No. _____

In the Supreme Court of the United States

DR. XIULU RUAN AND DR. JOHN PATRICK COUCH,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Ruan v. United States*, 142 S. Ct. 2370 (2022) (App., *infra*, 19a-54a), this Court held that a physician may be convicted under 21 U.S.C. § 841(a)(1) of the Controlled Substances Act ("CSA") only if the government proves that the defendant "knew or intended that his or her conduct *was unauthorized*." *Id.* at 2382 (App., *infra*, 37a) (emphasis added). The Court remanded Petitioners' case to the Eleventh Circuit, and Dr. Shakeel Kahn's companion case to the Tenth Circuit, so that those courts could consider whether the jury instructions comported with the "except as authorized" requirement of the statute.

The question presented, on which the circuits are divided, is whether, in a CSA jury instruction, 21 C.F.R. § 1306.04(a) may replace the statute's "except as authorized" requirement, thereby permitting the jury to convict a physician simply because she knew that her prescription would fall outside the "usual" course of medical practice or would be regarded as "illegitimate" by most other doctors, and thus empowering a federal agency to create a felony offense that Congress itself did not enact.

PARTIES TO THE PROCEEDING

Petitioners, defendants-appellants below, are Dr. Xiulu Ruan and Dr. John Patrick Couch.

Respondent, appellee below, is the United States of America.

RELATED PROCEEDINGS

Xiulu Ruan v. United States, No. 20-1410, The Supreme Court of the United States. Judgment entered July 29, 2022.

John Patrick Couch v. United States, No. 20-7934, The Supreme Court of the United States. Judgment entered August 1, 2022.

United States v. Xiulu Ruan & John Patrick Couch, Nos. 17-12653, 17-12654, United States Court of Appeals for the Eleventh Circuit. Judgments entered July 10, 2020 and January 5, 2023.

United States v. John Patrick Couch, No. 16-16361, United States Court of Appeals for the Eleventh Circuit. Judgment entered August 15, 2017.

United States v. Xiulu Ruan, No. 19-11508, United States Court of Appeals for the Eleventh Circuit. Judgment entered January 8, 2020.

United States v. Ling Cui, No. 19-12661, United States Court of Appeals for the Eleventh Circuit. Judgment entered May 11, 2020.

United States v. Lori L. Carver, No. 17-13402, United States Court of Appeals for the Eleventh Circuit. Judgment entered October 17, 2018.

United States v. John Patrick Couch, No. 1:15-cr-00088, United States District Court for the Southern District of Alabama. Judgments entered on May 31, 2017 and July 14, 2021.

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OPINIONS AND RULINGS BELOW

The opinion of the United States Court of Appeals for the Eleventh Circuit on remand is reported at 56 F.4th 1291. *See* Petitioners' Appendix ("App."), *infra*, 1a-18a. This Court's opinion is reported at 142 S. Ct. 2370. *See* App., *infra*, 19a-54a. The order of the Eleventh Circuit denying rehearing on remand is not reported. *See* App., *infra*, 55a-56a. The order of the Eleventh Circuit denying rehearing of its prior opinion in this case is not reported. *See* App., *infra*, 57a-58a.

JURISDICTION

The Eleventh Circuit's judgment was entered on January 5, 2023. App., *infra*, 1a. The court denied rehearing on March 2, 2023. App., *infra*, 55a-56a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the CSA, 21 U.S.C. § 841(a)(1), provides, in pertinent part:

> (a) Unlawful acts
>
> 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[.]

Section 846 of the CSA, 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 C.F.R. § 1306.04(a) provides, in pertinent part:

> Purpose of issue of prescription.
>
> (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.

STATEMENT

Following this Court's decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022) (App., *infra*, 19a-54a), the Eleventh Circuit vacated Petitioners' Section 841(a)(1) convictions but sustained the remaining ones, nearly all of which were other CSA charges or rested on CSA predicates. *See* App., *infra*, 5a-18a. It did so, despite the fact that the instructions on which the remaining CSA convictions were based replaced the CSA's "without authorization" requirement with the "ambiguous" language of 21 C.F.R. § 1306.04(a), *see* 142 S. Ct. at 2377 (App., *infra*, 26a), and the convictions with CSA predicates relied on instructions for those predicates that contained the same error. By contrast, the Tenth Circuit, on remand from the very

same decision, held that all of Dr. Shakeel Kahn's convictions must be vacated, precisely because the instructions, like those in Petitioners' case, replaced the statutory requirement ("except as authorized") with the language from the regulation. *United States v. Kahn*, 58 F.4th 1308, 1316-17, 1321-22 (10th Cir. 2023).

Since then, the circuit conflict has widened, and the confusion in the lower federal courts has deepened. Indeed, although nearly a year has passed since *Ruan* was decided, the lower federal courts continue to sustain instructions that substitute the language of 21 C.F.R. § 1306.04(a) for the "except as authorized" language required by this Court's decision, *see* 142 S. Ct. at 2376 (App., *infra*, 24a), thereby allowing an agency regulation to create a criminal offense that Congress itself did not enact.

Whether that substitution is permissible is an issue of surpassing importance to physicians and other health care professionals. If a doctor faces criminal prosecution simply because she knows that her conduct differs from what other physicians "usually" do, or what other physicians might regard as "illegitimate," she will be chilled from offering patients novel but promising treatment. That is precisely what prompted this Court in *Ruan* to hold that "it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful." *Id.* at 2377 (App., *infra*, 26a). Giving doctors a wide enough berth to provide outlying treatment is reason enough—if more reason

were needed—to stick to the text that Congress enacted, and which this Court embraced in *Ruan*.

Now is the right time for this Court to intervene. The lower courts confront CSA cases against practitioners on nearly a daily basis, and are in an acknowledged disagreement about whether this Court meant what it said in *Ruan*. In just a year since *Ruan* was decided, numerous courts have sustained convictions based on a knowing violation of a regulation, rather than the actual CSA text; a far smaller number of courts have adhered to this Court's mandate in *Ruan*.

The petition for a writ of certiorari should be granted.

A. Statutory and Regulatory Framework

The CSA makes it unlawful for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense" a controlled substance," "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). "[T]his subchapter" authorizes persons who have registered with the Attorney General to dispense controlled substances "to the extent authorized by their registration." *Id.* § 822(b). The CSA also directs the Attorney General to accept the registration of a medical doctor or other practitioner if he is "authorized to dispense . . . controlled substances under the laws of the State in which he practices." *Id.* § 823(g)(1). The CSA's conspiracy statute makes it unlawful for any person to conspire to commit any offense under the CSA. *Id.* § 846.

21 C.F.R. § 1306.04(a) provides, in pertinent 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.

B. Factual Background

1. Petitioners Dr. Xiulu Ruan and Dr. John Patrick Couch "were board-certified doctors specializing in pain management" in Mobile, Alabama. *United States v. Ruan*, 966 F.3d 1101, 1121 (11th Cir. 2020), *vacated and remanded*, 142 S. Ct. 2370 (2022) and 142 S. Ct. 2895 (2022). They owned a pain clinic (Physicians Pain Specialists of Alabama) and an affiliated pharmacy (C&R Pharmacy). *Id.*

A grand jury indicted Petitioners for unlawful distribution of controlled substances under Section 841(a)(1) and conspiracy to violate the CSA by unlawfully distributing controlled substances under Sections 841(a)(1) and 846, as well as racketeering conspiracy, health care fraud conspiracy, wire and mail fraud conspiracy, and conspiracy to violate the anti-kickback statute. *Id.* at 1120. Dr. Ruan (but not Dr. Couch) was charged with money laundering and conspiracy to commit money laundering. *Id.*

2. The government's entire case was based on the CSA charges—the non-CSA charges relied either on the CSA charges as predicates or on the facts underlying them. *See* Doc. 269 ¶¶ 55, 57-58, 74(a) (racketeering conspiracy), ¶ 114 (health care fraud conspiracy), ¶¶ 135, 137, 139, 141 (anti-kickback conspiracy), ¶¶ 170, 174 (wire and mail fraud conspiracy), ¶ 181 (money laundering conspiracy),

¶ 184 (money laundering); *see also* Doc. 269 ¶¶ 1-52, 53, 77, 80, 84, 87, 91, 95, 99, 103, 107, 111, 116, 133, 152, 168, 180, 183 (incorporation into each count of fifty-two paragraphs of allegations largely concerning controlled substances). The government insisted that "prescribing a controlled substance is illegal unless there's two things that happen: It's prescribed in the usual course of professional practice and it's prescribed for a legitimate medical purpose." Tr. 28:6-9.

Although the government acknowledged that "there were certainly instances where Dr. Ruan and Dr. Couch did a really good job for their patients," Tr. 47:2-4, it urged the jury to convict them on all counts if it found that they acted outside "the usual course of professional practice" and without a "legitimate medical purpose." *See, e.g.*, Tr. 6121:4-6, 6276:5-6, 6276:9-10, 6276:12-13, 6276:20-21, 6277:10-11, 6278:3-4, 6278:13-14, 6279:14-15, 6279:24-25, 6281:2-4, 6281:7-9, 6283:21-22, 6289:9-10, 6289:11-12, 6289:22-23, 6291:6-7, 6291:13-14, 6291:19-21, 6292:6-7, 6299:14, 6303:4-5, 6304:12-13, 6307:17-18.

Consistent with the government's theory, the district court instructed the jury based on 21 C.F.R. § 1306.04(a), telling the jury, with respect to both Section 841(a)(1) and Section 846, that it was unlawful to prescribe "outside the usual course of professional medical practice" or without a "legitimate medical purpose." App., *infra*, 59a-68a.

To guard against the prospect that they might be convicted on what amounted to a simple negligence standard, Petitioners submitted a proposed

instruction on good faith, which emphasized their subjective beliefs that their prescriptions were medically appropriate. Doc. 462 at 23 (Defendants' Requested Instruction Number 18). Rejecting that request, the district court instead told the jury that:

> A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The defendants in this case maintain at all times they acted in good faith and in accordance with [the] standard of medical practice generally recognized and accepted in the United States in treating patients.
>
> Thus a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice.

App., *infra*, 61a-62a; *see also* App., *infra*, 68a, 71a-75a. This "good faith" instruction was given with respect to both the substantive and conspiracy CSA counts. App., *infra*, 61a-62a, 68a.

3. Dr. Ruan was convicted on all but two counts against him, and Dr. Couch was convicted on all but one count against him; Dr. Ruan was acquitted on one CSA count, and the government dismissed one anti-

kickback conspiracy count against both Petitioners. 966 F.3d at 1121. Dr. Ruan was sentenced to 21 years of imprisonment, and Dr. Couch was sentenced to 20 years. *Id.*

Of the twenty convictions, twelve were CSA charges, *id.* at 1120-21, nine of which were vacated on remand, App., *infra*, 17a-18a. One anti-kickback conspiracy count was reversed on appeal for insufficient evidence. 966 F.3d at 1144-46. Four of the remaining seven convictions (racketeering conspiracy and, as to Dr. Ruan, money laundering conspiracy and money laundering) relied on the CSA charges as predicate offenses, and all seven relied on the factual theory that Petitioners prescribed improperly. *See supra* at 5-6.

C. Appellate Proceedings

1. Petitioners appealed, raising, among other issues, the district court's treatment of their proposed good faith instruction. 966 F.3d at 1165-67.

The Eleventh Circuit found the requested instruction to be "an incorrect statement of the law," because, in its view, "[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard." *Id.* at 1166. The court of appeals thereafter denied rehearing. App., *infra*, 57a-58a.

2. This Court granted certiorari in Petitioners' case and a consolidated petition from the Tenth Circuit filed by Dr. Kahn. On June 27, 2022, the Court vacated the judgments below and remanded both cases. 142 S. Ct. at 2382 (App., *infra*, 38a).

The plain text of Section 841(a)(1), the Court noted, "makes it a federal crime, '*[e]xcept as authorized*[,] … for any person knowingly or intentionally … to manufacture, distribute, or dispense … a controlled substance,' such as opioids." *Id.* at 2374-75 (App., *infra*, 20a) (quoting 21 U.S.C. § 841(a)). The Court held that Section 841(a)(1)'s "'knowingly or intentionally' *mens rea* applies to" the "except as authorized" requirement. *Id.* at 2375 (App., *infra*, 20a). As the Court explained, "[a]fter a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting *in an unauthorized manner*, or intended to do so." *Id.* (emphasis added); *see also id.* at 2376, 2382 (App., *infra*, 24a, 38a). After all, the Court observed, "it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself. In other words, authorization plays a 'crucial' role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct." *Id.* at 2377 (App., *infra*, 26a).

In holding that "except as authorized" is "crucial" to convicting a physician of drug dealing, the Court recognized that the language of 21 C.F.R. § 1306.04(a) ("legitimate medical purpose"; "usual course of his professional practice") was "ambiguous." *Id.* That regulatory language, the Court noted, is "written in 'generalit[ies], susceptible to more precise definition and open to varying constructions.'" *Id.* And so, the

Court explained, although the Government "can prove knowledge of a lack of authorization through circumstantial evidence," including "by reference to objective criteria such as 'legitimate medical purpose' and 'usual course' of 'professional practice,'" in the end the government must prove "that a defendant knew or intended that his or her conduct was unauthorized." *Id.* at 2382 (App., *infra*, 37a).

The Court remanded both Petitioners' case and Dr. Kahn's case so that the respective courts of appeals could determine, among other things, whether the instructions as a whole sufficiently required that the physicians knowingly or intentionally acted without authorization. *Id.* (App., *infra*, 37a-38a).

3. And that's when the circuit conflict began. On remand in *Kahn*, the Tenth Circuit took this Court at its word. The court of appeals "conclude[d] that the jury instructions issued in Dr. Kahn's case are inconsistent with the mens rea standard articulated in *Ruan*, as they do not require the government to prove beyond a reasonable doubt that Dr. Kahn knowingly or intentionally *acted in an unauthorized manner*." 58 F.4th at 1315 (emphasis added). The court noted that the jury "was repeatedly instructed" that it could convict if Dr. Kahn "acted outside the usual course of professional medical practice or without a legitimate medical purpose." *Id.* Those instructions were erroneous, said the Tenth Circuit, because they allowed the jury to convict simply because Dr. Kahn "subjectively knew a prescription was issued not for a legitimate medical purpose" or

"issued a prescription that was objectively not in the usual course of professional practice," both of which "run counter to *Ruan*." *Id.* at 1316. The court held that that instructional error was not harmless. *See id.* at 1317-21.

The Tenth Circuit then considered Dr. Kahn's other convictions, and "determine[d] that *each* of Dr. Kahn's convictions was impacted by erroneous instructions in a way that prejudiced him." *Id.* at 1321. The court said that the Section 846 charges "also include the good faith exception," which was "erroneous and did not result in harmless error." *Id.* The remaining convictions (aiding and abetting the co-defendant's Section 841(a)(1) violations, use of a communication facility in furtherance of certain CSA charges, possession of a firearm in furtherance of a federal drug trafficking crime, continuing criminal enterprise, and money laundering) were erroneous because "the instructions predicate[d] conviction on the jury's finding of guilt in the erroneously-instructed" counts. *Id.* at 1321-22. Because the instructions pertaining to all charges were "predicated, at least in part, on one or more of the erroneous § 841(a)(1) instructions," the error "infected the instructions given on all counts." *Id.* at 1322. The court thus concluded that all convictions must be vacated. *Id.*

Put another way: In the Tenth Circuit, the failure to instruct the jury on the "except as authorized" requirement undermined both the CSA counts and the remaining counts that relied on the CSA counts as predicates.

4. The Eleventh Circuit took a very different path. App., *infra*, 1a-18a. Recognizing that under *Ruan* "it is the defendant's subjective intent that matters," the Eleventh Circuit held that "the district court's instruction for the substantive drug charges inadequately conveyed the required mens rea to authorize conviction under § 841(a)." App., *infra*, 6a-7a. The court further concluded that, with respect to the Section 841(a)(1) charges, the erroneous instruction was not harmless and vacated those convictions. App., *infra*, 8a-9a.

With respect to the conspiracy counts under Section 846, however, the court of appeals held that the instructions were correct. App., *infra*, 10a-12a. In the court's view, "[b]ecause a conviction under § 846 requires the jury to find that the defendants knew of the illegal nature of the scheme and agreed to participate in it, the erroneous jury instruction for the substantive charges has a limited impact here." App., *infra*, 10a. Although the instructions made no mention of the "except as authorized" requirement, App., *infra*, 59a-65a, the court found it sufficient that Petitioners knew or intended that their prescriptions were not within the "usual course" of practice or lacked a "legitimate medical purpose." App., *infra*, 10a-12a; *see also* App., *infra*, 59a-65a. On much the same basis, the Eleventh Circuit sustained the balance of Petitioners' convictions. App., *infra*, 12a-17a.

The court of appeals thereafter denied rehearing. App., *infra*, 55a-56a.

REASONS FOR GRANTING THE PETITION

In *Ruan*, this Court held that a physician may not be convicted of controlled substances violations unless the government proves that she knew or intended that "her conduct was unauthorized." 142 S. Ct. at 2382 (App., *infra*, 37a). The Court vacated both Petitioners' and Dr. Kahn's convictions and remanded so that the Eleventh and Tenth Circuits could determine, among other things, whether the instructions, taken as a whole, required the jury to find this "crucial" statutory mandate. *Id.* at 2377, 2382 (App., *infra*, 26a, 37a-38a).

Once on remand, the Eleventh and Tenth Circuits, like the two Model-T Fords at (what was then) the only intersection in Kansas, collided. The Tenth Circuit, faithfully applying this Court's directive, vacated *all* of Dr. Kahn's convictions, including convictions under Section 846, because "*each* of Dr. Kahn's convictions was impacted by erroneous instructions in a way that prejudiced him." *Kahn*, 58 F.4th at 1321. Without an instruction requiring a finding of "except as authorized," the jury instructions, on both the CSA counts and the counts charging CSA predicates, could not stand. The Tenth Circuit applied the same principles in vacating a second doctor's Section 841(a)(1) and 846 convictions in *United States v. Henson*, 2023 WL 2319289, at *1-2 (10th Cir. Mar. 2, 2023).

Petitioners were not as lucky. Although Petitioners' CSA jury instructions, like Dr. Kahn's, replaced the "authorization" requirement with language from 21 C.F.R. § 1306.04(a), the Eleventh Circuit vacated *only* Petitioners' Section 841(a)(1)

convictions, and sustained both the Section 846 instructions and the instructions on the compound charges. App., *infra*, 5a-18a. The Eleventh Circuit took the same view in other post-*Ruan* cases, confirming that, in its judgment, the regulatory language may substitute for the statutory text. *United States v. Germeil*, 2023 WL 1991723, at *8-10 (11th Cir. Feb. 14, 2023); *United States v. Heaton*, 59 F.4th 1226, 1241 (11th Cir. 2023); *United States v. Maltbia*, 2023 WL 1838783, at *5 (11th Cir. Feb. 9, 2023), *cert. petition filed*, No. 22-7531 (U.S. May 11, 2023); *United States v. Mencia*, 2022 WL 17336503, at *14 (11th Cir. Nov. 30, 2022). The Fifth and Sixth Circuits have now followed suit. *United States v. Ajayi*, 64 F.4th 243, 247-48 (5th Cir. 2023); *United States v. Anderson*, 2023 WL 2966356, at *7-8 (6th Cir. Apr. 17, 2023).

The circuit conflict has not gone unnoticed. As one district court recently declared (with a soupcon of exasperation), "[i]t is far above this Court's pay grade to resolve a Circuit split—if, indeed, there is one." *United States v. Lamartiniere*, 2023 WL 2645343, at *2 (M.D. La. Mar. 27, 2023). And indeed there is one. That division gets deeper by the day, as more and more courts affirm the use of 21 C.F.R. § 1306.04(a) as a substitute for "authorization" in the text of the CSA.

The implications for physicians and other health care professionals are dismaying. If physicians may be convicted merely because they knew they were acting outside the "usual" course of medical practice, or in ways that other doctors might find "illegitimate," it effectively smuggles a quasi-negligence standard through the back door. A doctor who knowingly

deviates from mainstream treatment practices, even if grounded in subjectively well-considered (and effective) medical practice, would become a criminal. Such a standard is inconsistent with the text of the CSA and with this Court's decision in *Ruan*. It also effectively permits a federal agency to create a criminal offense that Congress itself did not enact.

This Court should grant the petition and reiterate that the text of the CSA means what it says: Doctors may not be treated as drug dealers unless they knowingly or intentionally act "without authorization."

A. The Circuits Are Divided on the Question Presented

Did this Court mean what it said in *Ruan*? One certainly would have thought so. After all, every party to that case urged the Court to adopt an instruction based on *some* incarnation of the "usual course of his professional practice" and/or "legitimate medical purpose" language. *See* Brief for the Petitioner at 4-5, 10-12, 14-16, *Ruan v. United States*, No. 20-1410 (Dec. 20, 2021); Brief of Petitioner at 3, 12-13, *Kahn v. United States*, No. 21-5261 (Dec. 20, 2021); Brief for the United States at 16-19, *Ruan v. United States* and *Kahn v. United States*, Nos. 20-1410, 21-5261 (Jan. 19, 2022). While the parties vigorously disagreed about what kind of *mens rea* should attach to those regulatory elements, they all agreed that *some* version of 21 C.F.R. § 1306.04(a) should be the basis for a CSA instruction.

But this Court had none of it. Instead, relying on the plain language of the statute itself, the Court held that a jury must be instructed that it may convict a physician only if she knowingly or intentionally acted without "authorization." *Ruan*, 142 S. Ct. at 2375 (App., *infra*, 20a). The terms of 21 C.F.R. § 1306.04(a) are simply too "ambiguous" to substitute for the text. *Id.* at 2377 (App., *infra*, 26a). While a knowing breach of the regulation may be *probative* of "unauthorized" conduct, it is not a substitute for the language that Congress actually enacted. *Id.* at 2382 (App., *infra*, 37a).

The Eleventh, Fifth, and Sixth Circuits did not get the memo. By contrast, the Tenth Circuit did.

1. Although the Eleventh Circuit correctly reversed Petitioners' Section 841(a)(1) instructions, it held that the Section 846 instructions were correct, App., *infra*, 10a-12a, as were all the compound offenses that rested on a CSA predicate (whether Section 841(a)(1), Section 846, or both), App., *infra*, 12a-13a, 15a-17a. The Section 846 instructions told the jury that:

> Each defendant can be found guilty of the conspiracy alleged in one or more of [the drug conspiracy] counts . . . only if . . . One, two or more people in some way agreed to try and accomplish a shared and unlawful plan to distribute or dispense outside the usual course of professional practice and not for a legitimate medical purpose the alleged controlled substance or substances; and, two, the defendant knew the unlawful purpose of the plan and willfully joined in it.

App., *infra*, 63a. In the Eleventh Circuit's view, because that instruction required the jury to find that Petitioners "knew" that they were acting "outside the usual course of professional practice" and without "a legitimate medical purpose," the jury necessarily concluded that Petitioners knew they were prescribing in an "unauthorized" manner. App., *infra*, 10a-12a.

The Eleventh Circuit reached this conclusion even though (1) the Section 846 instructions (and indeed, the instructions as a whole) made no mention of the "without authorization" element, App., *infra*, 59a-65a; *see also* Tr. 6321:25-6360:5; (2) this Court characterized the language of 21 C.F.R. § 1306.04(a) as "ambiguous," *Ruan*, 142 S. Ct. at 2377 (App., *infra*, 26a); and (3) the Section 846 instructions included an erroneous "good faith" instruction that referenced "[t]he standard of medical practice generally recognized and accepted in the United States," App., *infra*, 61a-62a. Having sustained the Section 846 instructions, the Eleventh Circuit had no trouble sustaining as correct the instructions on all other offenses that rested on CSA charges as predicates. App., *infra*, 12a-13a, 15a-17a.

The Eleventh Circuit's most recent cases confirm that, in that court's view, the regulatory language may be substituted for the CSA text. *See Heaton*, 59 F.4th at 1238, 1241-42 (instructions that described "unauthorized" element as dispensing "outside the usual course of professional practice or for no legitimate medical purpose" were erroneous because they "allowed the jury to convict Heaton without

considering *whether he knowingly or intentionally issued prescriptions outside the usual course of professional practice*," but finding error harmless due to "overwhelming evidence that Heaton subjectively *knew his conduct fell outside the usual course of his professional practice*" (italics added)); *see also Germeil*, 2023 WL 1991723, at *8-10 (approving instructions that the defendant was "charged with *knowingly and intentionally* prescribing controlled substances to her patients outside the usual course of professional medical practice"); *Maltbia*, 2023 WL 1838783, at *5 (equating "authorization" with regulatory criteria).

2. The Fifth and Sixth Circuits have now joined the Eleventh Circuit in sustaining CSA instructions that substitute 21 C.F.R. § 1306.04(a) for the statutory "authorization" requirement. *See Ajayi*, 64 F.4th at 247-48; *Anderson*, 2023 WL 2966356, at *7-8.

In *Ajayi*, a case against a pharmacist, the jury was instructed that an element of Section 846 charges is that "two or more persons . . . reached an agreement to dispense and distribute and possess with intent to dispense and distribute a controlled substance outside the scope of professional practice and not for a legitimate medical purpose." Jury Charge at 12, *United States v. Ajayi*, No. 4:20-cr-00290-O (N.D. Tex. Mar. 2, 2021) (Doc. 1208). The Section 841(a)(1) instructions similarly charged that it is a crime to distribute controlled substances "outside the scope of professional practice or not for a legitimate medical purpose." *Id.* at 13-14. The court further instructed that the jury:

> [M]ust decide whether the controlled substances were (1) prescribed for what the defendant *subjectively* considered to be a legitimate medical purpose; and (2) from an *objective* standpoint, were dispensed in the usual course of professional practice.
>
> The phrase "usual course of professional practice" means acting in accordance with a standard of medical practice generally recognized and accepted in the United States. This is an *objective standard* that considers what is generally recognized in the medical profession, not what an individual practitioner *subjectively* believes the standard should be.

Id. at 18-19 (emphasis added). The Fifth Circuit upheld those instructions. 64 F.4th at 247-48.

In *Anderson*, the Sixth Circuit considered Section 841(a)(1) instructions. The district court had instructed that the elements were: "First, the defendant knowingly or intentionally dispensed or distributed a Schedule II controlled substance . . . ; and, Second, that the defendant, Dr. Anderson, prescribed the drug without a legitimate medical purpose and outside the course of professional practice." 2023 WL 2966356, at *7. The court further told the jury that it could convict if the defendant "deliberately ignored a high probability that the controlled substance was distributed or dispensed without a legitimate medical purpose in the usual course of professional practice" or "was aware of a high probability that the controlled substances were distributed or dispensed other than for a legitimate

medical purpose while acting in the usual course of professional practice." *Id.* Despite the fact that these instructions replaced the "authorization" requirement with the language of 21 C.F.R. § 1306.04(a), the Sixth Circuit held that they "appear to comport with *Ruan*," *id.* at *8, although one member of the panel dissented in part because "the second element's instruction identified no *mens rea* requirement," which did not "comport with *Ruan*," *id.* at *12-13 (White, J. concurring in part and dissenting in part).

In short, the Fifth and Sixth Circuits, like the Eleventh Circuit, permit the government to substitute the dictates of 21 C.F.R. § 1306.04(a) for the statutory language that this Court held to be "crucial," 142 S. Ct. at 2377 (App., *infra*, 26a).

3. The Tenth Circuit, by contrast, has applied the text of the CSA and this Court's *Ruan* decision faithfully. Noting that this Court "ruled that, to establish mens rea, it is insufficient for the government to prove that a defendant acted without 'a legitimate medical purpose' or outside the 'usual course' of generally recognized 'professional practice,'" the court rejected Section 841(a)(1) jury instructions because they "repeatedly" told the jury "that it could convict Dr. Kahn if it concluded that he acted outside the usual course of professional medical practice or without a legitimate medical purpose." *Kahn*, 58 F.4th at 1314-15. The court noted that "*Ruan* treats the two criteria in § 1306.04(a) not as distinct bases to support a conviction, but as 'reference to objective criteria' that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner."

Id. at 1316 (quoting *Ruan*, 142 S. Ct. at 2377, 2382). The regulatory language cannot substitute for the text: "Under § 841(a)(1)," the Tenth Circuit held, "the government always has the burden of 'proving that a defendant knew or intended that his or her conduct was unauthorized.'" *Id.* (quoting *Ruan*, 142 S. Ct. at 2382).

The Tenth Circuit therefore reversed all of Dr. Kahn's convictions, including under Sections 841(a)(1) and 846, because they were "impacted by erroneous instructions in a way that prejudiced him." 58 F.4th at 1321. The court reasoned that "[f]or each § 841(a)(1) charge on which Dr. Kahn was convicted, the instructions erroneously articulated the mens rea requirement in light of *Ruan*. As regards the remaining charges, the instructions pertaining to those charges are likewise predicated, at least in part, on one or more of the erroneous § 841(a)(1) instructions." *Id.* at 1322.

The Tenth Circuit has since applied the identical principle in vacating another physician's Section 841(a)(1) and 846 convictions and most other convictions. *See Henson*, 2023 WL 2319289, at *1. The jury instructions for Sections 841 and 846 again relied on 21 C.F.R. § 1306.04(a). Jury Instructions at 21-22, 29-30, 32, 34, *United States v. Henson*, No. 6:16-cr-10018-JWB (D. Kan. Oct. 23, 2018) (Doc. 368).

The circuit conflict has not gone unnoticed. As one district court has observed, "the Eleventh Circuit [in *Mencia*] *affirmed* that 'authorization' is still measured by reference to" 21 C.F.R. § 1306.04(a), whereas in *Kahn* "the Tenth Circuit seems to question this

interpretation (without mentioning *Mencia*)." *Lamartiniere*, 2023 WL 2645343, at *1. The court then said "[i]t is far above this Court's pay grade to resolve a Circuit split—if, indeed, there is one." *Id.* at *2. The court resolved to "stay in its lane—determining the facts—leaving the law for appeal," *id.*, suggesting, correctly, that it is this Court's province to address the problem.

The conflict is as unjustified as it is palpable. Petitioners will sit in jail for two decades (and Ajayi for over a decade and Anderson for eight years) on the basis of instructions that warranted a new trial for Dr. Kahn in the Tenth Circuit. That conflict—and injustice—alone justify a grant of certiorari.

B. The Question Presented Is Important and Recurring

1. Jury instructions that replace the statutory "as authorized" language with the regulatory language—"usual" course of professional practice and "legitimate" medical purpose—effectively lower the standard for criminal conviction, and threaten to chill novel but promising medical approaches to patient care.

The key regulatory words—"usual" and "legitimate"—beg the question: in whose eyes? Those terms focus, most naturally, on what *most doctors* deem "usual" and "legitimate." That may not constitute a *pure* negligence standard, since the doctor must still "know" or "intend" to depart from what most physicians would do. But it comes pretty close to simple negligence, and the chilling effect is just about

the same. A physician who proposes a novel treatment regime likely "knows" that he is acting differently from the "usual" medical practitioner, and perhaps in ways that the "usual" practitioner would regard as "illegitimate." So simply adding "knowingly or intentionally" to the language of 21 C.F.R. § 1306.04(a) is cold comfort to a doctor whose approach to medical practice differs from the mainstream. That is precisely what this Court sought to forestall in *Ruan*. *See Ruan*, 142 S. Ct. at 2381 (App., *infra*, 34a-35a) (rejecting the government's proposed standard that "would turn a defendant's criminal liability on the mental state of a hypothetical 'reasonable' doctor, not on the mental state of the defendant himself or herself"). The regulatory factors may be *probative* of criminal conduct, but they do not define it. *See id.* at 2382 (App., *infra*, 37a).

A criminal standard based on 21 C.F.R. § 1306.04(a), rather than the actual text of the CSA, sends physicians back to Square 1. A doctor who, for example, knowingly adheres to older prescribing trends, rather than the most current prescribing trends, would be a criminal, even if she believed that the earlier treatment methods were more effective. A doctor who evaluated the pros and cons of different courses of treatment (*e.g.*, the tradeoff between efficacy and side effects) and follows her reasoned conclusion that she knows falls outside the mainstream would be a criminal. Or a doctor who developed an innovative but off-label use of a controlled substance to treat an illness in a new way would be a criminal. By replacing the plain language

of the CSA with words plucked from an agency regulation, jury instructions stifle innovation and creativity. And simply requiring that the doctor must "know" that she is prescribing "unusually" or even "illegitimately" (in the eyes of mainstream physicians) provides little to no protection for an innovative practitioner (or any practitioner who thinks differently from other doctors).

That is why this Court emphasized in *Ruan* that deliberately acting *without authorization* is of utmost importance: "In § 841 prosecutions, then, it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself. In other words, authorization plays a 'crucial' role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct." *Id.* at 2377 (App., *infra*, 26a). In holding that a "strong scienter requirement" applies, the Court noted that "§ 841 imposes severe penalties upon those who violate it, including life imprisonment and fines up to $1 million." *Id.* (App., *infra*, 27a). By imposing such severe penalties on doctors simply because they knew they were departing from the mainstream threatens to turn dissenters into criminals, to the obvious detriment of therapeutic practice and medical progress.

Substituting 21 C.F.R. § 1306.04(a) for the statutory text is especially chilling in those circuits (including the Eleventh) that permit CSA convictions for physicians who *either* knew they were acting outside the "usual" norms *or* knew they lacked a

"legitimate" medical purpose. *See Heaton*, 59 F.4th at 1239-40 (Eleventh Circuit case rejecting challenge to disjunctive instruction); *United States v. Oppong*, 2022 WL 1055915, at *4-5 (6th Cir. Apr. 8, 2022) (approving disjunctive instruction under plain error standard and discussing use of disjunctive standard in the Fifth, Tenth, and Eleventh Circuits and conjunctive standard in Eighth and Ninth Circuits). In those circuits, doctors face felony prosecution simply because they knew they were acting outside professional norms. Perhaps the doctor was trying a method of last resort for a patient for whom the "usual" techniques had failed. Or maybe the physician applied experimental treatments for a patient intent on exhausting every possible medical approach. Must such physicians look over their shoulders for Inspector Javert seeking mandatory minimum jail sentences for knowing departures from the "usual" medical practices?

To be sure, the further a physician departs from what she knows to be "usual" and "legitimate," the likelier it is that she will also know she is acting without authorization. So a deliberate violation of 21 C.F.R. § 1306.04(a) is, as we noted, *probative* of the "except as authorized" inquiry. But it cannot be a *substitute* for that inquiry, and courts should not continue to invite juries to convict on that basis.

2. Nevertheless, in just a year since this Court's June 27, 2022 decision, dozens of courts have substituted, and continue to substitute, the regulatory language for the CSA text, in plain defiance of the statute and this Court's *Ruan* decision. *See supra* 16-

20 (discussing *Ruan*, *Heaton*, *Germeil*, *Maltbia*, *Ajayi*, and *Anderson*); *Mencia*, 2022 WL 17336503, at *14 (instructions using language of 21 C.F.R. § 1306.04 were "not plain error" under *Ruan* because they "communicated" that the government must prove "that the prescriptions he had written were unauthorized or, *in other words*, that they were outside the scope of professional practice and not for a legitimate medical purpose" (emphasis added)); *United States v. Kamra*, 2022 WL 4998978, at *1-3 (3d Cir. Oct. 4, 2022) (in a case against pharmacy marketing executive, approving instruction that purpose of conspiracy was to distribute "outside the usual course of professional practice and for no legitimate medical purpose"); *United States v. La*, 2023 WL 2731036, at *10-11 (M.D. Tenn. Mar. 30, 2023) (approving instruction that "[t]he defendant knowingly or intentionally distributed the substance without a legitimate medical purpose outside the usual course of professional practice"); *United States v. Lamartiniere*, 2023 WL 2424585, at *3 (M.D. La. Mar. 9, 2023) (instruction equating "authorization" with "issued for a legitimate medical purpose and within the usual course of a practitioner's professional practice" was "complete and correct" under *Ruan* because "21 C.F.R. § 1306.04 remains the touchstone for defining 'authorization' under § 841"), *reconsideration denied*, 2023 WL 2645343 (M.D. La. Mar. 27, 2023); *United States v. Murphy*, 2023 WL 2090279, at *3 (N.D. Ala. Feb. 17, 2023) (vacating Section 841(a)(1) conviction but sustaining Section 846 convictions, where instructions for both sections used regulatory language); *United States v. Parasmo*,

2023 WL 1109649, at *16-21 (E.D.N.Y. Jan. 30, 2023) (instruction that "the defendant knowingly and intentionally prescribed the controlled substances outside the bounds of professional medical practice and not for a legitimate medical purpose" "is precisely what *Ruan* commands"); *see also United States v. Ferris*, 52 F.4th 235, 241 (5th Cir. 2022) (sentencing challenge by non-provider; "21 U.S.C. § 841(a) permits registered doctors to prescribe controlled substances to their patients if the prescriptions are for a legitimate medical purpose in the usual course of professional practice" (cleaned up)), *cert. denied*, 143 S. Ct. 846 (2023); *United States v. Wells*, 2023 WL 3341673, at *3-4 (D. Nev. May 10, 2023) (dismissing indictment because *mens rea* applied "to the act of distribution but not to the language defining without authorization," which was from 21 C.F.R. § 1306.04(a)); *United States v. Alvear*, 2023 WL 3061551, at *4 (D. Nev. Apr. 24, 2023) (motions in limine; citing 21 C.F.R. § 1306.04(a) for definition of "authorized"); Order (1) Denying Defendant's Motion to Withdraw Plea and (2) Denying Government Ex Parte Application for Judicial Finding of Breach of Plea Agreement at 3, *United States v. Pham*, No. 8:19-cr-00010-JLS (C.D. Cal. Apr. 7, 2023) (motion to withdraw plea; stating that *Ruan* "equates 'lack of authorization' with conduct 'outside of the ordinary course of professional practice and not for a legitimate medical purpose'"); *United States v. Kistler*, 2023 WL 1099726, at *1 (S.D. Ohio Jan. 30, 2023) (motions in limine; defendant charged with prescribing "outside of the usual course of professional practice and not for legitimate medical purposes"); *United States v.*

Taylor, 2022 WL 17582270, at *8 (E.D. Ky. Dec. 12, 2022) (motion to suppress; citing 21 C.F.R. § 1306.04(a) for definition of "authorized"); *United States v. Ferrell*, 2022 WL 17404891, at *2 (E.D. Tex. Dec. 2, 2022) (motion to withdraw plea; "Ferrell thus admitted that he 'knowingly and intentionally' possessed with the intent to distribute controlled substances 'outside the normal course of practice and without legitimate medical purpose'"); *United States v. Adelglass*, 2022 WL 6763791, at *3 (S.D.N.Y. Oct. 11, 2022) (motion to dismiss indictment; equating "authorization" with regulatory criteria); *United States v. Parker*, 2022 WL 5213206, at *3 (W.D. Ark. Oct. 5, 2022) (motion for admittance of deposition testimony; "the government must establish . . . that Defendant: was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose"); *United States v. Naylor*, 2022 WL 4371489, at *1 (E.D. Tenn. Sept. 21, 2022) (motion to exclude; charges for distributing and conspiring to distribute outside the usual course of professional practice and without a legitimate medical purpose); *Brizuela v. United States*, 2022 WL 4369977, at *6 (N.D.W. Va. Sept. 21, 2022) (motion to vacate, set aside, or correct sentence; "the Court twice informed Brizuela that, should he decide to go to trial, the Government would be required to prove beyond a reasonable doubt that he knowingly distributed controlled substances outside the bounds of

professional medical practice, or in other words that he knew the distribution was not authorized"); *United States v. Spayd*, 2022 WL 4367621, at *7 (D. Alaska Sept. 20, 2022) (motions in limine in case against nurse practitioner; "pursuant to *Ruan*, a medical professional will only be held liable under § 841 if the Government proves beyond a reasonable doubt that they *knowingly* or *intentionally* prescribed medications without a legitimate medical purpose and while acting outside the usual course of professional practice"); *United States v. Ranochak*, 2022 WL 4298568, at *11, *15 (N.D. Ind. Sept. 19, 2022) (motions in limine in case against pharmacist; prescription "'authorized' when a licensed practitioner issues it 'for a legitimate medical purpose … acting in the usual course of his professional practice'"); *United States v. Spayd*, 2022 WL 4220192, at *4 (D. Alaska Sept. 13, 2022) (motion to dismiss indictment by nurse practitioner; rejecting argument that "the definition of authorization was broader than 21 C.F.R. § 1306.04(a)" because "the *Ruan* Court specifically recognized that 21 C.F.R. § 1306.04(a) determined the bounds of a prescriber's authorization"); *United States v. Taylor*, 2022 WL 4227510, at *1-4 (E.D. Ky. Sept. 13, 2022) (motion to dismiss indictment; equating "authorization" with regulatory criteria); *United States v. Blume*, 2022 WL 3701449, at *2 (S.D.W. Va. Aug. 26, 2022) (motion for production of grand jury materials; "Defendants point out that the Fourth Superseding Indictment fails to reference 21 C.F.R. § 1306.04, which is the subjective standard aligned with the scienter requirement set forth in *Ruan*"), *set aside*, 2022 WL 4076065 (S.D.W. Va. Sept. 3, 2022);

United States v. Sachy, 2022 U.S. Dist. LEXIS 148403, at *2 (M.D. Ga. Aug. 18, 2022) (motion to withdraw plea; citing 21 C.F.R. § 1306.04(a) for definition of "authorized"); *United States v. Kraynak*, 2022 WL 3161907 (M.D. Pa. Aug. 8, 2022) (motion to withdraw plea; "the only dispute as to Kraynak's guilt is whether he knowingly or intentionally issued the controlled substances outside the usual course of professional practice and not for a legitimate medical purpose").

There is every reason to think that the problem will persist. None of the circuits has yet to issue a pattern instruction properly implementing *Ruan*. In fact, the Sixth Circuit pattern instructions expressly equate the "without authorization" requirement with the regulatory language. *See* Sixth Circuit Committee on Pattern Criminal Jury Instructions, Pattern Criminal Jury Instructions, Instruction 14.02C (Mar. 1, 2023), *available at* https://www.ca6.uscourts.gov/pattern-jury-instructions. Although the Eighth and Ninth Circuit pattern instructions reference *Ruan* in comments, they do not contain model instructions for practitioners. *See* Judicial Committee on Model Jury Instructions for the Eighth Circuit, Manual of Model Criminal Jury Instructions for the District Courts of the Eighth Circuit, 610-614, 626, 639-640 (2022), *available at* https://juryinstructions.ca8.uscourts.gov/instructions/criminal/Criminal-Jury-Instructions.pdf.; Ninth Circuit Jury Instructions Committee, Manual of Model Criminal Jury Instructions for the District

Courts of the Ninth Circuit, Instructions 12.4 & 12.5 (Mar. 2023), *available at* https://www.ce9.uscourts.gov/jury-instructions/model-criminal. The remaining circuits either do not publish pattern instructions or do not include in their pattern instructions specific instructions for CSA charges against practitioners.

C. The Eleventh Circuit's Decision Below Is Wrong

1. The Eleventh Circuit was wrong to vacate only Petitioners' Section 841(a)(1) convictions and not the closely related Section 846 charges. That decision departs from the statutory text and this Court's *Ruan* decision and dilutes the *mens rea* requirement.

The CSA makes it unlawful to distribute or dispense controlled substances "[e]xcept as authorized by this subchapter," 21 U.S.C. § 841(a)(1), and "this subchapter" authorizes persons registered by the Attorney General, like physicians, to distribute or dispense controlled substances "to the extent authorized by their registration," 21 U.S.C. § 822(b). The statute does not say that it is unlawful to prescribe "outside the course of professional practice" or not for a "legitimate medical purpose." 21 U.S.C. § 841(a)(1).

Nonetheless, for both the substantive and conspiracy CSA charges in this case, the jury instructions substituted the language of 21 C.F.R. § 1306.04(a) for the text of the CSA. App., *infra*, 59a-68a. That substitution is reason enough to reject the Eleventh Circuit's decision—the Attorney General's

rulemaking authority under the CSA, *see* 21 U.S.C. §§ 821, 871(b), does not give him the power rewrite criminal laws enacted by Congress (and, if the Attorney General *had* such authority, it would be an impermissible delegation of Congress' lawmaking power). *See Gundy v. United States*, 139 S. Ct. 2116, 2144-45 (2019) (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.) ("To allow the nation's chief law enforcement officer to write the criminal laws he is charged with enforcing—to unit[e] the legislative and executive powers ... in the same person—would be to mark the end of any meaningful enforcement of our separation of powers and invite the tyranny of the majority that follows when lawmaking and law enforcement responsibilities are united in the same hands."); *Whitman v. United States*, 135 S. Ct. 352, 354 (2014) (Scalia, J., respecting denial of certiorari) ("[T]he rule of lenity . . . vindicates the principle that only the *legislature* may define crimes and fix punishments. Congress cannot, through ambiguity, effectively leave that function to the courts—much less to the administrative bureaucracy."). Nor does Section 841(a)(1) make violating a regulation promulgated by the Attorney General unlawful. *See* 21 U.S.C. § 841(a)(1); *Loving v. United States*, 517 U.S. 748, 768 (1996) ("We have upheld delegations whereby the Executive or an independent agency defines by regulation what conduct will be criminal, *so long as Congress makes violation of regulations a criminal offense* . . . . (emphasis added)).

Likewise, courts should not unduly defer, if at all, to agencies' interpretations of what statutes mean and instead should stick to the text of the statutes. *See, e.g.*, *Buffington v. McDonough*, 143 S. Ct. 14, 22 (2022) (Gorsuch, J., dissenting) ("We should acknowledge forthrightly that *Chevron* did not undo, and could not have undone, the judicial duty to provide an independent judgment of the law's meaning in the cases that come before the Nation's courts. Someday soon I hope we might."); *Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 142 S. Ct. 2354, 2368-69 (2022) (Kavanaugh, J., dissenting) ("[T]his case is resolved by the most fundamental principle of statutory interpretation: Read the statute."); *Michigan v. EPA*, 576 U.S. 743, 761 (2015) (Thomas, J., concurring) ("*Chevron* deference precludes judges from exercising [their independent] judgment, forcing them to abandon what they believe is the best reading of an ambiguous statute in favor of an agency's construction. It thus wrests from Courts the ultimate interpretative authority to say what the law is and hands it over to the Executive."). Indeed, it may well be that the government's interpretations of criminal statutes are entitled to *no* deference by courts. *See United States v. Apel*, 571 U.S. 359, 369 (2014) (addressing United States Attorneys' Manual and opinions of the Air Force Judge Advocate General, and stating, "we have never held that the Government's reading of a criminal statute is entitled to any deference"); *see also Abramski v. United States*, 573 U.S. 169, 191 (2014) (addressing ATF circular and prior version of ATF form, and stating, "[t]he critical point is that criminal laws are for courts, not the

Government, to construe" (citing *Apel*, 571 U.S. at 369)).

The widespread substitution of 21 C.F.R. § 1306.04(a) for the actual text of the statute also defies this Court's decision in *Ruan* and the principles that animated it. As the Court noted, the regulatory language is "ambiguous" and "open to varying constructions." 142 S. Ct. at 2377 (App., *infra*, 26a). What does "usual" mean"? What does "legitimate" mean? In whose eyes must those terms be defined? If, as the terms suggest, it suffices to convict a doctor as a drug dealer because she knows that most other doctors disagree, 21 C.F.R. § 1306.04(a) would just re-establish the very problem this Court sought in *Ruan* to resolve. That is why the *Ruan* Court concluded that, while the government may rely on "circumstantial evidence . . . by reference to objective criteria such as 'legitimate medical purpose' and 'usual course' of 'professional practice,'" the ultimate question—the one the jury must be asked to decide—is whether "a defendant knew or intended that his or her conduct was unauthorized." *Id.* at 2382 (App., *infra*, 37a).

The Eleventh Circuit disregarded these principles. In its view, Petitioners' jury was perfectly entitled to convict them of conspiracy if Petitioners "agreed to try and accomplish a shared and *unlawful plan to distribute or dispense outside the usual course of professional practice and not for a legitimate medical purpose* the alleged controlled substance or substances; and, two, [they] knew the unlawful purpose of the plan and willfully joined in it." App.,

infra, 63a (emphasis added); *see also* App., *infra*, 10a-12a. The instructions defined the "unlawful plan" of the conspiracy as "distribut[ing] or dispens[ing] outside the usual course of professional practice and not for a legitimate medical purpose"—not distributing without authorization. App., *infra*, 63a. The jury could therefore convict Petitioners if it found that they knew that their prescriptions were *objectively* outside the usual course of professional practice or not for a legitimate medical purpose, *i.e.*, if other physicians would disagree with their medical determinations but Petitioners themselves believed the prescriptions were appropriate. But, under *Ruan*, that is wrong—a jury may convict only when the physician has subjective knowledge that prescriptions are *unauthorized*. The Eleventh Circuit departed from the statutory text and *Ruan* by substituting the language of the regulation.

Put another way, the Eleventh Circuit has created a back door to convict a physician under Section 846 for conspiracy to do something that is not itself unlawful under Section 841(a)(1). That is wrong. *See Woo Wai v. United States*, 223 F. 412, 415 (9th Cir. 1915) ("If no violation of the law was to be accomplished by the act of the defendants, it follows that they could not be held for conspiracy to do that act.").

2. The same basic error infects the court of appeals' treatment of most of Petitioners' remaining convictions. With respect to racketeering conspiracy, the Eleventh Circuit said that, even if the jury relied on the Section 841(a)(1) convictions as predicates, the

instructional error made no difference because the jury "would still have made a finding that the defendants *intended* to violate § 841, which means that the defendants would have to have known their acts were unauthorized." App., *infra*, 15a-16a. But that conclusion founders on the same error the court of appeals made with respect to the CSA instruction—the jury could convict Petitioners if it found that they knew that their prescriptions were *objectively* outside the usual course of professional practice or not for a legitimate medical purpose. The racketeering instructions themselves contained no instruction about lack of authorization. Tr. 6328:9-6331:4.

So, too, for the health care fraud conspiracy charges. The district court told the jury that it could convict if it found that "a defendant conspired to commit healthcare fraud by one or more of the[] four means [listed in the indictment]." App., *infra*, 68a-69a. Two of the four means were taken straight from 21 C.F.R. § 1306.04(a): (1) "[b]illing patients' insurance providers for Controlled Substances that were not prescribed for a legitimate medical purpose or were prescribed outside the usual course of professional practice," and (2) "[r]unning and then billing patients' insurance providers for various lab tests, including urine drug screens, for no legitimate medical purpose and outside the usual course of professional practice." Doc. 269 ¶ 114.

As for Dr. Ruan's money laundering and money laundering conspiracy convictions, those were compound offenses predicated, in pertinent part, on CSA conspiracy and health care fraud conspiracy.

App., *infra*, 16a-17a. Because those predicates relied on the impermissible language of 21 C.F.R. § 1306.04(a), the compound offenses cannot stand.

D. This Case Presents an Ideal Vehicle to Resolve the Question Presented

Petitioners' case was very close on the merits. As the court of appeals recognized in rejecting the government's harmless error argument with respect to the Section 841(a)(1) convictions:

> The jury could have weighed all of this evidence and concluded that Dr. Ruan and Dr. Couch subjectively believed their conduct was in accord with the appropriate standard of care. But under the erroneous instruction that was given, the jury could convict the defendants if they found that a reasonable doctor would not have believed the conduct was in accord with the appropriate standard. In other words, a properly instructed jury may not have convicted the defendants had it known that Dr. Ruan's and Dr. Couch's subjective beliefs that they were acting properly was a defense to these charges. Similar to *McDonnell*, under the erroneous instruction in this case the jury was authorized to convict the defendants for conduct that was lawful.

App., *infra*, 9a. It follows that the erroneous jury instructions on the compound offenses were almost surely outcome-determinative.

Moreover, the circuit conflict could scarcely be starker. Petitioners' case in the Eleventh Circuit and Dr. Kahn's case in the Tenth arise from the same

decision of this Court. They involve jury instructions exhibiting the same problem—the language of 21 C.F.R. § 1306.04(a) erroneously substitutes for the language of the CSA. Each of the physicians challenged the instructions for much the same reasons. The only difference is that the Tenth Circuit faithfully applied this Court's *Ruan* decision and the Eleventh Circuit didn't.

Finally, Petitioners' case returns to this Court at the right time. As we noted above, *supra* at 25-30, as each day goes by, another district court instructs a jury that a knowing violation of 21 C.F.R. § 1306.04(a) constitutes a violation of the CSA. Undoing that spiraling error is doubtless "far above th[e] [lower federal] [c]ourt[s'] pay grade." *Lamartiniere*, 2023 WL 2645343, at *1. That leaves only this Court to set matters right.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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May 31, 2023

APPENDIX

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APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED JANUARY 5, 2023

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-12653

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

XIULU RUAN, JOHN PATRICK COUCH,

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Alabama
D.C. Docket No. 1:15-cr-00088-CG-B-2

January 5, 2023, Filed

Opinion of the Court

ON REMAND FROM THE SUPREME COURT OF THE UNITED STATES

Before WILSON, NEWSOM, Circuit Judges, and COOGLER,* Chief District Judge.

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* Honorable L. Scott Coogler, United States Chief District Judge for the Northern District of Alabama, sitting by designation.

Appendix A

PER CURIAM:

This case returns to our court on remand from the Supreme Court. *Ruan v. United States*, 142 S. Ct. 2370, 213 L. Ed. 2d 706 (2022) (*Ruan II*). We ordered supplemental briefing to address whether the mens rea jury instruction used in this case was error and whether any such error was harmless. After careful consideration, we conclude that the jury instruction used in this case is inconsistent with the Supreme Court's guidance and did not convey an adequate mens rea to the jury for the substantive drug convictions under 21 U.S.C. § 841. We further find that this error was not harmless beyond a reasonable doubt for Dr. Xiulu Ruan's and Dr. John Couch's (collectively, the defendants) substantive drug charges. However, we conclude that the instructional error was harmless as to the other convictions in this case. Accordingly, we **VACATE** in part and **AFFIRM** in part the defendants' convictions.[1]

I.

The factual and procedural history at trial were thoroughly recounted in our prior panel opinion, *United*

1. In the defendants' original appeal, they raised a number of other challenges, including sufficiency of the evidence, evidentiary, and sentencing challenges. On remand these issues were not re-briefed, and nothing in the Supreme Court's decision alters our consideration of those issues. Accordingly, we adopt the reasoning of the previous panel opinion, but not the discussion relating to the good-faith instruction in Part C.1. *See United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020).

States v. Ruan, 966 F.3d 1101, 1119-36 (11th Cir. 2020) (Ruan I). Among other things, the defendants challenged the jury instructions used for their substantive drug convictions under 21 U.S.C. § 841(a), which prohibits the "knowing[] or intentional[]" dispensing of controlled substances "[e]xcept as authorized." The relevant drugs in this case are only "authorized" to be dispensed pursuant to a prescription, and an effective prescription must be made 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). The defendants requested that the jury be instructed that their good faith be a defense to an allegation that they acted outside the "usual course of professional practice."

In *Ruan I*, we affirmed on all but Count 16[2] and held that we were bound by prior Eleventh Circuit precedent to reject the defendants' request for a good-faith instruction. *See, e.g., United States v. Joseph*, 709 F.3d 1082 (11th Cir. 2013); *United States v. Tobin*, 676 F.3d 1264 (11th Cir. 2012); *United States v. Merrill*, 513 F.3d 1293 (11th Cir. 2008); *United States v. Williams*, 445 F.3d 1302 (11th Cir. 2006). We reaffirmed that the "usual course of professional practice" prong was evaluated using an objective standard, not a subjective one. *Ruan I*, 966 F.3d at 1167. Accordingly, good faith was irrelevant to the question of whether a doctor acted in the usual course of professional practice; though it was relevant to whether the doctor prescribed a

2. We remanded the remaining counts for resentencing and after the district court resentenced the defendants they appealed again. Those appeals are currently pending and stayed awaiting resolution of this case.

controlled substance for a "legitimate medical purpose." *See id.* The defendants then petitioned for, and the Supreme Court granted, certiorari to consider whether good faith is a defense on the usual course of professional practice prong. *See Ruan v. United States*, 142 S. Ct. 457, 211 L. Ed. 2d 278 (2021).

The Supreme Court reversed. It reasoned that § 841(a)'s scienter provision (requiring the defendant to act "knowingly or intentionally") applied not only to the statute's actus reus—here dispensing—but also to the "except as authorized" exception. *Ruan II*, 142 S. Ct. at 2378. Thus, to obtain a conviction under this section, the government must prove beyond a reasonable doubt that a defendant (1) knowingly or intentionally dispensed a controlled substance; and (2) knowingly or intentionally did so in an unauthorized manner. *Id.* at 2382. The Court held that an objective standard would inappropriately import a civil negligence standard into a criminal prosecution. *See id.* at 2381. Instead, what matters is the defendant's subjective mens rea. *Id.* at 2382.

The Supreme Court expressly declined to apply its new standard to the facts in this case and remanded to this court to consider the issue in the first instance. *Id.*

II.

We review de novo whether a challenged jury instruction "misstated the law or misled the jury to the prejudice of the objecting party." *United States v. Cochran*, 683 F.3d 1314, 1319 (11th Cir. 2012). Jury instructions

need not be perfect, and we review the instructions in light of the "entire charge" and do not isolate individual statements in order to contrive error. *Id.*

Where the error is the omission of an element of the crime we will reverse unless it can be shown the error was harmless beyond a reasonable doubt. *Neder v. United States*, 527 U.S. 1, 15-16, 119 S. Ct. 1827, 144 L. Ed. 2d 35 (1999).

III.

The district court in this case followed then-binding Eleventh Circuit precedent and denied the defendants' request for a good-faith instruction reflecting their subjective intent. Instead, the district court gave an alternative instruction on good faith:

> A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully, if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.

The government argues in its supplemental briefing that this instruction, read together with the whole charge, adequately instructed the jury that it had to find the defendants acted with knowledge or intent in order to convict them under § 841(a). We disagree for three reasons.

First, the passing reference to "good faith" excerpted above is inadequate. The Supreme Court recognized that § 841 "uses the familiar mens rea words 'knowingly or intentionally.' It nowhere uses words such as 'good faith' . . . ." *Ruan II*, 142 S. Ct. at 2381. The Supreme Court then explicitly rejected the government's proffered compromise instruction that objective good faith or "honest effort" should govern the usual course of professional practice prong. *Id.* Instead, it is the defendant's subjective intent that matters. The government argues that our cases have conceptually linked "good faith" and "knowledge" in the past, and that this instruction gave the "functional equivalent of a knowledge instruction." But, at best, even if the concepts are linked, good faith is an imprecise proxy for knowledge.

Without further qualification, the phrase "good faith" encompasses both subjective and objective good faith. In the context of § 841 though, as the Supreme Court has explicitly held, only the subjective version is appropriate. The instruction given by the district court did not contain any qualification to make this clear to the jury. And, of course, the instruction did not contain this qualification. The district court's instruction is substantially identical to one this court first approved in *Williams*. *See* 445 F.3d at 1309. Over the next fifteen years we reaffirmed this language repeatedly because it comported with our understanding that the "usual course of his professional practice must be evaluated based on an objective standard." *See, e.g., Joseph*, 709 F.3d at 1097. At the same time, we consistently rejected attempts by defendants to change this language and introduce other formulations

that had a subjective character. *Id.*; *Tobin*, 676 F.3d at 1283; *Merrill*, 513 F.3d at 1306. Based on all of this, we conclude this phrase on its own inadequately conveyed the required mens rea.

Second, even viewing this phrase in the context of the "entire charge," the remaining jury instructions did not help convey that a subjective analysis was required for the "except as authorized" exception. The district court enumerated the elements of a § 841(a) charge: (1) the defendant dispensed the controlled substance; (2) "the [d]efendant did so knowingly and intentionally;" and (3) the defendant *did* not have authorization. Grammatically, the "did so" phrase links the mens rea element to the preceding element describing the actus reus of dispensing the controlled substance, but not to the "except as authorized" exception.

Third and finally, the summary of the charge also did not help to convey the required mens rea. The district court essentially repeated the language from 21 C.F.R. § 1306.04(a) without linking it to any requirement that the jury find a lack of good faith or scienter for this exception.

Therefore, we conclude that the district court's instruction for the substantive drug charges inadequately conveyed the required mens rea to authorize conviction under § 841(a).

IV.

We turn now to whether the error in the jury instructions was harmless beyond a reasonable doubt. *Neder*, 527 U.S. at 15-16. The Supreme Court has held that while the omission of an element from the jury instruction is unconstitutional, "most constitutional errors can be harmless." *Id.* at 8 (quoting *Arizona v. Fulminante*, 499 U.S. 279, 306, 111 S. Ct. 1246, 113 L. Ed. 2d 302 (1991)).

In *McDonnell v. United States*, the Supreme Court held that the erroneous omission of limiting language for the definition of "official act" under the federal bribery statute was not harmless. 579 U.S. 550, 577-80, 136 S. Ct. 2355, 195 L. Ed. 2d 639 (2016). In that case, extensive evidence was presented both of acts that arguably fell within the overinclusive instruction, and of acts that would still qualify as "official acts" had the proper limiting instruction been given. *Id.* at 577. Under this circumstance, the Supreme Court held that the jury may have convicted the defendant "for conduct that [was] not unlawful," and therefore the error was not harmless beyond a reasonable doubt. *Id.* at 579-80.

Here, the district court did not adequately instruct the jury that the defendants must have "knowingly or intentionally" prescribed outside the usual course of their professional practices. At a minimum, as discussed above, without the limiting qualification that only *subjective* good faith was sufficient for conviction, the jury was authorized to convict under the sort of objective good faith or honest effort standard rejected by the Supreme Court.

For Dr. Ruan, both sides presented expert evidence about the appropriate standard of care. In his defense, Dr. Ruan introduced witnesses who testified to his practices and procedures at the clinic to guard against abuse. He also testified in his own defense about how he always centered the patient's medical needs. Dr. Couch also introduced both expert witnesses who testified to the standard of care and lay witnesses who testified to his activities at the clinic. Like Dr. Ruan, Dr. Couch testified that he believed his actions to be in accord with the applicable standard of care.

The jury could have weighed all of this evidence and concluded that Dr. Ruan and Dr. Couch subjectively believed their conduct was in accord with the appropriate standard of care. But under the erroneous instruction that was given, the jury could convict the defendants if they found that a reasonable doctor would not have believed the conduct was in accord with the appropriate standard. In other words, a properly instructed jury may not have convicted the defendants had it known that Dr. Ruan's and Dr. Couch's subjective beliefs that they were acting properly was a defense to these charges. Similar to *McDonnell*, under the erroneous instruction in this case the jury was authorized to convict the defendants for conduct that was lawful. Thus, we cannot conclude that these errors were harmless. We therefore **vacate** the defendants' substantive drug convictions under § 841(a).

V.

Given that we have found error in the district court's instructions for the § 841(a) charges, all that remains is to decide which, if any, of the other charges must also be vacated.

1.

We begin with the conspiracy to violate the Controlled Substances Act charges, violations of 21 U.S.C. § 846. To violate § 846 the government must prove: "(1) there was an agreement between two or more people to commit a crime (in this case, unlawfully dispensing controlled substances in violation of § 841(a)(1)); (2) the defendant knew about the agreement; and (3) the defendant voluntarily joined the agreement." *United States v. Azmat*, 805 F.3d 1018, 1035 (11th Cir. 2015).

Because a conviction under § 846 requires the jury to find that the defendants knew of the illegal nature of the scheme and agreed to participate in it, the erroneous jury instruction for the substantive charges has a limited impact here. Consider what a jury who voted to convict under § 846 would have to find. The jury would need to find that the defendant knew the illegal object of the conspiracy. For a defendant to know that the aim of their agreement was illegal in this context means that they would need to know both that (1) they were dispensing a controlled substance and (2) that they were doing so in an unauthorized manner. If the jury concluded that the defendant did not know either of these things, then they

could not conclude the defendant knew the illegal object of the conspiracy and could not vote to convict.

In this circumstance, the inadequate substantive jury instruction would have no effect on the jury's analysis for the conspiracy counts. The jury did not need an additional instruction clarifying between subjective and objective good faith for the "except as authorized" exception, because the conspiracy instructions already required them to find that the defendant acted with subjective knowledge.

Here, the jury instructions for the drug conspiracy charges tracked our precedent and conveyed the adequate mens rea. The jurors in this case were instructed to convict only if they found "two or more people in some way agreed to try and accomplish a shared unlawful plan to distribute or dispense . . . the alleged controlled substance or substances." Further, they were instructed to convict only if they found that the defendants "knew the unlawful purpose of the plan and willfully joined it." The instructions told the jury that a person acts with willfulness only when they act "voluntarily and purposefully . . . to do something the law forbids." Had the jury in this case concluded that Dr. Ruan or Dr. Couch believed their actions to be for a legitimate medical purpose they could not have found the defendants made an "unlawful plan" and "knew" its "unlawful purpose," nor could they have concluded they "willfully" joined that plan. The jury was properly instructed on these counts, and considering all the evidence, voted to convict. So the instructions for the drug conspiracy charges were not

erroneous, and any error in the substantive drug charges was harmless to these convictions.

2.

Next, the inadequate instruction does not affect the defendants' convictions for conspiracy to commit health care fraud in violation of 18 U.S.C. §§1347 and 1349. A health care fraud conspiracy is fundamentally about the submission of false medical claims to health care benefit programs. *United States v. Gonzalez*, 834 F.3d 1206, 1214 (11th Cir. 2016). Here, the government proceeded on four distinct factual theories, that the defendants conspired to: (1) falsely certify that some patients had cancer when they did not; (2) bill office visits with nurse practitioners as if Dr. Couch conducted them; (3) bill insurers for medically unnecessary drug tests; and (4) bill insurers for office visits that prescribed medically unnecessary drugs. *See Ruan I*, 966 F.3d at 1142-44 (summarizing charges and evaluating sufficiency of the evidence).

None of these theories is affected by the inadequate jury instruction for the substantive drug charges. The jury was properly instructed by the district court for the health care fraud conspiracy charges, and the defendants do not challenge the jury instructions for these charges. They argue nonetheless that *United States v. Ignasiak*, 667 F.3d 1217 (11th Cir. 2012), requires us to consider the substantive drug charges and the fraud counts "together" because in that case we stated such charges may be "inextricably intertwined." *Id.* at 1235. But the defendants overstate *Ignasiak*. In that case we considered

the sufficiency of the evidence for substantive drug convictions under § 841 and convictions for health care fraud under 18 U.S.C. § 1347. *Id.* at 1219. The government's theory of the case for the drug charges turned on whether the prescriptions were legitimate, and submitting the illegitimate prescriptions was the fraud perpetrated on the health care benefit programs. *Id.* at 1227. Thus, in the context of a sufficiency of the evidence challenge, both sets of charges rose and fell together. Had the defendant in that case shown the evidence was insufficient for the jury to find the prescriptions were illegitimate, then both the substantive drug charges and the fraud counts would fall. This is all *Ignasiak* was saying; it was not announcing any broader principle about how the two types of charges relate to one another.

Here, whether or not the defendants had subjective knowledge that their prescriptions were outside the "usual course" is irrelevant to whether or not the defendants also (1) falsely certified that patients had cancer; (2) falsely billed for office visits when the doctor was not present; (3) falsely billed insurers for unnecessary medical tests; or (4) falsely billed insurers for office visits to prescribe unnecessary drugs. Thus, the inadequate jury instruction was harmless as to the health care fraud conspiracy convictions.

3.

Nor are the defendants' convictions under Count 17 for conspiring to violate the Anti-Kickback Statute, 18 U.S.C. § 371 and 42 U.S.C. § 1320a-7b, affected by the

inadequate instruction. The defendants were convicted of willfully receiving compensation from the pharmaceutical company InSys in exchange for increased prescriptions of InSys branded fentanyl. By doing so the jury found that the defendants willfully received compensation from the pharmaceutical company InSys in exchange for increased prescriptions of fentanyl. Like the health care fraud charges, the jury was properly instructed on this count. For the reasons previously stated for the health care fraud conspiracy charges, the inadequate instruction is equally irrelevant to the defendants' conviction under the Anti-Kickback Statute.

4.

The defendants were convicted of two counts of conspiracy to commit mail or wire fraud, in violation of 18 U.S.C. §§ 1341, 1343, and 1349. Three different theories were used to convict the defendants, none of which is affected by the inadequate instruction. Two theories overlapped with the health care fraud conspiracy charges: (1) falsely billing insurers for visits with a nurse practitioner at the higher rate for a visit with a doctor; and (2) falsely certifying that patients had cancer to justify prescribing expensive drugs. These theories are unaffected by the jury instructions for the same reasons stated previously. Unique to this count, the government's third theory alleged that the defendants selected more expensive drugs to stock in their workers' compensation dispensary and made decisions about which drug to prescribe based on the profit generated by the higher reimbursement for these drugs rather than medical need.

Again, the jury was properly instructed on this count. The mens rea instructions for the § 841 conviction have nothing to do with these theories.

5.

The defendants were charged with one count of conspiring to violate the Racketeer Influenced and Corrupt Organizations Act (RICO). 18 U.S.C. § 1962(d). RICO requires the government to prove a "pattern of racketeering activity" which generally means the commission of two or more predicate offenses. 18 U.S.C. § 1962(a); id. § 1961(1), (5). In this case, the government identified 21 U.S.C. § 841 (substantive drug charges); 21 U.S.C. § 846 (conspiracy drug charges); 18 U.S.C. § 1341 (mail fraud); and 18 U.S.C. § 1343 (wire fraud) as the predicate offenses. To prove a RICO conspiracy, the government need only prove that the defendants agreed to participate in the enterprise and that there was an agreement to preform the predicate offenses. *United States v. Pepe*, 747 F.2d 632, 660 n.44 (11th Cir. 1984). There is no requirement that the predicate offenses even occur, just that the defendants agreed to commit them.

As an initial matter, we have already held that the inadequate instruction for the substantive drug charges did not affect the defendants' convictions for conspiracy to violate the Controlled Substances Act and conspiracy to commit mail or wire fraud. To the extent the jury relied on these charges, the inadequate instruction was harmless to the RICO conspiracy conviction. But even had the jury been relying entirely on the substantive drug charges as

the predicates for the RICO conspiracy, the inadequate instruction is still harmless. Similar to the § 846 charges, in order to convict the defendants for RICO conspiracy, the jury was instructed it had to find "the Defendant[s] had the specific intent either to personally participate in committing . . . or else to participate in the enterprise's affairs, knowing that other members of the conspiracy would commit" the predicate offenses. Thus, if the jury relied entirely on the § 841 charges, they would still have made a finding that the defendants *intended* to violate § 841, which means that the defendants would have to have known their acts were unauthorized. For these reasons we hold the inadequate jury instruction for the substantive drug charges was harmless to the RICO conspiracy conviction.

6.

Finally, turning to Dr. Ruan's money laundering convictions, these were also unaffected by the inadequate instruction. He was convicted of two counts of substantive money laundering offenses in violation of 18 U.S.C. § 1957(a) and one count of conspiracy to commit money laundering in violation of 18 U.S.C. § 1956(h).

Substantive money laundering under § 1957 criminalizes the knowing execution of "monetary transaction[s]" over $10,000 that use money "derived from specified unlawful activity." 18 U.S.C. § 1957(a). Here, the government alleged that the health care conspiracies (18 U.S.C. § 1347); the Anti-Kickback Statute conspiracies (18 U.S.C. § 371; 42 U.S.C. § 1320a-7b); and the drug

conspiracies (21 U.S.C. § 846) were the specified unlawful activity. As we have previously said, these convictions were unaffected by the inadequate instruction for the substantive drug charges. Therefore, the inadequate instruction was harmless to the substantive money laundering convictions under § 1957(a).

Conspiracy to commit money laundering criminalizes those who conspire to violate either of the two money laundering sections, 18 U.S.C. §§ 1956 and 1957. Because we hold that the instruction was harmless to the substantive money laundering convictions it cannot possibly affect the money laundering conspiracy conviction.

VI.

For the reasons stated above we **VACATE** in part and **AFFIRM** in part the defendants' convictions. We **VACATE** both of the defendants' sentences on all counts consistent with our ordinary practice in multi-indictment cases. *See United States v. Fowler*, 749 F.3d 1010, 1017-18 (11th Cir. 2014) (collecting cases and noting "we have always . . . presumed that sentences on each count of a multi-count indictment are part of a package"). We remand to the district court for further proceedings consistent with the following instructions:

(1) We **VACATE** Dr. Ruan's convictions under 21 U.S.C. § 841 in Counts 8, 9, 11, and 12. We **REMAND** for new trial.

(2) We **VACATE** Dr. Couch's convictions under 21 U.S.C. § 841 in Counts 5, 6, 7, 13, and 14. We **REMAND** for new trial.

(3) We **AFFIRM** the defendants' convictions on all remaining counts.

(4) We **VACATE** the defendants' sentence for all counts and **REMAND** for resentencing on the surviving counts.

APPENDIX B — OPINION AND CONCURRING IN JUDGMENT OF THE SUPREME COURT OF THE UNITED STATES, DATED JUNE 27, 2022

SUPREME COURT OF THE UNITED STATES

Nos. 20-1410 and 21-5261

20-1410

XIULU RUAN,

Petitioner,

v.

UNITED STATES.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

21-5261

SHAKEEL KAHN,

Petitioner,

v.

UNITED STATES.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

[June 27, 2022]

Appendix B

JUSTICE BREYER delivered the opinion of the Court.

A provision of the Controlled Substances Act, codified at 21 U. S. C. §841, makes it a federal crime, "*[e]xcept as authorized*[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance," such as opioids. 84 Stat. 1260, 21 U. S. C. §841(a) (emphasis added). Registered doctors may prescribe these substances to their patients. But, as provided by regulation, a prescription is only authorized when a doctor issues it "for a legitimate medical purpose . . . acting in the usual course of his professional practice." 21 CFR §1306.04(a) (2021).

In each of these two consolidated cases, a doctor was convicted under §841 for dispensing controlled substances not "as authorized." The question before us concerns the state of mind that the Government must prove to convict these doctors of violating the statute. We hold that the statute's "knowingly or intentionally" *mens rea* applies to authorization. After a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.

I

The question we face concerns §841's exception from the general prohibition on dispensing controlled substances contained in the phrase "[e]xcept as authorized." In particular, the question concerns the defendant's state

of mind. To prove that a doctor's dispensation of drugs via prescription falls within the statute's prohibition and outside the authorization exception, is it sufficient for the Government to prove that a prescription was *in fact* not authorized, or must the Government prove that the doctor *knew* or *intended* that the prescription was unauthorized?

Petitioners Xiulu Ruan and Shakeel Kahn are both doctors who actively practiced medicine. They both possessed licenses permitting them to prescribe controlled substances. The Government separately charged them with unlawfully dispensing and distributing drugs in violation of §841. Each proceeded to a jury trial, and each was convicted of the charges.

At their separate trials, Ruan and Kahn argued that their dispensation of drugs was lawful because the drugs were dispensed pursuant to valid prescriptions. As noted above, a regulation provides that, "to be effective," a prescription "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR §1306.04(a). We assume, as did the courts below and the parties here, that a prescription is "authorized" and therefore lawful if it satisfies this standard. At Ruan's and Kahn's trials, the Government argued that the doctors' prescriptions failed to comply with this standard. The doctors argued that their prescriptions did comply, and that, even if not, the doctors did not knowingly deviate or intentionally deviate from the standard.

Ruan, for example, asked for a jury instruction that would have required the Government to prove that he

subjectively knew that his prescriptions fell outside the scope of his prescribing authority. The District Court, however, rejected this request. The court instead set forth a more objective standard, instructing the jury that a doctor acts lawfully when he prescribes "in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States." App. to Pet. for Cert. in No. 20-410, p. 139a. The court further instructed the jury that a doctor violates §841 when "the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice." *Ibid.* The jury convicted Ruan, and the trial court sentenced him to over 20 years in prison and ordered him to pay millions of dollars in restitution and forfeiture.

The Eleventh Circuit affirmed Ruan's convictions. See 966 F. 3d 1101, 1120, 1166-1167 (2020). The appeals court held that a doctor's "subjectiv[e] belie[f] that he is meeting a patient's medical needs by prescribing a controlled substance" is not a "complete defense" to a §841 prosecution. *Id.*, at 1167. Rather, the court said, "'[w]hether a defendant acts in the usual course of his professional practice must be evaluated based on an *objective* standard, not a subjective standard.'" *Id.*, at 1166 (quoting *United States* v. *Joseph*, 709 F. 3d 1082, 1097 (CA11 2013); emphasis added; alteration in original).

Kahn's trial contained similar disagreements over the proper *mens rea* instructions. Ultimately, the District Court instructed the jury that it should not convict if it found that Kahn acted in "good faith," defined as "an

attempt to act in accordance with what a reasonable physician should believe to be proper medical practice." App. 486. The court added that to find "good faith," the jury must conclude that Kahn "acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." *Ibid.* The court also told the jury that "good faith" was a "complete defense" because it "would be inconsistent with knowingly and intentionally distributing and/or dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose." *Ibid.* The jury convicted Kahn of the §841 charges, and he was sentenced to 25 years in prison.

The Tenth Circuit affirmed Kahn's convictions. See 989 F. 3d 806, 812, 824-826 (2021). In doing so, the court held that to convict under §841, the Government must prove that a doctor "either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice." *Id.*, at 825.

Both Ruan and Kahn filed petitions for certiorari. We granted the petitions and consolidated the cases to consider what *mens rea* applies to §841's authorization exception.

II

As we have said, §841 makes it unlawful, "[e]xcept as authorized[,] . . . for any person knowingly or intentionally . . . to manufacture, distribute, or

dispense . . . a controlled substance." We now hold that §841's "knowingly or intentionally" *mens rea* applies to the "except as authorized" clause. This means that once a defendant meets the burden of producing evidence that his or her conduct was "authorized," the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. Our conclusion rests upon several considerations.

A

First, as a general matter, our criminal law seeks to punish the "'vicious will.'" *Morissette* v. *United States*, 342 U. S. 246, 251, 72 S. Ct. 240, 96 L. Ed. 288 (1952); see also *id.*, at 250, n. 4, 72 S. Ct. 240, 96 L. Ed. 288 (quoting F. Sayre, Cases on Criminal Law, p. xxxvi (R. Pound ed. 1927)). With few exceptions, "'wrongdoing must be conscious to be criminal.'" *Elonis* v. *United States*, 575 U. S. 723, 734, 135 S. Ct. 2001, 192 L. Ed. 2d 1 (2015) (quoting *Morissette*, 342 U. S., at 252, 72 S. Ct. 240, 96 L. Ed. 288). Indeed, we have said that consciousness of wrongdoing is a principle "as universal and persistent in mature systems of [criminal] law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil." *Id.*, at 250, 72 S. Ct. 240, 96 L. Ed. 288.

Consequently, when we interpret criminal statutes, we normally "start from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Rehaif* v. *United States*, 588 U. S. ___ , ___ , 139 S. Ct.

2191, 2195, 204 L. Ed. 2d 594 (2019). We have referred to this culpable mental state as "scienter," which means the degree of knowledge necessary to make a person criminally responsible for his or her acts. See *ibid.*; Black's Law Dictionary 1613 (11th ed. 2019); *Morissette*, 342 U. S., at 250-252, 72 S. Ct. 240, 96 L. Ed. 288.

Applying the presumption of scienter, we have read into criminal statutes that are "*silent* on the required mental state"—meaning statutes that contain no *mens rea* provision whatsoever—"'that *mens rea* which is necessary to separate wrongful conduct from "otherwise innocent conduct."'" *Elonis*, 575 U. S., at 736, 135 S. Ct. 2001, 192 L. Ed. 2d 1 (quoting *Carter* v. *United States*, 530 U. S. 255, 269, 120 S. Ct. 2159, 147 L. Ed. 2d 203 (2000); emphasis added). Unsurprisingly, given the meaning of scienter, the *mens rea* we have read into such statutes is often that of knowledge or intent. See, *e.g.*, *Staples* v. *United States*, 511 U. S. 600, 619, 114 S. Ct. 1793, 128 L. Ed. 2d 608 (1994); *United States* v. *United States Gypsum Co.*, 438 U. S. 422, 444-446, 98 S. Ct. 2864, 57 L. Ed. 2d 854 (1978).

And when a statute is not silent as to *mens rea* but instead "*includes* a general scienter provision," "the presumption applies with equal or greater force" to the scope of that provision. *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 2195, 204 L. Ed. 2d 594 (emphasis added). We have accordingly held that a word such as "knowingly" modifies not only the words directly following it, but also those other statutory terms that "separate wrongful from innocent acts." *Id.*, at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594; see, *e.g.*, *ibid.*; *United States* v. *X-Citement*

Video, Inc., 513 U. S. 64, 72, 115 S. Ct. 464, 130 L. Ed. 2d 372 (1994); *Liparota* v. *United States*, 471 U. S. 419, 426, 105 S. Ct. 2084, 85 L. Ed. 2d 434 (1985).

Section 841 contains a general scienter provision—"knowingly or intentionally." And in §841 prosecutions, a lack of authorization is often what separates wrongfulness from innocence. Defendants who produce evidence that they are "authorized" to dispense controlled substances are often doctors dispensing drugs via prescription. We normally would not view such dispensations as inherently illegitimate; we expect, and indeed usually want, doctors to prescribe the medications that their patients need. In §841 prosecutions, then, it is the fact that the doctor issued an *unauthorized* prescription that renders his or her conduct wrongful, not the fact of the dispensation itself. In other words, authorization plays a "crucial" role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct. *X-Citement Video*, 513 U. S., at 73, 115 S. Ct. 464, 130 L. Ed. 2d 372. Applying §841's "knowingly or intentionally" *mens rea* to the authorization clause thus "helps advance the purpose of scienter, for it helps to separate wrongful from innocent acts." *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594; see also *X-Citement Video*, 513 U. S., at 72-73, 115 S. Ct. 464, 130 L. Ed. 2d 372.

In addition, the regulatory language defining an authorized prescription is, we have said, "ambiguous," written in "generalit[ies], susceptible to more precise definition and open to varying constructions." *Gonzales* v. *Oregon*, 546 U. S. 243, 258, 126 S. Ct. 904, 163 L. Ed.

2d 748 (2006); see *id.*, at 257, 126 S. Ct. 904, 163 L. Ed. 2d 748 (regulation "gives little or no instruction on" major questions); see also 21 CFR §1306.04(a) (regulation defining "effective" prescription as one "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice"). The conduct prohibited by such language (issuing invalid prescriptions) is thus "often difficult to distinguish from the gray zone of socially acceptable . . . conduct" (issuing valid prescriptions). *United States Gypsum*, 438 U. S., at 441, 98 S. Ct. 2864, 57 L. Ed. 2d 854. A strong scienter requirement helps to diminish the risk of "overdeterrence," *i.e.*, punishing acceptable and beneficial conduct that lies close to, but on the permissible side of, the criminal line. *Ibid.*

The statutory provisions at issue here are also not the kind that we have held fall outside the scope of ordinary scienter requirements. Section 841 does not define a regulatory or public welfare offense that carries only minor penalties. Cf. *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594 (slip op., at 6); *Staples*, 511 U. S., at 606, 114 S. Ct. 1793, 128 L. Ed. 2d 608. Rather, §841 imposes severe penalties upon those who violate it, including life imprisonment and fines up to $1 million. See §841(b)(1)(C); see generally §841(b). Such severe penalties counsel in favor of a strong scienter requirement. See *Staples*, 511 U. S., at 618-619, 114 S. Ct. 1793, 128 L. Ed. 2d 608 (noting that "a severe penalty is a further factor tending to suggest that . . . the usual presumption that a defendant must know the facts that make his conduct illegal should apply"); *United States Gypsum*, 438 U. S., at 442, n. 18, 98 S. Ct. 2864, 57 L. Ed. 2d 854.

Nor is the "except as authorized" clause a jurisdictional provision, to which the presumption of scienter would not apply. Cf. *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594 (slip op., at 4); *United States* v. *Yermian*, 468 U. S. 63, 68-69, 104 S. Ct. 2936, 82 L. Ed. 2d 53 (1984). To the contrary, and as we have explained, a lack of authorization is often the critical thing distinguishing wrongful from proper conduct.

B

Analogous precedent reinforces our conclusion. In *Liparota*, we interpreted a statute penalizing anyone who "'knowingly uses [food stamps] in any manner not authorized by'" statute. 471 U. S., at 420, 105 S. Ct. 2084, 85 L. Ed. 2d 434. We held that "knowingly" modified both the "use" of food stamps element and the element that the use be "not authorized." *Id.*, at 423, 433, 105 S. Ct. 2084, 85 L. Ed. 2d 434. We applied "knowingly" to the authorization language even though Congress had not "explicitly and unambiguously" indicated that it should so apply. *Id.*, at 426, 105 S. Ct. 2084, 85 L. Ed. 2d 434. But if knowingly did not modify the fact of nonauthorization, we explained, the statute "would . . . criminalize a broad range of apparently innocent conduct." *Ibid.*

Similarly, in *X-Citement Video*, we interpreted a statute penalizing anyone who "'knowingly transports'" or "'knowingly receives'" videos "'involv[ing] the use of a minor engaging in sexually explicit conduct.'" 513 U. S., at 68, 115 S. Ct. 464, 130 L. Ed. 2d 372. We held that "knowingly" applied not only to the element of transporting

or receiving videos but also to the elemental fact that the videos involve "the use of a minor." *Id.*, at 66, 115 S. Ct. 464, 130 L. Ed. 2d 372. We recognized that this was not "the most grammatical reading of the statute." *Id.*, at 70, 115 S. Ct. 464, 130 L. Ed. 2d 372. But, we explained, "the age of the performers is the crucial element separating legal innocence from wrongful conduct," for possessing sexually explicit videos involving *nonminors* is protected First Amendment activity. *Id.*, at 72-73, 115 S. Ct. 464, 130 L. Ed. 2d 372.

Finally, in *Rehaif*, we interpreted a statutory scheme in which one statutory subsection provided penalties for anyone who "knowingly violates" a separate subsection. 588 U. S., at ___-___, 139 S. Ct. 2191, 2195-2196, 204 L. Ed. 2d 594. This latter subsection made it "unlawful" for people with certain statuses (*i.e.*, being a felon or being in the country unlawfully) to possess a gun. *Ibid.* We held that the first subsection's "knowingly" language applied to the status element in the second subsection. *Id.*, at ___, 139 S. Ct. 2191, 204 L. Ed. 2d 594 (slip op., at 5). To convict under the statute, then, the Government had to prove that a defendant knew he had one of the listed statuses. *Ibid.* "Without knowledge of that status," we reasoned, "the defendant may well lack the intent needed to make his behavior wrongful," because "[a]ssuming compliance with ordinary licensing requirements, the possession of a gun can be entirely innocent." *Id.*, at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594.

Like the statutes at issue in these cases, the statute here contains a scienter provision. Section 841 states:

"Except as authorized by this subchapter, it shall be unlawful for any person *knowingly or intentionally* . . . to manufacture, distribute, or dispense . . . a controlled substance." (Emphasis added.) Like those three cases, the question here concerns the mental state that applies to a statutory clause ("[e]xcept as authorized") that does not immediately follow the scienter provision. Like the three cases, the statutory clause in question plays a critical role in separating a defendant's wrongful from innocent conduct. And, like the Court in those cases, we conclude that the statute's *mens rea* applies to that critical clause.

III

We are not convinced by the Government's arguments to the contrary. First, the Government correctly points out, and the concurrence emphasizes, that the statutory language at issue in the cases we have just described set forth *elements* of the offense. Here, the Government and the concurrence say, the "except as authorized" clause does not set forth an element. See, *e.g.*, *post*, at 4-7 (ALITO, J., concurring in judgment).

The Government and the concurrence point to two ways in which the "except as authorized" clause is unlike an element, both of which rely on a different provision of the Controlled Substances Act—§885. Section 885 says that the Government need not "negative"—*i.e.*, refute—"any exemption or exception . . . in any complaint, information, indictment, or other pleading." This means that, in a prosecution under the Controlled Substances Act, the Government need not refer to a lack of authorization

(or any other exemption or exception) in the criminal indictment. Cf. *United States* v. *Resendiz-Ponce*, 549 U. S. 102, 108, 127 S. Ct. 782, 166 L. Ed. 2d 591 (2007) (criminal indictment must set forth all elements of the charged crime). Section 885 also says that the Government need not "negative any exemption or exception . . . in any trial," and that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit," not upon the prosecution. Cf. *Patterson* v. *New York*, 432 U. S. 197, 210, 97 S. Ct. 2319, 53 L. Ed. 2d 281 (1977) (Government bears burden of proving all elements of charged offense).

But even assuming that lack of authorization is unlike an element for the two purposes that §885 sets forth, those two purposes have little or nothing to do with scienter requirements. The first has to do with the indictment. It simply says that the Government need not set forth in an indictment a lack of authorization, or otherwise allege that a defendant does not fall within the many exceptions and exemptions that the Controlled Substances Act contains. The Act excepts, for example, licensed professionals such as dentists, veterinarians, scientific investigators, and pharmacists from the prohibition on dispensing controlled substances. See 21 U. S. C. §802(21). The Act also excepts employees of drug manufacturers, common carriers, and people with sick family members or pets from the prohibition on possessing controlled substances. See §§802(27), 822(c). Section 885 merely absolves the Government of having to allege, in an indictment, the inapplicability of every statutory exception in each Controlled Substances Act prosecution.

Section 885's second purpose refers only to "the burden of going forward with the evidence," *i.e.*, the burden of *production*. See Black's Law Dictionary, at 244. It says nothing regarding the distinct issue of the burden of *persuasion*—*i.e.*, the burden of proving a lack of authorization. Cf. *Director, Office of Workers' Compensation Programs* v. *Greenwich Collieries*, 512 U. S. 267, 274, 114 S. Ct. 2251, 129 L. Ed. 2d 221 (1994) ("our opinions consistently distinguis[h] between burden of proof, which we defined as burden of persuasion, and . . . the burden of production or the burden of going forward with the evidence"); see also *Schaffer* v. *Weast*, 546 U. S. 49, 56, 126 S. Ct. 528, 163 L. Ed. 2d 387 (2005). Section 885 can thus be understood as providing a presumptive device, akin to others we have recognized in the criminal context, which "merely shift[s] the burden of production to the defendant, following the satisfaction of which the ultimate burden of persuasion returns to the prosecution." *County Court of Ulster Cty.* v. *Allen*, 442 U. S. 140, 157-158, n. 16, 99 S. Ct. 2213, 60 L. Ed. 2d 777 (1979); see *Parker* v. *Matthews*, 567 U. S. 37, 42, n. 1, 132 S. Ct. 2148, 183 L. Ed. 2d 32 (2012) (*per curiam*). Contrary to the concurrence's assertion, see *post*, at 9-11, the differences between these two burdens and the use of procedural mechanisms to shift one burden but not the other are well established. See, *e.g.*, 29 Am. Jur. 2d Evidence §207, p. 246 (2019) ("due process does not prohibit the use of a . . . procedural device that shifts to a defendant the burden of producing some evidence contesting a fact that may otherwise be inferred, provided the prosecution retains the ultimate burden of proof"); 1 W. LaFave, Substantive Criminal Law §1.8(a), p. 102 (3d ed. 2018) (similar). In a §841 prosecution,

then, once the defendant satisfies the initial burden of production by producing evidence of authorization, the burden of proving a lack of authorization shifts back to the Government. And, as with §885's indictment-related purpose, §885's burden-related purpose simply relieves the Government from having to disprove, at the outset of every Controlled Substances Act prosecution, every exception in the statutory scheme.

Section 885 thus does not provide a basis for inferring that Congress intended to do away with, or weaken, ordinary and longstanding scienter requirements. At the same time, the language of §841 (which explicitly includes a "knowingly or intentionally" provision); the crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct; the serious nature of the crime and its penalties; and the vague, highly general language of the regulation defining the bounds of prescribing authority all support applying normal scienter principles to the "except as authorized" clause. That statutory requirement, while differing from an element in some respects, is sufficiently like an element in respect to the matter at issue here as to warrant similar legal treatment.

And the Government does not deny that, once a defendant claims that he or she falls within the authorization exception and the burden shifts back to the Government, the Government must prove a lack of authorization by satisfying the ordinary criminal law burden of proof—beyond a reasonable doubt. See Brief for United States 26; Tr. of Oral Arg. 50-51; see also *id.*,

at 62-65. But see *post*, at 10-11 (concurrence suggesting, contrary to the position advanced by all parties to these cases, that the Government need only prove lack of authorization by a preponderance of the evidence). Once the defendant meets his or her burden of production, then, the Government must prove lack of authorization beyond a reasonable doubt.

Resisting the "knowingly or intentionally" standard, the Government instead offers a substitute *mens rea* standard. The Government says that rather than simply apply the statute's "knowingly or intentionally" language to the authorization clause, we should read the statute as implicitly containing an "objectively reasonable good-faith effort" or "objective honest-effort standard." Brief for United States 16-17; cf. *post*, at 13 (concurrence arguing that doctors can defend against a §841 prosecution by proving that they have "act[ed] in subjective good faith in prescribing drugs"). That is to say, once a defendant meets his or her burden of production, the Government can convict "by proving beyond a reasonable doubt that [the defendant] did not even make an objectively reasonable attempt to ascertain and act within the bounds of professional medicine." Brief for United States 16.

We are not convinced. For one thing, §841, like many criminal statutes, uses the familiar *mens rea* words "knowingly or intentionally." It nowhere uses words such as "good faith," "objectively," "reasonable," or "honest effort."

For another, the Government's standard would turn a defendant's criminal liability on the mental state of

a hypothetical "reasonable" doctor, not on the mental state of the defendant himself or herself. Cf. *id.*, at 24 (Government arguing that "a physician can violate Section 841(a) when he makes no objectively reasonable attempt to conform his conduct to something *that his fellow doctors would view* as medical care" (emphasis added)).

We have rejected analogous suggestions in other criminal contexts. In *Elonis*, for example, we considered the mental state applicable to a statute that criminalized threatening communications but contained no explicit *mens rea* requirement. 575 U. S., at 732, 135 S. Ct. 2001, 192 L. Ed. 2d 1. The Government argued that the statute required proof that a *reasonable person* would find the communications threatening. *Id.*, at 738-739, 135 S. Ct. 2001, 192 L. Ed. 2d 1. But, we said, "[h]aving liability turn on whether a 'reasonable person' regards the communication as a threat—regardless of what the defendant thinks—reduces culpability on the all-important element of the crime to negligence." *Id.*, at 738, 135 S. Ct. 2001, 192 L. Ed. 2d 1 (some internal quotation marks omitted). "[A]nd," we emphasized, "we 'have long been reluctant to infer that a negligence standard was intended in criminal statutes.'" *Ibid.* (quoting *Rogers* v. *United States*, 422 U. S. 35, 47, 95 S. Ct. 2091, 45 L. Ed. 2d 1 (1975) (Marshall, J., concurring)). We believe the same of the Government's proposed standard here.

The Government asserts that we held to the contrary, and "effectively endorsed" its honest-effort standard, in *United States* v. *Moore*, 423 U. S. 122, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975). Brief for United States 26. But the

question in *Moore* was whether doctors could *ever* be held criminally liable under §841. 423 U. S., at 124, 96 S. Ct. 335, 46 L. Ed. 2d 333. *Moore* did not directly address the issue before us here regarding the *mens rea* required to convict under the statute.

Further, the Government, citing *Yermian*, notes that the authorization clause precedes the words "knowingly or intentionally." And, the Government argues, grammatically speaking, that fact prevents the latter *mens rea* provision from modifying the former clause. See Brief for United States 24-25. But *Yermian* based its holding on the fact that the clause preceding the *mens rea* provision set forth a jurisdictional criteria, which is typically not subject to a scienter requirement. 468 U. S., at 68-69, 104 S. Ct. 2936, 82 L. Ed. 2d 53; see also *Rehaif*, 588 U. S., at ____, 139 S. Ct. 2191, 204 L. Ed. 2d 594 (slip op., at 4). *Yermian* did not base its holding on the grammatical positioning of the statutory language.

Finally, the Government argues that requiring it to prove that a doctor knowingly or intentionally acted not as authorized will allow bad-apple doctors to escape liability by claiming idiosyncratic views about their prescribing authority. See, *e.g.*, Brief for United States 33. This kind of argument, however, can be made in many cases imposing scienter requirements, and we have often rejected it on bases similar to those we have set forth in Part II of this opinion. See, *e.g.*, *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 204 L. Ed. 2d 594 (slip op., at 8); *Liparota*, 471 U. S., at 433-434, 105 S. Ct. 2084, 85 L. Ed. 2d 434.

We do the same here. The Government, of course, can prove knowledge of a lack of authorization through circumstantial evidence. See *ibid.* And the regulation defining the scope of a doctor's prescribing authority does so by reference to objective criteria such as "legitimate medical purpose" and "usual course" of "professional practice." 21 CFR §1306.04(a); see *Gonzales*, 546 U. S., at 285, 126 S. Ct. 904, 163 L. Ed. 2d 748 (Scalia, J., dissenting) ("The use of the word 'legitimate' connotes an *objective* standard of 'medicine'"); *Moore*, 423 U. S., at 141-142, 96 S. Ct. 335, 46 L. Ed. 2d 333 (describing Congress' intent "to confine authorized medical practice within *accepted* limits" (emphasis added)). As we have said before, "the more unreasonable" a defendant's "asserted beliefs or misunderstandings are," especially as measured against objective criteria, "the more likely the jury . . . will find that the Government has carried its burden of proving knowledge." *Cheek* v. *United States*, 498 U. S. 192, 203-204, 111 S. Ct. 604, 112 L. Ed. 2d 617 (1991). But the Government must still carry this burden. And for purposes of a criminal conviction under §841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.

IV

The Government argues that we should affirm Ruan's and Kahn's convictions because the jury instructions at their trials conveyed the requisite *mens rea*. Alternatively, the Government argues that any instructional error was harmless. But the Court of Appeals in both cases evaluated the jury instructions under an incorrect understanding

of §841's scienter requirements. We decline to decide in the first instance whether the instructions complied with the standard we have set forth today. Cf. *Rehaif*, 588 U. S., at ____, 139 S. Ct. 2191, 204 L. Ed. 2d 594 (slip op., at 11). We leave that and any harmlessness questions for the courts to address on remand.

* * *

We conclude that §841's "knowingly or intentionally" *mens rea* applies to the "except as authorized" clause. This means that in a §841 prosecution in which a defendant meets his burden of production under §885, the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner. We vacate the judgments of the Courts of Appeals below and remand the cases for further proceedings consistent with this opinion.

It is so ordered.

Appendix B

JUSTICE ALITO, with whom JUSTICE THOMAS joins, and with whom JUSTICE BARRETT joins as to Parts I-A, I-B, and II, concurring in the judgment.

In criminal law, the distinction between the elements of an offense and an affirmative defense is well-known and important. In these cases, however, the Court recognizes a new hybrid that has some characteristics of an element and some characteristics of an affirmative defense. The consequences of this innovation are hard to foresee, but the result may well be confusion and disruption. That risk is entirely unnecessary.

We granted certiorari in these cases to decide whether a physician may be convicted of dispensing or distributing drugs by prescription under a provision of the Controlled Substances Act of 1970 (CSA), 21 U. S. C. §841(a), if he or she believed in good faith that the prescription was within the course of professional practice. In my view, there is a straightforward answer to this question. The CSA contains an exception for prescriptions issued in the course of professional practice, and this exception is a carry-over from the CSA's predecessor, the Harrison Narcotics Act of 1914, 38 Stat. 785. In interpreting the Harrison Act, this Court held that a registered physician acts "in the course of his professional practice" when the physician writes prescriptions "in good faith." *Linder* v. *United States*, 268 U. S. 5, 17-18, 45 S. Ct. 446, 69 L. Ed. 819 (1925). I would hold that this rule applies under the CSA and would therefore vacate the judgments below and remand for further proceedings.

The Court declines to adopt this approach and instead takes a radical new course. It holds that the mental state expressed by the terms "knowingly or intentionally" in §841(a) applies to the provision's "[e]xcept as authorized" proviso. It bases this conclusion not on anything in the language of the CSA, but instead on the "presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state." *Rehaif* v. *United States*, 588 U. S. ____, ____, 139 S. Ct. 2191, 2195, 204 L. Ed. 2d 594 (2019) (slip op., at 3).

The Court's analysis rests on an obvious conceptual mistake. A culpable mental state—or, to use the traditional Latin term, "*mens rea*"—is the mental state an accused must have in relation to the *elements* of an offense. But the authorizations in the CSA that excuse acts that are otherwise unlawful under §841(a) are not elements of the offenses created by that provision. They are *affirmative defenses*. The presumption that elements must be accompanied by a culpable mental state—which I will call "the *mens rea* canon"—provides no guidance on what a defendant must prove to establish an affirmative defense. And for that reason, that canon does not help to decide whether there is a good-faith defense in §841(a) prosecutions of physicians.

The Court does not claim that the "[e]xcept as authorized" proviso actually constitutes an element of dispensing or distributing a controlled substance. But it concludes, based on a vague four-part test, that the proviso is "sufficiently like an element in respect to the matter at issue here as to warrant similar treatment." *Ante*, at

12. How many other affirmative defenses might warrant similar treatment, the Court does not say. It leaves prosecutors, defense attorneys, and the lower courts in the dark. I cannot accept this cavalier treatment of an important question.

Nor can I accept the Court's conclusion that once a defendant produces evidence that his or her conduct was "authorized," "the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." *Ante*, at 5. We did not grant certiorari on the question of the burden of proof applicable to authorizations to dispense or distribute controlled substances. No party has briefed this issue, and its resolution is not essential to our decision in these cases. In keeping with our normal practice, I would not address this question. But because the Court volunteers its own answer, I will offer one as well. As I see it, the text of the CSA does not show that Congress intended to deviate from the common-law rule that the burden of proving "affirmative defenses—indeed, 'all . . . circumstances of justification, excuse or alleviation'—rest[s] on the defendant." *Patterson* v. *New York*, 432 U. S. 197, 202, 97 S. Ct. 2319, 53 L. Ed. 2d 281 (1977) (quoting 4 W. Blackstone Commentaries *201). And absolutely nothing in the text of the statute indicates that Congress intended to impose a burden on the Government to disprove all assertions of authorization beyond a reasonable doubt.

Appendix B

I

A

As relevant here, §841(a)(1) provides that "except as authorized by this subchapter, it shall be unlawful for any per-son knowingly or intentionally . . . to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, . . . a controlled substance." According to the Court's reasoning, the terms "knowingly or intentionally" in §841(a)(1) apply to the "except as authorized" proviso at the beginning of the provision. But it is hard to see how this could be true.

As a matter of elementary syntax, the adverbs "knowingly" and "intentionally" are most naturally understood to modify the verbs that follow, *i.e.*, "manufacture," "distribute," *etc.*, and not the introductory phrase "except as authorized." That phrase, in turn, clearly modifies the term "unlawful."

The Court does not suggest otherwise. It does not claim that "knowingly or "intentionally" *modifies* the introductory proviso in a grammatical sense. (If it did, the introductory phrase would clearly be an element, and for reasons that I will explain, *infra*, at 5-6, 21 U. S. C. §885 unmistakably rules that out.) Instead, the Court pointedly uses different terminology. It repeatedly says that the phrase "knowingly or intentionally" "*applies*" to the introductory phrase, *ante*, at 2, 4, 6, 9, 15 (emphasis added). And it reaches this conclusion based on grounds that have nothing to do with grammar or syntax.

Specifically, the Court relies on a substantive canon of interpretation—the *mens rea* canon. Under this canon, the Court interprets criminal statutes to require a *mens rea* for each element of an offense "even where 'the most grammatical reading of the statute' does not support" that interpretation. *Rehaif*, 588 U. S., at ___, 139 S. Ct. 2191, 2197, 204 L. Ed. 2d 594 (quoting *United States* v. *X-Citement Video, Inc.*, 513 U. S. 64, 70, 115 S. Ct. 464, 130 L. Ed. 2d 372 (1994)).* But until today, this canon has been applied only to elements, and the "except as authorized" introductory phrase in §841(a)(1) is plainly not an element.

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* Why we have held that the *mens rea* canon allows courts to ignore obvious textual evidence of congressional intent is not obvious. In our constitutional system, it is Congress that has the power to define the elements of criminal offenses, not the federal courts. *Liparota* v. *United States*, 471 U. S. 419, 424, 105 S. Ct. 2084, 85 L. Ed. 2d 434 (1985); see also *United States* v. *Davis*, 588 U. S. ___, ___, 139 S. Ct. 2319, 2325, 204 L. Ed. 2d 757 (2019) ("Only the people's elected representatives in the legislature are authorized to 'make an act a crime'" (quoting *United States* v. *Hudson*, 11 U.S. 32, 7 Cranch 32, 34, 3 L. Ed. 259 (1812))). The *mens rea* canon is legitimate when it is used to determine what elements Congress *intended* to include in the definition of an offense. See, *e.g.*, *Staples* v. *United States*, 511 U. S. 600, 605, 114 S. Ct. 1793, 128 L. Ed. 2d 608 (1994) (explaining that the canon is founded on an inference of congressional intent). But applying that canon to *override* the intentions of Congress would be inconsistent with the Constitution's separation of powers. Federal courts have no constitutional authority to re-write the statutes Congress has passed based on judicial views about what constitutes "sound" or "just" criminal law. Cf. *X-Citement Video*, 513 U. S., at 80-82, 115 S. Ct. 464, 130 L. Ed. 2d 372 (Scalia, J., dissenting) (criticizing our *mens rea* canon precedents for "convert[ing a] rule of interpretation into a rule of law" binding on Congress).

"The definition of the elements of a criminal offense is entrusted to the legislature, particularly in the case of federal crimes, which are solely creatures of statute." *Liparota* v. *United States*, 471 U. S. 419, 424, 105 S. Ct. 2084, 85 L. Ed. 2d 434 (1985). See also *Dixon* v. *United States*, 548 U. S. 1, 7, 126 S. Ct. 2437, 165 L. Ed. 2d 299 (2006). But authorization to dispense or distribute a controlled substance lacks the most basic features of an element of an offense. For one thing, it is black-letter law that an indictment must allege "the elements of the offense charged." *Hamling* v. *United States*, 418 U. S. 87, 117, 94 S. Ct. 2887, 41 L. Ed. 2d 590 (1974). So if lack of authorization were an element, it would be necessary to allege that in every §841(a)(1) indictment. But §885 says that it is not "necessary for the United States to negative any exemption or exception set forth in [the relevant subchapter] in any . . . indictment." Beyond that, the prosecution bears the burden of producing evidence with respect to every element of a crime. *Patterson*, 432 U. S., at 215, 97 S. Ct. 2319, 53 L. Ed. 2d 281. But §885(a)(1) also provides that "the burden of going forward with the evidence with respect to any such exemption or exception shall be upon the person claiming its benefit." It could hardly be more obvious that Congress did not cast the "except as authorized" introductory proviso as an element of distributing or dispensing a controlled substance.

Instead, that proviso clearly creates an affirmative defense—that is, a "justification or excuse which is a bar to the imposition of criminal liability" on conduct that satisfies the elements of an offense. 1 W. LaFave, Substantive Criminal Law §1.8(c) (3d ed. 2018). Section

841(a)(1) has two main parts: a principal clause generally prohibiting "knowingly or intentionally" doing certain things with respect to controlled substances (*i.e.*, manufacturing them, distributing them, etc.), and a proviso indicating that these acts are unlawful "except as authorized" by other statutory provisions. As we have long held, the default rule for interpreting provisions with this structure is that "'an exception made by a proviso or other distinct clause'" designates an affirmative defense that the Government has no duty to "'negative.'" *Dixon*, 548 U. S., at 13, 126 S. Ct. 2437, 165 L. Ed. 2d 299 (quoting *McKelvey* v. *United States*, 260 U. S. 353, 357, 43 S. Ct. 132, 67 L. Ed. 301 (1922)); see also *United States* v. *Dickson*, 40 U.S. 141, 15 Pet. 141, 165, 10 L. Ed. 689 (1841) (calling this "the general rule of law which has always prevailed"). When this rule applies, it is "'incumbent on one who relies on such an exception to set it up and establish it.'" *Dixon*, 548 U. S., at 13, 126 S. Ct. 2437, 165 L. Ed. 2d 299 (quoting *McKelvey*, 260 U. S., at 357, 43 S. Ct. 132, 67 L. Ed. 301).

The CSA explicitly incorporates this default rule. As noted, §885(a)(1) provides that the prosecution need not "*negative any exemption or exception set forth in this subchapter* in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding." (Emphasis added.) Short of using the words "affirmative defense," there is no clearer way of indicating that authorization constitutes an affirmative defense.

On the most natural reading, then, §841(a)(1) creates an offense that has as its elements (1) knowingly or intentionally (2) distributing or dispensing (3) a controlled

substance. The "[e]xcept as authorized" proviso recognizes an affirmative defense that excuses or justifies conduct that otherwise would fall within §841(a)(1)'s general prohibition. The *mens rea* canon does not speak to the constituents of that defense.

B

While the Court does not claim that the "[e]xcept as authorized" proviso is an element of a §841(a)(1) offense, the Court argues that the proviso is "sufficiently like an element in respect to the matter at issue here" for the *mens rea* canon to apply, *ante*, at 12. The Court provides four reasons for this conclusion: "[T]he language of §841 (which explicitly includes a 'knowingly or intentionally' provision); the crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct; the serious nature of the crime and its penalties; and the vague, highly general language of the regulation defining the bounds of prescribing authority." *Ibid.* Not one of these reasons withstands scrutiny.

"[T]he language of §841." The Court notes that this provision expressly sets out a *mens rea* that applies to the elements of the offense, *ante*, at 13, but the vast majority of criminal statutes share this characteristic. Therefore, this feature does not set §841 apart.

"[T]he crucial role authorization (or lack thereof) plays in distinguishing morally blameworthy conduct from socially necessary conduct." The Court claims that

authorization separates out morally blameworthy innocent conduct; but something very similar may be said about most, if not all, affirmative defenses. Take the common-law defense of duress. Duress "excuse[s] criminal conduct where the actor was under an unlawful threat of imminent death or serious bodily injury" and the "threat caused the actor to engage in conduct violating the literal terms of the criminal law." *United States* v. *Bailey*, 444 U. S. 394, 409, 100 S. Ct. 624, 62 L. Ed. 2d 575 (1980). But a person who acts under duress is not "morally blameworthy"—that is part of what it means to say that duress excuses otherwise-criminal conduct. Similarly, individuals who kill or wound another person in self-defense to prevent their own death or serious injury are not considered morally blameworthy. No one supposes that these defenses are hybrids, or that the *mens rea* canon is a guide to their content.

It is unclear why the Court thinks that §841(a)'s affirmative defense is different. There are hints in the Court's opinion that it has crafted a special rule for doctors—for example, the Court describes their conduct in writing prescriptions as not just "innocent," but "socially beneficial" and "socially necessary." *Ante*, at 6, 12. But §841(a) is not a doctor-specific provision. Section 841(a)'s proviso presumably applies in the same way for all §841(a) defendants—whether they are drug dealers accused of selling heroin or are physicians charged with abusing their authority to prescribe painkillers.

"[T]he serious nature of the crime and its penalties." The Court also suggests that authorization is "like an

element" because dispensing or distributing a controlled substance is a felony that carries a substantial sentence. But would all felonies qualify? If not, where would the Court draw the line? The Court provides no answers.

"[T]he vague, highly general language of the regulation defining prescribing authority." As the Court explains, the regulation defining the authority of physicians to prescribe controlled substances allows them to issue a prescription "for a legitimate medical purpose . . . in the usual course of . . . professional practice." 21 CFR §1306.04(a) (2021). But §841(a) applies to many other types of violations and many other categories of defendants. Is the proviso a hybrid element/defense only for doctors? Would its status change if the regulation were reframed in more specific terms? How can the status of a phrase in a statute depend upon an implementing regulation? The Court provides no answer to these or any other questions naturally raised by its *ipse dixit* that the exception in §841(a) is "sufficiently like" an element to require that it be treated as such in some respects but not others.

C

The Court also errs in holding that, if a §841(a)(1) defendant "meets the burden of producing evidence that his or her conduct was 'authorized,'" the Government has the burden to "prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner," *ante*, at 5. As noted, the common-law rule was that the defendant had the burden of production and persuasion on any affirmative defense.

And the Court has held that when Congress does not address the burden of proof in the text of a statute, "we presume that Congress intended to preserve the common-law rule." *Smith* v. *United States*, 568 U. S. 106, 112, 133 S. Ct. 714, 184 L. Ed. 2d 570 (2013); see also *Dixon*, 548 U. S., at 13-14, 126 S. Ct. 2437, 165 L. Ed. 2d 299.

The Court identifies one and only one reason for deviating from this background rule—the fact that §885(a)(1) states that "the burden of going forward with the evidence with respect to any . . . exemption or exception shall be upon the person claiming its benefit." Because this provision does not say expressly that a defendant also has the burden of persuasion, the Court infers that Congress meant to allocate that burden to the prosecution. That inference is unwarranted. Section 885(a)(1) explicitly relieves the Government of the burden of "negativ[ing]" exceptions "in any trial." And it is hard to see how the Government does not have the burden to "negative" exceptions if it must affirmatively disprove a prima facie case of authorization any time a defendant satisfies the initial burden of production.

But even if one credits the majority's assumption that the CSA partly deviates from the common-law rule by shifting the burden of persuasion to the Government, the majority's further holding that the Government must carry that burden with proof "beyond a reasonable doubt" comes out of thin air. The usual rule is that affirmative defenses must be proved "by a preponderance of the evidence." *Id.*, at 17, 126 S. Ct. 2437, 165 L. Ed. 2d 299. But the majority does not identify a single word in §§841(a)(1),

885(a)(1), or any other provision of the CSA that even suggests that the statute imposes a burden of disproving authorization defenses beyond a reasonable doubt.

The only thing that could conceivably justify reading a reasonable-doubt requirement into a statute that says nothing on the subject is the principle that an ambiguous statute must be interpreted, when possible, to avoid unconstitutionality. See A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 247-251 (2012). But the Court does not claim that it would be unconstitutional for Congress to require the Government to prove lack of authorization by only a preponderance of the evidence. Indeed, the Court does not even claim that it would be unconstitutional to shift the burden of persuasion to the defendant. Nor could it. Our precedents establish that governments are "foreclosed from shifting the burden of proof to the defendant only 'when an affirmative defense . . . negate[s] an element of the crime.'" *Smith*, 568 U. S., at 110, 133 S. Ct. 714, 184 L. Ed. 2d 570 (quoting *Martin* v. *Ohio*, 480 U. S. 228, 237, 107 S. Ct. 1098, 94 L. Ed. 2d 267 (1987) (Powell, J., dissenting)). And we have held that when an affirmative defense instead justifies or "'excuse[s] conduct that would otherwise be punishable,'" the "Government has no constitutional duty to overcome the defense beyond a reasonable doubt." 568 U. S., at 110, 133 S. Ct. 714, 184 L. Ed. 2d 570 (quoting *Dixon*, 548 U. S., at 6, 126 S. Ct. 2437, 165 L. Ed. 2d 299).

The authorization defense made available to prescribing physicians by the CSA plainly does not negate any of the defining elements of dispensing or

distributing a controlled substance in violation of §841(a)(1). As a result, the Court has no basis for reading a requirement to disprove authorization into the CSA. And at a minimum, even if the Government must bear the ultimate burden of persuasion once the burden of production is satisfied, the CSA should be read to preserve a traditional preponderance-of-the-evidence standard for authorization defenses.

II

My analysis thus far establishes that authorization is an affirmative defense to liability under §841(a)(1), and the constituents of that defense cannot be identified through brute-force application of a canon designed to identify the elements of an offense. In my view, the contours of that defense can be elucidated only by examining the text, structure, and history of the provisions of the CSA that define it. I turn to that task now.

The authorization relied on by the petitioners in these cases permits physicians registered with the federal Drug Enforcement Administration to prescribe controlled substances to patients by prescription. §§822(b), 823(f), 829(a). As we have previously interpreted it, this authorization does not allow physicians to dispense controlled substances by prescription for any reason they choose; instead, the authorization "is limited to the dispensing and use of drugs 'in the course of professional practice or research.'" *United States* v. *Moore*, 423 U. S. 122, 141, 96 S. Ct. 335, 46 L. Ed. 2d 333 (1975) (quoting §802(20) (1970 ed.)).

The notion of action taken "in the course of professional practice" is not defined in the CSA, but our precedents hold that when Congress employs a term of art "obviously transplanted from another legal source," it "brings the old soil with it." *George* v. *McDonough*, 596 U. S. ____, ____, 2022 U.S. LEXIS 2944 at *11 (2022) (quoting *Taggart* v. *Lorenzen*, 587 U. S. ____, ____, 139 S. Ct. 1795, 1801, 204 L. Ed. 2d 129 (2019); internal quotation marks omitted). And the notion that a prescription is authorized if it is issued in the course of professional practice is directly traceable to the Harrison Act, which prohibited "any person" from distributing or dispensing coca leaves or opium "except in pursuance of a written order" issued by a practitioner "in the course of his professional practice only." §2, 38 Stat. 786. Arguably, the phrase "in the course of . . . professional practice" could have been read to refer only to conduct that conforms to the standards of medical practice as a purely objective matter. But our Harrison Act precedents interpreted that phrase to refer to "*bona fide* medical practice," which meant that any prescription issued "in good faith" qualified as an authorized act of dispensing one of the drugs proscribed by the statute. *Linder*, 268 U. S., at 17-18, 45 S. Ct. 446, 69 L. Ed. 819; see also *Boyd* v. *United States*, 271 U. S. 104, 107, 46 S. Ct. 442, 70 L. Ed. 857 (1926); *Webb* v. *United States*, 249 U. S. 96, 99, 39 S. Ct. 217, 63 L. Ed. 497, 17 Ohio L. Rep. 88 (1919).

Nothing in the CSA suggests that Congress intended to depart from the preexisting understanding of action "in the course of professional practice." We have previously held that the CSA incorporates settled understandings of

"the exemption given to doctors" to dispense controlled substances "'in the course of . . . professional practice'" under the Harrison Act. *Moore*, 423 U. S., at 139-140, 96 S. Ct. 335, 46 L. Ed. 2d 333 (quoting 38 Stat. 786). And the language of the CSA supports the same conclusions that we previously reached about the Harrison Act. As our CSA precedents have explained, to act "in the course of professional practice" is to engage in the practice of medicine—or, as we have put it, to "act 'as a physician.'" *Moore*, 423 U. S., at 141, 96 S. Ct. 335, 46 L. Ed. 2d 333. For a practitioner to "practice medicine," he or she must act for a medical purpose—which means aiming to prevent, cure, or alleviate the symptoms of a disease or injury—and must believe that the treatment is a medically legitimate means of treating the relevant disease or injury.

But acting "as a physician" does not invariably mean acting as a *good* physician, as an objective understanding of the "in the course of professional practice" standard would suggest. A doctor who makes negligent or even reckless mistakes in prescribing drugs is still "acting as a doctor"—he or she is simply acting as a *bad doctor*. The same cannot be said, however, when a doctor knowingly or purposefully issues a prescription to facilitate "addiction and recreational abuse," *Gonzales* v. *Oregon*, 546 U. S. 243, 274, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006). Objectives of that kind are alien to medical practice, and a doctor who prescribes drugs for those purposes is not "acting as a physician" in any meaningful sense.

I would thus hold that a doctor who acts in subjective good faith in prescribing drugs is entitled to invoke

the CSA's authorization defense. Under the correct understanding of that defense, a doctor acts "in the course of professional practice" in issuing a prescription under the CSA if—but only if—he or she believes in good faith that the prescription is a valid means of pursuing a medical purpose. A doctor who knows that he or she is acting for a purpose foreign to medicine—such as facilitating addiction or recreational drug abuse—is not protected by the CSA's authorization to distribute controlled substances by prescription. Such doctors may be convicted of unlawfully distributing or dispensing a controlled substance under §841(a)(1).

Based on this holding, I would vacate the judgments of the Courts of Appeals below. And like the Court, I would leave it to those courts to determine on remand whether the instructions provided in petitioners' respective trials adequately described the good-faith defense and whether any errors in the instructions were harmless.

APPENDIX C — ORDER DENYING REHEARING IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED MARCH 2, 2023

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-12653-DD

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

versus

XIULU RUAN, JOHN PATRICK COUCH,

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Alabama

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

BEFORE: WILSON, NEWSOM, Circuit Judges, and COOGLER,* Chief District Judge.

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* Honorable L. Scott Coogler, United States Chief District Judge for the Northern District of Alabama, sitting by designation.

Appendix C

PER CURIAM:

The Petitions for Rehearing En Banc are DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petitions for Panel Rehearing are also denied. (FRAP 40)

APPENDIX D — ORDER DENYING REHEARING IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT, FILED NOVEMBER 4, 2020

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 17-12653-DD

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

XIULU RUAN, JOHN PATRICK COUCH,

Defendants-Appellants.

Appeal from the United States District Court
for the Southern District of Alabama

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

Before WILSON and NEWSOM, Circuit Judges, and COOGLER,* District Judge.

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* Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.

Appendix D

PER CURIAM:

The Petitions for Rehearing En Banc are DENIED, no judge in regular active service on the Court having requested that the Court be polled on rehearing en banc. (FRAP 35) The Petitions for Panel Rehearing are also denied. (FRAP 40)

APPENDIX E — TRANSCRIPT EXCERPTS FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ALABAMA, DATED FEBRUARY 17, 2017

[6314]

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

CASE NO. CR15-00088
COURTROOM 2B
MOBILE, ALABAMA
FRIDAY, FEBRUARY 17, 2017

UNITED STATES OF AMERICA

v.

JOHN PATRICK COUCH, M.D.,
and XIULU RUAN, M.D.,

Defendants.

DAY 28 OF TRIAL BEFORE THE HONORABLE CALLIE V. S. GRANADE, UNITED STATES DISTRICT JUDGE, AND JURY

* * *

[6331:5] Counts two, three, and four of the indictment each allege that the defendants conspired with each other and with others to violate the Controlled Substances Act, Title 21, United States Code, Section 846.

That statute makes it a separate federal crime or offense for anyone to conspire or agree with someone else to do something which, if actually carried out, would be a violation of section 841(a)(1). That section makes it a crime for anyone to knowingly or intentionally distribute or dispense a controlled substance, unless it was prescribed by a practitioner within the usual course of professional practice and for a legitimate medical purpose.

Specifically, count two of the indictment charges that beginning during or at least in 2011 and continuing through May 20, 2015, Defendants Couch and Ruan conspired to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed schedule II controlled substances, including oxycodone, oxymorphone, hydromorphone, and morphine, by means of prescriptions and other methods outside the usual course of professional medical practice and not for a legitimate medical [6332] purpose, in violation of Title 21, United States Code, Section 841(a)(1).

Count three charges that beginning during and at least in 2011 and continuing through May 20, 2015, Defendants Couch and Ruan conspired to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed more than 40 grams of the schedule II controlled substance fentanyl outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1).

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Count four charges that beginning during or at least in 2011 and continuing through May 20, 2015, Defendants Couch and Ruan conspired to knowingly and unlawfully distribute and dispense, possess with intent to distribute and dispense, and cause to be distributed and dispensed schedule III controlled substances, including hydrocodone, by means of prescriptions and other methods outside the usual course of professional medical practice and not for a legitimate medical purpose, in violation of Title 21, United States Code, Section 841(a)(1).

Title 21, United States Code, Section 841(a)(1) makes it a crime for a physician to knowingly or intentionally distribute or dispense a controlled substance unless it was done within the usual course of professional practice and for a legitimate medical purpose. Dispense can mean to prescribe a [6333] controlled substance. Distribute can mean to deliver other than by dispensing a controlled substance.

For a controlled substance to be lawfully dispensed by a prescription, the prescription must have been issued by a practitioner both within the usual course of professional practice and for a legitimate medical purpose. If the prescription was issued either, one, not for a legitimate medical purpose or, two, outside the usual course of professional practice, then the prescription was not lawfully issued.

A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully if the substance is prescribed by him in good faith

as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The defendants in this case maintain at all times they acted in good faith and in accordance with standard of medical practice generally recognized and accepted in the United States in treating patients.

Thus a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice.

[6334] A conspiracy is an agreement by two or more persons to commit an unlawful act. In other words, it is a kind of partnership for criminal purposes. Every member of the conspiracy becomes the agent or partner of every other member.

The government does not have to prove that all the people named in the conspiracy counts were members of the plan or that those who were members made any kind of formal agreement. The heart of a conspiracy is the making of the unlawful plan itself, so the government does not have to prove that the conspirators succeeded in carrying out the plan.

A person may be a conspirator even without knowing all the details of the unlawful plan or the names and identities of all the other alleged coconspirators.

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If the defendant played only a minor part in the plan but had a general understanding of the unlawful purpose of the plan and willfully joined in the plan on at least one occasion, that's sufficient for you to find the defendant guilty.

But simply being present at the scene of an event or merely associating with certain people and discussing common goals and interests does not establish proof of a conspiracy. Also a person who doesn't know about a conspiracy but happens to act in a way that advances some purpose of one doesn't automatically become a conspirator.

Each defendant can be found guilty of the conspiracy alleged in one or more of counts two, three, and four only if [6335] all of the following facts are proved beyond a reasonable doubt as to the count in question: One, two or more people in some way agreed to try and accomplish a shared and unlawful plan to distribute or dispense outside the usual course of professional practice and not for a legitimate medical purpose the alleged controlled substance or substances; and, two, the defendant knew the unlawful purpose of the plan and willfully joined in it.

Now, as you heard during the course of the trial, the schedule II and III controlled substances alleged to have been prescribed either not for a legitimate medical purpose or outside the usual course of professional practice are sold under a variety of brand names, including -- and then there's a chart in your instructions.

The first substance is fentanyl. The brand names are Subsys, Abstral, Fentora, Lazanda, and Duragesic, and it is in schedule II.

The second is oxymorphone, under the brand name Opana. It is schedule II.

The third is hydromorphone. Brand names, Exalgo and Dilaudid, schedule II.

The fourth is oxycodone. Brand names, OxyContin, Roxicodone, Percocet, and Endocet. It is schedule II.

Morphine. Brand names, MS Contin, Kadian, Embeda, Avinza. It is schedule II.

[6336] And lastly, hydrocodone. Brand names are Lortab, Norco, Vicodin, and Zohydro. It is schedule II or III, and that is because hydrocodone was reclassified as a schedule II controlled substance on October 6, 2014. Prior to that date, hydrocodone was a schedule III controlled substance.

For purposes of this case, I instruct you that all of these substances are controlled substances.

With regard to count three only, the defendants are charged with dispensing more than 40 grams of fentanyl outside the usual course of professional practice and not for a legitimate medical purpose. You may find one or both of the defendants guilty of that crime even if the amount of fentanyl for which he or they should be held responsible

is less than the amount alleged. If you find any defendant guilty as to count three, you must also unanimously agree on whether the weight of the fentanyl involved in this offense exceeds 40 grams.

Counts five through 14 charge Defendants Couch and Ruan with substantive violations of Title 21, United States Code, Section 841(a)(1) which, as I said earlier, makes it a federal crime for anyone to knowingly and unlawfully distribute or dispense or possess with intent to distribute or dispense a controlled substance unless it was prescribed by a practitioner within the usual course of professional practice and for a legitimate medical purpose.

[6337] Counts five and six each charge that on or about August 5 and September 8, 2014, Defendant Couch knowingly and unlawfully distributed and dispensed 90 pills of Roxicodone 15 milligrams to an undercover DEA task force officer for no legitimate medical purpose and outside the usual course of professional practice. Additionally, count seven charges that on November 3rd, 2014, Defendant Couch knowingly and unlawfully distributed and dispensed 110 pills of Roxicodone 15 milligrams to the same person for no legitimate medical purpose and outside the usual course of professional practice.

Count eight charges that on or about February 26, 2015, Defendant Ruan knowingly and unlawfully distributed and dispensed specified amounts of Abstral, Subsys, OxyContin, and Norco to Diane Greathouse (or, as stated in the indictment, a patient with the initials D.G.)

for no legitimate medical purpose and outside the usual course of professional practice.

Count nine charges that on or about April 27, 2015, Defendant Ruan knowingly and unlawfully distributed and dispensed specified amounts of Fentora, OxyContin, and oxycodone to Kimberly Lowe (or, as stated in the indictment, a patient with the initials K.L.) for no legitimate medical purpose and outside the usual course of professional practice.

Count 10 charges that on or about July 15, 2014, Defendant Ruan knowingly and unlawfully distributed and dispensed specified amounts of Fentora and Zohydro ER to Erick [6338] Gist (or, as stated in the indictment, a patient with the initials E.G.) for no legitimate medical purpose and outside the usual course of professional practice.

Count 11 charges that on or about November 25, 2014, Defendant Ruan knowingly and unlawfully distributed oxymorphone under the brand name of Opana to Deborah Walker (or, as stated in the indictment, a patient with the initials D.W.) for no legitimate medical purpose and outside the usual course of professional practice.

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Count 12 charges that on or about October 10, 2012, Defendant Ruan knowingly and unlawfully distributed morphine sulfate under the brand name MS Contin to John Bosarge (or, as stated in the indictment, a patient with the initials J.B.) for no legitimate medical purpose and outside the usual course of professional practice.

Count 13 charges that on or about March 5 and March 11, 2015, Defendant Couch knowingly and unlawfully distributed oxycodone hydrochloride under the brand name Roxicodone and oxycodone under the brand name OxyContin to Karen Daw (or, as stated in the indictment, a patient with the initials K.D.) for no legitimate medical purpose and outside the usual course of professional practice.

Count 14 charges that on or about March 18 and March 31, 2014, Defendant Couch knowingly and unlawfully distributed oxymorphone and Morphine Sulfate Instant Release to Patrick [6339] Chausse (or, as stated in the indictment, a patient with the initials P.C.) for no legitimate medical purpose and outside the usual course of professional practice.

The defendant can be found guilty of each offense only if all of the following facts are proved beyond a reasonable doubt as to that offense: One, on or about the date charged, the defendant dispensed by prescription the identified controlled substance to the identified individual; two, the defendant did so knowingly and intentionally; and, three, the defendant did not have a legitimate medical purpose to do so or did not do so in the usual course of professional practice.

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As I stated previously, for a controlled substance to be lawfully dispensed by a prescription, the prescription must have been issued by a practitioner both within the usual course of professional practice and for a legitimate medical purpose. If the prescription was issued either, one, not for a legitimate medical purpose or, two, outside the usual course of professional practice, then the prescription was not lawfully issued.

A controlled substance is prescribed by a physician in the usual course of professional practice and therefore lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The defendants in this case [6340] maintain at all times they acted in good faith and in accordance with standard of medical practice generally recognized and accepted in the United States in treating patients.

Thus, a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional practice.

* * *

[6344:3] Also as to count 15, the indictment identifies four means by which the defendants allegedly conspired to commit healthcare fraud. You may find a defendant guilty of this conspiracy if you conclude beyond a reasonable

doubt that a defendant conspired to commit healthcare fraud by one or more of these four means, provided that you unanimously agree on which ones.

* * * *

APPENDIX F — TRANSCRIPT EXCERPTS FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF ALABAMA, DATED FEBRUARY 16, 2017

[6088]

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ALABAMA

CASE NO. CR15-00088
COURTROOM 2B
MOBILE, ALABAMA
THURSDAY, FEBRUARY 16, 2017

UNITED STATES OF AMERICA

v.

JOHN PATRICK COUCH, M.D.,
and XIULU RUAN, M.D.,

Defendants.

DAY 27 OF TRIAL
BEFORE THE HONORABLE
CALLIE V. S. GRANADE,
UNITED STATES DISTRICT JUDGE, AND JURY

* * *

[6103] THE COURT: So next?

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MR. ESSIG: Next, Your Honor, the second aspect of it is that the Court's proposed instructions do not contain a definition of "usual course of medical practice or legitimate medical purpose."

We think there needs to be one in this case and it's sort of a two-part issue, is that, one, those terms wholly undefined are, I think, difficult for the jury to determine.

Second, Your Honor, is that there is sort of a -- the Eleventh Circuit certainly doesn't have a pattern jury instruction on this issue. But through United States v. Moore, which is sort of the beginning case, the Supreme Court case from the '70s that kind of starts the juris prudence on the Controlled Substances Act as applied to physicians, it's sort of developed an accepted jury instruction that the Eleventh Circuit has given.

Now, we have proposed in Couch instruction 18 various aspects of the concept of usual course for the jury to be instructed on and we think those are appropriate. All of the requested instructions that we provide, most of them are taken from Eleventh Circuit case law, some of them are taken from the Fourth Circuit -- a Fourth Circuit case as well. But, Your Honor, particularly we think the Court included a good faith instruction as it was related to the fraud counts in this case. But we think some sort of good faith or honest faith, [6104] honest effort language or instruction should be included along with the -- with the usual course instruction, the Controlled Substances Act portion of the Court's instructions to the jury.

MS. GRIFFIN: Your Honor, excuse me. Are you finished?

MR. ESSIG: Yes.

MS. GRIFFIN: Are you finished? We would be opposed to that. I don't think there is a definition by the Eleventh Circuit about "outside the usual course of professional care" and I think to charge them anything would invite confusion. Further, I don't think there's been any argument or any suggestion about good faith or honest effort through the testimony of the defense.

MR. BODNAR: As it applies to the drugs. For the fraud --

MS. GRIFFIN: As to the drugs.

MR. BODNAR: -- of course, it is our burden to show that it wasn't done in good faith, as instructed.

MR. ESSIG: Judge, we would disagree with the notion there's been no good faith. Both Dr. Ruan and Dr. Couch in their testimony stated that they did everything with their patients that they believed was appropriate, based on their medical training and experience as board certified pain management doctors. So that's certainly sufficient.

THE COURT: Well, the problem with your requested [6105] instruction, as I understand it -- and having looked at some, although I looked at not all of the case law in this regard -- is what you are proposing is a subjective view

of what is the usual course of professional practice. And the standard should be an objective one, not a subjective one. I understand that good faith is a subjective aspect, although the Eleventh Circuit has approved the language from the Williams case that included good faith.

MR. ESSIG: Yes, ma'am. Yes, ma'am. And that's -- the Williams case, I mean, that instruction has kind of emerged from the case law as kind of the standard Eleventh Circuit instruction that's been given repeatedly in these cases. I mean, it's Williams, it's Merrill, I think the most recent Eleventh Circuit case that applies that is the case of Joseph, which is at --

THE COURT: Yeah, I read the Joseph case.

MR. ESSIG: And that case sort of gives -- that case gives an analysis of the jury instructions there.

THE COURT: But that was not national versus -- not a national standard of care. I mean, it was more of a jurisdictional-type argument.

MR. ESSIG: Yes, ma'am. I think it was. And I think that's right. And one of the challenges, of course, with the Eleventh Circuit case law on this is it's muddled, it is not clear. The Eleventh Circuit's gone both ways on this issue. I [6106] mean, I think they rejected a more robust request for a good faith instruction from the defense but defaulted to this instruction which incorporates -- which incorporates good faith while recognizing that their position that a more robust good faith instruction was not required.

We think it is. Again, our position is that we think that defense instruction 18 should be given. However, if the Court --

THE COURT: Portions of instruction 18 are not what the law is in that regard, at least as I understand it, in that regard. And so that's why I rejected 18. The government didn't propose any definition on that.

MR. BODNAR: For the reason being there's not a defined --

THE COURT: No. But, I mean, there have been cases where they say the giving of such instruction was not plain error. Although we're not -- you know, you're talking about this now, and so it wouldn't be plain error. It would be whether or not it's error not to give the instruction. So I am willing to give the instruction that was in the Williams case.

MR. ESSIG: Yes, ma'am.

THE COURT: That would say: "The defendants in this case maintain at all times they acted in good faith and in accordance with the standard of medical practice generally recognized and accepted in treating patients. Thus a medical [6107] doctor has violated the Controlled Substances Act when the government has proved beyond a reasonable doubt that the doctor's actions were not for legitimate medical purpose in the usual course of professional practice or were beyond the bounds of professional medical practice." But that's as far as I'm

willing to go, given the state of the law on this issue. But it throws a bone to your good faith language while still being fairly general.

MR. BODNAR: We would have no problem with that instruction.

MR. ESSIG: Judge, without waiving our objection that we would like to see instruction 18 --

THE COURT: You would rather see that than nothing at all?

MR. ESSIG: -- we will accept the Court's -- no, we will accept the Court's position.

THE COURT: All right. Okay. Then I'll stick that in there. And that would be -- where I will stick that would be -- there are two places where I describe that. One is on page 15 and --

MR. ESSIG: It becomes a little bit cumbersome because it relates to multiple parts.

THE COURT: Yeah. And then the other place I discuss it is on page 23. 15 is under the conspiracy charge, the substantive portion of the conspiracy charge. And page 23 is [6108] concerning the -- no. Well, it's --

MR. ESSIG: The substantive offenses.

Appendix F

THE COURT: -- the substantive offenses. It starts over on page 22. So I would be inclined to stick it in there where the substantive offenses are. And actually I'll just append it to after "issued," the period and "issued," then start with: "The defendants maintain at all times they acted in good faith," blah, blah, blah, blah, blah.

MR. SHARMAN: That would be at the bottom of 15, Your Honor?

THE COURT: That would be -- yeah, and also on page 23 at the end of that very first paragraph. So it's in those two places. Okay?

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