No. _____

IN THE SUPREME COURT OF THE UNITED STATES

ROBERT HOFSCHULZ,
LISA 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

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Did Congress delegate authority to the Attorney General to define what constitutes an "effective prescription" or an "authorized" distribution of narcotics under 21 U.S.C. § 841 of the Controlled Substances Act ("CSA")?
2. May a court uncritically defer to administrative regulations when defining authorization for purposes of 21 U.S.C. § 841(a)'s criminal prohibitions, or must courts conduct an independent interpretation of the statute to ascertain its meaning?
3. Does stepping outside of "generally accepted standards of practice" render a prescription unauthorized under the CSA, even where it is issued for a medical purpose?
4. Does 21 U.S.C. § 841(a)'s *mens rea* attach to the statutory requirement of authorization, such that the government bears the burden of proving that a defendant knew a given prescription was legally unauthorized, or does the statute's *mens rea* attach to regulatory interpretations of 21 U.S.C. § 829's prescription requirement?

LIST OF PARTIES TO THE PROCEEDINGS

Petitioner, defendant-appellant below, Lisa Hofschulz.

Petitioner, defendant appellant below, Robert Hofschulz.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

Seventh Circuit Court of Appeals:

United States v. Lisa Hofschulz, No. 21-3403, *United States v. Robert Hofschulz*, No. 21-3404. United States Court of Appeals for the Seventh Circuit. Judgment entered June 25, 2024. *United States v. Hofschulz*, 105 F.4th 923 (7th Cir. 2024).

United States District Court for the Eastern District of Wisconsin:
United States v. Hofschulz, Nos. No. 18-cr-00145-PP-1 & 18-cr-00145-PP-2. Judgement and conviction entered December 17, 2021.

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United States v. Hofschulz, 105 F.4th 923, 925 (7th Cir. 2024).

JURISDICTION

This is a federal criminal case involving an appeal from a final judgment entered in the Eastern District of Wisconsin. The Seventh Circuit of Appeals entered judgement on June 25, 2024. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSITUTIONAL AND STATUTORY PROVISIONS INVOLVED

21 U.S.C.A § 841 (a)(1) states:

> "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally -to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance."

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."

21 U.S.C. § 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."

21 U.S.C. §802 states:

> "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."

21 U.S.C. §829(a) states:

> **"**Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written

> prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled."

21 C.F.R § 1306.04(a) purports to define what constitutes an effective prescription:

> "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."

STATEMENT

This petition involves the pre-*Ruan* trial of a registered medical practitioner and her then ex-husband and office manager under 18 U.S.C. §§ 841 and 846.[1] At the time of trial, petitioner Lisa Hofschulz was a Nurse Practitioner, duly registered and licensed under the Controlled Substances Act ("CSA") to issue prescriptions for controlled substances. R.29 at 2. She owned and operated a small pain management clinic (Clinical Pain Consultants). *Id.* Petitioner Robert Hofschulz had no medical training. Tr.331; 410. He assisted Clinical Pain Consultants with administrative matters. Tr.331; 410.

[1] At the time of trial petitioners were divorced. They have since remarried.

This petition asks the Court to resolve two related issues upon which the circuits have split following this Court's decision in *Ruan v. United States*, 597 U.S. 450 (2022). The Tenth Circuit holds that under *Ruan*, it is no longer sufficient for the government to prove that the defendant knowingly took actions that violate the standard articulated by the Attorney General in CFR §1306.04. *United States v. Kahn*, 58 F.4th 1308, 1316 (10th Cir. 2023). Instead, in the Tenth Circuit, "[t]he government must prove that a 'defendant knew or intended that his or her conduct was unauthorized'" by her registration under the CSA. *Id.* (quoting, *Ruan*, 597 U.S. at 455). Furthermore, the Tenth Circuit held that following *Ruan,* the "medical purpose" and "usual course of professional practice" language from CFR §1306.04 no longer defines what it means for a prescription to be "authorized" under §841. *Id.* at 1316.

The Fifth, Sixth, Eleventh and the Seventh Circuit below hold that *Ruan* does not disturb their case law defining the limit of a practitioner's "authorization" under § 841 by the language of § 1306.04. *United States v. Hofschulz*, 105 F.4th 923, 929 (7th Cir. 2024); *United States v. Lamartiniere*, 100 F.4th 625, 641 (5th Cir. 2024); *United States v. Anderson*, 67 F.4th 755, 764 (6th Cir. 2023); *United States v. Heaton*, 59 F.4th 1226, 1240 (11th Cir. 2023). In those circuits, the government is *not* required to prove "that a defendant knew or intended that his or her conduct was unauthorized." *Ruan*, 597 U.S. at 467. Rather, the government is required to prove either that the defendant knew that the charged prescriptions were issued "outside the usual course of professional practice" or "without a legitimate medical

purpose." 21 C.F.R. § 1306.04. As those circuits interpret CFR §1306.04, neither phrase involves consideration of "[a] prescriber's own treatment methods" but instead turn on the "norms of professional practice." R.167 at 30-31.

This is not an academic difference. In the Tenth Circuit a defendant who testifies that she knew that most doctors would not issue the charged prescription or deem it legitimate under the circumstances, but honestly believed that the prescriptions were within the scope of her authorization under the CSA has articulated a defense to § 841 charges. In the Fifth, Sixth, Eleventh, and Seventh Circuits, she has confessed guilt.

Case law in this area has become ontologically untenable. The CSA states that "[p]ersons registered by the Attorney General under this subchapter to .. distribute … controlled substances … are authorized to … distribute… such substances … to the extent authorized by their registration and in conformity with the other provisions of this subchapter." 21 U.S.C. § 822(b). The CSA includes a number of penalty provisions targeted specifically at registrants. *See*, *e.g.,* 21 U.S.C. §§ 842 & 843. In *Moore* this Court described these provisions as outlining "minor or technical" violations that fall short of rendering a prescription "unauthorized" under § 841. *United States v. Moore*, 423 U.S. 122, 135 (1975). Prosecution of registered medical practitioners under § 841 was reserved for those doctors that act "as a large-scale 'pusher' not as a physician." *Id*. at 122; *Gonzales v. Oregon*, 546 U.S. 243, 269–70(2006) ("The statute and our 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. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.").

Yet, as circuit court case law has developed, a violation of a later-promulgated regulation has become sufficient to render a prescription unauthorized. That "regulatory language defining an authorized prescription is … 'ambiguous,' written in 'generalit[ies], susceptible to more precise definition and open to varying constructions.'" *Ruan*, 597 U.S. at 459 (quoting *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006)). The circuit courts have interpreted that regulatory language as turning, not on an individual "prescriber's own treatment methods," but rather on the "norms of medical practice." R.167 at 30-31. This language is based not on any meaning that Congress might have given to the words "usual course of professional practice" or "legitimate medical purpose," but on a parsing of the CFR language itself.

At the time the CSA was enacted the "usual course of professional practice" language prohibited one and only one thing: issuing a prescription for the purpose of promoting addiction or catering to the needs of a drug addict. *See Linder v. United States*, 268 U.S. 5, 13 (1925); *Boyd v. United States*, 271 U.S. 104, 105 (1926).

Review from this Court is necessary to vindicate significant Separation of Powers error that has worked its way into the case law. Congress did not delegate to the attorney general, or any other branch of the executive the authority limit the scope of a registrants' "authorization" as used in §841 or to define what constitutes

an "effective prescription" as it purports to do in 21 C.F.R. §1306.04. 21 U.S.C. §823(g)(2)(H)(i) ("Nothing in this subchapter shall be construed as to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."). In fact, as argued below, the authors of the CSA sought to *limit* federal prosecutors' *de facto* ability to regulate the means and manner of medical practice 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. Rept. 91-144 at 15.

If Congress did not delegate to the Attorney General the authority to issue CFR §1306.04, then it cannot be that the "knowledge" requirement of §841 attaches to the elements articulated in that regulation. It must attach to the fact of authorization itself.

The circuit split here is not one that can resolve itself short of review from this Court. The circuits that disagree with the Tenth Circuit's interpretation of *Ruan* do so in reference to language from this Court: "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. This Court, however, made that assumption in the face of the solicitor general's concession, that (1) the words "usual course of professional practice" and "legitimate medical purpose" should be read as a single unified phrase and (2) that the meaning of 21 C.F.R. § 1306.04(a) cannot say more than the statute itself. Transcript of Oral Arg., *Ruan v. United States*,

Nos. 20-1410 and 21-5261, at 67-86. Nevertheless, the Seventh Circuit, as well as the Fifth and Eleventh, rely on this language in support of defining the elements of §841 based on their pre-*Ruan* interpretation of CFR §1306.04—interpretations that are inconsistent with the position taken by the government in *Ruan. See, e.g.*, *Hofschulz*, 105 F.4th at 929, *Lamartiniere*, 100 F.4th at 641; *Heaton*, 59 F.4th at 1240.

Until this Court provides further guidance on what it is that renders a prescription "unauthorized" under §841, district courts will continue to issue, and the circuit court's will continue to uphold, inconsistent instructions based on the parsing of a regulation that Congress did not authorize the Attorney General to issue.

FACTUAL BACKGROUND

Petitioner Lisa Hofschulz was charged with fourteen substantive counts of distributing specific prescriptions outside the usual course of professional practice and without a legitimate medical purpose, including one resulting in the overdose death of a patient. R.29 at 6-7. Petitioner Robert Hofschulz was charged with aiding and abetting the distribution charged in four of those counts (Counts Eight, Nine, Eleven and Twelve). R.29 at 6-7. Both petitioners were convicted on all counts and sentenced to 240 months and 36 months respectively. R.169; R.233; R.232.

At all times relevant to this petition, Petitioner Lisa Hofschulz was a Registered Nurse licensed under the CSA to distribute controlled substances. She owned and was the primary practitioner at Clinical Pain Consultants ("CPC), a

small pain management clinic. CPC required patients to sign pain contracts. It conducted regular urinalysis testing. Tr.131, 309. When the possibility of diversion was brought to the attention of CPC employees, pill counts were conducted. Tr.131. Patients were discharged from the practice on a regular basis for failure to abide by the term of the pain contracts. Tr. 523, 1419. CPC did not accept all patients referred to the clinic. Tr.1956. CPC required potential patients to provide medical records and imaging. Tr.571, 968, 989, 1004, 1090, 183-84, 196, 1873. When it was not available, imaging was ordered. Tr.429, 328. Some patients were referred to physical therapy. Tr.1518. CPC paid for continuing education on pain management for medical staff. Tr.1527.

Appointments were lengthy (at least 20 minutes even for returning patients). Tr.949, 1401. Every patient witness who testified indicated that Lisa Hofschulz asked them about their pain, adjusted their medication accordingly, and appeared to be trying to help alleviate their suffering. Tr.949-50, 979, 1089, 1090, 1101, 185, 1416, 1887. CPC did not issue the same set of prescriptions or dosage strengths to every patient and adjusted dosages and medications in response to patient needs. Tr.977, 1090, 1887.

In total, nine patients testified at trial. Six testified that that they were taking their prescriptions as directed and that the medication was helping and increased their functionality and quality of life. Tr.1001-02, 1402; 1416; 1877; 1887-90; 1898. Three testified that they actively lied for the purpose of convincing Lisa Hofschulz and CPT employees that they were in more pain than they were actually

suffering. Tr.948-47; 1093-95; 185. For example, one witness testified that because she knew CPC conducted urinalysis at every visit, she took prescriptions as directed prior to her visits in an attempt to show that she was taking her medication as opposed to selling them. Tr.974. Medical records for patients who did not testify disclose significant injuries and medical problems that are capable of causing significant pain. Tr. 674, 1667-68; 767-68, 1600-01, 1577-78.

The government's expert, Dr. King, testified that each of the charged prescriptions failed to adhere to what he called the four pillars of pain management: evaluation, diagnosis, treatment plan, and monitoring. Tr.638-47. Each pillar had to be addressed, documented, and correctly formatted at each appointment. Tr.673, 730, 742. King repeatedly testified that any deviation from the standard of care as he defined it automatically rendered a prescription outside the "usual course of professional practice" and that any prescription not within the usual course of professional practice was not "practicing medicine." Tr.675, 891-92.

King testified that a pain management practitioner is required to identify an objectively verifiable physical ailment supporting the complained of pain. Tr.691. A practitioner may not rely on another medical professional's diagnosis or treatment plan. Tr.640. A patient's subjective report of pain is not sufficient to justify treatment. Tr.677. King testified that the use of opioids to treat chronic pain was not medically justified. Tr.685. Ultimately King testified each of the charged prescriptions were not issued in the usual course of professional practice and were

outside the practice of medicine. Tr.702-03, 738-39, 751, 760, 767, 775-76, 788, 795-96.

The defendant's expert witness, Dr. Halikas, disagreed with many of King's opinions. Halikas testified that there were two types of pain practitioners: "interventional pain management" specialists and "medical pain management" specialists. Tr.1244. While the former focuses on injections and physical interventions, the latter primarily focuses on alleviating pain through medications. Tr.1244. He testified that the primary goal of pain management practitioners is to alleviate pain to get the patient to "a level of pain relief where they have a good quality of life where they can function." Tr.1247.

Halikas testified that a pain physician not only can but *should* rely on the diagnosis and treatment plan previously provided by other physicians. Tr.1248, 1250. Halikas testified that the goal of pain management is not to cure the underlying condition causing pain. Tr.1258. Halikas testified that there are many conditions which cause pain that will not show up in objective imaging or other tests. Tr.1249, 1263. Therefore, Halikas testified that in determining whether a patient is suffering pain, practitioners must rely on a patient's self-report. Tr.1251.

The charges against petitioner Robert Hofschulz involve four prescriptions issued to patients while Ms. Lisa Hofschulz was traveling to California to visit her ailing father. At the time, Robert Hofschulz oversaw the administrative aspects of CPC, such as purchasing medical equipment and recruiting and hiring support staff. Tr.409-10; 500; 409-10; 500. Among the staff hired by Mr. Robert Hofschulz

were four nurse practitioners who had not yet received their DEA registration to distribute controlled substances. Tr.427, 516-517.

On July 16, 2016, Lisa was informed that her father was terminally ill. In order to care for him she needed to travel to California. Tr. 244. A regulation, 21 C.F.R. §1306.12, explicitly allows for practitioners to issue multiple prescriptions for up to a 90-day supply of a Schedule II controlled substance without a patient appointment. 21 C.F.R. §1306.12. Rather than canceling the appointments and simply mailing out prescriptions, Lisa Hofschulz told her staff that she would review patients scheduled for appointments for the following couple of days, write prescriptions for those patients, and include them in the medical charts. Her employees could then conduct patient appointments as normal, and assuming there were no discrepancies or questions raised by the patient, provide the patient with their prescription. If the Nurse Practitioners ran into any issues, they should contact her before handing out the prescriptions. Tr.539.

CPC employees stated that they were uncomfortable providing prescriptions to patients when Lisa Hofschulz was not present in the office. Tr.449, 519. The meeting became at least somewhat heated. Tr.450. Lisa explained that she believed it was entirely appropriate and legal for the nurse practitioners to distribute prescriptions at her direction. Tr.550. As a result, Robert contacted a medical recruiting agency and hired RN Donna Kowske to work on a temporary basis. Tr.558. RN Kowske had been a registered nurse for approximately 30 years. Tr.556-57.

While Lisa was in California, Kowske saw patients and delivered the prescriptions charged in the four counts against Mr. Robert Hofschulz. R.29. In each case, Kowske took patients' vital signs, reviewed their medical records, which included "detailed and thorough notes [from Lisa Hofschulz] about what to look for and what to go over with the patient". Tr.598. A completely filled out and correctly dated prescription was attached to the note. Tr.564. If the patient was "stable," Kowske would deliver the prescription to the patient. Tr.574.

A. Instructions And Seventh Circuit Opinion Below

Trial in this case occurred prior to this Court's decision in *Ruan*. The district court rejected the defendants' argument that a defendant's guilt under § 841 must be based on her subjective belief that a prescription is not serving a legitimate medical purpose. R.158 at 39-40. The district court rejected the defendants' proposed instruction that would have provided an absolute defense if petitioners were acting with "good intentions and the honest exercise of professional judgment as to a patient's medical needs." R.75 at 5-6; R.158 at 39-40. The district court also rejected an instruction which would have required the government prove that the defendants' acted willfully, i.e. that they knew the charged prescriptions were issued in violation of the law. R.158 at 38-39.

Instead, the district court issued an instruction that, defined the criteria of CFR § 1306.04 in purely objective terms. R.167 at 31-32.

> Federal law authorizes registered medical practitioners to dispense a controlled substance by issuing a lawful prescription. Registered practitioners are exempt from criminal liability if they distribute or dispense controlled substances for a legitimate medical

> purpose while acting in the usual course of professional practice. A registered practitioner violates Section 841(a)(l) of Title 21 of the United States Code if the practitioner intentionally distributes or dispenses a controlled substance without a legitimate medical purpose and outside the usual course of standard professional practice.
>
> In making a medical judgment concerning the right treatment for a patient, prescribers have discretion to choose among a wide range of available options. Therefore, in determining whether a defendant acted without a legitimate medical purpose, you should examine all of that defendant's actions and the circumstances surrounding them.
>
> *A prescriber's own treatment methods do not themselves establish what constitutes professional medical practice.* In determining whether a defendant's conduct was outside the usual course of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice. *You should consider that defendant's actions as a whole, the circumstances surrounding them, and the extent of severity of any violations of professional norms you find that defendant may have committed.*

R.167 at 30-31 (emphasis added).

On appeal to the Seventh Circuit petitioners argued that *Ruan* imposes something close to specific intent. That is, even where a registrant knows he or she is acting outside the scope of professional practice, or without what other doctors might view as a legitimate medical purpose, the government is still required to prove that the defendant knew she was unauthorized by the CSA to issue that prescription. *Ruan*, 597 U.S. at 467 ("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."). Specifically, petitioner argued that, as interpreted by *Ruan*, the language of § 841, like the language in *Liparota*, attaches knowledge to the word "authorization". Therefore, the government must prove knowledge of a

lack of authorization, as opposed to knowledge of the factors that render a prescription unauthorized.

Petitioners further argued that a practitioner's guilt under § 841 does not turn on compliance with the Seventh Circuit's pre-*Ruan* interpretation of CFR §1306.04. Under that interpretation, "usual course of professional practice" turns on a violation of medical "norms." Petitioners argued that Congress did not delegate to the attorney general the authority to regulate the manner of medical practice or police compliance with medical norms. The definition of "authorization" must come from the CSA itself.

The Seventh Circuit rejected the petitioners' argument. The Seventh Circuit concluded that the relevant knowledge was not "knowledge of nonauthorization" but "knowledge of status." *Hofschulz*, 105 F.4th at 929. The crime is not issuing a prescription that the defendant knows to be outside the outside the scope of her authorization to distribute controlled substances under the CSA, but rather issuing a prescription knowing the facts that render it outside the scope of the usual course of professional practice. *United States v. Hofschulz,* 105 F.4th 923, 929 (7th Cir. 2024).

The Seventh Circuit did not identify any section of the CSA that delegated to the attorney general the authority to define what constitutes an "authorized" prescription, or to enact regulations defining what constitutes an "effective" prescription. Nor did the Seventh Circuit identify any language in the CSA that purports to render a prescription "unauthorized" under § 841 if it is not issued in

conformity with medical norms. Instead, the Seventh Circuit, relying on this Court's decision in *Gonzalez,* reasoned that 21 C.F.R. § 1306.04(a) is a parroting regulation that does no more than restate the language of the statute. *Hofschulz,* 105 F.4th at 929. The Seventh Circuit concluded that "We therefore assume, as *Ruan* did, "that a prescription is 'authorized' and therefore lawful if it satisfies [the § 1306.04(a)] standard." *Hofschulz*, 105 F.4th at 929 (quoting *Ruan*, 597 U.S. at 455).

REASONS FOR GRANTING REVIEW

I. REVIEW FROM THIS COURT IS NECESSARY TO RESOLVE A CIRCUIT SPLIT BETWEEN THE TENTH AND SEVENTH CIRCUITS REGARDING WHETHER, AS APPLIED TO MEDICAL PRACTITIONERS, § 841 REQUIRES THE GOVERNMENT TO PROVE THAT THE DEFENDANT KNEW A CHARGED PRESCRIPTION TO BE OUTSIDE OF HER AUTHORIZATION UNDER THE CSA.

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*, 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 circuit's 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 CFR § 1306.04, without reference to the plain meaning or intent of the drafters of the CSA.

In the opinion below, the Seventh Circuit held that *Ruan* did nothing more than tell the Fifth, Tenth, and Eleventh Circuits that they erred in not imputing a knowledge requirement into the "usual course of professional practice" prong of the regulation. *Hofschulz,* 105 F.4th at 929 (7th Cir. 2024).

The Fifth, Eleventh, and Sixth 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 didn't 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. 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 Seventh Circuit upheld in the instant case. On remand from *Kahn II*, the district court issued a jury instruction defining authorization that is materially similar, if not even more explicit, than those offered by the instant petitioners and rejected by both the district court and the Seventh Circuit in this case.[2] That instruction defined an

[2] 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.

"authorized" prescription as one issued with the aim to "prevent, cure, or alleviate the symptoms of a disease or injury." *United States v. Kahn*, 17-cr-00029-ABJ, U.S. Dist. Wyoming, Dkt. No. 1301, pp. 25 (2017). A prescription was 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). In substance, these instructions are materially identical to the medical purpose and willfulness instructions rejected by the Court in petitioners' case below. *See* R.158 at 38-39.

Defendants in the Tenth Circuit are tried based on a radically different *mens rea* (and as argued below radically different actus reus) than are defendants in the Fifth, Sixth, Seventh and Eleventh Circuits. Both sides of the circuit split rest their positions on this Court's language in *Ruan*. Someone is wrong.

> 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).

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 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.*, *Hofschulz*, 105 F.4th at 929, *Lamartiniere*, 100 F.4th at 641; *Heaton*, 59 F.4th at 1240.

II. FURTHER GUIDANCE FROM THIS COURT IS NECESSARY TO RESOLVE CONFUSION AS TO WHAT IT IS THAT RENDERS A PRESCRIPTION "AUTHORIZED" UNDER § 841 AND RECTIFY A SIGNIFICANT SEPARATION OF POWER'S ERROR THAT HAS WORKED ITS WAY INTO THE CASE LAW SINCE *MOORE*.

As this court has recognized §1306.04 is "'ambiguous,' written in 'generalit[ies], susceptible to more precise definition and open to varying constructions.'" *Ruan*, 597 U.S. at 459 (quoting *Gonzales*, 546 U.S. at 258 (2006)). The circuit courts have interpreted that language as not turning on an individual "prescriber's own treatment methods" but rather on the "norms of medical practice." R.167 at 30-31. This language is based not on any meaning that Congress might have given to the words "usual course of professional practice," but on a parsing of the regulation.

Because of that, the circuit courts have refrained from defining exactly what it means to issue a prescription "outside the usual course of professional practice without a legitimate medical purpose." *United States v. Singh,* 54 F.3d 1182, 1187

(4th Cir.1995); *United States v. August,* 984 F.2d 705, 713 (6th Cir.1992) ("There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice."). Defining usual course of professional practice as dependent upon compliance with medical "norms" would seem to render any prescription that violated the civil standard of care "unauthorized" under § 841. Under the Seventh Circuit's interpretation of CFR §1306.04 "the two standards overlap." *Hofschulz*, 105 F.4th at 931 (quotation omitted).

This is exactly the result that Congress sought to avoid in drafting the CSA. The House Report states that Congress did not believe it appropriate for "federal officials to determine the appropriate method of the practice of medicine." H.R. Rept. 91-144 at 14. The House Report goes on to note that "it is necessary to acknowledge that this is precisely what has happened through the criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutor of what constitutes appropriate methods of professional practice". *Id.* at 15.

The CSA did not grant the Attorney General the authority to regulate the manner of medical practice or determine what constitutes an effective prescription. Nothing in the text of the CSA suggests that Congress intended federal prosecutors to police violations of state medical norms. The effect of the circuit courts' interpretation of CFR § 1304.06 has been to allow prosecutors to do exactly what the drafter's of the CSA sought to prevent.

The CSA includes only two potentially relevant grants of authority to the Attorney general. 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."

Under the CSA, the Attorney General, in coordination with the Secretary of Health and Human services is charged with two basic functions. First, the Attorney General is given the authority to review new medications and place them on a temporary and permanent basis on 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 procedures specifically outlined in the statute. 21 U.S.C. §824. Defining what constitutes authorization under §841 simply does not fall within the ambit of either function. Importantly, in these two areas, the CSA provides explicit and detailed procedures and criteria that the Attorney General should use in exercising its rule making authority. *Id.*

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 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

effective 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."). The CSA does not include any explicit grant of authority allowing the attorney general to define what constitutes an "effective" prescription under §841 or to articulate the criteria against which "authorization" should be measured. *Gonzales*, 546 U.S. at 269–70; *see also id.* at 262 ("The problem with the design of the Interpretive Rule is that it cannot, and does not, explain why the Attorney General has the authority to decide what constitutes an underlying violation of the CSA in the first place.").

Even were a contrary construction possible, §§821 and 871 fall far short of providing an "intelligible principle" guiding the delegation of that power. *United States v. Touby*, 500 U.S. 160, 166 (1991). 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) (Brennan, J., concurring) (explaining that "the area of permissible indefiniteness narrows … when the regulation invokes criminal sanctions").

Any ambiguity in §§821 and 871 is affirmatively obviated by the legislative history and Major Questions Doctrine. Under the Major Questions Doctrine, courts must presume 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). "Where 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'—whether Congress in fact meant to confer the power the agency has asserted." *Id.* at 2607–08. The regulation of medical practice is an area of traditional state concern that Congress has been (perhaps uncharacteristically) inclined to protect. *Hawker v. New York*, 170 U.S. 189 (1898) (detailing how the medical practice had been policed by the states); *Bond v. United States*, 134 S. Ct. 2077, 2088 (2014) (rejecting presumption "that Congress had meant to effect a significant change in the sensitive relation between federal and state criminal jurisdiction"); 21 U.S.C. §823(g)(2)(H)(i) ("Nothing in this subchapter shall be construed as to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."); H.R. Rept. 91-1444 at 14. Courts must "be certain of Congress's intent" before "legislating in areas traditionally regulated by the States." *Gregory v. Ashcroft*, 501 U.S. 452, 459-60 (1991).

In *Moore*, this Court considered the question of whether a registered medical practitioner was "exempted from prosecution under § 841 by virtue of his status as a registrant" under the CSA. *Moore*, 423 U.S. at 124. The Court recognized that a doctor's scope of authority as defined in the CSA is somewhat circular. *Id. Moore* held that, were the CSA construed to authorize all prescriptions a registrant was licensed to issue, it would "constitute a sharp departure from other laws." *Id.* 132-33

("It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act…").

The Seventh Circuit below held that because this Court has described the CFR as a "parroting regulation," the language of that regulation controls the meaning of the statute, and therefore, one need not examine what was intended by the word "authorized" under the statute. That gets the question exactly backwards. The words of the statute are not interpreted in light of the regulation. If anything, the regulation must be limited to the words and meaning of the statute.

As the *Ruan* concurrence noted: [t]he notion of action taken 'in the course of professional practice' is not defined in the CSA, but our precedents hold that when Congress employs a term of art 'obviously transplanted from another legal source,' it 'brings the old soil with it.'" *Ruan v. United States*, 597 U.S. 450, 478 (2022) (Alito, J., concurring) (quoting *George v. McDonough*, 119 S. Ct. 1953 (2022)). The "old soil" at issue here is the Harrison Act, 38 Stat. 785 and this Court's case law interpreting that statute. Under the Harrison Act, distribution of controlled substances by registered medical professionals was permitted "in the course of his professional practice only." *Linder v. United States*, 268 U.S. 5, 13 (1925). In *Linder*, the Court reversed because the indictment failed to articulate facts that the defendant doctor had any "conscious design to violate the law." 268 U.S at 17. In *Boyd* the "disputed question was whether the defendant issued the prescriptions in good faith." *Boyd v. United States*, 271 U.S. 104, 105 (1926). The instruction in *Boyd* read in part: "whether or not the defendant in prescribing morphine to his patients

was honestly seeking to cure them of the morphine habit, while applying his curative remedies, it is not necessary for the jury to believe that defendant's treatment would cure the morphine habit, but it is sufficient if defendant honestly believed his remedy was a cure for this disease." *Id.* 107–08.

Nothing in these cases discusses a defendant's conformity with medical "norms" or "generally recognized" standards of medical practice. As the *Ruan* concurrence correctly explained "acting 'as a physician' does not invariably mean acting as a *good* physician, as an objective understanding of the 'in the course of professional practice' standard would suggest." *Ruan*, 597 U.S. at 479 (Alito, J., concurring). "A doctor who makes negligent or even reckless mistakes in prescribing drugs is still 'acting as a doctor'—he or she is simply acting as a *bad doctor*." *Id.*

If Congress wished to render every doctor who issued a prescription for a controlled substance in violation of the standard of care a drug dealer under §841, they could have done so. However, if Congress had intended such a radical departure from previous policy, one would expect them to have said as much.

Unless and until this Court speaks with greater clarity on what it is that renders a prescription "unauthorized," district and circuit courts will continue to struggle over the "ambiguous" language of § 1306.04. There is a significant difference between a medical practitioner who is sloppy in his record keeping, or who deviates from medical norms in what he believes to be in the best interest of his patients, and one who simply uses his medical licenses as a cover for drug

dealing "as conventionally understood." This is a policy area that Congress explicitly reserved to the states.

III. REVIEW BY THIS COURT IS NECESSARY TO CLARIFY THAT COURTS HAVE A DUTY TO DISCERN THE BEST MEANING OF CRIMINAL STATUTES WITHOUT DEFERRING TO EXECUTIVE INTERPRETATIONS.

At its core, this case is about authorization. But the authorization at the heart of this case runs deeper than that described in the CSA. The decision below and similar decisions in other circuits put at issue the authority to define crimes and the authority to say what the law is.

This Court has long recognized that "[o]nly 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)). As such, "[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*, 471 U.S. at 424 (citing *Hudson*, 7 Cranch 32).

The judiciary, too, plays a vital role in the criminal law: "It is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. 137, 177 (1803). And this Court has "never held that the Government's reading of a criminal statute is entitled to any deference." *United States v. Apel*, 571 U.S. 359, 369 (2014). "Indeed. Judges have always been expected to apply their 'judgment' *independent* of the political branches when interpreting the laws those branches enact." *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2273, 219 L. Ed. 2d 832 (2024) (citing The Federalist No. 78, p. 523 (J. Cooke

ed. 1961) (A. Hamilton)). "The critical point is that criminal laws are for courts, not for the Government, to construe." *Abramski v. United States*, 573 U.S. 169, 191 (2014).

Lower courts, however, have ceded their authority and abdicated their duty to say what the law is to the executive. In this case, rather than employing the traditional tools of statutory construction to reach the best interpretation of the CSA, the Seventh Circuit deferred to the regulatory definition of an "effective prescription" and held that a prescription that falls outside of that standard is not authorized for purposes of § 841. In doing so, the court did not undertake a thorough analysis of the statute's text, structure, and history. Instead, the court spent less than one paragraph discussing the text of the statute and concluded that CFR § 1306.04 "pulls . . . together" requirements from different parts of the CSA. *Hofschulz*, 105 F.4th at 929.

A critical flaw in the Seventh' Circuit's analysis is that ignores a basic principle of statutory construction—"statutory language cannot be construed in a vacuum." *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme," *id.*, but the court below jettisoned this fundamental canon in favor of deference to the regulation. The Seventh Circuit cited this Court's opinion in *Gonzales* to support its holding that the regulation defines authorization for purposes of § 841. Its opinion, however, suffers from the same flaw as the government's argument in

Gonzales; "it cannot, and does not, explain why the Attorney General has the authority to decide what constitutes an underlying violation of the CSA in the first place." *Gonzales*, 546 U.S. at 262.

Even more troubling, by deferring to the regulatory language rather than the statutory requirement of authorization in construing § 841's *mens rea*, the court below sanctioned the executive branch in "aggrandizing its power at the expense of" both the legislative and judicial branches. *See Freytag v. Comm'r*, 501 U.S. 868, 878 (1991). This Court has recognized that the "vague, highly general language of the regulation" is "'ambiguous,' written in 'generalities, susceptible to more precise definition and open to varying constructions.'" *Ruan*, 597 U.S. at 464, 459 (quoting *Gonzales*, 546 U.S. at 258). And this Court has warned that "language of such a standardless sweep allows policemen, prosecutors, and juries to pursue their personal predilections." *Smith v. Goguen*, 415 U.S. 566, 575 (1974).

Here, however, the legislature did not "abdicate [its] responsibilit[y] for setting the standards of the criminal law." *See id.* To the contrary, in passing the CSA, "Congress sought to change the fact 'that "criminal prosecutions" in the past had turned on the opinions of federal prosecutors.'" *Gonzales*, 546 U.S. at 266 (quoting *Moore,* 423 U.S. at 144). The text of § 841 is clear: "Except as authorized by this subchapter . . . ." 21 U.S.C.A. § 841(a). "Applying § 841's 'knowingly or intentionally' *mens rea* to the authorization clause thus . . . helps to diminish the risk of 'overdeterrence,' *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line." *Ruan*, 597 U.S. at 459

(quoting *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978)). And, by setting a clear standard, adherence to the statutory language in defining § 841's *mens rea* limits limit the ability of prosecutors and law enforcement to pursue their own predilections.

The regulation, on the other hand, "gives little or no instruction on [the] central issue in this case: Who decides whether a particular activity is in 'the course of professional practice' or done for a 'legitimate medical purpose'?" *Gonzales*, 546 U.S. at 257. Under the vague regulatory language, that task is left to "clever prosecutors riffing on equivocal language." *See Dubin v. United States*, 599 U.S. 110, 129–30 (2023).

"In the business of statutory interpretation, if it is not the best, it is not permissible." *Loper Bright*, 144 S. Ct. at 2266. As with other statutes, § 841 "has a best meaning, necessarily discernible by a court deploying its full interpretive toolkit." *See id.* at 2271. Review by this Court is necessary to ensure that lower courts fulfil their duty to reach the best meaning when interpreting criminal statutes.

CONCLUSION

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

Respectfully Submitted,

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