No. _____

IN THE SUPREME COURT OF THE UNITED STATES

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**HASNA BASHIR IWAS,**

*Petitioner*,

v.

**UNITED STATES OF AMERICA,**

*Respondent*.

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

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# PETITION FOR WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

I. Is authorization under the Controlled Substances Act defined in terms of the regulatory definition of an effective prescription or by the plain meaning of the statutory text?

II. Does the *mens rea* required under 21 U.S.C. § 841(a) and this Court's opinion in *Ruan* attach to the fact of non-authorization or to the regulatory standard for an effective prescription contained in 21 C.F.R. § 1306.04?

## LIST OF PARTIES TO THE PROCEEDINGS

Petitioner, defendant-appellant below, Hasna Bashir Iwas.

Respondent is the United States of America, appellee below.

## RELATED PROCEEDINGS

Ninth Circuit Court of Appeals:

*United States v. Iwas,* No. 24-1234, 2025 WL 2955197, at *1 (6th Cir. Oct. 20, 2025)

Mandate Issued December 11, 2025.

United States District Court for the Eastern District of Michigan:

*United States v. Iwas*, No 2:18-cr-20769LJM-RSW-5.

Judgement and conviction entered March 19, 2024.

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*United States v. Iwas,* No. 24-1234, 2025 WL 2955197, at *1 (6th Cir. Oct. 20, 2025)

## JURISDICTION

This is a federal criminal case involving an appeal from a final judgment entered in the Western District of Michigan. The Sixth Circuit of Appeals entered judgement on December 11, 2025. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

## STATEMENT

This case involves a registered pharmacist's petition for relief from criminal conviction under 21 USC § 841 based on this Court's holding in *Ruan v. United States*, 597 U.S. 450 (2022). In *Ruan*, this Court held that 21 U.S.C. § 841's "'knowingly or

intentionally' *mens rea* applies to authorization." *Ruan v. United States*, 597 U.S. 450, 454 (2022). "[F]or purposes of a criminal conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized." *Id.* at 467.

Petitioner was charged with one count of conspiracy to distribute a controlled substance in violation of 21 U.S.C. § 841(a)(1), one count of maintaining a drug involved premises in violation of 21 U.S.C. 856(a)(1), and several counts for specific acts of distribution. Each count stemmed from allegations that Petitioner, a licensed pharmacist, filled prescriptions that were written for no legitimate medical purpose and outside the usual course of professional practice, or that were, in fact, forgeries.

Ms. Iwas did not deny filling the charged prescriptions. The question at trial was whether the defendant knew that the charged prescriptions were fraudulent or whether she filled them outside the usual course of her professional practice. The relevant portion of the jury instructions defining *mens rea* required only that the government prove "That the defendant knowingly or intentionally distributed an unauthorized prescription, that is, one not issued for a legitimate medical purpose in the usual course of professional practice."

Since this Court's decision in *Ruan*, a circuit split has developed as to the correct *mens rea* under § 841. The Tenth Circuit, on remand from one of the companion cases in *Ruan*, construed the *Ruan* opinion as requiring the government to prove a defendant's subjective knowledge or intent as it pertains to the fact of non-authorization. Other circuits have continued to rely on the regulatory language to

define authorization and the statute's *mens rea*. Even among these circuits, however, there remain substantial variations in how they apply the statute. This Court's review is necessary to resolve the split.

## FACTUAL BACKGROUND

Petitioner owned and operated Beacon Pointe Pharmacy in Grosse Pointe Park, Michigan. R. 183 at 18–19. Between August 2013 and November 2018, Petitioner filled nearly 1,300 forged prescriptions for controlled substances—primarily oxymorphone, oxycodone with acetaminophen, promethazine with codeine, and alprazolam. R. 258 at 57, 63–65. The forged prescriptions were issued in the names of fifty-eight "patients" associated with one individual, Rochelle Edwards. Id. at 110. The forged prescriptions were labeled as being issued by eight different prescribers to whom patients "migrate[d]" in groups. R. 258 at 109.

Some of the forged prescriptions contained on their faces incorrect phone numbers and addresses for the named prescribers; labels on the backs that were printed and affixed by Beacon Pointe Pharmacy staff, however, displayed the correct phone numbers and addresses, indicating that the pharmacy system contained the correct information. See, e.g., R. 166 at 33–34; R. 258 at 101–02. Other forged prescriptions displayed the correct phone numbers for the prescribers. See, e.g., R. 166 at 69–70, 74–75. In some instances, Petitioner handwrote notes on the back of prescriptions indicating that they had been verified with the prescriber. *See, e.g., id.* at 77–80; R. 169 at 71–73; R. 183 at 69–70, 81. The prescribers or their

agents testified that those prescriptions were not in fact verified, and in most cases verification would have been impossible because the supposed patient was not actually a patient of the prescriber. See, e.g., R. 166 at 33, 73–81, 123; R. 168 at 28–33; R. 259 at 174–77.

Additionally, Petitioner filled many prescriptions issued by Dr. Otis Crawford. Dr. Crawford wrote controlled-substance prescriptions for patients whom he never examined, *see, e.g.*, R. 172 at 99–110), and, sometimes, for patients who had never even been to his clinic, *see, e.g.*, R. 173 at 23. Petitioner filled controlled-substance prescriptions from Dr. Crawford, despite acknowledging in a text, "I always don't feel good filling his scripts." *Id.* at 47

Petitioner testified that she did not know that any of the charged prescriptions were fraudulent, R. 183 at 34, or that Dr. Crawford was, in any way, operating outside the usual course of professional practice or that she was not authorized to fill prescriptions issued by his office. R. 183 at 47.

Petitioner argued below that the jury instructions issued in this case failed to fully capture either the mens rea or the actus reus required by *Ruan v. United States*, 597 U.S. 450, 478 (2022).

The instructions on the substantive counts defined the elements of a § 841 offense as follows:

> In order to find the defendant guilty of a violation of 21 U.S.C. 841(a)(1), the government must prove beyond a reasonable doubt each of the following elements:
>
> (1) That the defendant knowingly or intentionally distributed to another person a controlled substance by filling a prescription in the name of the person listed in a particular count, for the controlled

> substance alleged in that count, either personally or in concert with an employee or agent;
>
> (2) That the particular prescription was unauthorized, that is, not issued for a legitimate medical purpose in the usual course of professional practice; and
>
> (3) That the defendant knowingly or intentionally distributed an unauthorized prescription, that is, one not issued for a legitimate medical purpose in the usual course of professional practice.

R. 177, Page ID 1949.

The jury instructions issued in this case define the words "usual course of professional practice" in purely objective terms:

> "(6) The term "usual course of professional practice" is defined by reference to an objective standard of medical and pharmacy practice generally recognized and accepted by the medical and pharmacy professions in the United States. This standard is not violated by mere negligence. This standard is breached when the doctor acts contrary to what a legitimate doctor would do in a medically valid effort to help patients."

R. 177, Page ID, 1950-51.

Based on the language from 21 C.F.R. § 1306.04, the district court placed upon pharmacists the "corresponding responsibility" to ensure that the doctor who issued a given prescription was acting within "generally recognized and accepted" standards of practice:

> "(5) A prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist to not fill an unauthorized prescription.

R. 177, Page ID 1950.

Petitioner was convicted on all counts except the drug-involved premises charge. R. 223. The district court sentenced Iwas to a term of imprisonment of 100 months.

On appeal, Petitioner argued that, under *Ruan*, it is insufficient for the government to prove that a defendant knowingly or intentionally acted in a manner that was objectively unauthorized, even if one knows the facts that could render a prescription unauthorized. App.R.29 at 11-12. Rather, the government must prove knowledge or intent as it relates to the fact of non-authorization. *Id.* Petitioner asserted that the definition of authorization must be a matter of statutory construction, rather than simply deferring to the regulatory language. *Id.* at 17-19.

The appellate court disagreed. Relying on *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023), the Sixth Circuit held that the district court comported with *Ruan* because it "juxtaposed knowledge with lesser levels of culpability." Cert.Appx. at 11. The jury instructions were sufficient, it found, because "[i]n defining 'knowingly,' the district court instructed the jury that '[c]arelessness, negligence, incompetence, or foolishness on [Iwas's] part are not the same as knowledge and are not enough to find [Iwas] guilty on' the § 841(a)(1) counts." *Id.* It thus affirmed the conviction.

## REASONS FOR GRANTING REVIEW

### I. THE CIRCUITS ARE DIVIDED ON THE QUESTION PRESENTED.

The regulation relied upon in the court below, 21 CFR §1306.04, states that in order for "[a] prescription for a controlled substance to be effective [it] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Prior to *Ruan*, the Circuits held that any prescription that is not "effective" as defined by CFR § 1306.04 is not "authorized" under § 841. The elements were, therefore, dependent upon the circuit's interpretation of the meaning of the language of the CFR.

Prior to *Ruan*, most of the circuits interpreted "medical purpose" and "usual course of professional practice" to provide two different theories of guilt that could be proven in the disjunctive. Under the circuits' interpretation of the CFR, "medical purpose" is a subjective question regarding whether the doctor intended the prescription to alleviate what she believed to be a *bona fide* medical condition. By contrast "usual course of professional practice" turns on a doctor's compliance with "medical norms" or "the standards of medical practice generally recognized throughout the United States." *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986); *United States v. Hurwitz*, 459 F.3d 463, 480 (4th Cir. 2006); *United States v. Norris*, 780 F.2d 1206, at 1209 (5th Cir. 1986); *United States v. Smith*, 573 F.3d 639, 647-48 (8th Cir. 2009); *United States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007);

*United States v. Feingold*, 454 F.3d 1101, 1011 n.3 (9th Cir. 2006); *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004); *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008).

Prior to *Ruan*, a circuit split had developed as to the *mens rea* the government must establish when it seeks to convict a defendant under the theory that the charged prescriptions were issued outside the "usual course of professional practice." While all circuits agreed that "medical purpose" was a subjective question, some circuits held that "usual course of professional practice" was an entirely objective one. *United States v. Tobin*, 676 F.3d 1264 (11th Cir. 2012); *United States v. Kahn*, 989 F.3d 806, 825 (10th Cir. 2021); *United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020). Others held that the government is required to prove that the defendant knew that the charged prescription was outside the "usual course of professional practice." *United States v. Kohli*, 847 F.3d 483, 490 (7th Cir. 2017); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006). Still others imposed something close to a negligence standard. *United States v. Sabean,* 885 F.3d 27, 45 (1st Cir. 2018); *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States v. Li*, 819 F. App'x 111, 118 (3d Cir. 2020) (unpublished); *United States v. Hurwitz,* 459 F.3d 463, 478, 480 (4th Cir. 2006); *United States v. Jones,* 825 F. App'x 335, 339 (6th Cir. 2020); *United States v. Kohli,* 847 F.3d 483, 490 (7th Cir. 2017); *United States v. Smith*, 573 F.3d 639, 649–50 n.4 (8th Cir. 2009).

Each circuit based its ruling on a parsing of the language of 21 CFR § 1306.04, without reference to the plain meaning or intent of the drafters of the CSA.

In the opinion below, the Sixth Circuit necessarily assumed that *Ruan* did nothing more than apply § 841's *mens rea* to the regulatory standard articulated in § 1306.04.

The Fifth, Seventh, Ninth, and Eleventh Circuits agree. In those circuits, CFR §1306.04 continues to define the elements of the offense. *United States v. Lamartiniere*, 100 F.4th 625, 638 (5th Cir. 2024). ("As to the third element, we acknowledged that it was 'not expressly required by the text of § 841, but relevant regulations [21 C.F.R. § 1306.04(a)] provide'…"); *Anderson*, 67 F.4th at 764; *Heaton*, 59 F.4th at 1240 ("As the government points out, the plain language of 21 C.F.R. § 1306.04(a) demonstrates that the jury instruction here correctly used "or" in defining the elements of a § 841(a) offense." … Thus, both requirements must be satisfied to make a prescription authorized."); *United States v. Lubetsky*, No. 23-10142, 2024 WL 577543, at 1 (11th Cir. Feb. 13, 2024) (unpublished) ("Because the government did not prove a lack of legitimate medical purpose, the argument goes, the government did not prove the prescriptions were unauthorized. …[defendants] first argument is squarely foreclosed by circuit precedent.") (unpublished); *see also*, *United States v. Cristobal*, No. 23-6107, 2024 WL 1506750, at 4 (2d Cir. Apr. 8, 2024) (upholding jury instructions that rest on the language of CFR § 1304.06 requiring that the defendant "act[] in accordance with a standard of medical practice generally recognized and accepted in the State of New York."); *United States v. Titus*, 78 F.4th 595, 598–99 (3d Cir. 2023) ("Here, the instructions required the jury to find that Titus had knowingly or intentionally distributed controlled

substances outside "the usual course of professional practice and not for a legitimate medical purpose.").

The Tenth Circuit's interpretation of the scope and breadth of *Ruan* is vastly different. The Tenth Circuit interpreted *Ruan* as imposing something close to specific intent, which a plain reading of *Ruan's* text supports. In the Tenth Circuit, the government is required to prove "that petitioner knew that his conduct was unauthorized or illegal." *Kahn II*, 58 F.4th at 1315 (quoting *Liparota*, 471 U.S. at 434); *id.* at 1317 (jury instructions did not require the government to prove that "[the defendant] intended to act without authorization"). In the Tenth Circuit, "it [is not] enough that the jury accepted that [the defendant] subjectively knew a prescription was issued not for a legitimate medical purpose, and/or issued a prescription that was objectively not in the usual course of professional practice. Both approaches run counter to *Ruan*." *Id.* at 1320.

Following *Ruan,* in the Tenth Circuit the language of CFR §1306.04 does not serve "as distinct bases to support a conviction, but as 'reference to objective criteria' that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner." *Kahn II*, 58 F.4th at 1316 (quoting *Ruan*, 597 U.S. at 455). In the Tenth Circuit, a defendant stepping outside of the bounds of medical practice is a data point a jury may consider when deciding whether she knew a given prescription to be outside of her authorization under the CSA. By contrast, under the instructions approved of by the Fifth, Sixth, Seventh, and Eleventh circuits, stepping outside of the "usual course of professional practice" as

defined by medical "norms" or "generally accepted standards of practice" or the "standard of care" is, itself, the crime. *Lamartiniere*, 100 F.4th at 638; *Anderson*, 67 F.4th at 764; *Heaton*, 59 F.4th at 1240.

This is not a minor or technical disagreement. The Tenth Circuit denounced as insufficient to capture the *mens rea* required by *Ruan* an elements instruction that is materially indistinguishable from that which the Sixth Circuit upheld in the instant case. On remand from *Kahn II*, the district court issued a jury instruction defining authorization that is materially aligned with the interpretation Petitioner argued below.[1] That instruction defined an "authorized" prescription as one issued with the aim to "prevent, cure, or alleviate the symptoms of a disease or injury."

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[1] The instruction issued in defendant Kahn's retrial following remand from the Tenth Circuit stated in part:

> "To be authorized under the law, a controlled substances prescription must be issued by an individual practitioner acting in the course of professional practice. For purposes of a registered practitioner, to act in the course of professional practice means to practice medicine. For a practitioner to practice medicine, he or she must act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury. Conversely, a prescription is not authorized when it is issued for a purpose foreign to medicine, such as facilitating addiction, recreational abuse, or unlawful distribution.
>
> However, issuing an unauthorized prescription (that is, a prescription not issued for a medical purpose while acting in the course of professional practice) is not, by itself, a crime. A registered practitioner only violates 21 U.S.C. § 841(a)(1) if he or she knowingly or intentionally issues an unauthorized prescription **and**, at the time, knew the prescription was unauthorized or intended it to be unauthorized."

*United States v. Kahn*, 17-cr-00029-ABJ, U.S. Dist. Crt. Wyoming, Dkt. No. 1301, pp. 25-26 (2017).

*United States v. Kahn*, 17-cr-00029-ABJ, U.S. Dist. Wyoming, Dkt. No. 1301, pp. 25 (2017). A prescription is not authorized, by contrast "when it is issued for a purpose foreign to medicine, such as facilitating addiction, recreational abuse, or unlawful distribution." *Id.* The instruction went on to state that:

> "A registered practitioner only violates 21 U.S.C. § 841(a)(1) if he or she knowingly or intentionally issues an unauthorized prescription **and**, at the time, knew the prescription was unauthorized or intended it to be unauthorized."

*Id.* (emphasis in original). These instructions are consistent with Petitioner's argument below.

The Fourth Circuit has adopted a similar interpretation of *Ruan*. *See United States v. Smithers*, 92 F.4th 237, 247 (4th Cir. 2024). Defendants in the Tenth and Fourth Circuits are therefore now tried based on a radically different *mens rea* (and as argued below radically different actus reus) than are defendants in the Fifth, Sixth, Seventh, Ninth and Eleventh Circuits. Both sides of the circuit split rest their positions on this Court's language in *Ruan*. Someone is wrong.

It is difficult to see how this circuit split can resolve itself in the absence of review from this Court. The government will not be able to appeal from acquittals in the Tenth or Fourth Circuit cases where instructions require the government to prove specific intent. Circuits that attach the knowledge element to the two theories of guilt under CFR §1306.04 do so in reliance on this Court's assumption that the scope of authorization under §841 is defined by 21 C.F.R. § 1306.04(a). *See, e.g.*,

*Pham*, 120 F.4th at 1371; *Hofschulz*, 105 F.4th at 929, *Lamartiniere*, 100 F.4th at 641; *Heaton*, 59 F.4th at 1240. They Court must clarify its *Ruan* language, which is necessarily being misinterpreted by two or more Courts of Appeal, and put an end to the Circuit split to make uniform the application of the law nationwide.

## II. THE SIXTH CIRCUIT'S OPINION BELOW IS WRONG.

### a. The Opinion Below is Based on a Fundamental Misreading of *Ruan*.

The Sixth Circuit's opinion below was explicitly based on its analysis in *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023), where it held that "[a] doctor's prescription is authorized within the meaning of § 841(a) when it is made 'for a legitimate medical purpose ... in the usual course of his professional practice.'" *Id.* at 764 (*citing* 21 C.F.R. § 1306.04(a)). In *Anderson,* the Sixth Circuit acknowledged this Court's holding in *Ruan*, but still somehow upheld the Defendant-Appellant's conviction because "a rational juror could conclude that Anderson knowingly prescribed controlled substances without a legitimate medical purpose and outside the usual course of professional practice." 67 F.4th at 769.

That understanding is incorrect both in regard to what this Court decided in *Ruan* and in regard to the meaning of the regulation. Whether the regulation does or does not define authorization was not at issue in *Ruan*. Because the cases below did not challenge the regulation, the Court assumed its applicability:

> As noted above, a regulation provides that, "to be effective," 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). *We assume, as did the courts below and the parties here*, that a prescription is "authorized" and therefore lawful if it satisfies this standard.

*Ruan*, 597 U.S. at 455 (emphasis added). While the Court assumed the applicability of the regulation, it continuously spoke in terms of "statutory provisions," *id.* at 459, and "the mental state that *applies to a statutory clause* ('[e]xcept as authorized') . . . ." *Id.* at 461 (emphasis added). The repeated reference to the text of the statute itself is consistent with the Court's long-held understanding that "[t]he definition of the elements of a criminal offense is entrusted to the legislature, particularly in the case of federal crimes, which are solely creatures of statute." *Liparota v. United States*, 471 U.S. 419, 424 (1985) (citing *United States v. Hudson*, 7 Cranch 32, 3 L.Ed. 259 (1812)).

Presumably, if the Court intended to depart from that paradigm of criminal statutory construction and instead rely on the regulation to define the *mens rea* required by the statutory provisions rather than the text of the statute itself, it would have said so clearly. Indeed, the petitioner in *Kahn* invited the Court to adopt a standard similar to that established in a prior Ninth Circuit case. If the Court had accepted the invitation, it simply could have resolved the circuit split in favor of the Ninth Circuit's interpretation. But it did not. It took what Justice Alito's

concurrence described as "a radical new course" and held "that the mental state expressed by the terms 'knowingly or intentionally' in § 841(a) applies to the '[e]xcept as authorized' proviso." *Ruan*, 597 U.S. at 469 (Alito, J., concurring). Had *Ruan* adopted the standard in the Ninth Circuit, there would be nothing radical or new about its holding.

The Sixth Circuit has ignored *Ruan*'s strong reliance on *Liparota*, which interpreted a similarly worded statute to require knowledge of the *fact* of non-authorization, not merely knowledge that an action taken meets the criteria for what would make the action unauthorized.

**b. Using the Regulatory Language to Define § 841's *Mens Rea* is Inconsistent with the Text, Structure, and History of the CSA.**

The Sixth Circuit's application of § 841's *mens rea* to the regulatory language defining an effective prescription cannot be squared with the text, structure, and history of the Controlled Substances Act. Section 841 states: "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to distribute[] or dispense . . . a controlled substance . . . ." 21 U.S.C. § 841(a). Section 822(b) outlines the scope of a registrant's authorization under the CSA:

> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in

> the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

21 U.S.C. § 822(b). Though this definition of authority may seem somewhat "circular," an examination of the text and structure of the CSA and the regulatory regime for registration elucidates the authority conferred by registration.

Section 802(21) defines the term "practitioner" for purposes of the CSA and the type of registration contemplated by the Act. *United States v. Moore*, 423 U.S. 122, 141 (1975). That provision provides:

> "The term 'practitioner' means a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute[ or] dispense . . . a controlled substance in the course of professional practice or research."

21 U.S.C. § 802(21). Thus, the text of the statute contemplates that the authorization conferred by registration extends to acts taken in the course of professional practice. *Moore*, 423 U.S. at 141.

The regulatory requirement that a prescription may only be written in the *usual* course of professional practice is narrower than the scope of authority provided for in the text of the CSA. Not only is the regulatory language narrower in scope than the statute, but it is also significantly less clear than the statutory language. The language, "usual course of professional practice" carries the implication that one can act within the course of professional practice while simultaneously acting outside the scope of their authority under the CSA. While it

is clear that one who acts "for a purpose foreign to medicine—such as facilitating addiction or recreational drug abuse"—has not acted in the course of professional practice, *Ruan*, 142 S. Ct. at 2389 (Alito, J., concurring), neither courts nor the government have been able to provide clear guidance as to what distinguishes the *usual* course of professional practice from the practice generally. How unusual must one's practice be to cross the line into criminal conduct? The regulation provides no answers.

Similarly, the text of the CSA only requires that there be a medical purpose for the distribution or dispensation of a controlled substance. 21 U.S.C.S. § 829(c) ("No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose."); *cf. Moore*, 423 U.S. at 137 n.13 ("The medical purpose requirement explicit in subsection (c) could be implicit in subsections (a) and (b)."). The regulation's requirement that there be a *legitimate* medical purpose is, once again, inconsistent with the text of the CSA itself. One need not strain to see the inconsistency. Certain schedule V controlled substances are prescription drugs. [2] Hence, one could satisfy the demands of the statute by issuing a prescription for a medical purpose. The regulation, however, imposes an undefined legitimacy requirement, and it again injects ambiguity into the scope of a registrant-physician's prescribing authority.

[2] There is no indication in the text of the CSA that there is a higher standard required for issuing a prescription for prescription drugs listed in schedules II-IV. Moreover, the text of CFR § 1306.04 does not limit the regulations application to prescriptions issued for controlled substances in any particular schedule.

Moreover, the most logical reading of the statute does not lead to the conclusion that § 829's use of the term "medical purpose" was intended to limit the scope of a practitioner's authority. *Moore*, 423 U.S. at 138 ("On its face s 829 addresses only the form that a prescription must take. . . . [Section] 829 by its terms does not limit the authority of a practitioner."). But the regulatory language has led to significant variation regarding whether there are two distinct means to secure a conviction under § 841.

Further textual evidence makes clear, however, that the authorization contemplated by §§ 841 and 822(b) does not contemplate regulatory restrictions on the scope of a practitioner's authority. Of particular note, both provisions refer back to the statute itself, rather than indicating that authorization requires compliance with the Attorney General's regulations. Section 822 contains other provisions that explicitly require one to act "in accordance with the rules and regulations promulgated by [the Attorney General]." § 822(a)(1), (a)(2). The inclusion of the requirement to act in accordance with the rules and regulations in subsection (a)(1) and (a)(2), combined with the absence of similar language in subsection (b) suggests that Congress did not intend for a practitioner's authorization to be dependent on compliance with implementing regulations. *See Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671 (2008). "[W]hen Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate

inclusion or exclusion." *Id.* (quoting *Barnhart v. Sigmon Coal Co.,* 534 U.S. 438, 452 (2002)) (alteration in original).

A similar rationale applies with respect to § 823(d), which expressly limits the authority of registrant manufacturers and dispensers of schedule I and II controlled substances and, in conjunction with § 826, permits the Attorney General to impose limitations on such registrants' authority. 21 U.S.C. §§ 823(d), 826. No similar restriction is imposed on registrant practitioners, and there is no authorization for the Attorney General to impose limitations on such registrants.

The historical context in which the CSA was passed provides further support for the contention that the Attorney General does not have the authority to restrict the prescribing authority of a registrant doctor beyond the restrictions imposed by the CSA itself. In drafting the CSA, Congress sought to correct the fact that, under the Harrison Act and its implementing regulations, "the appropriate method of the practice of medicine" was effectively determined "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." H.R. Rep. No. 91-1444, p. 15. Vague regulations permitted prosecutors and narcotics authorities to target physicians who treated narcotics addicts, leading many in the medical profession to fear accepting such persons as patients would create an undue risk of prosecution:

> The practicing physician has thus been confused as to when he may prescribe narcotic drugs for an addict. Out of a fear of prosecution many

> physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients.

*Id.* (quoting Report of the President's Advisory Commission on Narcotic and Drug Abuse, 57 (1963) ("Prettyman Report").

Congress's solution was to enact a provision "require[ing] the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to 'determine the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction . . . .'" *Moore*, 423 U.S. at 144 (quoting Pub.L. 91-513, Title I, § 4, Oct. 27, 1970, 84 Stat. 1241 (current version at 42 U.S.C. § 290bb-2a)). That was the only area "in which Congress set general, uniform standards of medical practice." *Gonzales v. Oregon*, 546 U.S. 243, 271 (2006). The scope of a registrant's prescribing powers is, at bottom, a medical decision. The fact that Congress deliberately vested authority over medical standards in the Secretary rather than the Attorney General indicates the CSA does not empower the Attorney General to define the scope of a physician's prescribing powers. By relying on the regulatory language, the Ninth Circuit adopted an interpretation "which is inconsistent with 'the context from which the statute arose.'" *Fischer v. United States*, 603 U.S. 480, 498 (2024) (quoting *Bond v. United States*, 572 U.S. 844, 860 (2014)). The Court should take this opportunity to correct the error.

### c. Deferring to the Regulation to Define Authorization for § 841's Criminal Prohibitions is Inconsistent with the Constitutional Separation of Powers.

"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) (quoting *United States v. Hudson*, 7 Cranch 32, 34 (1812)). Despite this axiomatic command of the constitutional separation of powers, prosecutions of medical professionals under § 841 have turned not on the meaning of the statutory text, enacted through the process of bicameralism and presentment. Instead, each case hinges on the case-by-case interpretation of vague regulatory language enacted by unelected bureaucrats. Unsurprisingly, this has led to variation in the application of the criminal law across jurisdictions, variation which has withstood this Court's opinion in *Ruan*.

Courts have assumed that the issuance of § 1306.04 was within the Attorney General's statutory under the CSA. But such assumptions are inconsistent with the major questions doctrine. That doctrine stands for the proposition that "in certain extraordinary cases, both separation of powers principles and a practical understanding of legislative intent make [courts] reluctant to read into ambiguous statutory text the delegation claimed to be lurking there." *W. Virginia v. Env't Prot. Agency*, 597 U.S. 697, 723 (2022). In such cases, "something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to 'clear congressional authorization' for the power it claims." *Id.* (quoting *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)).

Authority over the regulation of medicine, as previously discussed, was an issue of major political and economic significance, and there is no textual basis sufficient to support a construction under which the Attorney General has the authority to define a registered practitioner's prescribing authority. To the contrary, "[t]he structure of the CSA, then, conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise." *Gonzales v. Oregon*, 546 U.S. 243, 266 (2006). Moreover, the "regulation of health and safety is primarily, and historically, a matter of local concern," *id.* at 271 (quotation marks omitted), and nothing in the statute shows a congressional intention to upset that balance. To the contrary, "[t]he statute and [this Court's] case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Id.* at 269-270. "Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Id.* at 270.

Regulation 1306.04, however, is inconsistent with this principle. The regulation makes the implicit judgment that some medical purposes are legitimate while others are not. So too does it imply that one's professional practice can become so unusual that, while they have not yet abandoned the practice of medicine, they entered the realm of drug trafficking. These unexplained assumptions are ungrounded in the text of the statute and inconsistent with Congress's delegation of decisions that require medical judgment to the Secretary.

Moreover, the requirement that a prescription be issued for a "legitimate medical purpose in the usual course of professional practice" is impermissibly vague as it provides no meaningful guidance to those enforcing the CSA. "It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

> A statute can be impermissibly vague for either of two independent reasons. First, if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits. Second, if it authorizes or even encourages arbitrary and discriminatory enforcement.

*Hill v. Colorado*, 530 U.S. 703, 732 (2000). While requiring knowledge of a lack of authorization lessens the concerns that one may be punished without adequate notice of the offense, *see Hoffman Estates v. Flipside, Hoffman Estates*, 455 U.S. 489, 499 (1982) (noting that "the scienter requirement may mitigate a law's vagueness, *especially with respect to the adequacy of notice* to the complainant that his conduct is proscribed" (emphasis added)), a scienter requirement does not alleviate all vagueness concerns:

> Although the doctrine focuses both on actual notice to citizens and arbitrary enforcement, [the Supreme Court has] recognized . . . that the more important aspect of the vagueness doctrine "is not actual notice, but the other principal element of the doctrine -- the requirement that a legislature establish minimal guidelines to govern law enforcement."

*Kolender v. Lawson*, 461 U.S. 352, 357-58 (1983) (quoting *Smith v. Goguen*, 415 U.S. 566, 574 (1974)).

The second element of the vagueness doctrine is rooted in the understanding that "[v]ague laws . . . undermine the Constitution's separation of powers and the democratic self-governance it aims to protect." *United States v. Davis*, 588 U.S. at 451. "Vague statutes threaten to hand responsibility for defining crimes to relatively unaccountable police, prosecutors, and judges, eroding the people's ability to oversee the creation of the laws they are expected to abide." *Id.* The language of the 21 CFR § 1306.04 is entirely deficient in this respect.

This is not the typical vagueness circumstance, where the statute itself leaves gaps that are ripe for abuse. Here, it is a regulatory interpretation that injects vagueness into a statute in a manner that invites arbitrary enforcement. And the vague regulation has been issued under the claimed authority of the very actor charged with enforcing the law. "If the separation of powers means anything, it must mean that the prosecutor isn't allowed to define the crimes he gets to enforce." *United States v. Nichols*, 784 F.3d 666, 668 (10th Cir. 2015) (Gorsuch, J., dissenting from the denial of rehearing *en banc*); *cf.* "Deferring to the prosecuting branch's expansive views of these statutes would turn their normal construction upside-down, replacing the doctrine of lenity with a doctrine of severity." *Whitman v. United States*, 574 U.S. 1003 (2014) (Scalia, J., statement respecting the denial of certiorari) (quotation marks, brackets, and ellipsis omitted)). Such an interpretation

is not compatible with the separation of powers, and has led to precisely the perils Congress sought to correct in drafting the CSA.

And, while Petitioner contends that the ordinary tools of statutory construction demonstrate the erroneousness of the Sixth Circuit and other Courts' reliance on the regulations, should the Court find the statue ambiguous, it should apply the rule of lenity.

## III. THE ISSUE PRESENTED IS OF VAST IMPORTANCE TO THE MEDICAL COMMUNITY AND IS RECURRANT.

The CSA was not intended to interfere with the legitimate practice of medicine. However, this is precisely what has occurred due to the lack of clear standards delineating when a prescriber can issue prescriptions for controlled substances and the due to the aggressive prosecution of prescribers. Rather than fulfilling the purpose of the CSA, the DEA and United States Attorney's Office have acted as a *de facto* national medical board, curtailing practices it disagrees with through criminal prosecutions of prescribing physicians. Congress witnessed a similar situation under the Harrison Act, and it sought to prevent its recurrence in drafting the CSA. However, reliance on the vague regulatory language has allowed and encouraged exactly that which Congress sought to cure.

One area that has been disproportionately impacted is the field of pain management. According to a 2019 report released by Health and Human Services,[3]

[3] U.S. Department of Health and Human Services (2019, May) ("HHS Report"). *Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations*. Retrieved from U. S. Department of Health

"[r]egulatory oversight has also led to fears of prescribing among clinicians, with some refusing to prescribe opioids even to established patients who report relief and demonstrate improved function on a stable opioid regimen." HHS report at 12. Fears of arbitrary enforcement have had a negative effect on proper prescribing:

> "Clinicians who treat acute and chronic pain, particularly with opioids, may experience stigma from colleagues and society in general that — in addition to fear of scrutiny from state medical boards and the DEA — may also dissuade them from using opioids appropriately."

*Id.* at 57. Intervention from this Court is needed to clarify the standards applicable to medical professionals under the CSA. This case provides an opportunity to clarify the standards for the medical community so it can minimize the patient harms that have resulted from the enduring uncertainty regarding the standards governing the CSA.

## CONCLUSION

For the foregoing reasons, Petitioner respectfully prays that this Honorable Court grant her Petition for Certiorari.

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and Human Services website: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.

Respectfully Submitted,

Hasna Bashir Iwas

March 10, 2026 By: /s/ Beau B Brindley

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