No. _____

IN THE

Supreme Court of the United States

SHAKEEL A. KAHN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Controlled Substances Act makes dispensing controlled substances unlawful "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). Section 822(b) grants registered practitioners authority subject to their registration and the statute. An administrative regulation, 21 C.F.R. § 1306.04(a), separately defines an "effective" prescription by reference to "legitimate medical purpose" and the "usual course" of professional practice. In *Ruan v. United States*, 597 U.S. 450, 455 (2022), this Court assumed the regulatory definition while deciding the required mens rea. The court below held that *United States v. Moore*, 423 U.S. 122 (1975), foreclosed petitioner's challenge to that definition. The questions presented are:

1. Whether *Moore* should be reconsidered and overruled or limited in light of *West Virginia v. EPA*, 597 U.S. 697 (2022), and *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), because § 1306.04(a) cannot define the scope of criminal culpability under § 841 independently of the statute, and *Ruan*'s knowledge requirement does not cure that defect.

2. Whether, independently of the regulation's use to define a criminal offense, the Attorney General exceeded the authority delegated by the CSA in promulgating § 1306.04(a) as a substantive medical-practice limitation on a registered practitioner's prescribing authority.

PARTIES TO THE PROCEEDINGS

Petitioner Shakeel A. Kahn was the defendant-appellant below. Respondent United States of America was the plaintiff-appellee below.

RELATED PROCEEDINGS

United States v. Kahn, No. 2:17-cr-00029-ABJ (D. Wyo.). Order denying post-trial relief entered August 14, 2024; sentence imposed January 3, 2025; criminal judgment entered January 10, 2025.

United States v. Kahn, No. 25-8004 (10th Cir.). Judgment affirming the retrial convictions entered August 20, 2026.

Kahn v. United States, No. 21-5261 (U.S.), decided with *Ruan v. United States*, No. 20-1410, 597 U.S. 450. Judgment entered June 27, 2022.

United States v. Khan, Nos. 19-8051 and 19-8054 (10th Cir.), 989 F.3d 806. Decision affirming the original convictions entered February 25, 2021. On remand in No. 19-8054, *United States v. Kahn*, 58 F.4th 1308, decision vacating petitioner's convictions entered February 3, 2023.

United States v. Kahn, No. 18-8079 (10th Cir.). Decision concerning pretrial detention entered May 6, 2019.

United States v. Kahn, No. 17-8035 (10th Cir.), 890 F.3d 937. Decision concerning seized assets and retained counsel entered May 17, 2018.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Shakeel A. Kahn respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Tenth Circuit.

OPINIONS BELOW

The court of appeals issued a published opinion on August 20, 2026, in *United States v. Kahn*, No. 25-8004, affirming petitioner's convictions following retrial. The opinion is reproduced at App. 1a–38a, and the notice of entry of judgment at App. 39a. "App." refers to the separately bound appendix to this petition. The district court's order denying petitioner's motion for judgment of acquittal or a new trial was entered August 14, 2024, as ECF No. 1373 in No. 2:17-cr-00029-ABJ (D. Wyo.). That order is reproduced at App. 50a–114a. The district court's order on expert testimony was entered October 27, 2023, as ECF No. 1238. App. 115a–129a. The October 17, 2023 order addressing authorization and mens rea, ECF No. 1219, is reproduced at App. 130a–135a. The criminal judgment was entered January 10, 2025, as ECF No. 1386. App. 40a–49a.

JURISDICTION

The court of appeals entered judgment on August 20, 2026. No petition for rehearing was filed. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Article I, Section 1, of the Constitution vests "[a]ll legislative Powers herein granted" in Congress. The Fifth Amendment provides that no person shall be deprived of liberty without due process of law.

Section 841(a)(1) of Title 21 provides: "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."

Section 822(b) provides that registered persons "are authorized to possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." Section 802(21) defines "practitioner" to include a physician licensed, registered, or otherwise permitted to distribute or dispense a controlled substance "in the course of professional practice or research."

Section 821 authorizes the Attorney General to promulgate rules and regulations "relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals." Section 871(b) permits rules, regulations, and procedures deemed necessary and appropriate "for the efficient execution of his functions under this subchapter." Section 842(a)(1) separately prohibits distribution or dispensing in violation of § 829, the statute governing prescriptions.

The relevant text of 21 C.F.R. § 1306.04(a), together with additional statutory and regulatory provisions, is reproduced in the statutory addendum following the petition and at App. 136a–139a. The challenge concerns the provisions applicable to the charged conduct, not subsequent changes in prescription procedures.

INTRODUCTION

This case returns to the Court because the question left assumed in *Ruan v. United States*, 597 U.S. 450 (2022), has become the premise on which the Government claims authority to define a federal felony. *Ruan* held that § 841's knowledge requirement reaches the absence of authorization. It did not decide whether the Attorney General possessed authority to promulgate

the substantive prescribing standard in 21 C.F.R. § 1306.04(a), or whether that regulation can supply the legal boundary of § 841's authorization exception. Those are the questions now presented.

In the Controlled Substances Act, Congress made distribution unlawful "[e]xcept as authorized by this subchapter." It did not say except as authorized by whatever medical practice standard the Attorney General might adopt. Yet the Government maintains that a regulation governing an "effective" prescription supplies the controlling definition of criminal authorization. That proposition does two different kinds of work, each requiring its own statutory justification. It gives the Executive power to prescribe a substantive medical standard. It then gives that standard the force of a felony element. Neither proposition follows merely because the regulation has long appeared in the Code of Federal Regulations.

The court of appeals regarded *United States v. Moore*, 423 U.S. 122 (1975), as dispositive. Petitioner argued that *Moore* was wrongly decided and that a regulation could not define the criminal prohibition Congress enacted. The panel answered that it "must follow Supreme Court precedent and reject his argument." App. 38a. Only this Court can provide the reconsideration the panel regarded as foreclosed.

West Virginia v. EPA, 597 U.S. 697 (2022), and *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), require that reconsideration. *West Virginia* requires clear congressional authorization for an agency's assertion of extraordinary regulatory power. *Loper Bright* requires courts to determine statutory meaning independently and to enforce the limits of delegated authority. Together with *Gonzales v. Oregon*, 546 U.S. 243 (2006), those decisions expose the defect in treating a general administrative rulemaking provision as authority to establish a nationwide medical standard carrying drug trafficking penalties.

Petitioner does not contend that this Court has yet expressly invalidated § 1306.04. Nor does he contend that *Loper Bright* quietly overruled *Moore* directly. He asks the Court to reconsider *Moore* expressly and to hold that the regulation cannot define § 841's criminal boundary. Independently, he challenges the Attorney General's authority to have promulgated § 1306.04(a)'s substantive medical-practice restriction in the first place. Even if some prescription administration applications of the regulation are permissible, that would not establish either the challenged substantive authority or the separate power to define felony culpability.

The record presents that distinction concretely. Throughout the evidence, government experts employed the regulatory definition of authorization under the district court's pretrial ruling. At the conclusion of the evidence, the court adopted petitioner's proposed statute-based instruction. It then denied a new trial because it presumed the jury followed that instruction and considered the evidence of guilt substantial. The court of appeals, however, held that the challenged regulatory testimony was legally proper, and rejected the underlying statutory challenge as foreclosed by *Moore*. This petition acknowledges the final instruction and the district court's prejudice analysis. It seeks review of the antecedent legal questions actually resolved against petitioner, followed by application of the correct law to the preserved trial challenge.

STATEMENT OF THE CASE

A. The prosecution and this Court's decision in *Ruan*

Petitioner operated medical practices in Arizona and Wyoming and held DEA registrations authorizing him to prescribe controlled substances. The operative indictment alleged that he used those practices to issue prescriptions outside the usual course of professional practice and without legitimate medical purpose. Third Superseding Indictment 2–3, ECF No.

356. At retrial, the district court instructed the jury that petitioner was a registered practitioner at all times relevant to the charges. Aplt. App. XXI at 51.

The charges included controlled-substance distribution and aiding and abetting, conspiracy with a death-resulting allegation, use of a communication facility, a continuing criminal enterprise, money laundering, and possession of firearms in furtherance of a drug-trafficking crime. App. 5a–6a & n.2. Petitioner's first trial resulted in convictions that the Tenth Circuit affirmed. *United States v. Khan*, 989 F.3d 806 (10th Cir. 2021).

This Court granted certiorari and considered petitioner's case in *Ruan*. The Court held that once a defendant produces evidence of authorization, the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted without authorization. *Ruan*, 597 U.S. at 454, 467–468. The Court rejected an objective good-faith standard that would measure criminal liability by the mental state of a hypothetical reasonable doctor. Id. at 465–467. On remand, the Tenth Circuit vacated petitioner's convictions because the instructional error affected the interrelated counts. *United States v. Kahn*, 58 F.4th 1308, 1321–1322 (10th Cir. 2023) (*Kahn II*).

B. The contested legal standard at retrial

Before retrial, petitioner challenged the use of § 1306.04 to define authorization and proposed an instruction grounded in medical purpose and the statutory concept of professional practice. The district court initially rejected that position and ruled that authorization would be defined by the regulation. App. 55a–56a. The Government's witnesses then used that definition. DEA Diversion Investigator Robert Churchwell described § 1306.04 as a regulation authorizing practitioners to prescribe, and government medical experts incorporated its criteria into their opinions. Aplt. App. II at 137; id. V at 19–21; App. 56a. Petitioner objected to the use of

witnesses to supply the governing legal standard. Aplt. App. I at 159–172; id. II at 138; Aplt. Opening Br. 21–26.

The Government's factual case was substantial and disputed. It offered evidence of recurring high-dose prescriptions, payments linked to the quantity prescribed, prescriptions issued without examinations, and patients who obtained pills for redistribution. App. 3a–5a, 19a–33a. Petitioner testified that his treatment philosophy involved prescribing sufficiently high doses to alleviate pain, improve quality of life, and prevent pain from becoming chronic, provided that side effects remained tolerable. App. 59a n.3. The question for the jury was whether the charged conduct constituted knowing unauthorized distribution, not whether government witnesses approved of his treatment methods.

The district court ultimately changed its position on the legal definition. During the final instruction conference, the prosecutor insisted that § 1306.04 remained the law defining authorization. Aplt. App. XXI at 22–27 (App. 143a–148a). Defense counsel responded that the statutory instruction did not prevent the Government from using departures from medical standards as circumstantial evidence of knowledge. Id. at 27–28 (App. 148a–149a). The dispute concerned whether those standards themselves supplied the legal restriction, not whether evidence of medical practice was categorically inadmissible.

The court gave petitioner's requested definition with minor changes. Instruction No. 20 explained that professional practice means practicing medicine, that a practitioner must act for a medical purpose and believe the treatment medically legitimate, and that a prescription issued for a purpose foreign to medicine is unauthorized. It separately required proof that petitioner knew or intended the prescription to be unauthorized. Aplt. App. XXI at 51–52 (App. 163a–164a); App. 57a–58a. The court also cautioned that malpractice, negligence, and medical-board

violations were insufficient. Aplt. App. XXI at 53–54 (App. 165a–166a). Regulatory and statutory exhibits were not to be sent into the jury room. Id. at 38–39 (App. 159a–160a).

After a 25-day retrial, the jury convicted petitioner on seventeen counts and acquitted him on four. App. 51a–53a. Petitioner sought a new trial because the evidence had been presented through a different legal definition of authorization, including expert opinions founded on that definition. The district court rejected the claim. It presumed the jury followed its final instructions, noted that both sides conformed their closings to Instruction No. 20, and found the evidence undermining petitioner's account substantial. App. 58a–60a. Petitioner received an aggregate sentence of 300 months. App. 7a.

C. The decision below

On appeal, petitioner challenged both the experts' legal testimony and the use of § 1306.04 as the source of criminal authorization. He argued that the Attorney General lacked the asserted rulemaking authority, that the regulation implemented the prescription provisions rather than § 841, and that *Moore* required reconsideration. Aplt. Opening Br. 21–28, 43–50; Aplt. Reply Br. 15–23.

The court of appeals affirmed. It held that *Ruan* permitted reliance on the regulation and that the challenged expert testimony did not constitute impermissible legal opinion. App. 9a–12a. When petitioner argued that authorization supplies the dividing line between lawful medicine and felony liability, the panel answered that the dividing line was the mens rea requirement. App. 12a. The panel also rejected petitioner's statutory challenge because *Moore* held that registered physicians may be prosecuted when they act outside the usual course of professional practice. App. 37a–38a.

The panel declined to resolve the Government's waiver and law-of-the-case arguments concerning the general expert challenge because it rejected that challenge on the merits. App. 8a n.3. It separately declined to consider Dr. Shay's "just as guilty" statement because defense counsel elicited it without objection and did not request plain-error review. App. 12a–13a. Petitioner's questions do not depend on obtaining review of that isolated statement. They concern the governing statutory standard, the authority to promulgate it, and the broader expert testimony upheld on the merits.

REASONS FOR GRANTING THE PETITION

I. *Moore* should be reconsidered because an administrative prescription standard cannot supply the criminal prohibition Congress chose to enact

A. The statute makes authorization a question of enacted law

Section 841 begins with a limitation: "Except as authorized by this subchapter." The reference is explicitly to the legislation Congress enacted. Section 822(b), in turn, affirmatively authorizes registered persons to dispense controlled substances within their registration and in conformity with the subchapter's other provisions. The statute therefore requires courts to identify the relevant statutory restriction and decide whether the charged conduct violated it. It does not permit the Government to replace that inquiry with the assertion that a prescription failed an administrative definition of effectiveness.

The distinction is essential in a statute that separately regulates registration, prescription procedures, recordkeeping, distribution, and criminal punishment. Those provisions cannot all be collapsed into § 841 merely by describing noncompliance as a loss of authorization. Congress's decision to impose a particular obligation and assign it a particular consequence must have operative significance.

Section 842(a)(1) demonstrates the point. It expressly addresses dispensing in violation of § 829. Section 842(a)(2) separately addresses certain transfers of substances not authorized by a registration. Congress also prescribed distinct penalties for the conduct covered by § 842, including knowing violations. If every failure to satisfy a prescription requirement necessarily eliminated authorization under § 841, the prosecutor could convert the specifically addressed violation into a trafficking felony through the definition of authorization alone. The text does not require that result, and the statutory structure strongly counsels against it.

Petitioner does not argue that overlapping offenses are impossible or that the existence of § 842 immunizes conduct independently satisfying § 841. The necessary proposition is narrower: a violation of a prescription rule cannot substitute for proof of the statutory basis that makes the conduct a § 841 offense. The same evidence may establish both offenses, but the legal requirements must remain distinct.

The regulation's own wording confirms the distinction. Section 1306.04(a) describes what makes a prescription "effective," and its operative reference is to a prescription within the meaning of § 829. Its concluding reference to penalties for violations of controlled-substance laws does not identify § 841 or create an independent statutory offense. A regulation cannot confer on itself the authority to determine which penalty Congress intended.

The contemporaneous scope provision is equally revealing. During the charged conduct, § 1306.01 specifically identified Part 1306 as rules governing issuance, filling, and filing of prescriptions *pursuant to § 829*. 21 C.F.R. § 1306.01 (2016) (emphasis added). The relevant provisions thus distinguished a prescription's regulatory effectiveness from the statutory source of a registrant's authorization. Even assuming the regulation was validly issued for prescription

administration, it does not follow that Congress incorporated its every substantive limitation into § 841.

B. The text does not confer categorical immunity on physicians, but neither does it delegate a general power to define criminal medicine

The Government's predictable response is that registration cannot authorize drug trafficking merely because the trafficker holds a medical credential. Petitioner's position does not require that conclusion. Section 802(21) describes a practitioner by reference to professional practice. Section 822(b) limits authorization to the registration and the statute. Conduct genuinely outside the practice of medicine may fall outside that statutory authorization. But the court must establish that boundary by interpreting the Act, not by treating the Attorney General's formulation as a substitute for it.

The difference matters where a physician acts for a medical purpose while knowingly using an unusual treatment method. Unusual treatment, a disputed therapeutic judgment, and prescribing for a nonmedical purpose are not interchangeable concepts. The phrase "usual course" can become a mechanism for replacing the statutory distinction between medicine and nonmedical distribution with an expert's judgment about conformity to professional norms. Neither a standard-of-care opinion nor knowledge of nonconformity establishes, by definition, the absence of statutory authorization.

Justice Alito's concurrence in *Ruan* articulated a statute-based account of professional medical practice: a physician acts for a medical purpose and believes the treatment is a medically legitimate means of addressing the condition. 597 U.S. at 479 (Alito, J., concurring in the judgment). That concurrence is not the Court's holding, but it demonstrates that the regulatory formulation is not the only available account of the statutory text. The district court ultimately

used a similar approach here. App. 56a–58a. The Court should now determine the governing law rather than allow an assumed regulatory premise to control it.

Congress has expressly used language resembling the regulation where it chose to do so. Section 829(e)(2)(A), governing the internet-dispensing subsection, defines a valid prescription by reference to medical purpose and the course of professional practice, together with specified evaluation requirements. That provision must be respected within its stated scope. It is not a general delegation to the Attorney General to define authorization throughout § 841, and these convictions were not prosecutions under that internet-specific provision. Congress's targeted use of the language demonstrates that it can legislate such requirements directly. Courts should not remove the limits Congress placed on its enactment and use a regulation to give the language universal criminal reach.

C. *Moore* did not resolve the distinct delegation and penalty questions presented here

Moore rejected the proposition that registration itself categorically exempted a physician from § 841. 423 U.S. at 131–132. It also held that registered physicians may be prosecuted when their activities falls outside the usual course of professional practice. Id. at 124. The decision relied on statutory structure, the history of federal narcotics law, and the character of the defendant's activity. Petitioner recognizes the breadth of that holding and asks this Court to reconsider it to the extent it permits an extra-statutory professional-practice standard to define criminal authorization.

But *Moore* did not conduct the inquiry now required into the Attorney General's asserted delegation to determine the substantive medical standard. Its discussion of the prescription regulation arose in addressing § 829 and the possibility of liability under § 842. Id. at 135–138 & nn.12–13. It did not hold that an agency's prescription rule automatically supplies all the content

of § 841's authorization clause, much less decide that §§ 821 and 871 confer a general power to determine the permissible practice of medicine through felony prosecutions.

Moore described § 822(b)'s authorization language as circular and looked beyond it to determine the limitations Congress intended. Id. at 140–141. But interpretive difficulty does not authorize an administrative solution to the meaning of a criminal statute. *Loper Bright* counsels that uncertainty about statutory meaning remains a judicial responsibility, including uncertainty about the extent of an agency's power. 603 U.S. at 400–402. A court may not resolve the problem by assuming the Executive possesses the authority whose existence is disputed.

The Court can preserve the proposition that a physician's credentials do not immunize ordinary drug trafficking while rejecting the proposition that the Attorney General may define a wider class of criminal prescribing. To the extent *Moore* itself requires the latter result, it should be overruled. To the extent later decisions have extended *Moore* beyond its statutory holding, this Court should confine it. Either course requires rejecting the panel's conclusion that invoking *Moore* ends the inquiry.

II. The Attorney General exceeded the CSA's delegation by promulgating a substantive medical-practice limitation in section 1306.04(a)

A. Sections 821 and 871 authorize execution of assigned functions rather than creation of a new substantive power

The challenge to promulgation is independent of the regulation's criminal use. Even if § 841 expressly incorporated valid regulations, the Government would still have to show that this regulation was within the authority Congress delegated. Conversely, even if the regulation were valid for some administrative purposes, the Government would still have to establish why it defines § 841's felony prohibition. The two inquiries cannot be answered by citing each other.

The Government invoked §§ 821 and 871(b) below. Gov't C.A. Br. 12–13. Section 821 concerns rules relating to registration and control. Section 871(b) concerns efficient execution of the Attorney General's statutory functions. Neither provision identifies a general power to declare which treatment purposes are medically legitimate or which modes of professional practice are sufficiently usual to avoid criminal prohibition.

Congress expressly defined the authority on which the Government relies. Section 821 permits rules relating to registration and "control," but Congress did not leave the latter term open-ended. Section 802(5) defines control in terms of adding a drug or other substance to a schedule, including transfer from another schedule. Section 802 makes that definition applicable throughout the subchapter, which includes § 821. A rule establishing which medical purposes and prescribing practices are permissible does not add a substance to a schedule or transfer it between schedules. The Government therefore cannot establish the necessary delegation merely by invoking the ordinary breadth of the word "control." Congress supplied a narrower meaning.

Gonzales v. Oregon applied that definition to § 821 itself. 546 U.S. at 259–262. The Court rejected the Attorney General's attempt to derive authority to define medical-practice standards from his power to control drugs. It reasoned that the challenged interpretive rule did not concern scheduling and therefore did not fall within that delegated power. Id. at 260. Justice Scalia disputed the application of § 802(5)'s definition to § 821, but that objection appeared in dissent. Id. at 282–283 (Scalia, J., dissenting). The majority's construction supplies direct statutory support for petitioner's challenge, independent of any broader dispute about administrative deference.

Oregon also supplied an alternative ground that forecloses reliance on a broader understanding of control. Even on that understanding, authority to establish measures against

diversion does not confer authority to define diversion according to the Attorney General's own view of legitimate medical practice. Id. at 260–261. Otherwise, the specified limits on registration and scheduling authority would cease to constrain the agency. That distinction matters here: asserting that § 1306.04(a) prevents diversion cannot answer whether Congress authorized the Attorney General to create the disputed substantive standard for defining diversion in the first place.

Section 821 also authorizes rules relating to registration. But authority to administer registration and apply Congress's specified grounds for denying or revoking it does not, without more, authorize a substantive medical practice restriction defining when a registered physician becomes a drug trafficker. Nor does § 871(b) fill that gap. Its authority to execute assigned statutory functions presupposes a function that Congress has expressly assigned; it does not create an additional function of defining permissible medical practice. See *Oregon*, 546 U.S. at 261–265. The Government must identify the delegation that supports the particular restriction, not merely an administrative responsibility to which that restriction might relate.

Oregon did not invalidate § 1306.04(a), and petitioner does not claim that it did. Its reasoning nevertheless requires scrutiny of the substantive authority asserted here. The fact that the disputed limitation appears in the underlying regulation, rather than a later interpretive directive, does not enlarge the delegation. An agency cannot acquire authority by placing an unsupported substantive restriction earlier in the regulatory chain.

The distinction between administrative implementation and substantive medical governance is decisive. Congress may authorize rules concerning registration applications, records, and prescription procedures without empowering the Attorney General to establish a national standard of medical legitimacy. Petitioner challenges § 1306.04(a)'s promulgation as

that substantive limitation. He does not need to establish that every provision in Part 1306, or every application of a prescription rule, is invalid.

B. The Act's specific delegations foreclose the asserted general delegation

Where Congress intended executive action to affect the reach of controlled substance prohibitions, it supplied concrete authority and conditions. Scheduling is the clearest example. In *Touby v. United States*, 500 U.S. 160, 165–167 (1991), the Court upheld temporary scheduling authority against a delegation challenge because Congress had constrained the authority with substantive requirements and procedures. *Touby* does not establish that every rule touching controlled substances falls within the Attorney General's power. It requires attention to the statutory grant actually made.

The prescription provisions likewise allocate particular responsibilities. Section 829(a) assigns the Secretary the role of prescribing emergency circumstances for oral Schedule II prescriptions, after consultation with the Attorney General. Section 829(e) legislates particular substantive requirements for internet dispensing. Sections 823 and 824 establish registration and revocation mechanisms. These provisions reflect explicit congressional choices about the decisionmaker, the subject, and the consequence in specifically enumerated circumstances. They do not support a residual power to define medical practice whenever the Attorney General considers it helpful to enforcement.

The Government's reading would invert that structure. The more consequential authority, defining the substantive boundary used to expose physicians to lengthy imprisonment, would arise from general execution language. The less consequential administrative authorities would be the ones Congress carefully described. Nothing in the Act requires or supports that inversion.

Oregon also recognized the CSA's division between federal control of drug trafficking and the States' traditional regulation of medical practice. 546 U.S. at 269–275. Section 903 preserves state law absent a positive conflict. These provisions do not make state approval conclusive or prevent federal prosecution of a physician. They do make it implausible that Congress silently authorized the Attorney General to set a comprehensive federal standard of permissible treatment through §§ 821 and 871.

C. *West Virginia* requires clear authorization for this extraordinary assertion of power

The power claimed here is not merely authority to require a name on a prescription or maintain a dispensing record. It is authority to decide, through an open-ended medical practice standard, which acts of registered physicians fall outside authorization and expose them to federal trafficking penalties. That claim reaches the treatment of pain, the selection and dosage of controlled medications, the relationship between medical innovation and prevailing practice, and the division of authority between federal prosecutors and state medical regulators.

West Virginia requires more than a plausible reading of broad administrative language when an agency claims power of extraordinary economic and political significance. 597 U.S. at 721–724. The Government must identify clear congressional authorization for the power it asserts. Here the asserted authority is especially consequential because the regulatory boundary determines exposure to imprisonment rather than merely a condition of administrative compliance.

The regulation is longstanding, and the Government will rely on that history. But longevity does not answer the question of delegation. The claimed power remains the power to determine substantive medical legitimacy with felony consequences. Nor is petitioner arguing that every old regulation presents a major question. The exceptional features are the breadth of

the medical authority claimed, the severity of the consequences, the intrusion into a traditionally state-regulated field, and Congress's detailed allocation of narrower federal powers.

Oregon is particularly instructive because *West Virginia* itself drew on that decision's rejection of an expansive claim to regulate medical practice under the CSA. *West Virginia*, 597 U.S. at 722. The reasoning applies with still greater force when the claimed medical standard is offered as the legal measure of a felony. At a minimum, ordinary statutory interpretation under *Oregon* defeats the asserted delegation even if the Court concludes that no separate major-questions analysis is necessary.

III. *Loper Bright* and criminal separation-of-powers principles require independent statutory judgment at both stages

A. A regulation cannot manufacture the delegation or its own criminal consequences

Loper Bright holds that courts must exercise independent judgment in deciding whether an agency acted within its statutory authority. 603 U.S. at 412–413. It does not eliminate valid delegations or prevent courts from giving persuasive weight to agency expertise. It does prohibit treating ambiguity as permission to surrender the judicial responsibility to determine what Congress authorized.

That responsibility has two applications here. The court must decide whether Congress delegated the substantive medical rulemaking authority. It must then decide whether the criminal statute gives the resulting rule the significance the Government claims. Saying that § 1306.04 defines authorization assumes both conclusions. Neither can be established by the rule's own text or its repetition in prior opinions that did not decide these questions.

Oregon described § 1306.04 as largely restating or summarizing statutory language and held that a parroting regulation does not change the inquiry from statutory meaning to regulatory

meaning. 546 U.S. at 257. That reasoning supplies an additional answer to the Government. If the regulation merely restates the statute, it has no independent power to enlarge the criminal prohibition. If its modifiers impose restrictions beyond the statute, those additions require a delegation that the Government must identify. On neither understanding does the regulation itself resolve the question presented.

B. Criminal liability requires a legislative foundation distinct from regulatory validity

The principle here is older than *Chevron*. *United States v. Eaton*, 144 U.S. 677, 688 (1892), rejected criminal punishment for failing to perform an administratively prescribed duty where Congress had not sufficiently made that omission criminal. *United States v. Grimaud*, 220 U.S. 506, 519–521 (1911), upheld criminal enforcement of regulations where Congress had supplied the relevant authority and made violation punishable. Those decisions do not forbid all regulation-backed crimes. They require the legislative foundation that the Government's theory assumes here.

The distinction between authority to administer a statute and authority to define a crime cannot disappear because both concern controlled substances. Congress supplied criminal penalties in § 841, but it also supplied an authorization exception and separate provisions governing prescription violations. The Executive cannot enlarge the prohibition by issuing a narrower account of the exception than the enacted law supports.

United States v. Davis, 588 U.S. 445, 451 (2019), explains why the allocation matters: defining crimes is a legislative responsibility, and indeterminate criminal rules risk transferring that responsibility to prosecutors and judges. The concern here is the absence of congressional authorization for the asserted substantive rule, not the combination of regulatory and prosecutorial functions within the Executive. *Touby* rejected the latter objection to properly

delegated scheduling authority. 500 U.S. at 167–168. Petitioner instead challenges the legislative foundation for the particular medical-practice restriction used in this prosecution.

Petitioner does not present an independent facial vagueness challenge as an additional question for review. The uncertainty of the regulatory terms instead reinforces the statutory and separation-of-powers arguments. A strong scienter requirement reduces the risk of punishing an innocent mistake. It does not supply missing legislative authority for the substantive prohibition, nor authorize prosecutors to define its scope case by case. If genuine ambiguity remains after examining the statutory text, structure, and delegated powers, lenity favors the narrower criminal construction. See *Liparota v. United States*, 471 U.S. 419, 427 (1985).

IV. *Ruan*'s mens rea requirement cannot cure an unauthorized definition of the underlying offense

A. *Ruan* assumed the regulatory premise and did not adjudicate its validity

Ruan expressly stated that the Court assumed, as had the parties and the lower courts, that a prescription was authorized if it satisfied the regulatory standard. 597 U.S. at 455. The decision then addressed the mental state required for conviction. An assumption made to decide that question is not a holding that the regulation was validly promulgated or that it supplies the exclusive statutory definition of authorization.

The panel treated *Ruan*'s later references to objective prescribing criteria as resolving that antecedent issue. App. 10a–12a, 38a. But the Court's explanation that those criteria can help prove knowledge does not transform them into an independently authorized source of criminal law. *Ruan* allowed circumstantial proof of subjective knowledge. 597 U.S. at 467. It did not dispense with the need to identify, under the statute, the legal boundary the defendant must knowingly cross.

Nor did *Ruan* settle the meaning of *Moore* against petitioner. It rejected reliance on *Moore* as having already resolved the mens rea issue because *Moore* had not addressed that question. Id. at 466. The same discipline is required here. The holding that registered physicians can be prosecuted does not resolve every question about the agency's power to define the conduct for which they can be prosecuted.

B. The Government must prove knowledge of statutory nonauthorization rather than merely knowledge of a professional departure

The panel's response to petitioner illustrates the unresolved problem. When petitioner identified authorization as the central dividing line between lawful practice and federal felony liability, the court answered that the dividing line was *mens rea*. App. 12a. But the statute requires both an unauthorized act and the applicable culpable mental state. A knowledge requirement cannot tell the court which acts Congress prohibited. It operates only after that legal question has been answered.

Ruan relied on *Liparota*, which required proof that the defendant knew his acquisition or possession was unauthorized, not merely that he knowingly engaged in the underlying transaction. *Ruan*, 597 U.S. at 460; *Liparota*, 471 U.S. at 425, 434. The Government may prove that knowledge circumstantially and need not establish mastery of statutory citations. But awareness of facts constituting a departure from professional norms cannot automatically replace knowledge of the legally relevant lack of authorization.

The distinction also explains why no categorical bar to standard-of-care testimony is sought. A physician's failure to examine patients, implausible treatment explanations, or knowing participation in diversion may provide powerful evidence of a nonmedical purpose or knowledge of unauthorized conduct. The strength of that evidence does not entitle a witness to declare that deviation from the regulatory standard is itself the legal event that removes statutory

authorization. Evidence bearing on a statutory element and a rule defining that element perform different functions.

Kahn II recognized that the regulation's objective criteria may furnish circumstantial evidence of subjective intent rather than independent substitutes for the knowledge required by *Ruan*. 58 F.4th at 1315–1316. The petition asks this Court to complete that analysis by determining the statutory meaning of authorization and the limits of the Executive's power to prescribe it. It does not seek a renewed holding that negligence alone is insufficient. *Ruan* already supplies that protection.

V. The reasons for reconsidering *Moore* satisfy statutory stare decisis

A. Petitioner seeks express reconsideration rather than an inference that *Moore* has disappeared

Moore is a statutory precedent of long standing. *Loper Bright* expressly preserved statutory stare decisis for earlier holdings and explained that reliance on *Chevron* alone is not a special justification for overruling them. 603 U.S. at 412. *Moore* also predates *Chevron*. Petitioner therefore does not argue that the elimination of *Chevron* mechanically disposes of this case.

The justification is cumulative and more specific. *Moore*'s open-ended professional practice formulation has been used to answer delegation and criminal incorporation questions it did not analyze. *Oregon* subsequently rejected the broad account of the Attorney General's medical authority on which that use depends. *Ruan* required a sharper separation between culpable intent and objective professional standards. *West Virginia* and *Loper Bright* now demand identification of actual delegated power and independent interpretation of the statute.

Those developments require reconsideration of the operative rule, not merely substitution of one interpretive preference for another.

The Tenth Circuit was correct that it could not itself overrule this Court's precedent. See *Agostini v. Felton*, 521 U.S. 203, 237 (1997). That is why its express reliance on *Moore* supports review here. The error requiring correction is the substantive rule it regarded as binding and its extension of that rule to the disputed regulatory foundation.

B. The existing approach obscures statutory structure and produces an unstable criminal boundary

The quality of the challenged reasoning is deficient in a consequential respect. It moves from the sound proposition that registration does not immunize all conduct to the unsupported proposition that an administrative professional practice standard defines the statutory exception. That inference does not examine the distinction between §§ 829, 841, and 842 or the scope of the rulemaking grants.

The practical difficulty is visible in this record. The Government insisted that the regulation remained the legal definition of authorization. The district court ultimately adopted a different definition because it tracked the statute and focused on genuine medical purpose. The Tenth Circuit approved the regulatory evidence while treating *mens rea* as the sufficient answer to petitioner's objection. These are disagreements over what makes conduct unauthorized, not merely disagreements about the quality of an individual prescription.

The same issue recurs in other physician prosecutions. For example, *United States v. Lamartiniere*, 100 F.4th 625, 637–642 (5th Cir. 2024), rejects a challenge to the regulatory authorization standard, including reliance on *Oregon* and *West Virginia*. That adverse decision illustrates the need for this Court to resolve the premise directly. The recurring national question

is whether the regulatory premise itself is lawful. Repetition of that premise across circuits is a reason for this Court to examine it, not a substitute for doing so.

C. Reliance interests do not justify preserving a rule that expands criminal liability beyond enacted law

The Government has a legitimate interest in prosecuting knowing diversion of controlled substances. A statutory construction preserving that authority while rejecting unauthorized regulatory expansion does not defeat that interest. Nor are physicians and patients well-served by the existing uncertainty over when and whether professional disagreement constitutes a federal trafficking offense.

The longstanding enforcement regime is entitled to serious consideration. But administrative familiarity cannot create a delegated power Congress did not confer. The relief sought would not erase the CSA, invalidate its scheduling system, or immunize registered practitioners who knowingly engage in distribution outside statutory authorization. It would require the Government to establish the crime Congress enacted and require courts to define that crime independently without unearned deference to the Executive.

The Court can also avoid unnecessary disruption by confining its holding to the disputed use of § 1306.04(a) and the substantive authority asserted to support it. It need not invalidate unrelated prescription procedures or decide the treatment of every final conviction. This case is on direct review and presents a preserved challenge to the legal framework of petitioner's retrial.

VI. This case permits review of the questions actually decided while leaving record-specific remedial issues for remand

A. The questions were contested at retrial and expressly resolved on appeal

The district court's post-trial order documents petitioner's repeated objections before and during retrial to using a federal regulation to define authorization. App. 55a–57a (citing ECF

Nos. 1203, 1217, 1279, and 1286). His opening appellate brief presented the statutory and delegation arguments, and his reply developed the effect of *West Virginia* and *Loper Bright*. The panel expressly rejected the statutory challenge under *Moore* and upheld the general expert testimony on the merits. App. 8a–12a, 37a–38a.

The Government invoked petitioner's failure to challenge the regulation at the first trial and the law-of-the-case doctrine. The court of appeals declined to resolve those objections to the general testimony challenge. App. 8a n.3. The new convictions followed a retrial at which petitioner repeatedly disputed the premise, and the district court itself reconsidered that premise before instructing the jury. Those circumstances distinguish this petition from an effort to introduce a new question for the first time in this Court.

The chronology also matters. *West Virginia* was decided after petitioner's first trial and before the retrial. *Loper Bright* was decided after the retrial but before the post-trial order and the appeal now under review. Petitioner relies on those decisions as intervening authority bearing on the statutory challenge actually presented.

B. The favorable final instruction does not eliminate the adverse statutory holding or resolve the evidentiary challenge

The Government will emphasize that petitioner obtained the final authorization instruction he requested. That fact must be confronted directly. Petitioner does not claim that the final instruction simply repeated § 1306.04 or omitted *Ruan*'s subjective knowledge requirement. Aplt. App. XXI at 51–54.

The claim is that the trial evidence had been admitted and framed under the competing regulatory rule, including opinions concerning legal authorization, and that the court of appeals upheld that use as legally correct. The final instruction did not decide whether those opinions rested on a permissible legal foundation. It also did not convert testimony defining authorization

into purely medical testimony. The instruction and the admissibility of evidence offered to satisfy it present related but distinct questions.

The district court found no prejudice, relying on the presumption that juries follow instructions, and on the strength of the evidence. App. 58a–60a. Petitioner acknowledges that ruling. The court of appeals took a different route: it found the challenged testimony proper and the statutory argument foreclosed. A decision from this Court rejecting the regulatory premise would therefore change the legal basis on which the appellate challenge was adjudicated.

Petitioner's position does not depend on speculation that jurors consciously disobeyed the court. Jurors following a statute-based instruction may still give weight to an expert conclusion presented as proof of unauthorized conduct without understanding that the expert's conclusion rests on a legally different test. The relevant inquiry is the nature and effect of the improperly grounded testimony in the context of the entire trial. General instructions to apply the court's law do not make that inquiry unnecessary.

Specht v. Jensen, 853 F.2d 805, 809–810 (10th Cir. 1988) (en banc), distinguishes assistance with facts from testimony defining the governing legal parameters. The panel invoked that distinction but concluded that the regulatory testimony fell on the permissible side. App. 9a–12a. Whether the regulation supplies the law necessarily affects that assessment. Petitioner seeks resolution of the antecedent statutory questions, with any remaining prejudice and remedial issues addressed under the correct legal framework on remand.

C. The Court need not reweigh the evidence or resolve unrelated appellate issues

The panel described substantial evidence of knowing diversion and rejected petitioner's separate sufficiency challenges. This petition does not ask the Court to resolve the credibility of

those witnesses, determine the cause of Jessica Burch's death, or recount the participants in the alleged enterprise. It asks who defines the legal prohibition and what Congress authorized.

A strong government factual case does not make those questions hypothetical. Petitioner challenged the legal basis of evidence used to establish unauthorized prescribing, and the panel rejected that challenge by giving the regulation the very legal force petitioner disputes. The proper consequence of an erroneous legal framework must be considered under the applicable standards, not assumed from the fact that sufficient evidence supported other aspects of the verdict.

The Court likewise need not hold that petitioner's registration alone requires acquittal on every count. It can reject the regulatory definition, resolve the scope of the Attorney General's delegation, and remand for consideration of the affected convictions and related counts. That relief would address the questions actually decided while respecting the lower courts' role in applying the governing law to the record.

The issue will persist unless this Court resolves it. *Ruan* corrected the required state of mind while expressly assuming the substantive authorization premise. The decision below now treats *Moore* and that assumption as sufficient to close the inquiry. Neither physicians facing prosecution nor courts conducting criminal trials should be left with a felony boundary whose legislative source remains merely assumed. The Court should grant review and firmly determine it.

CONCLUSION

The petition for a writ of certiorari should be granted. The Court should reconsider and overrule *United States v. Moore* to the extent it permits an extra-statutory professional practice standard to define authorization under § 841, or alternatively confine *Moore* to its statutory holding; hold that § 1306.04(a) cannot independently define the scope of criminal culpability under § 841; and hold that the Attorney General exceeded the authority delegated by the CSA in promulgating that regulation as a substantive limitation on medical practice. The judgment should be vacated and the case remanded for application of the correct statutory framework to petitioner's preserved challenges and the appropriate relief.

Respectfully submitted,

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STATUTORY AND REGULATORY ADDENDUM

The following are relevant excerpts. Ellipses identify omitted text. The historical scope provision of § 1306.01 is reproduced as it appeared during the charged conduct.

21 U.S.C. § 802(5)

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. § 802(21)

The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

21 U.S.C. § 821

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. § 822(b)

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. § 829(a)

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 [21 U.S.C. 301 et seq.], 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 [21 U.S.C. 353(b)]. 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 U.S.C. § 829(c)

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

21 U.S.C. § 829(e)(1) and (2)(A)

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by . . . (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner.

21 U.S.C. § 841(a)(1)

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. § 842(a)(1) and (2)

It shall be unlawful for any person . . . (1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title; (2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration . . . .

21 U.S.C. § 871(b)

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. § 903

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 C.F.R. § 1306.01 (2016)

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

21 C.F.R. § 1306.04(a)

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.