

No. _____

**In the
Supreme Court of the United States**

EVANN HERRELL AND KERI MCFARLANE,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

Richard Gaines
LAW OFFICE OF RICHARD L. GAINES
625 Market St., Ste. 900
Knoxville, TN 37902

Loretta Cravens
Counsel of Record
ELDRIDGE AND CRAVENS, PC
400 W. Church Ave., Ste. 101
Knoxville, TN 37902
(865) 544-2010
lcravens@ecattorneys.law

Counsel for Petitioner McFarlane

Counsel for Petitioner Herrell

QUESTION PRESENTED

Whether, after *Ruan v. United States*, 597 U.S. 450 (2022), a jury instruction requiring proof that a physician knew the prescribing was unauthorized adequately protects § 841's subjective *mens rea* requirement when the Government relies on objective professional standards as evidence of knowledge and the district court refuses a requested instruction explaining that malpractice and deviations from the standard of care do not themselves establish criminal knowledge.

PARTIES TO THE PROCEEDINGS

Petitioners and Defendants-Appellants below

- Evann Herrell
- Keri McFarlane

Respondent and Plaintiff-Appellee below

- United States of America

Respondent and Defendant-Appellant below

- Mark Grenkoski, was a co-defendant
but is not a petitioner herein

CORPORATE DISCLOSURE STATEMENT

There are no corporate parties.

LIST OF PROCEEDINGS

U.S. District Court, Eastern District of Kentucky
No. 6:21-cr-00013-GFVT-HAI
United States, *Plaintiff* v. Herrell, et al., *Defendants*
Judgment as to Evann Herrell: May 9, 2024
Judgment as to Keri McFarlane: July 12, 2024

U.S. Court of Appeals for the Sixth Circuit
Consolidated Nos.
24-5498 (Herrell appeal);
24-5664 (McFarlane appeal);
24-5499 & 25-5017 (Grenkoski appeals)
Published: 180 F.4th 245 (6th Cir. 2026)
United States, *Plaintiff-Appellee* v.
Herrell, et al., *Defendants-Appellants*
Judgment: June 16, 2026

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS	ii
CORPORATE DISCLOSURE STATEMENT	ii
LIST OF PROCEEDINGS.....	iii
TABLE OF AUTHORITIES	ix
PETITION FOR A WRIT OF CERTIORARI.....	1
OPINIONS BELOW	1
JURISDICTION.....	1
STATUTORY PROVISIONS AND REGULATIONS INVOLVED	2
STATEMENT OF THE CASE.....	3
A. Statutory Background and the Prosecution....	3
B. The Government Relied Extensively on Objective Medical and Regulatory Standards	4
C. Petitioners Disputed Both the Medical Conclusions and the Inference of Criminal Knowledge	5
D. Petitioners Expressly Asked the District Court to Distinguish Professional Fault from Criminal Knowledge.....	6
E. The Charge Conference Confirmed that Medical Impropriety and Criminal Unauthorized Prescribing were not Interchangeable	7

TABLE OF CONTENTS (Cont.)

	Page
F. The Final Instructions Omitted Petitioners □ Requested Civil-Criminal Distinction	8
G. The Sixth Circuit Held that <i>Ruan</i> Required no Further Clarification	9
REASONS FOR GRANTING THE PETITION.....	10
I. Conflict Among the Circuits Exists as to How a Jury Must Be Instructed to Meet Ruan □ s Subjective <i>Mens Rea</i> Requirement When Objective Professional Standards Are Used to Prove Knowledge and Only This Court Can Provide a Uniform Rule.....	10
A. The Second Circuit Holds That Correct Knowledge Language Does Not Save a Charge That Permits Objective Professional Standards to Alter the Subjective Inquiry.....	12
B. The Fourth Circuit Has Relied on the Very Civil-Criminal Safeguards Petitioners Requested Here	13
C. The Fifth and Tenth Circuits Likewise Distinguish Evidence of Professional Fault from the Criminal Element Itself ..	14
D. The Eleventh Circuit Similarly Rejects Instructions in Which Objective Concepts Dilute Otherwise Correct Subjective Terminology	16
E. The Sixth, Seventh, and Third Circuits Permit a Materially Different Approach .	16

TABLE OF CONTENTS (Cont.)

	Page
F. Only This Court Can Provide a Uniform Rule	18
II. The Question Presented Goes to the Line Between Medical Error and Federal Criminal Liability That <i>Ruan</i> Was Meant to Protect	18
A. Professional Standards May Prove Knowledge, but they Cannot Become the Criminal Element Itself	19
B. The Danger is Greatest Precisely Where Medical Judgment is Contestable	20
C. An Uncertain Criminal Boundary Creates the Very Risk of Overdeterrence <i>Ruan</i> Sought to Avoid	21
III. This Court's Prior Remands Gave the Courts of Appeals an Opportunity to Implement <i>Ruan</i> ; Four Years of Experience Have Produced Divergence, Not a Uniform Rule.....	23
A. This Court Previously Returned Physician Prosecutions to the Courts of Appeals for Reconsideration Under <i>Ruan</i>	23
B. The Post- <i>Ruan</i> Decisions Show That Further Percolation is Unlikely to Eliminate the Disagreement	24
C. The Disagreement is Methodological, Not Merely Factual.....	25

TABLE OF CONTENTS (Cont.)

	Page
D. This Case Presents the Issue After Full Post- <i>Ruan</i> Development.....	25
IV. This Case is a Clean Vehicle to Resolve the Question Presented.....	26
A. The Issue was Squarely Raised and Decided Below	26
B. The § 846 Posture Presents no Obstacle to Review	28
C. This Court Can Resolve the Question as a Matter of Law Without Reweighing the Evidence	28
CONCLUSION.....	30

TABLE OF CONTENTS (Cont.)

Page

APPENDIX TABLE OF CONTENTS**OPINIONS AND ORDERS**

Opinion, U.S. Court of Appeals for the Sixth Circuit (June 16, 2026)	1a
Judgment, U.S. Court of Appeals for the Sixth Circuit (June 16, 2026)	33a
Amended Judgment (Keri McFarlane), U.S. District Court for the Eastern District of Kentucky (May 11, 2026)	35a
Amended Judgment (Evann Herrell), U.S. District Court for the Eastern District of Kentucky (May 11, 2026)	47a

OTHER DOCUMENTS

Defense Joint Motion for Jury Instruction (August 8, 2023)	59a
Indictment, U.S. District Court for the Eastern District of Kentucky (March 4, 2021)	71a

NOTE: The Judgments were amended after the Sixth Circuit opinion was issued. They modify the original judgments, by imposing restitution, which previously had been held in reserve.

TABLE OF AUTHORITIES

	Page
CASES	
<i>Elonis v. United States</i> , 575 U.S. 723 (2015)	18
<i>Gonzales v. Oregon</i> , 546 U.S. 243 (2006)	20, 21
<i>Hofstetter v. United States</i> , 143 S. Ct. 351 (2022)	24
<i>Newman v. United States</i> , 143 S. Ct. 350 (2022)	24
<i>Ruan v. United States</i> , 597 U.S. 450 (2022)	i, 3, 4, 10-26, 28, 29
<i>Santos v. United States</i> , 143 S. Ct. 350 (2022)	23
<i>United States v. Akwuba</i> , 2023 WL 6460040 (11th Cir. Oct. 4, 2023)	16
<i>United States v. Ball</i> , No. 24-4078, 2026 WL 2023811 (4th Cir. July 14, 2026)	13, 14
<i>United States v. Duldulao</i> , 87 F.4th 1239 (11th Cir. 2023).....	16, 23
<i>United States v. Hofschulz</i> , 105 F.4th 923 (7th Cir. 2024).....	11, 17
<i>United States v. Kahn</i> , 58 F.4th 1308 (10th Cir. 2023).....	15
<i>United States v. Lamartiniere</i> , 100 F.4th 625 (5th Cir. 2024).....	14, 15
<i>United States v. Naum</i> , 134 F.4th 234 (4th Cir. 2025).....	13

TABLE OF AUTHORITIES (Cont.)

	Page
<i>United States v. Parasmó,</i> 176 F.4th 220 (2d Cir. 2026)	12
<i>United States v. Smithers,</i> 92 F.4th 237 (4th Cir. 2024).....	13
<i>United States v. Titus,</i> 78 F.4th 595 (3d Cir. 2023)	17

STATUTES

18 U.S.C. § 3231.....	4
21 U.S.C. § 822(b)	2, 3
21 U.S.C. § 841.....	i, 3, 14, 17, 18, 20, 22, 23, 29
21 U.S.C. § 841(a)(1)	2, 3, 28
21 U.S.C. § 846.....	2, 3, 28
28 U.S.C. § 1254(1)	1

REGULATIONS

21 C.F.R. § 1306.04(a).....	2, 3, 19
-----------------------------	----------



PETITION FOR A WRIT OF CERTIORARI

Petitioners Evann Herrell and Keri McFarlane respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit.



OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit (App.1a) is published and reported at *United States v. Herrell*, 180 F.4th 245 (6th Cir. 2026). The court of appeals affirmed Petitioners' convictions and sentences in the U.S. District Court for the Eastern District of Kentucky. Following the issuance of the Sixth Circuit opinion, the district court issued amended judgments. (App.33a, 47a).



JURISDICTION

The United States Court of Appeals for the Sixth Circuit entered judgment on June 16, 2026. App.33a. No petition for rehearing was filed. This Court has jurisdiction under 28 U.S.C. § 1254(1).



STATUTORY PROVISIONS AND REGULATIONS INVOLVED

21 U.S.C. § 841(a)(1), in relevant part:

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally□(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

21 U.S.C. § 846 provides:

Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

21 U.S.C. § 822(b), in relevant part:

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

21 C.F.R. § 1306.04(a), in relevant part:

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.



STATEMENT OF THE CASE

A. Statutory Background and the Prosecution

The Controlled Substances Act makes it unlawful, □[e]xcept as authorized□ knowingly or intentionally to distribute or dispense a controlled substance. 21 U.S.C. § 841(a)(1). Registered practitioners may prescribe controlled substances within the scope of their registration and in conformity with the Act. *Id.* § 822(b). A prescription is effective when issued □for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.□ 21 C.F.R. § 1306.04(a).

In *Ruan v. United States*, 597 U.S. 450 (2022), this Court held that § 841□s □knowingly or intentionally□ *mens rea* applies to the authorization requirement. The Government therefore must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. *Id.* at 454, 457.

Petitioners Evann Herrell and Keri McFarlane are physicians who practiced at Express Health Care (□EHC□), an opioid-addiction treatment practice that opened in Tennessee in 2013. McFarlane worked at EHC until October 2016. Herrell remained until the clinic closed in 2018 and served as medical director of its Harriman location. App.2a.

The Government charged Petitioners and other EHC physicians and employees with offenses arising from the clinic□s prescribing and related practices. As relevant here, Count One charged Petitioners under 21 U.S.C. § 846 with conspiring to violate § 841(a)(1)

through unauthorized prescribing. The United States District Court for the Eastern District of Kentucky had jurisdiction under 18 U.S.C. § 3231.

At the thirty-day trial, the Government characterized EHC as a “pill mill” and relied on evidence of high patient volume, brief patient encounters, prescribing despite indicators of diversion, prescriptions issued for patients a physician had not personally seen, and deficient medical documentation. App.2a–4a. Petitioners disputed what that evidence established about the question *Ruan* makes essential to criminal liability: whether they actually knew the prescribing underlying the alleged conspiracy was unauthorized.

B. The Government Relied Extensively on Objective Medical and Regulatory Standards

Much of the Government’s proof asked the jury to compare EHC’s practices with what other medical professionals considered legitimate addiction treatment. The jury heard evidence concerning patient volume, examinations, medical records, buprenorphine dosage, concurrent benzodiazepine prescribing, drug-screen results, suspected diversion, regulatory requirements, and individualized treatment. The Government relied on those comparisons in closing argument.

The Government relied heavily on patient volume and other professional-practice evidence to argue that EHC’s prescribing departed from legitimate addiction treatment. It urged the jury to treat those departures, together with other evidence, as circumstantial proof that Petitioners understood the prescribing practices to be improper.

The Government also relied on McFarlane's later statements to law enforcement. The jury heard that she compared high-volume days to "herding cattle," described aspects of EHC's practice as "not good medicine," and used the term "pill mill." The Government offered those statements, together with the professional-standard evidence, as proof that she understood the clinic's prescribing practices to be improper. App.5a.

Regulatory requirements supplied another benchmark. The Government introduced evidence concerning the federal waiver then required to prescribe buprenorphine for opioid-use disorder and the patient limits associated with it. That evidence formed part of the Government's broader effort to prove that Petitioners knowingly participated in unauthorized prescribing.

Professional standards and regulatory deviations therefore served two roles at trial: they bore on whether the prescribing was authorized, and the Government relied on those same circumstances as circumstantial evidence that Petitioners knew it was unauthorized.

C. Petitioners Disputed Both the Medical Conclusions and the Inference of Criminal Knowledge

The defense contested the Government's characterization of EHC's prescribing and presented expert testimony challenging the Government's interpretation of the medical evidence. The parties' experts also disagreed about appropriate treatment methodology, reinforcing Petitioners' position that professional disagreement could not itself establish criminal knowledge.

The parties' experts also disagreed about appropriate treatment methodology, reinforcing Petitioners' position that professional disagreement could not itself establish criminal knowledge.

McFarlane also presented evidence bearing directly on her state of mind. She testified that in 2016 she discovered a record bearing her signature in connection with prescribing she had not authorized, copied the record, and reported it to the FBI. Trial Tr. Day 27, R. 1045, PageID 19708-10. She later left EHC and instructed clinic personnel not to change prescriptions into her name unless she had signed them. *Id.* at PageID 19710-11.

The parties thus disputed not only whether EHC's prescribing departed from professional norms, but what those departures proved about Petitioners' knowledge. The Government argued that professional deviations, regulatory warnings, high patient volume, and Petitioners' own statements showed knowing participation in unauthorized prescribing. Petitioners maintained that medical disagreement, professional shortcomings, or even objectively poor medicine did not itself establish that they knew the prescribing was unauthorized.

D. Petitioners Expressly Asked the District Court to Distinguish Professional Fault from Criminal Knowledge

Before deliberations, Petitioners expressly sought instructions distinguishing medical malpractice and professional fault from criminal unauthorized prescribing. Petitioners submitted written supplemental instructions addressing that distinction.

Proposed Instruction No. 1 stated: □This case is not a medical malpractice lawsuit. A practitioner becomes a criminal not when he or she is a bad or negligent physician but when he or she ceases to be a physician at all.□ Mot. for Proposed Jury Instructions, R. 742. Proposed Instruction No. 2 stated: □The law imposes a much higher burden on the government than merely proving malpractice or that a practitioner negligently, recklessly or foolishly failed to adhere to a standard of care.□ R. 742.

The proposed instructions further explained that conduct is knowingly undertaken when performed voluntarily rather than because of mistake or another innocent reason, and that physicians retain discretion among available treatment options. R. 742.

The district court rejected the requested civil-criminal clarification, reasoning that the pattern instructions already made clear □that this is a criminal case, not a civil negligence□or a civil trial,□ and that adding the requested language risked confusing the jury. Trial Tr. Day 27, R. 1045, PageID 19838□39. In addressing Petitioners□ additional proposed language, the court explained that the Sixth Circuit pattern instructions were □the teaching of the Sixth Circuit□ and □presumptively reasonable.□ R. 1045, PageID 19843.

E. The Charge Conference Confirmed that Medical Impropriety and Criminal Unauthorized Prescribing were not Interchangeable

The proposed deliberate-ignorance instruction permitted the jury to infer knowledge from separate factual predicates, including whether prescriptions were unauthorized and, for other counts, whether

prescriptions or urine-drug testing were “medically unnecessary.” Trial Tr. Day 27, R. 1045, PageID 19859–62. Defense counsel objected that the formulation risked allowing medical impropriety to substitute for the knowledge required for criminal liability.

The court then asked the Government directly:

THE COURT: Do the words “medically unnecessary” mean the same thing as “not issued for a legitimate medical purpose?”

MR. ROSENBERG: No.

THE COURT: That’s the heart of the argument here.

MR. ROSENBERG: I think those are two different concepts, Your Honor.

R. 1045, PageID 19862–63.

The Government later described deliberate ignorance as “a way that you can find the defendants had knowledge” and argued that knowledge was not limited to a “purely subjective sense” because deliberate ignorance could establish it. R. 1045, PageID 19867. The district court retained the deliberate-ignorance instruction.

F. The Final Instructions Omitted Petitioners’ Requested Civil-Criminal Distinction

For Count One, the district court required the Government to prove that Petitioners knowingly joined a conspiracy to dispense controlled substances through prescriptions they knew were not issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice. *See*

Jury Instructions, R. 747; *Herrell*, 180 F.4th at 267–68.

The final instructions required the jury to determine whether Petitioners knowingly participated in unauthorized prescribing. The deliberate-ignorance instruction permitted the jury to find knowledge if a defendant deliberately ignored a high probability that controlled substances were distributed through unauthorized prescriptions, that records contained materially false statements, or that controlled-substance prescriptions or urine-drug testing were “medically unnecessary.” Jury Instructions, R.747, PageID 8804. The court cautioned that “[c]arelessness or negligence or foolishness” was not the same as knowledge. R. 747, PageID 8804.

The court did not, however, give Petitioners requested clarification that malpractice, recklessness, or deviation from a professional standard of care, standing alone, does not establish knowledge that prescribing was unauthorized.

The jury convicted Herrell and McFarlane on Count One and other offenses. Herrell was sentenced to 120 months imprisonment, and McFarlane to 52 months. App.37a.

G. The Sixth Circuit Held that *Ruan* Required no Further Clarification

The Sixth Circuit affirmed in a published decision, recognizing the Petitioners had requested supplemental instructions expressly distinguishing general “standards of care” from unauthorized prescribing, including an instruction that the Government’s burden was higher than proving “malpractice or that

a practitioner negligently, recklessly or foolishly failed to adhere to a standard of care.□ App.49a; *United States v. Herrell*, 180 F.4th 245, 267□68 (6th Cir. 2026), but nevertheless holding that the requested instruction was unnecessary and likely to confuse the jury. Because the charge required the Government to prove that Petitioners knew their prescriptions were □not issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice,□ the Sixth Circuit concluded that the instructions expressed *Ruan* □nearly verbatim□ and were therefore □acceptable.□ App.29a;*Herrell*, 180 F.4th at 267□68.

The court separately upheld the deliberate-ignorance instruction, explaining that such an instruction provides □another way that knowledge may be proven.□ App.29a;*Herrell*, 180 F.4th at 268□69.



REASONS FOR GRANTING THE PETITION

I. Conflict Among the Circuits Exists as to How a Jury Must Be Instructed to Meet Ruan's Subjective *Mens Rea* Requirement When Objective Professional Standards Are Used to Prove Knowledge and Only This Court Can Provide a Uniform Rule

Ruan established the governing *mens rea* rule: the Government must prove that a practitioner knowingly or intentionally acted in an unauthorized manner. *Ruan v. United States*, 597 U.S. 450, 454, 457 (2022). Objective professional standards remain relevant as circumstantial evidence of what the defendant

actually knew, but criminal liability may not turn on what a hypothetical reasonable physician would have known or believed. *Id.* at 465–67.

The unresolved question is how that distinction must be conveyed to a jury. Professional standards perform two functions in these prosecutions: they help determine whether prescribing was authorized, and they may provide circumstantial evidence that a defendant knew it was unauthorized. Unless the charge keeps those functions separate, proof of professional fault can become a substitute for proof of criminal knowledge.

The courts of appeals split on how to maintain that distinction after *Ruan*. The Second and Eleventh Circuits have rejected charges in which objective professional-reasonableness concepts dilute otherwise correct subjective language. The Fourth and Fifth Circuits have approved charges containing express safeguards separating professional fault from criminal knowledge. The Tenth Circuit expressly treats objective professional criteria as circumstantial evidence of subjective knowledge rather than a substitute for it. The Sixth Circuit, by contrast, held here that because the charge expressed *Ruan*’s knowledge requirement —nearly verbatim,— Petitioners’ requested clarification distinguishing malpractice and professional fault from criminal knowledge was unnecessary and potentially confusing. *United States v. Herrell*, 180 F.4th 245, 267–68 (6th Cir. 2026). The Seventh Circuit has gone further, holding that an instruction expressly requiring intentional unauthorized prescribing satisfies *Ruan*: “[*Ruan* requires nothing more.” *United States v. Hofschulz*, 105 F.4th 923, 929 (7th Cir. 2024). This clear split of authority warrants this Court’s review.

A. The Second Circuit Holds That Correct Knowledge Language Does Not Save a Charge That Permits Objective Professional Standards to Alter the Subjective Inquiry

The Second Circuit's recent decision in *United States v. Parasmó*, 176 F.4th 220 (2d Cir. 2026), illustrates the conflict. The jury there was repeatedly told that the Government had to prove Parasmó "knowingly and intentionally" prescribed outside professional medical practice and without a legitimate medical purpose. It was also told that negligence, malpractice, carelessness, and sloppiness were insufficient. *Id.* at 223–25. The Second Circuit nevertheless found instructional error. Elsewhere, the district court defined good faith as "acting reasonably" and directed the jury to consider what Parasmó "reasonably believed to be the standard of medical practice." *Parasmó*, 176 F.4th at 225. Considering the instructions "as a whole," the court held that the objective reasonableness formulation impermissibly transformed *Ruan*'s subjective inquiry into an objective one. *Id.* at 225–26.

The court distinguished the permissible use of professional standards as circumstantial evidence from their impermissible use as part of the legal test for *mens rea*. *Parasmó*, 176 F.4th at 225–26. Thus, express "knowingly" and "intentionally" language did not end the inquiry; the charge as a whole still had to preserve the defendant's subjective state of mind.

Although the objective language in *Parasmó* appeared in a good-faith instruction rather than, as here, through the professional-standard framework surrounding authorization, the methodological disagreement remains. The Second Circuit asks whether the

charge as a whole permits objective professional judgment to alter the subjective inquiry. The Sixth Circuit treated the express knowledge formulation as sufficient and the requested civil-criminal clarification as unnecessary.

B. The Fourth Circuit Has Relied on the Very Civil-Criminal Safeguards Petitioners Requested Here

The Fourth Circuit's post-*Ruan* decisions likewise emphasize the need to preserve the distinction between objective professional standards and subjective criminal knowledge.

In *United States v. Smithers*, 92 F.4th 237 (4th Cir. 2024), the court reversed where the offense and good-faith instructions permitted an objective determination of whether the physician acted outside medical practice. Professional standards remained relevant, but they could not substitute for the physician's own state of mind. *Id.* at 246-50.

The Fourth Circuit again found instructional error in *United States v. Naum*, 134 F.4th 234 (4th Cir. 2025). Although the jury had to find that the defendant knowingly and intentionally wrote prescriptions, the charge did not adequately require a finding that he knew the prescribing fell outside authorized professional practice. *Id.* at 239-40. Relief was unavailable under the applicable standard of review, but the court did not deem the instruction correct.

United States v. Ball, No. 24-4078, 2026 WL 2023811 (4th Cir. July 14, 2026), shows the safeguards the Fourth Circuit has found sufficient. The jury was required to find that Ball knew she was acting, or intended to act, without authorization. Good faith was

defined by her “subjective good intentions” and what she “subjectively believed to be proper medical practice.” The charge also expressly distinguished civil negligence from criminal conduct and prohibited an inference of knowledge from “mistake, negligence, carelessness or a belief in an inaccurate proposition.” Taken together, those protections required “the subjective finding that *Ruan* demands.” *Id.* at *4–5.

Petitioners sought substantially the same protection here: an instruction that malpractice, negligence, recklessness, foolishness, and failure to adhere to a standard of care do not themselves establish criminal knowledge. The Sixth Circuit held that clarification unnecessary. *Herrell*, 180 F.4th at 267–68.

Ball did not hold that every § 841 case requires a separately labeled malpractice instruction, and Petitioners seek no such categorical rule. Its significance is that the Fourth Circuit treated safeguards separating professional fault from subjective knowledge as part of what ensured the charge, taken as a whole, satisfied *Ruan*. The Sixth Circuit assigned those safeguards no necessary role.

C. The Fifth and Tenth Circuits Likewise Distinguish Evidence of Professional Fault from the Criminal Element Itself

The Fifth Circuit has likewise approved the use of objective professional evidence while preserving an express boundary between that evidence and criminal liability. In *United States v. Lamartiniere*, 100 F.4th 625 (5th Cir. 2024), the jury was instructed that conduct outside the standard of care generally required of physicians did not, standing alone, establish guilt. Such conduct could instead be considered in deciding

whether the physician intended to act without authorization. *Id.* at 646–50.

That is the distinction Petitioners requested here: a departure from professional standards may support an inference of knowledge, but the departure is not itself the required knowledge.

The Tenth Circuit stated the principle directly in *United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023), on remand from this Court. Proof that a physician acted without a legitimate medical purpose or outside generally recognized professional practice was not sufficient by itself. That proof could constitute circumstantial evidence, but the Government still had to establish that the defendant “knew or intended that his or her conduct was unauthorized.” *Id.* at 1314.

The Tenth Circuit reversed because the instructions repeatedly permitted conviction based on objective professional criteria without adequately requiring that separate subjective determination. *Kahn*, 58 F.4th at 1314–16.

The distinction is fundamental. Professional standards may establish what authorized medical practice requires and may provide powerful evidence of what a defendant knew. But *Ruan* makes the defendant’s knowledge a separate criminal requirement. Evidence of that element cannot become the element itself.

D. The Eleventh Circuit Similarly Rejects Instructions in Which Objective Concepts Dilute Otherwise Correct Subjective Terminology

The Eleventh Circuit has likewise rejected charges that leave an objective route to criminal liability despite the use of subjective terminology elsewhere.

In *United States v. Duldulao*, 87 F.4th 1239 (11th Cir. 2023), the court held that a charge errs when it directs the jury to apply an objective standard to the usual-course-of-professional-practice requirement or otherwise fails to convey the subjective inquiry required by *Ruan*. *Id.* at 1258.

Similarly, in *United States v. Akwuba*, 2023 WL 6460040 (11th Cir. Oct. 4, 2023), the charge contained “sprinklings” of “knowingly and intentionally” but also employed an objective conception of good faith. The Eleventh Circuit held that combining those standards was plain error because subjective terminology did not cure an alternative objective route to liability. *Id.* at *4–5.

Those decisions do not remove professional standards from the case. They require the charge to preserve their proper role: evidence bearing on the defendant’s state of mind, not a replacement for the state of mind Congress required.

E. The Sixth, Seventh, and Third Circuits Permit a Materially Different Approach

The decision below lies on the other side of that divide. The Sixth Circuit acknowledged Petitioners’ request for an express distinction between professional standards and criminal liability but deemed the

requested clarification unnecessary and potentially confusing. Because the elements charge required knowledge that the prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice, the court held that the instruction stated *Ruan* “nearly verbatim” and was “acceptable.” *Herrell*, 180 F.4th at 267–68.

The Seventh Circuit has articulated a similar position even more directly. In *United States v. Hofschulz*, 105 F.4th 923 (7th Cir. 2024), the jury was required to find that the defendants intentionally distributed controlled substances outside the usual course of medical practice and without a legitimate medical purpose. The Seventh Circuit rejected the argument that *Ruan* required an additional good-faith or malpractice instruction: “[*Ruan* requires nothing more.” *Id.* at 929.

The Third Circuit has also upheld an instruction requiring the Government to prove that a physician “knowingly or intentionally distributed controlled substances outside the usual course of professional practice and not for a legitimate medical purpose.” *United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023).

The disagreement is therefore not over whether § 841 contains a subjective *mens rea* requirement. Every circuit recognizes *Ruan*. The disagreement concerns what a jury charge must do when objective professional standards remain central to determining authorization and proving knowledge. One line of decisions examines the entire charge to ensure that those standards remain evidence of subjective *mens rea* rather than a substitute for it. The Sixth and Seventh Circuits treat an express knowledge-or-intent formulation tied to unauthorized prescribing as

sufficient without the additional civil-criminal clarification Petitioners requested here.

F. Only This Court Can Provide a Uniform Rule

The circuits have now had several years to apply *Ruan*, and their decisions reflect different answers to the same recurring instructional problem. This Court should grant review to clarify what § 841 requires when objective professional standards are used both to determine authorization and as evidence of the subjective knowledge that separates professional fault from a federal felony.

II. The Question Presented Goes to the Line Between Medical Error and Federal Criminal Liability That *Ruan* Was Meant to Protect

The question presented concerns the central protection this Court adopted in *Ruan*: criminal punishment must turn on the practitioner's own culpable state of mind, not on a jury's retrospective assessment of whether the practitioner practiced medicine reasonably.

Ruan began with the principle that, with few exceptions, "[w]rongdoing ~~must~~ be conscious to be criminal." 597 U.S. at 457 (quoting *Elonis v. United States*, 575 U.S. 723, 734 (2015)). *Scienter* separates wrongful conduct from otherwise innocent conduct, and that principle carries particular force under § 841 because Congress expressly required that a defendant act "knowingly or intentionally." *Ruan*, 597 U.S. at 457–58.

That protection is especially important for physicians because prescribing controlled substances is

not inherently wrongful. Society ordinarily □expect[s], and indeed usually want[s], doctors to prescribe the medications that their patients need.□*Ruan*, 597 U.S. at 459. Authorization therefore plays a □crucial□ role in separating criminal conduct from conduct that may be innocent or □socially beneficial.□*Id.* The question presented determines whether that protection survives when objective professional standards become central to proving criminal knowledge.

A. Professional Standards May Prove Knowledge, but they Cannot Become the Criminal Element Itself

An authorized prescription must be issued for a □legitimate medical purpose□ by a practitioner acting in the □usual course of his professional practice.□ 21 C.F.R. § 1306.04(a). Those concepts necessarily draw upon professional medical standards.

But *Ruan* makes knowledge of nonauthorization a separate requirement. Objective medical evidence may provide circumstantial evidence of that knowledge. The more unreasonable a defendant□s asserted understanding appears against objective criteria, the stronger the inference of knowledge may become. *Ruan*, 597 U.S. at 467.

A jury may infer from a substantial departure from accepted medicine that a physician knew the prescribing was unauthorized. It may not substitute a finding that a reasonable physician would have recognized the departure for proof of the defendant□s actual knowledge. *Ruan* rejected that approach because measuring culpability by the mental state of a hypothetical reasonable doctor □reduces culpability on the

all-important element of the crime to negligence. □ 597 U.S. at 465.

That distinction becomes difficult to maintain when a jury spends weeks hearing evidence about standards of care, accepted prescribing practices, patient volume, documentation, medical necessity, dosage, and regulatory requirements. This trial illustrates the problem. The Government asked the jury to compare Petitioners' practices with those of physicians treating addiction patients □ in a legitimate manner, □ emphasized patient volumes it characterized as unreasonable, and relied on regulatory and professional departures as evidence of criminal knowledge. *See supra*. Petitioners therefore requested an instruction explaining that malpractice, negligence, recklessness, and departure from professional standards did not themselves establish the knowledge § 841 requires.

An elements instruction stating that a defendant must □ know □ the prescribing was unauthorized without more does not resolve this issue. It may leave the jury to determine knowledge through the □ very reasonable-physician □ reasoning *Ruan* rejected.

B. The Danger is Greatest Precisely Where Medical Judgment is Contestable

This Court recognized that the authorization standard is unusually susceptible to uncertainty. The regulatory language is stated in □ generalit[ies], □ is □ susceptible to more precise definition, □ and may be □ open to varying constructions. □ *Ruan*, 597 U.S. at 459 (quoting *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006)). The resulting □ gray zone □ may make socially accept-

able medical treatment difficult to distinguish from unauthorized prescribing. *Id.*

That concern was concrete here. The experts disagreed about appropriate buprenorphine treatment. The Government's expert advocated a "low and slow" dosing methodology, while the defense expert described a different approach and testified that it remained within the usual course of professional practice. Petitioners likewise disputed the significance of patient volume, treatment guidance, regulatory requirements, and particular clinic practices. The jury therefore had to draw criminal-state-of-mind inferences from competing accounts of professional medical practice. A physician may be negligent without knowing a prescription is unauthorized. A physician may exercise poor judgment without intending to practice outside authorized medicine. And a physician may hold a medically unreasonable belief that the jury ultimately rejects. Objective unreasonableness may strengthen the Government's circumstantial proof of knowledge. It cannot eliminate the obligation to prove knowledge. The jury instruction is therefore not a technical matter of preferred wording. It is the mechanism by which the legal distinction between professional fault and criminal knowledge reaches the factfinder.

C. An Uncertain Criminal Boundary Creates the Very Risk of Overdeterrence *Ruan* Sought to Avoid

Ruan also recognized the consequences of weakening scienter where criminal law operates near socially beneficial conduct. An inadequate mental-state requirement risks "overdeterrence" by discouraging acceptable conduct near the permissible side of the criminal boundary. 597 U.S. at 459.

That concern has particular force in medicine. Physicians make individualized judgments about medications Congress permits them to prescribe. Professional standards inform those decisions, but disagreement, imperfect judgment, and error are inherent where medicine requires judgment rather than mechanical compliance.

Section 841 imposes criminal punishment *only* when the Government proves the additional culpable state of mind Congress required. If juries are not adequately instructed to separate professional fault from that criminal element, the operative question shifts from whether the defendant physician knew the prescribing was unauthorized to whether the jury believes a competent physician should have known better. That is the negligence standard *Ruan* rejected.

The consequences are also qualitatively different from malpractice liability or professional discipline. Section 841 and its conspiracy provision carry felony convictions and imprisonment. Herrell received a 120-month sentence, and McFarlane received 52 months. The distinction between professional fault and criminal knowledge therefore marks a boundary between civil liability for medical error and loss of liberty.

This Court should grant review to ensure that the subjective *mens rea* requirement recognized in *Ruan* remains a genuine criminal-law boundary when objective professional standards supply the evidence from which knowledge is inferred.

III. This Court's Prior Remands Gave the Courts of Appeals an Opportunity to Implement *Ruan*; Four Years of Experience Have Produced Divergence, Not a Uniform Rule

This Court need not speculate whether the question presented will recur or whether additional percolation will clarify the law. Both have already occurred.

After deciding *Ruan*, this Court granted certiorari, vacated judgments, and remanded physician prosecutions for reconsideration under the newly announced subjective *mens rea* requirement. Those remands did not resolve the instructional questions now before the Court, but they ensured that the courts of appeals would confront how *Ruan* operates in physician prosecutions. Four years of post-*Ruan* decisions have now produced materially different approaches rather than a uniform rule.

A. This Court Previously Returned Physician Prosecutions to the Courts of Appeals for Reconsideration Under *Ruan*

In *Santos v. United States*, 143 S. Ct. 350 (2022), this Court granted certiorari, vacated the Eleventh Circuit's judgment, and remanded for reconsideration in light of *Ruan*. On remand, the Eleventh Circuit recognized that the case had returned because this Court vacated its earlier judgment following *Ruan*. *United States v. Duldulao*, 87 F.4th 1239, 1247 (11th Cir. 2023). It ultimately vacated Santos's substantive § 841 convictions while separately upholding conspiracy convictions whose instructions independently required subjective knowledge. *Id.* at 1251–62.

This Court likewise remanded Sixth Circuit physician prosecutions for reconsideration after *Ruan*.

See Hofstetter v. United States, 143 S. Ct. 351 (2022); *Newman v. United States*, 143 S. Ct. 350 (2022).

Those remands gave the courts of appeals the opportunity to apply *Ruan*’s subjective *mens rea* requirement in concrete physician prosecutions. The resulting decisions have not produced consistency.

B. The Post-*Ruan* Decisions Show That Further Percolation is Unlikely to Eliminate the Disagreement

The current disagreement is not the product of courts applying pre-*Ruan* law without this Court’s guidance. The principal decisions discussed above were issued after *Ruan* and with its subjective standard firmly established.

The courts agree the Government must prove subjective knowledge or intent, but have nevertheless developed varying approaches to determining whether a jury charge adequately instructs that requirement when objective professional standards remain central to the proof. Some examine the charge as a whole for language that may introduce an objective route to liability. Others emphasize express safeguards separating professional fault from criminal knowledge. The Sixth and Seventh Circuits have treated an express knowledge-or-intent formulation tied to unauthorized prescribing as sufficient without the additional clarification Petitioners sought here. *See supra* Part I. The disagreement is therefore not over *Ruan*’s holding. It is over how that holding must be applied at trial.

That makes this a second-generation *Ruan* question. *Ruan* answered what mental state the Government must prove. The question presented asks what a jury must be instructed when objective professional

standards are used both to establish nonauthorization and as evidence of subjective mental state.

C. The Disagreement is Methodological, Not Merely Factual

The competing decisions reflect different methods for evaluating jury instructions. Some circuits scrutinize the charge as a whole to determine whether objective professional concepts have altered the subjective inquiry. Others treat an express knowledge-or-intent formulation as sufficient even when defendants seek additional language separating professional fault from criminal *mens rea*.

Another physician prosecution applying one of those approaches will not reconcile them. It will produce another application of the same methodology. Additional percolation is most useful when lower courts are still testing possible answers to a new question. Sufficient time has now passed to make clear the Circuits will not reconcile.

D. This Case Presents the Issue After Full Post-*Ruan* Development

This case also arrives in a posture the earliest post-*Ruan* cases could not provide. Petitioners were tried after *Ruan* had already been decided. They raised the civil-criminal distinction at trial, submitted written supplemental instructions addressing it, objected before deliberations, and argued that objective medical concepts could not substitute for subjective criminal knowledge. The district court had the benefit of *Ruan*. So did the Sixth Circuit. The court of appeals did not resolve the issue on forfeiture or plain-error grounds. It addressed Petitioners' requested clarification and held that it was unnecessary because

the instructions already expressed *Ruan* —nearly verbatim.—*United States v. Herrell*, 180 F.4th 245, 267—68 (6th Cir. 2026).

The Court therefore has before it a post-*Ruan* trial, a preserved instructional dispute, a published appellate decision squarely resolving that dispute, and several years of post-*Ruan* decisions applying materially different approaches. Percolation has produced divergence, not convergence. This Court should now resolve the remaining question.

IV. This Case is a Clean Vehicle to Resolve the Question Presented

This case presents the question without the procedural complications that affected many early post-*Ruan* appeals. *Ruan* had already been decided when Petitioners went to trial. Petitioners raised the instructional issue before deliberations, proposed specific language addressing it, and obtained a merits ruling from the Sixth Circuit in a published opinion. No antecedent factual or procedural issue prevents this Court from reaching the question presented.

A. The Issue was Squarely Raised and Decided Below

Petitioners did not raise the civil-criminal distinction for the first time on appeal. During trial, defense counsel advised the district court that the jury needed additional guidance distinguishing malpractice from criminal unauthorized prescribing. The court invited the defense to submit proposed language, and Petitioners later submitted written supplemental instructions.

Among other things, Petitioners asked the court to instruct:

This case is not a medical malpractice lawsuit. A practitioner becomes a criminal not when he or she is a bad or negligent physician but when he or she ceases to be a physician at all.

They also proposed:

The law imposes a much higher burden on the government than merely proving malpractice or that a practitioner negligently, recklessly or foolishly failed to adhere to a standard of care.

Mot. for Proposed Jury Instructions, R. 742.

The same concern arose during the charge conference. Defense counsel objected that language concerning "medically unnecessary" treatment could lead jurors toward a negligence inquiry. The district court asked whether "medically unnecessary" meant the same thing as "not issued for a legitimate medical purpose." The Government answered no. The court responded: "That's the heart of the argument here." Trial Tr. Day 27, R. 1045, PageID 19862-63.

The district court nevertheless declined to give Petitioners' requested clarification. The Sixth Circuit then addressed that ruling on the merits. It acknowledged that Petitioners sought instructions distinguishing general standards of care from unauthorized prescribing and specifically requested an instruction that the Government's burden was higher than proving "malpractice or that a practitioner negligently, recklessly or foolishly failed to adhere to a standard of

care. □ *United States v. Herrell*, 180 F.4th 245, 267 □ 68 (6th Cir. 2026).

The court rejected the claim because the final charge required proof that Petitioners knew the prescriptions were not issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice. Because that formulation expressed *Ruan* □ nearly verbatim, □ the Sixth Circuit held the instructions □ acceptable. □ *Herrell*, 180 F.4th at 267 □ 68.

The question presented is therefore preserved and squarely decided.

B. The § 846 Posture Presents no Obstacle to Review

Although Count One arose under 21 U.S.C. § 846, the alleged conspiracy had as its object violations of § 841(a)(1), and the Sixth Circuit directly adjudicated whether the Count One instructions adequately conveyed the subjective knowledge required by *Ruan*. See *Herrell*, 180 F.4th at 267 □ 69. The question presented is therefore embedded in the conviction under review. Resolving it requires no separate interpretation of § 846 and no antecedent ruling unrelated to the question presented.

C. This Court Can Resolve the Question as a Matter of Law Without Reweighing the Evidence

Review does not require this Court to act as a second jury. The Government presented substantial evidence concerning EHC and Petitioners, and Petitioners disputed both the medical characterization of their conduct and the inferences to be drawn concern-

ing their states of mind. This petition does not ask the Court to reconsider those factual disputes. It asks what legal instruction is required when objective professional standards are used to prove the subjective knowledge that § 841 demands and whether it was sufficient here. That question can be resolved on the existing record. This case therefore presents an appropriate vehicle for resolving the conflict and clarifying the protection *Ruan* requires.



CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

/s/ Loretta Cravens

Loretta Cravens

Counsel of Record for Petitioners

ELDRIDGE AND CRAVENS, PC

400 W. Church Ave Ste. 101

Knoxville, TN 37902

(865) 544-2010

lcravens@ecattorneys.law

Counsel for Petitioner Herrell

Richard Gaines

LAW OFFICE OF RICHARD L. GAINES

625 Market St., Ste. 900

Knoxville, TN 37902

Counsel for Petitioner McFarlane

Counsel for Petitioners

September 14, 2026