No. 22-1175

In the Supreme Court of the United States

XIULU RUAN AND JOHN PATRICK COUCH,

Petitioners,

v.

UNITED STATES,

Respondent.

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

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

The government does not dispute that the petition presents important and recurring issues,[1] nor does it dispute that, if 21 C.F.R. § 1306.04(a) is allowed to replace "as authorized" in the text of 21 U.S.C. § 841(a)(1), a physician can spend decades in jail simply because she subjectively knew that her prescriptions fell outside professional norms. And while the government downplays the circuit conflict, it all but admits that there is one.

Instead, the government says that the conflict is not as stark as we say, the issue was not presented below, and use of the regulatory standard is correct.[2] None of those points justifies denying certiorari—the

[1] No surprise there—just since the petition was filed, over a dozen additional cases have conflated the statutory "as authorized" requirement with the regulatory language. *See, e.g.*, *United States v. Bauer*, 2023 WL 6211784, at *7 (6th Cir. Sept. 25, 2023); *United States v. Hofstetter*, 80 F.4th 725, 731-32 (6th Cir. 2023); *United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023); *United States v. Capistrano*, 74 F.4th 756, 770-73 (5th Cir. 2023); *United States v. Kim*, 71 F.4th 155, 164 (4th Cir. 2023); *United States v. Turner*, 2023 WL 6248688, at *9 (M.D. Fla. Sept. 26, 2023); *United States v. Herrell*, 2023 WL 5111953, at *2 (E.D. Ky. Aug. 9, 2023).

[2] The government also offers a recitation of purported facts to try to tar Petitioners. U.S. BIO at 2-7. As Chief Justice Roberts previously observed, the government is "arguing evidence in a case that's about legal standards." Tr. of Oral Argument at 48:14-15, *Ruan v. United States*, No. 20-1410 (Mar. 1, 2022). And as the Eleventh Circuit recognized on remand, "[t]he 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." Pet. App. at 9a.

circuit conflict is real; the issue was presented below; and, far from being correctly decided, the decision below permits criminal legislation by bureaucracy and is unfaithful to *Ruan v. United States*, 142 S. Ct. 2370 (2022) (Pet. App. at 19a-54a), this Court's other precedents, and the CSA. Accordingly, the Eleventh Circuit was wrong to uphold Petitioners' convictions for offenses other than violations of Section 841(a)(1) (which it appropriately vacated).

1. The circuit conflict is real.

The government does cartwheels in downplaying the conflict between *United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023), and the decision below. In the government's view (at 19-22), *Kahn did not foreclose* conviction under Section 841(a)(1) based on the language of Section 1306.04(a).

False. Here is the Tenth Circuit's holding in *Kahn* (quoting this Court's decision in *Ruan*):

> [I]t 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." Proof that a defendant did so is "circumstantial evidence" that may be used to prove knowledge of a lack of authorization. . . . *But, in order to a convict a defendant, the government must prove that the defendant "knew or intended that his or her conduct was unauthorized."*

58 F.4th at 1314 (emphasis added). The jury in *Kahn* "was repeatedly instructed 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." *Id.* at 1315. That instruction was erroneous because, as the Tenth Circuit concluded, "*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 (citing *Ruan*, 142 S. Ct. at 2377, 2382 (Pet. App. at 26a, 37a)).

The government also says (at 22) that the Tenth Circuit did not consider whether the instructions for CSA conspiracy "avoided the mens rea error found in *Ruan*." Again, incorrect. *Kahn* says: "Accordingly, as discussed above, the instructions as to Count[] One [CSA conspiracy] . . . are erroneous and did not result in harmless error." 58 F.4th at 1321.

2. The issue was presented below.

The government's principal argument (at 12-14) is that this issue was not raised below and the Eleventh Circuit did not consider it. Wrong again.

In its opinion, *this Court* told the Eleventh Circuit what the correct standard is for conviction under the CSA. *See Ruan*, 142 S. Ct. at 2375-76, 2382 (Pet. App. at 20a, 24a, 37a-38a). Thus, *this Court* put the issue squarely before the Eleventh Circuit to consider on remand. *See id.* at 2382 (Pet. App. at 38a). Indeed, that was the whole point of the remand.

Although Petitioners made additional arguments on remand, they also made the "as authorized" argument they now present in the petition. For instance, Dr. Ruan argued:

> The instructions given to Dr. Ruan's jury did not remotely comply with the standard articulated by the Supreme Court in this case. Indeed, they were the polar opposite: Whereas the Supreme Court required that juries must find that the physician *subjectively intended* to exceed his authorization, Dr. Ruan's jury was told that it could convict him even if all it found was that, as an *objective* matter, Dr. Ruan's prescriptions strayed outside professional norms.

Suppl. Br. of Appellant (Ruan) on Remand (Doc. 161) at 6; *see also id.* at 8, 12 (similar); Suppl. Reply Br. of Appellant (Ruan) on Remand (Doc. 171) at 1 (similar); Suppl. Br. for the Appellant (Couch) (Doc. 167) at v (adopting Ruan's arguments); Appellant's (Couch) Suppl. Reply Br. on Remand (Doc. 172) at i (same).

It may be added that, even were the government correct (and it isn't), the worst that can be said is that the petition advances other aspects of an overall argument that plainly *was* presented to the court of appeals: Whether this Court's decision in *Ruan* requires reversal of all of Petitioners' convictions. In such circumstances, this Court has not hesitated to treat the contention as fully preserved. *See Yee v. City of Escondido, Cal.*, 503 U.S. 519, 534 (1992) ("Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below.").

3. Far from being correctly decided, the decision below permits criminal legislation by bureaucracy and is unfaithful to *Ruan*, this Court's other precedents, and the CSA.

a. The decision below improperly permits the Attorney General to rewrite criminal laws.

The government says (at 15-16) that the CSA grants rulemaking authority to the Attorney General, who has promulgated Section 1306.04(a) pursuant to that authority. But the CSA does not (and, as a separation-of-powers matter, cannot) authorize the Attorney General to rewrite federal criminal law. Pet. at 31-32. Indeed, in *Gonzales v. Oregon*, 546 U.S. 243 (2006), on which the government prominently relies (at 16-17, 19), this Court made clear that the Attorney General's rulemaking authority under the CSA does *not* grant him the authority "to decide what constitutes an underlying violation of the CSA in the first place." *Id.* at 262. Yet that is exactly the authority the government now claims, by asking this Court to accept an *agency regulation* as a substitute for the actual text of Title 21.

Nor is such a substitution permissible as a matter of *Chevron* deference. As Justice Scalia noted in his concurrence in *Crandon v. United States*, 494 U.S. 152, 177 (1990) (Scalia, J., concurring in the judgment), "we have never thought that the interpretation of those charged with prosecuting criminal statutes is entitled to deference."

b. The decision below, and the government's position, are inconsistent with *Ruan* and this Court's other precedents. The government notes that this

Court "'assume[d] . . . that a prescription is "authorized" and therefore lawful if it satisfies'" the standard set forth in Section 1306.04(a). U.S. BIO at 18 (citing Pet. App. 21a). But this Court manifestly did *not* say that a criminal conviction under Section 841(a)(1) requires the government to prove only that the defendant knew or intended to prescribe not "for a legitimate medical purpose" or not "in the usual course of his professional practice." The Court said—repeatedly—that, to obtain a criminal conviction, the government must prove "that the defendant knowingly or intentionally acted *in an unauthorized manner*." 142 S. Ct. at 2382 (emphasis added) (Pet. App. at 38a); *see also id.* at 2375-76, 2382 (Pet. App. at 20a, 24a, 37a). While a doctor's non-compliance with Section 1306.04(a) may be "circumstantial evidence" of "knowledge of a lack of authorization," it is not synonymous with, and may not be used as a substitute for, a violation of the statutory text. *See id.* at 2382 (Pet. App. at 37a). Thus, "'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.'" *Id.* (citation omitted). But the regulatory criteria, though relevant as circumstantial proof, cannot altogether supplant what this Court held to be the ultimate question: Whether the "defendant knew or intended that his or her conduct was unauthorized." *Id.*

As for the government's suggestion (at 17) that our position "cannot be squared" with *United States v. Moore*, 423 U.S. 122 (1975), this Court has already

"squared" the two and rejected the government's position: "[T]he question in *Moore* was whether doctors could *ever* be held criminally liable under § 841. *Moore* did not directly address the issue before us here regarding the *mens rea* required to convict under the statute." *Ruan*, 142 S. Ct. at 2381 (Pet. App. at 35a-36a) (citation omitted).

c. The CSA itself undermines the government's argument. Under the CSA, "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances in schedule II, III, IV, or V . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(g)(1). The CSA defines "practitioner[s]" to include "physician[s]." *Id.* § 802(21). "Persons registered by the Attorney General under this subchapter to . . . dispense controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter." *Id.* § 822(b). The CSA does *not* limit a physician to dispensing controlled substances only "for a legitimate medical purpose . . . in the usual course of his professional practice," 21 C.F.R. § 1306.04(a), which is why the government relies on the regulation for that limitation.

The government further argues (at 16 & n.1) that Section 1306.04(a) should be accepted as a substitute for "as authorized" because the language of the regulation is also found in disparate parts of the CSA, even if not in the provisions at issue. But the use of the same or similar language in *other* provisions

shows that Congress knew how to use those terms when it wanted. *See Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest."). Section 844(a), a criminal provision relating to "simple possession" of controlled substances is most telling. It provides: "It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, *while acting in the course of his professional practice*, or except as otherwise authorized by this subchapter or subchapter II." 21 U.S.C. § 844(a) (emphasis added). Congress could have used the same language in Section 841(a)(1) (and thus in Section 846 in cases of conspiracy to violate Section 841(a)(1)). It did not.

d. Nor does requiring the government to prove that "a defendant knew or intended that his or her conduct was unauthorized," *Ruan*, 142 S. Ct. at 2382 (Pet. App. at 37a), make each doctor "a law unto himself," U.S. BIO at 18.

This Court rejected that argument:

> [T]he 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. 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. *We do the same here.*

142 S. Ct. at 2382 (Pet. App. at 36a-37a) (emphasis added) (citations omitted). The Court noted that juries need not accept practitioners' unreasonable beliefs. *Id.* (Pet. App. at 37a).

And, if the government fails to prevail in a criminal case, it is not without recourse. It can suspend or revoke a practitioners' registration if it is "inconsistent with the public interest." 21 U.S.C. § 824(a). Practitioners also are subject to state laws and criminal regulations.

The government says (at 19) that this Court "already addressed" Petitioners' concerns about chilling novel and innovative medical practice. That is true, but the lower courts continue to misinterpret (or ignore) this Court's decision. *See supra* note 1 (listing cases); Pet. at 25-30 (same). And the government has no answer to Petitioners' point that the chilling effect is especially pronounced in circuits (including the Eleventh) that treat 21 C.F.R. § 1306.04(a) in the disjunctive, permitting convictions for doctors who *either* knew they were acting outside "usual" norms *or* knew they lacked a "legitimate" medical purpose. Pet. at 24-25. In those circuits, a doctor can be sent to jail simply because she knows that most doctors don't agree with her. How can such a standard possibly coexist with the progress of medicine (which is often lead by innovative off-label prescribing), or, for that matter, the progress of science generally?

4. The Eleventh Circuit was wrong to uphold Petitioners' convictions for offenses other than violations of Section 841(a)(1) (which it appropriately vacated).

The government embraces the Eleventh Circuit's reasoning that the CSA conspiracy instructions were not erroneous because they "required the jury to find that petitioners 'agreed to try and accomplish a shared unlawful plan' to distribute drugs and 'knew the unlawful purpose of the plan and willfully joined it." U.S. BIO at 12 (citing Pet. App. at 11a). The government says those instructions "accorded with basic principles of conspiracy law, which require proof that a defendant 'reach[] an agreement with the specific intent that the underlying crime be committed.'" *Id.* (citing *Ocasio v. United States*, 578 U.S. 282, 288 (2016)).

The preceding page of *Ocasio* says, "under established case law, the fundamental characteristic of a conspiracy is a joint commitment to an 'endeavor which, if completed, would satisfy all of the elements of [the underlying substantive] criminal offense.'" 578 U.S. at 287 (citations omitted). Petitioners' jury was instructed that the "unlawful plan" was "distribut[ing] or dispens[ing] outside the usual course of professional practice and not for a legitimate medical purpose." Pet. App. at 63a. Such conduct is not unlawful, *see Ruan*, 142 S. Ct. at 2382 (Pet. App. at 37a), and thus conspiring to engage in such conduct is not unlawful, *see Ocasio*, 578 U.S. at 287. Petitioners' jury was never told that it could convict the doctors only if it found that they conspired to knowingly or intentionally act "in an unauthorized

manner." *See Ruan* 142 S. Ct. at 2375 (Pet. App. at 20a).

For racketeering conspiracy, the Eleventh Circuit relied on the same faulty logic: 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." Pet. App. at 16a. But as instructed, the jury could "have made a finding that defendants intended to violate § 841" if it found that they knew their prescriptions were *objectively* outside the usual course of professional practice or not for a legitimate medical purpose, even if they believed they were *subjectively* authorized to issue those prescriptions. Pet. App. 65a-68a. Just like with CSA conspiracy, Petitioners could be convicted of racketeering conspiracy for conspiring to do something that is not unlawful. *See Ocasio*, 578 U.S. at 287.

For healthcare fraud conspiracy, two of the four means of the conspiracy were taken directly from Section 1306.04(a): (1) billing insurers for controlled substances "that were not prescribed for a legitimate medical purpose or were prescribed outside the usual course of professional practice," and (2) billing insurers for lab tests "for no legitimate medical purpose and outside the usual course of professional practice." Doc. 269 ¶ 114. Again, the jury could have convicted Petitioners for conspiring to prescribe or test differently from other doctors and bill insurers for those prescriptions or tests, even if Petitioners subjectively believed the prescriptions or tests were appropriate.

And Dr. Ruan's money laundering and money laundering conspiracy convictions were predicated, in part, on the CSA conspiracy and health care fraud conspiracy convictions, Pet. App. at 16a-17a, and thus those convictions cannot stand.

This case is, in short, the right vehicle for clarifying that *Ruan* meant what it said. Title 21, and the compound offenses based on Title 21, require proof that Petitioners knew or intended to act "in an unauthorized manner." *See Ruan* 142 S. Ct. at 2375 (Pet. App. at 20a). Permitting an agency regulation to substitute for the statute is not merely unlawful. It also threatens to unsettle the medical profession in exactly the fashion this Court addressed in *Ruan* the last time around.

CONCLUSION

The petition for a writ of certiorari should be granted. The Court may also wish to consider summarily reversing the decision below.

Respectfully submitted.

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