found that, it then

apparently found there was no reasonable doubt that the source of his actions was homicidal intent." *Id*.

But the Court of Appeals of Kansas properly overturned that conviction, finding a bona fide medical dispute about criminal intent that negates a conviction. "[T]here is a reason why there has yet to be in Anglo-American law an affirmed conviction of a physician for homicide arising out of medical treatment based on such highly controverted expert evidence as here." *Id.* The Court then ordered entry of a verdict of acquittal. *Id.* at 323.

Juries are not trained to establish the outer limits of a highly skilled profession. The proper task for the jury is to determine whether defendant was acting in good faith, rather than try to ascertain the boundaries of his skilled profession. It is the ultimate injustice for a compassionate and dedicated physician to be imprisoned for the rest of his active life for practicing medicine in a manner he thought best, based on his extensive training, for his patients.

III. Eliminating the Good Faith Defense Is an Anathema to Individual Rights.

In contrast with other legal systems, ours is one based on individual rights. The Bill of Rights, enacted as promised to obtain ratification of the original Constitution, leaves no doubt about our foundation.

A dystopia results when the most basic individual right – innocence amid a lack of criminal intent – is infringed upon under the guise of a so-called War on Drugs. The federal government can revoke the DEA registration at any time to stop a physician's prescription of controlled medications. State medical

boards can and do impose summary suspensions of physicians licensed to practice. A 21-year incarceration of a physician by denying him the basic defense of good faith is not justifiable on any rationale.

Benjamin Franklin famously stated, "Those who would give up essential Liberty, to purchase a little temporary Safety, deserve neither Liberty nor Safety." Votes and Proceedings of the House of Representatives 1755–1756, pp. 19–21 (Philadelphia, 1756).⁵ Eliminating a prescriber scatters the volume of his prescriptions elsewhere, which increases the overall potential for misuse of controlled substances. Dr. Franklin was spot on: safety is not enhanced by sacrificing liberty to convict physicians who treat pain.

CONCLUSION

For the foregoing reasons and those stated by petitioner and the other amicus briefs in his support, this Court should fully reverse his conviction.

Respectfully submitted,

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⁵ <u>https://founders.archives.gov/documents/Franklin/01-06-02-</u>0107#BNFN-01-06-02-0107-fn-0005-ptr (viewed Dec. 24, 2021).