No. 24-5646

IN THE SUPREME COURT OF THE UNITED STATES

LISA HOFSCHULZ
ROBERT HOFSCHULZ,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

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

REPLY IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Treatises

The instant petition asks this Court to provide guidance as to what it is that defines "authorization" as that term is used in 21 U.S.C.A. §841 of the Controlled Substances Act; Is "authorization" defined by regulations issued by the Attorney General (21 C.F.R. §§1306.03 & 1306.04) or is "authorization" defined by the language and history of the CSA itself?

The government has yet to articulate any reason, based on either the text or legislative history of the CSA, to believe that the authors of the CSA intended to criminalize medical practitioners who intentionally deviate from the standard of care, generally recognized standards of medical practice, or medical norms. Nor does the government disagree that, as currently interpreted by the Fifth, Sixth, Seventh, and Eleventh Circuits, §1306.04 does exactly that. If §1306.04 criminalizes conduct that is not prohibited by the text of the CSA itself, then there must be some constitutionally legitimate delegation of authority that permits the attorney general to enact that regulation. *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989).

The Government's response to the instant petition relies heavily on its responses to petitions in *Ruan v. United States*, 144 S. Ct. 377 (2023) (No. 22-1175) ("*Ruan* Cert. II") and *Lubetsky v. United States*, cert. denied, No. 24-137 (Nov. 12, 2024) ("*Lubetsky* Cert."). Neither identifies any part of the CSA that grants the attorney general the authority to define what constitutes either an "effective" or "authorized" prescription. Neither response brief addresses whether the government is required to prove "that a defendant knew or intended that his or her

conduct was unauthorized," *Ruan*, 597 U.S. at 467, or whether, as the Seventh Circuit found, it is sufficient for the government to prove that the defendant had knowledge of the factors that render a given prescriptions unauthorized. *United States v. Hofschulz,* 105 F.4th 923, 929 (7th Cir. 2024).

Petitioners present this Court with discrete questions of statutory construction: What does the word "authorized" in the context of §841 allow or prohibit? Does the definition of authorization turn on the language of CFR §1306.04, or does it turn on the language of the statute itself? Does the CSA require the government to prove that the defendant knew the prescription to be unauthorized or is it sufficient for the government to prove that the defendant was aware of the facts that render a prescription "effective" under §1306.04?

The answer to those questions turns largely on whether the CSA delegated Congress the legislative authority to define what constitutes an effective or authorized prescription in the first place. Any effective delegation of legislative authority to the executive must include an "intelligible principle" guiding the delegation of that power. *United States v. Touby*, 500 U.S. 160, 166 (1991). Under the Major Question Doctrine this Court presumes that "Congress intends to make major policy decisions itself, not leave those decisions to agencies." *W. Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2609 (2022).

The government's response briefs in *Ruan* Cert. II and *Lubetsky* Cert do not identify language in the CSA that delegates to the attorney general the authority to

define the standard for "authorization" under § 84, let alone grapple with either the Non-Delegation or Major Questions doctrine.

ARGUMENT

"Only the people's elected representatives in the legislature are authorized to 'make an act a crime.'" *United States v. Davis*, 588 U.S. 445, 451 (2019). This Court has "upheld delegations whereby the Executive or an independent agency defines by regulation what conduct will be criminal, so long as Congress makes violation of regulations a criminal offense." *Loving v. United States*, 517 U.S. 748, 768 (1996). Section 841 states "[e]xcept as authorized *by this subchapter*." It does not say: "except in conformity with regulations promulgated by the attorney general." As argued in the petition, as the circuits have applied the language of CFR §1306.04 it extends far beyond what was excluded as unauthorized under §841 of the CSA. At a fundamental level, there is no language from Congress, which criminalizes the violation of a regulation issued by the attorney general. There is no language in the CSA delegating to the Attorney General the authority to regulate the *manner* of medical practice in any way.

In its response to *Ruan Cert. II*, the government identifies 21 USC §§821 & 871(b) to justify a grant of authority. *Ruan Cert. II*, Gov. Resp. at 15-16. Those sections simply do not delegate any authority to the attorney general to define the scope of a practitioner's "authorization" under §841.

21 U.S.C. §871 states:

> "The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and

> appropriate for the efficient execution of his functions under this subchapter."

The CSA charges the Attorney General, with three basic functions. First, the Attorney General is given the authority to review new medications and place them on a temporary and permanent basis in one of the five schedules. 21 U.S.C. §811. Second, the Attorney General is charged with registering medical practitioners to issue controlled substances. 21 U.S.C. §823. The Attorney General also has the authority to revoke a medical practitioner's CSA registration, pursuant to specifically outlined procedures. 21 U.S.C. §824.

Section 821 states:

> "The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals."

The word "control" is explicitly defined by the CSA. It does not include the power to generally regulate the practice of medicine or to further define what constitutes an authorized prescription. 21 U.S.C. §802 ("The term 'control' means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise."). Defining what constitutes authorization under §841 simply does not fall within the ambit of either function. *Gonzales v. Oregon,* 546 U.S. 243, 269–70 (2006).

Even were a contrary construction possible, §§821 and 871 fall far short of providing an "intelligible principle" guiding the delegation of that power. See *Touby*, 500 U.S. at 166. Separation of Powers requires that where Congress delegates

rulemaking authority to the executive branch, it must "clearly delineate[] the general policy, the public agency which is to apply it, *and the boundaries of this delegated authority*." *Mistretta v. United States*, 488 U.S. 361, 372–73 (1989) (emphasis added); *United States v. Robel*, 389 U.S. 258, 275 (1967). Where Congress did delegate to the executive the authority to classify controlled substances, it articulated the procedures to be used, 21 USC §811(a)(2), and provided a list of factors to consider in making that determination, 21 U.S.C. §§823, 811(c). *Touby*, 500 U.S. at 166.

Statutory construction starts with the plain text of the statute. However, "[w]here the statute at issue is one that confers authority upon an administrative agency, that inquiry must be 'shaped, at least in some measure, by the nature of the question presented.'" *W. Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2607-08 (2022). Under the Major Questions Doctrine, the Court presumes that "Congress intends to make major policy decisions itself, not leave those decisions to agencies." *Id.* at 2609.

The regulation of medical care is one that Congress has been careful to reserve to the states. *Hawker v. New York*, 170 U.S. 189 (1898); *Bond v. United States*, 134 S. Ct. 2077, 2088 (2014); 21 U.S.C. §823(g)(2)(H)(i). The legislative history of the CSA, and indeed the text of the CSA itself, establishes that Congress did not intend for federal prosecutors to function as the law enforcement arm of state medical boards, or to establish the scope of allowed medical practice through criminal prosecutions. H.R. Rept. 91-1444 at 14-15.

There are areas of the medical practice where the authors of the CSA did believe a federal standard was necessary: specifically, the use of narcotics to treat addiction. 21 U.S.C. §823(h). The result was the "Narcotic Addict Treatment Act of 1974", PL 93–281 (S 1115), 88 Stat 124 (May 14, 1974), which amended the CSA by providing guidelines for the dispensing of medication for the treatment of drug addiction. The intent of the statute was to insulate physicians who complied with the standards articulated from prosecution:

> The committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice. In view of this situation, this section will provide guidelines, determined by the principal health agency of the federal government, after consultation with appropriate national professional organizations. Those physicians who comply with the recommendations made by the secretary will no longer jeopardize their professional careers by accepting narcotic addicts as patients."

H.R. Rept. 91-1444 at 14-15. Where Congress intended to impose federal regulation of the manner of medical practice, it directed the Secretary of Health and Human Services to issue regulations that were specifically and explicitly directed to that area of practice. The CSA is entirely silent on the standards required to issue medication for the treatment of chronic pain. The fact that Congress did not outline a standard for the use of opioids to treat pain does not mean that it intended "in this oblique way" to delegate to the Attorney General, or an individual prosecutor, to fill that space through criminal prosecution. *United States v. Moore*, 423 U.S. 124, 132-33 (1975).

The petitions in *Lubetsky Cert, and Ruan Cert. II* are readily distinguishable from this petition and the government's response to those petitioners only demonstrates the need for further guidance from this Court on the meaning of "authorization" in §841. In *Lubetsky*, petitioner conceded that CFR §1306.04 is a duly issued regulation, but argued that a disjunctive interpretation of §1306.04 violated the Commerce Clause. *Lubetsky Cert*. at 10. The government's response argued that the only preserved issue properly before the Court challenged the sufficiency of the evidence. *Lubetsky Cert*, Gov. Resp. at 15-16.

Ruan Cert II involved the petitioner's appeal of a conspiracy conviction where the jury was required to "find[] that [petitioners] intended to violate § 841, which means that [petitioners] would have to have known their acts were unauthorized." *Ruan* Cert II, Gov. Resp. at 10. There, as the government ably pointed out, petitioner in *Ruan II* raised the legal question presented for the first time before this Court. *Ruan* Cert. II, Gov. Resp at 14 ("This Court is 'a court of review, not of first view,' and it traditionally does not grant a writ of certiorari 'when the question presented was not pressed or passed upon below'") (quoting *United States v. Williams*, 504 U.S. 36, 41 (1992)).

The petitions presented in *Ruan* II and *Lubetsky* do not address the fundamental question of whether the government is required to prove that registered practitioners had actual knowledge that the charged prescriptions were unauthorized.

Contrary to the government's response brief, the Tenth Circuit interprets *Ruan* as imposing a requirement that the government prove the defendant's specific intent to violate the law. In the Tenth Circuit, the government is required to prove that "that petitioner knew that his conduct was unauthorized or illegal." *United States v. Kahn,* 58 F.4th 1308, 1315 (10th Cir. 2023)(*"Kahn II")*; *Ruan v. United States*, 597 U.S. 450, 467 (2022) ("And for purposes of a criminal conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.")

Ruan resolved the *mens rea* issue, not with reference to the language of the CFR, but with reference to the language of the statute itself. Under *Ruan*, "authorization" is the element that separates innocent from guilty conduct. Therefore, according to the Tenth Circuit's interpretation of *Ruan*, it is to the statutory term "authorization" to which the *mens rea* must attach. *Kahn II*, 58 F.4th at 1315; *Ruan*, 597 U.S. at 467.

The Tenth Circuit compared the prosecution of medical practitioners under §841 to the decision in *Liparota v. United States*, 471 U.S. 419, 430 (1985). In that case, the Court held that to obtain a conviction for the unlawful sale of food stamps the government must prove "that petitioner knew that his conduct was unauthorized or illegal." *Id*. at 434. The fact that the defendant had knowledge of the facts that would render his actions illegal was not sufficient. *Id.* at 421–22. "The Supreme Court held that knowingly engaging in conduct that is, in fact,

unauthorized is not sufficient, even if one is aware of all the factors that render it unauthorized." *Kahn II*, 58 F.4th at 1315 n.3.

The Tenth Circuit was clear that the instructions would have been erroneous *even if* they had attached subjective scienter to the language of CFR §1306.04(a).

> "[T]he jury instructions were erroneous because they allowed the jury to convict Dr. Kahn after concluding either that Dr. Kahn subjectively knew a prescription was issued not for a legitimate medical purpose, or that he knowingly issued a prescription that was objectively not in the usual course of professional practice. *Both approaches run counter to Ruan*."

Id. at 1316 (emphasis added).

Contrary to the government's position, that is a direct and irreconcilable circuit split with the Seventh Circuit. *Cf. Hofschulz,* 105 F.4th at 929 ("The Court did not mention a "knowledge-of-law" requirement (i.e., knowledge that conduct was illegal). The difference between the two standards "is so important … that the Supreme Court would not have adopted the broader [knowledge-of-law] reading without saying so with unmistakable clarity.") (citing *United States v. Maez*, 960 F.3d 949, 954–55 (7th Cir. 2020)) with the requirement that the government prove "that petitioner knew that his conduct was unauthorized or illegal." *Kahn II*, 58 F.4th at 1315.

One of the two circuits is wrong.

Prosecution of medical practitioners under §841 has become ontologically untenable and arrived at exactly the place that Congress sought to avoid. There is no provision of the CSA that purports to delegate to the Attorney General the power to define "authorization," much less any provision which criminalizes a violation of

such a regulation. Nevertheless, as the case law currently stands, a violation of a later passed regulation is sufficient to establish a practitioner's guilt.

Out of fear of prosecution, medical practitioners have been chilled from not only prescribing pain medication in the treatment of chronic pain, but also from even accepting chronic pain patients in a general practice setting. Lagisetty, Pooja, *et al*., "*Assessing reasons for decreased primary care access for individuals on prescribed opioids*," PAIN. 2021 May; Vol 162. Issue 5. p 1379-1386 (*Available at*, DOI: 10.1097/j.pain.0000000000002145); Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 Law & Psychol. Rev. 1, 51 (2016); Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 85 (2004); MM. Reisenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients,* 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 903 (2007).

This is not the result of the considered judgement of the legislature but "clever prosecutors riffing on [the] equivocal language" of §1306.04. *Dubin v. United States*, 599 U.S. 110, 129–30 (2023) (quotation marks and brackets omitted).

Petitioners present a significant issue of national importance. Medical professionals, investigators, and expert witnesses are taught that the language of §1306.04 is controlling. Because the regulation is "ambiguous" and "open to varying constructions" *Ruan*, 597 U.S. at 451, the meaning of that regulation ends up being

circularly defined by the very law enforcement agents tasked with enforcing it. *Cf. Gundy v. United States*, 588 U.S. 128, 172 (2019) (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.) ("To allow the nation's chief law enforcement officer to write the criminal laws he is charged with enforcing—to unit[e] the legislative and executive powers . . . in the same person—would be to mark the end of any meaningful enforcement of our separation of powers and invite the tyranny of the majority that follows when lawmaking and law enforcement responsibilities are united in the same hands.") (citing The Federalist No. 47, at 302).

"Only the people's elected representatives in the legislature are authorized to 'make an act a crime.'" *United States v. Davis*, 588 U.S. 445, 451 (2019). Where the legislature has remained silent on a major question, this Court does not infer that they intended to leave the answer to that question in the hands of the executive branch. *W. Virginia v. Env't Prot. Agency*, 142 S. Ct. 2587, 2609 (2022). The CSA explicitly regulated the manner of practice in the use of narcotics to treat addiction. It did so after receiving input from the Secretary of Health and Human Services. Congress did not impose any limitations on the manner of practice in the use of narcotics to treat chronic or acute pain. It is implausible and impermissible to conclude that, in not addressing that issue, Congress intended the Attorney General to step in.

The stark circuit split in the interpretation of the Court's opinion in *Ruan* must be finally and plainly resolved.

CONCLUSION

For the foregoing reasons, Petitioners respectfully pray that the Court will grant their Petition for Certiorari.

Respectfully Submitted,

January 2, 2025
DATE

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