No. 22-1175

IN THE
Supreme Court of the United States

DR. XIULU RUAN AND DR. JOHN PATRICK COUCH,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

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

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

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QUESTION PRESENTED

In *Ruan v. United States*, 142 S. Ct. 2370 (2022), this Court held that a physician may be convicted under 21 U.S.C. § 841(a)(1) of the Controlled Substances Act ("CSA") only if the government proves that the defendant "knew or intended that his or her conduct was unauthorized." *Id.* at 2382 (emphasis added). The Court remanded Petitioners' case to the Eleventh Circuit, and Dr. Shakeel Kahn's companion case to the Tenth Circuit, so that those courts could consider whether the jury instructions comported with the "except as authorized" requirement of the statute.

The question presented, on which the circuits are divided, is whether, in a CSA jury instruction, 21 C.F.R. § 1306.04(a) may replace the statute's "except as authorized" requirement, thereby permitting the jury to convict a physician simply because she knew that her prescription would fall outside the "usual" course of medical practice or would be regarded as "illegitimate" by most other doctors, and thus empowering a federal agency to create a felony offense that Congress itself did not enact.

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INTERESTS OF *AMICI CURIAE*[1]

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, and 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* AAPS, *et al.*, provided the requisite ten days' prior written notice to all the parties. 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*, AAPS's members, and its counsel – 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 medical degree 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.

Reflecting the interests by these *Amici* in this landmark case, they previously filed an *amicus* brief on the merits decided in *Ruan v. United States*, 142 S. Ct. 2370 (2022). Subsequently the insistence by multiple circuits to continue using a vague, difficult-to-understand regulatory definition of criminal intent rather than the one prescribed by this Court, on the fundamental issue of pain relief, is a matter in which *Amici* have continuing strong interests.

SUMMARY OF ARGUMENT

The governing test articulated by this Court is straightforward for jurors to understand: in order to convict, a prosecutor must prove that a prescriber of pain medication "was acting in an unauthorized manner, or intended to do so." *Ruan*, 142 S. Ct. at 2375. The term "unauthorized" is a familiar concept encountered nearly every day in a variety of contexts, ranging from parking a car to taking a transfer of funds. The issue is not whether there is a consensus of support for the activity, but whether it is within or

outside the parameters of what is authorized. Only if someone knew or intended to do something unauthorized does he then have the *mens rea* essential for a criminal conviction.

This clear, recent standard established by this Court should not be replaced, diluted, and confused by very different, convoluted language coming from an administrative agency. The alternative regulatory wording is that a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). That is not what this Court held, and thus is not how juries should be instructed. This regulatory jargon should not substitute for the simpler standard using ordinary terminology as recently required by this Court.

There are multiple defects in the regulatory wording as a jury instruction. First, it is vague and thus impermissibly unfair to a defendant. Second, it requires a jury to make a determination about what a legitimate medical purpose is, for which jurors are ill-equipped to decide. Third, nearly every physician inevitably acts outside his usual course of professional practice in order to properly treat an unusual patient who has a rare or difficult medical problem. Yet the regulatory wording would render every physician a criminal when he tries to address a severe pain issue, and Congress has surely not criminalized every medical practice with the 20-year prison sentence imposed below.

ARGUMENT

The Eleventh Circuit and other lower courts have split with the Tenth Circuit after the remand from *Ruan*, thereby necessitating clarification here that, indeed, this Court's standard of proving *mens rea* concerning an unauthorized manner of prescribing must be proven in order to obtain a conviction of physician carrying a 20-year prison sentence.

I. The Petition Should Be Granted to Attain Consistent Fidelity by the Lower Courts to the *Mens Rea* Test Articulated by this Court.

This Court was clear in holding that the burden of proof for prosecutors is to demonstrate that the defendant physician "was acting in an unauthorized manner, or intended to do so." *Ruan*, 142 S. Ct. at 2375. Simple, direct, and clear. The majority decision left no doubt that this is the standard that must be applied. Indeed, this Court used "unauthorized" six times in its relatively short 6-3 majority opinion.

As this Court has repeatedly held and is often quoted:

> If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.

Rodriguez de Quijas v. Shearson/American Express, Inc., 490 U.S. 477, 484 (1989). "[T]here remains the question whether [a precedent] deserves continuing respect under the doctrine of *stare decisis*. The Court of Appeals was correct in applying that principle despite disagreement with [the precedent], for it is this

Court's prerogative alone to overrule one of its precedents." *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997); *see also Am. Trucking Ass'ns v. Smith*, 496 U.S. 167, 180 (1990) (quoting same).

Here, there is not even any other line of decisions on which lower courts rely in contravening the precedent of this Court. Instead, the lower courts are depending entirely on a mere regulation by a federal agency. On that insufficient basis the lower courts are imprisoning good physicians for decades. This plainly contravenes the teaching of this Court in *Ruan*, and the imperative of this Court in *Rodriguez* for lower courts not to overrule Supreme Court holdings.

The concurrence by this Court in *Ruan* was not based primarily on opposition to this requirement of proving a criminal intent to do something unauthorized. Rather, the concurrence felt this issue should not have been reached in that case, yet it was fully decided by the Court majority. *Ruan*, 142 S. Ct. at 2383-84 (Alito, J., concurring, joined in this part by Thomas, J.). The concurrence disagreed with the majority as to who should bear the burden of proving a lack of authorization, but did not dispute the appropriateness of the "unauthorized" standard of intent itself.

The failure of the Eleventh Circuit to abide by this Court's ruling and thereby reverse the convictions of Petitioners is particularly striking in light of the rule of lenity in criminal prosecutions. Dr. Ruan remains in prison on a 20-year sentence, which is incredibly harsh for professional conduct not entailing criminal *mens rea*. The rule of lenity militates against this result that the Eleventh Circuit insists upon. As explained by a remarkable study of this important

check against prosecutorial abuse:

> Upon examination of these criminal law statutory interpretation cases, the Supreme Court's approach to lenity stands in relief from the practice of appellate courts. For its part, in those cases [of the Roberts Court], the Supreme Court almost always considers the lenity framework. Moreover, the Supreme Court applies the rule of lenity in about one-third of those cases ….

Instisar A. Rabb, "The Appellate Rule of Lenity," 131 Harv. L. Rev. F. 179 (June 2018).[2]

Yet appellate courts generally ignore this important protection against wrongful conviction. "By contrast, it turns out that appellate courts considered in this data set … hardly ever invoked the [rule of lenity] framework or applied the rule." *Id.* The rule of lenity reinforces the need to grant the Petition here.

II. The Substitute Regulatory Wording Is Improper, Defective, and Inadequate as Jury Instructions for Multiple Reasons.

Improperly relying on wording by a regulatory agency, the Eleventh Circuit affirmed much of the conviction of Dr. Ruan without any proof that he intended to do anything unauthorized. The Eleventh Circuit continues to rely on a regulatory definition of the crime, rather than the elements as established by Congress and interpreted by this Court in *Ruan*.

The regulatory wording is as follows:

A prescription for a controlled substance to be

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[2] https://harvardlawreview.org/forum/vol-131/the-appellate-rule-of-lenity/ (viewed June 11, 2023).

> effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

21 C.F.R. § 1306.04(a).

This regulatory wording is defective and inadequate as jury instructions for multiple reasons in addition to not complying with this Court's ruling.

A. It Is Improper to Use Regulatory Wording as the Definition of a Felony Punishable by Decades in Prison.

As Chief Justice John Marshall wrote for a unanimous Court in overturning a conviction:

> The rule that penal laws are to be construed strictly, is perhaps not much less old than construction itself. It is founded on the tenderness of the law for the rights of individuals; and on the plain principle that ***the power of punishment is vested in the legislative***, not in the judicial department.

United States v. Wiltberger, 18 U.S. (5 Wheat.) 76, 95 (1820) (emphasis added). Regulatory agencies are not properly vested with the power to define the elements of a federal felony, as the Eleventh Circuit and other courts continue to do after *Ruan*.

The substitute regulatory wording used by the Eleventh Circuit and several circuits other than the Tenth Circuit is significantly different from the "unauthorized" standard held by this Court in *Ruan* to be the proper one. By declining to require proof that a prescription was unauthorized, and instead allowing convictions of prescriptions that are merely unusual, nearly any good physician could be wrongly convicted.

Incorporating the regulation, the Eleventh Circuit below embraced this wording:

> prescribing a controlled substance is illegal unless there's two things that happen: It's prescribed in the usual course of professional practice and it's prescribed for a legitimate medical purpose.

Petition at 6 (quoting Tr. 28:6-9). Both parts of the regulatory standard must be satisfied for a defendant-physician to be acquitted under the incorrect view of the Eleventh Circuit.

The first part – "usual course of professional practice" – renders criminal every authorized prescription that is unusual or outside of what physicians typically do. Under this regulatory view, every innocent outlier becomes a felony punished by 20 years in prison. Statistically, there are always outliers, as there should be; there is always a top prescriber in a state, and always some prescriptions written by physicians that are different from what he usually writes. Unusual medical problems require unusual or more aggressive medical treatments. Congress did not criminalize any of this, and nothing can be inferred in the statute to allow such a vast criminalization of the practice of medicine. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress … does not, one might say, hide elephants in mouseholes" for regulatory power).

The second part of the regulation-based wording above is also significantly different from the proper test of "unauthorized". Juries are not equipped to determine whether a prescription is "for a legitimate medical purpose." It is a phrasing that carries a prejudicial negative connotation to it, in contrast with

asking whether a prescription was "unauthorized". Jurors understand the distinction between what is authorized and unauthorized, while they are unlikely to grasp any abstract line-drawing concerning what is "a legitimate medical purpose."

B. The Regulatory Wording Used Below Further Contravenes *Ruan* and *Morissette* by Obscuring the Requisite *Mens Rea*.

The regulatory wording is impermissibly vague and thus improper on this additional, independent basis. Taken literally, the regulatory wording is at odds with the physician's professional duty to care in his finest way possible for the individual needs of each patient. It criminalizes any variation by a physician from his usual course of practice, even when in the best interest of the patient.

The seminal decision of this Court in *Morissette v. United States* requires proof of actual criminal intent, to which the Eleventh Circuit below has declined to adhere. 342 U.S. 246 (1952). This Court held in *Morissette*:

> Crime, as a compound concept, generally constituted only from concurrence of an evil-meaning mind with an evil-doing hand, was congenial to an intense individualism and took deep and early root in American soil.

Morissette, 342 U.S. at 251-52. This oft-cited decision also held that:

> The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability

> and duty of the normal individual to choose between good and evil.

Id. at 250-51.

There is "the longstanding legal principle that an act is not culpable unless the mind is guilty." *Wooden v. United States*, 142 S. Ct. 1063, 1076 (2022) (Kavanaugh, J., concurring) (citing *Morissette*, 342 U.S. 246, 250-252 (1952)). "[W]e 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 statutory elements that criminalize otherwise innocent conduct.'" *Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019) (quoting *United States* v. *X-Citement Video, Inc.*, 513 U. S. 64, 72 (1994)). The "otherwise innocent conduct" here is the practice of medicine to relieve suffering in patients, and this quintessentially innocent conduct is not criminal.

The substitute regulatory phrasing of the burden of proof obscures rather than clarifies the *mens rea* requirement as this Court's holding in *Ruan* did. The phrasing insisted upon by the Eleventh Circuit is an incorrect objective standard that marginalizes the need to prove *mens rea*, despite how the essential element of criminal intent was central to this Court's articulation in *Ruan*: "the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so." *Ruan*, 142 S. Ct. at 2375.

C. The Regulatory Jargon Is Beyond What Can Be Reasonably Expected of a Jury to Understand.

Jurors readily understand the concept of "unauthorized", as everyone confronts that concept frequently in routine activities. But the same is not true about what is meant by "legitimate medical practice" or what constitutes "the usual course of his professional practice." This technical regulatory jargon may be understood on K Street in D.C., where lobbyists thrive, but it is predictably incomprehensible to a typical juror. *See, e.g.*, *Trudell Med. Int'l v. D R Burton Healthcare LLC*, No. 4:18-CV-00009-BO, 2023 U.S. Dist. LEXIS 34195, at *10 (E.D.N.C. Mar. 1, 2023) (denying a motion for a new trial in part because "it is reasonable to infer the jury found this presentation incomprehensible" and thus did not have to give it significant evidentiary weight).

Administrative agencies produce regulations loaded with jargon perhaps understandable by an attorney, but such jargon is not a proper substitute for the clear layman's standard articulated by this Court in *Ruan*. As explained by an exasperated D.C. Circuit that hears far more cases concerning regulations than any other appellate court:

> We assume the author of these sentences understands them. Perhaps so do those thoroughly versed in the intricacies of the Clean Water Act, in its regulatory jargon, in mathematics, in toxicology, in biology, oncology and so on. Too bad AISI did not take the trouble to educate the court. The first rule of advocacy is to make your argument understandable.

Am. Iron & Steel Inst. v. EPA, 115 F.3d 979, 990 (D.C. Cir. 1997).

Unclear jury instructions cause unjust jury verdicts, in deprivation of due process. This Court has held that:

> Because a reasonable juror could have understood the challenged portions of the jury instruction in this case as creating a mandatory presumption that shifted to the defendant the burden of persuasion on the crucial element of intent, and because the charge read as a whole does not explain or cure the error, ***we hold that the jury charge does not comport with the requirements of the Due Process Clause***.

Francis v. Franklin, 471 U.S. 307, 325 (1985) (emphasis added).

When jurors strain to understand the meaning of jury instructions, then injustice is likely to result. While it may appear to a lower court that the regulatory language is similar to the wording prescribed by the *Ruan* decision, a jury could be easily confused by the jury instructions being substituted below. That results in a denial of due process to the defendant, and a denial of access by patients to the medical care they need to alleviate their suffering. *See, e.g.*, *United States v. Jett*, 908 F.3d 252, 268 (7th Cir. 2018) (reversing a conviction for attempted bank robbery and ordering an acquittal on that charge, after observing that "[t]he jury instructions provided no clarity either"). *See also United States v. Lanier*, 520 U.S. 259, 266 (1997) ("due process bars courts from applying a novel construction of a criminal statute to conduct that neither the statute nor any prior judicial

decision has fairly disclosed to be within its scope").

D. The Regulatory Wording Makes Nearly Every Physician a Felon, Contrary to what Congress Enacted.

Finally, nearly every physician sometimes acts outside his usual course of professional practice in order to treat an unusual patient who has a rare or difficult medical problem. Under the non-*Ruan* jury instruction being used below, and affirmed by the Eleventh Circuit after remand by this Court, nearly every physician could be convicted and imprisoned for 20 years for writing an unusual prescription for an unusually suffering patient, because that would be outside his usual course of professional practice.

Regulators typically do not practice medicine and, even if a few do, they are unlikely to attempt to treat any irregular and highly unusual cases that arise in many medical offices nationwide. Practicing physicians, particularly in rural areas, do not have the luxury of denying care in a difficult case and referring it elsewhere. When a patient is in extreme and unusual pain, most physicians feel a professional obligation to treat that pain even though it is outside the scope of his usual professional practice. Indeed, the Oath of Hippocrates requires such treatment. *See* Oath of Hippocrates (c. 400 B.C.), quoted in Mary L. Davenport, M.D., et al., "Right of Conscience for Health-Care Providers," 79 Linacre Q. 169 (2012) (vowing to "benefit my patients according to my greatest ability and judgment").[3]

Yet under regulatory wording used by the Eleventh

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[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6026968/ (viewed June 28, 2023).

Circuit and other courts below, all that a prosecutor need do in his summation to the jury is to explain that the physician departed from his ordinary prescriptions, for a patient about whom the prosecution was based. Many innocent physicians could be convicted by prosecutorial whim if this jury instruction were allowed to continue to be used.

The *Ruan* decision properly shut that down. Yet the Eleventh Circuit and a few other circuits persist in allowing this incorrect test of criminality for physicians as they treat patients in pain. The Petition should be granted to rein in the departure by some circuits with what this Court expressly held in *Ruan*.

CONCLUSION

This Court should grant the Petition for the reasons stated within it, and for those explained above.

Respectfully submitted,

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