No. 22-1175

In the Supreme Court of the United States

XIULU RUAN AND JOHN PATRICK COUCH, PETITIONERS

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals, which vacated petitioners' convictions for unlawful drug distribution under 21 U.S.C. 841(a) following a remand from this Court, was required to vacate more of petitioners' convictions based on a theory—never raised by petitioners and not reflected in their own proposed jury instructions—that jury instructions relating to their "authoriz[ation]" to distribute drugs, *ibid.*, erroneously incorporated the language in 21 C.F.R. 1306.04(a) that defines the scope of that authorization.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is reported at 56 F.4th 1291. A previous decision of this Court (Pet. App. 19a-54a) is reported at 142 S. Ct. 2370, and a previous order of this Court is reported at 142 S. Ct. 2895. A previous opinion of the court of appeals is reported at 966 F.3d 1101.

JURISDICTION

The judgment of the court of appeals was entered on January 5, 2023. Petitions for rehearing were denied on March 2, 2023 (Pet. App. 55a-58a). The petition for a writ of certiorari was filed on May 31, 2023. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Southern District of Alabama, petitioners Xiulu Ruan and John Patrick Couch were convicted of racketeering conspiracy, in violation of 18 U.S.C. 1962(d); three counts of conspiring to unlawfully distribute controlled substances, in violation of 21 U.S.C. 841(a)(1) and 846; conspiring to commit healthcare fraud and mail and wire fraud, in violation of 18 U.S.C. 1347 and 1349; and two counts of conspiring to receive kickbacks in relation to a federal healthcare program, in violation of 18 U.S.C. 371 and 42 U.S.C. 1320a-7b(b). Ruan Judgment 1; Couch Judgment 1. Petitioners were also each individually convicted on multiple counts of unlawfully distributing a controlled substance, in violation of 21 U.S.C. 841(a)(1). Ruan Judgment 1; Couch Judgment 1. Ruan was further convicted of conspiring to launder the proceeds of illegal activity, in violation of 18 U.S.C. 1956(h), and two counts of laundering the proceeds of illegal activity, in violation of 18 U.S.C. 1957. Ruan Judgment 1. Ruan was sentenced to 252 months of imprisonment, to be followed by four years of supervised release. *Id.* at 2-3. Couch was sentenced to 240 months of imprisonment, to be followed by four years of supervised release. Couch Judgment 2-3.

The court of appeals vacated one of petitioners' kickback-conspiracy convictions, affirmed their remaining convictions, and remanded for resentencing. 966 F.3d 1101. While petitioners' petitions for writs of certiorari were pending with this Court, the district court again sentenced petitioners to the same terms of imprisonment. Ruan Am. Judgment 2-3; Couch Am. Judgment 2-3. This Court granted writs of certiorari, vacated, and remanded. 142 S. Ct. 2895; 142 S. Ct. 2370.

On remand, the court of appeals vacated petitioners' convictions for unlawfully distributing a controlled substance, affirmed their remaining convictions, and remanded for resentencing. Pet. App. 1a-18a.

1. Section 841(a) of the Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, prohibits the knowing or intentional distribution of controlled substances "[e]xcept as authorized by" the Act. 21 U.S.C. 841(a). The CSA's exceptions to the prohibition against drug distribution include an exception for physicians who are "registered by" the Drug Enforcement Administration (DEA) and who prescribe controlled substances—but the exception applies only "to the extent authorized by their registration and in conformity with the other provisions" of the Act. 21 U.S.C. 822(b); see 21 U.S.C. 823(f). And controlled substances generally may be dispensed only pursuant to a "written prescription of a practitioner." 21 U.S.C. 829(a).

A federal regulation, 21 C.F.R. 1306.04(a), limits the scope of the authorization by specifying that 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." Section 1306.04(a) specifies that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment" is deemed "not a prescription," and the "person issuing it[] shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Ibid.* And in *United States* v. *Moore*, 423 U.S. 122 (1975), this Court "h[e]ld that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *Id.* at 124.

2. Petitioners were business partners and DEA-registered physicians who engaged in a long-running scheme of issuing prescriptions that "tracked financial incentives rather than their patients' medical needs." 966 F.3d at 1123. They operated through a jointly owned medical clinic in Mobile, Alabama, and a connected pharmacy whose sole business was dispensing drugs prescribed at the clinic. *Id.* at 1121. Between January 2011 and May 2015, the clinic issued nearly 300,000 controlled-substance prescriptions, the majority of which were for Schedule II drugs—"the most powerful and dangerous drugs that can be lawfully prescribed." *Id.* at 1122.

Petitioners frequently signed prescriptions without seeing patients and failed to provide patients with warnings before prescribing dangerous opioids. 966 F.3d at 1126-1130. Many records at the clinic "contained numerous errors, including not listing all prescriptions written" and listing "exams and tests" that "did not occur." *Id.* at 1129-1130. Patients whose drug-test results were inconsistent with the drugs they were being prescribed—"indicating potential diversion or abuse of drugs"—were seldom "fired" because that would mean that petitioners "would lose * * * revenue." *Id.* at 1126. In contrast, petitioners would "fire patients whose insurance would no longer pay for their" prescriptions. *Ibid.*

Petitioners also prescribed massive quantities of transmucosal immediate-release fentanyl (TIRF) drugs, which are approved by the Food and Drug Administration only to treat breakthrough pain in certain adult cancer patients. 966 F.3d at 1122-1123. Petitioners "often surpassed the next highest prescriber" of TIRFs "by more than double"—even though "no more than 15% of [their] patients had cancer." *Id.* at 1123.

Petitioners "lied to insurers, telling them that some patients had cancer so that insurers would pay for their TIRF prescriptions." *Id.* at 1131. And over the course of a few months, petitioners purchased more than $1.3 million in the stock of a manufacturer of TIRFs—increasing their prescriptions of that manufacturer's drugs during and after the stock purchases. *Id.* at 1123-1124. Petitioners dispensed so many of those drugs that when their clinic was shut down in 2015, the manufacturer's nationwide sales dropped "significantly." *Id.* at 1124.

Petitioners were also paid by another TIRF manufacturer to host weekly programs promoting a TIRF drug marketed as "Subsys," even though no new prospective prescribers attended those programs. 966 F.3d at 1122, 1124-1125. According to the drug representative who arranged the speaking engagements for petitioners, the purpose was not to educate other doctors, but instead to influence petitioners to continue prescribing Subsys. *Id.* at 1124-1125. The strategy worked: petitioners' clinic ranked among the top ten prescribers of Subsys, and the manufacturer considered petitioners to be "'whales'"—*i.e.*, "the top prescribing doctors" for the drug. *Id.* at 1125.

3. a. In 2016, a federal grand jury in the Southern District of Alabama returned an indictment charging petitioners with 22 counts of conspiracy, unlawfully distributing controlled substances, fraud, illegal kickbacks, and money laundering. 966 F.3d at 1120.

At the close of trial, petitioners proposed jury instructions that incorporated the regulatory language in Section 1306.04(a) as the touchstone for Section 841(a) liability, as well as liability for other violations based on violations of the CSA. See D. Ct. Doc. 462 (Feb. 6, 2017).

Petitioners represented to the district court that "Section 841(a)(1) makes it a crime for any 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." *Id.* at 19; see *id.* at 19-20, 22-24. And they asked to instruct the jury that "[i]f a physician dispenses or distributes a Controlled Substance in good faith while medically treating a patient, then the physician has dispensed or distributed that Controlled Substance for a legitimate medical purpose and within the usual course of professional practice," while guilt required proof beyond a reasonable doubt "that the decision to dispense or distribute a Controlled Substance fell below a standard of medical practice generally recognized and accepted in the United States" and "that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating a pain patient." 966 F.3d at 1165-1166.

The district court rejected petitioners' proposed instructions as too "subjective," Pet. App. 72a-73a, but incorporated the regulatory standard, instructing the jury that, "[f]or 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," *id.* at 61a. The court further explained that

> [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. [Petitioners] 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.

Id. at 61a-62a.

At the close of its case, the government dismissed one count that charged both petitioners with conspiring to receive kickbacks in relation to a federal healthcare program. 966 F.3d at 1120-1121. The jury convicted Couch on all remaining counts and convicted Ruan on all remaining counts except one count of unlawfully distributing a controlled substance. *Ibid.*; see p. 2, *supra*. The district court sentenced Ruan to 252 months of imprisonment and Couch to 240 months of imprisonment, to be followed by four years of supervised release for each petitioner. Ruan Judgment 2-3; Couch Judgment 2-3.

b. The court of appeals vacated one of petitioners' kickback-conspiracy convictions and affirmed their other convictions. 966 F.3d 1101. Relying on circuit precedent for the view that "whether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard," the court concluded that the district court had correctly instructed the jury on the CSA charges. *Id.* at 1166 (brackets and citation omitted).

While petitioners' petitions for writs of certiorari were pending in this Court, the district court resentenced petitioners, imposing the same terms of imprisonment that it had previously imposed. Ruan Am. Judgment 2-3; Couch Am. Judgment 2-3.

4. This Court granted Ruan's petition for a writ of certiorari, consolidated his case with the case of Shakeel Kahn—another doctor who had been convicted of violating Section 841(a) and other statutes in the Tenth Circuit—and vacated and remanded. Pet. App. 19a-54a.

The Court held that the "'knowingly or intentionally' *mens rea*" in Section 841(a) "applies to the [statute's] 'except as authorized' clause," such 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." 142 S. Ct. at 2376. The Court reasoned, *inter alia*, that "a lack of authorization is often what separates wrongfulness from innocence." *Id.* at 2377. "In addition," the Court noted, Section 1306.04(a)'s "regulatory language defining an authorized prescription is * * * 'ambiguous,' written in 'generalities, susceptible to more precise definition and open to varying constructions,'" and a "strong scienter requirement helps to diminish the risk of 'overdeterrence'" of medical practitioners. *Id.* at 2377-2378 (brackets and citations omitted).

The Court remanded Ruan's case to the Eleventh Circuit and Kahn's case to the Tenth Circuit for consideration of whether the jury instructions at their trials complied with its interpretation of Section 841(a) and whether any errors were harmless. 142 S. Ct. at 2382. The Court also granted Couch's pending petition for a writ of certiorari, vacated, and remanded his case to the Eleventh Circuit. 142 S. Ct. 2895.

5. On remand, the court of appeals vacated petitioners' Section 841(a) convictions, affirmed their remaining convictions, and remanded for a new trial on the Section

841(a) convictions and for resentencing. Pet. App. 1a-18a.

The court of appeals concluded that the jury instructions for the unlawful-distribution counts had "inadequately conveyed" the mens rea required by this Court because the instructions did not adequately explain that petitioners must have known or intended that their conduct was unauthorized under the CSA. Pet. App. 7a; see *id.* at 5a-7a. The court of appeals rejected the government's harmless-error argument as to the Section 841(a) counts and accordingly vacated petitioners' convictions on those counts. *Id.* at 8a-9a.

The court of appeals found, however, that the instructional error did not require it to invalidate petitioners' remaining convictions. Pet. App. 10a-17a. The court explained that petitioners' convictions for conspiring to unlawfully distribute controlled substances remained valid because the instructions for those counts had 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." *Id.* at 11a. The court observed that "[h]ad the jury in this case concluded that [petitioners] believed their actions to be for a legitimate medical purpose they could not have found [that petitioners] made an 'unlawful plan' and 'knew' its 'unlawful purpose,' nor could they have concluded they 'willfully' joined that plan." *Ibid.*

The court of appeals similarly found that the instructional error did not affect petitioners' convictions for conspiring to commit healthcare fraud. Pet. App. 12a-13a. The court explained that a "health care fraud conspiracy is fundamentally about the submission of false medical claims to health care benefit programs" and

observed that "whether or not [petitioners] had subjective knowledge that their prescriptions were outside the 'usual course' is irrelevant to whether or not" petitioners submitted false medical claims. *Ibid.* The court found the instructional error "equally irrelevant to" petitioners' kickback-conspiracy convictions, explaining that, as to those counts, the jury necessarily determined that petitioners "willfully received compensation from [a] pharmaceutical company * * * in exchange for increased prescriptions of fentanyl." *Id.* at 14a. Finally, the court found that "[t]he mens rea instructions for the § 841 conviction[s] have nothing to do with the[] theories" underlying petitioners' convictions for conspiring to commit mail and wire fraud, which were based on allegations that "overlapped" with the ones underlying the healthcare-fraud conspiracy, as well as allegations that petitioners made stocking and prescribing decisions "based on the profit generated by the higher reimbursement for" particular "drugs rather than medical need." *Id.* at 14a-15a.

The court of appeals also upheld petitioners' convictions for racketeering conspiracy. Pet. App. 15a-16a. The court noted that it had already found that two of the three possible predicate offenses for those convictions—conspiring to unlawfully distribute controlled substances and mail fraud—remained valid. *Id.* at 15a. And as to the remaining possible predicate offense—unlawful distribution—the court found that the racketeering-conspiracy instruction correctly articulated the applicable mens rea because the jury was required to "find[] that [petitioners] intended to violate § 841, which means that [petitioners] would have to have known their acts were unauthorized." *Id.* at 16a (emphasis omitted). Finally, the court upheld Ruan's convictions for money

laundering and conspiring to commit money laundering because convictions that "were unaffected by the inadequate instruction for the substantive drug charges" qualified as the required "specified unlawful activity" under the money-laundering statute. *Id.* at 17a.

ARGUMENT

Petitioners contend (Pet. 13-38) that this Court's decision in *Ruan* v. *United States*, 142 S. Ct. 2370 (2022), requires most of their convictions to be set aside. The court of appeals correctly rejected that argument on remand and determined that the instructional error identified by this Court required vacatur only of petitioners' convictions for unlawfully distributing controlled substances, in violation of 21 U.S.C. 841(a). The petition for a writ of certiorari, however, presents a new argument that petitioners have never raised before—namely, that the jury instructions at their trial erroneously used language from Section 1306.04(a) as the measure of whether their drug-prescribing practices were "authorized" under the CSA. *Ibid.* That claim was neither pressed nor passed upon below, is foreclosed by precedent, rests on a fundamental misunderstanding of the CSA and this Court's decision in *Ruan*, and implicates no conflict among the courts of appeals. The petition for a writ of certiorari should be denied.

1. On remand from this Court, the court of appeals applied *Ruan* and vacated petitioners' convictions for unlawful distribution under Section 841(a) because the jury instructions for those counts did not apply the statute's "knowingly or intentionally" mens rea to its "except as authorized" clause. Pet. App. 7a. The court correctly recognized, however, that the error did not affect petitioners' other convictions. *Id.* at 10a-17a.

The court of appeals correctly upheld petitioners' convictions for conspiring to distribute controlled substances because the relevant instructions 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." Pet. App. 11a. That accorded with basic principles of conspiracy law, which require proof that a defendant "reach[ed] an agreement with the specific intent that the underlying crime be committed." *Ocasio* v. *United States*, 578 U.S. 282, 288 (2016) (citation, emphasis, and internal quotation marks omitted); see *United States* v. *Bailey*, 444 U.S. 394, 405 (1980) (explaining that the "heightened mental state" needed for inchoate offenses like conspiracy serves to "separate[] criminality itself from otherwise innocuous behavior"). By requiring that petitioners knew that their plans would violate Section 841(a)—that is, that they had knowledge that controlled substances would be dispensed without "authoriz[ation]," 21 U.S.C. 841(a)—the conspiracy instructions avoided the mens rea problem that this Court identified in *Ruan*.

For the same reason, the court of appeals correctly upheld petitioners' convictions for racketeering conspiracy. See Pet. App. 15a-16a. And the court correctly observed that petitioners' remaining convictions were all premised on conduct separate from the conduct underlying petitioners' unlawful-distribution convictions—and therefore in no way turned on "whether or not [petitioners] had subjective knowledge." *Id.* at 13a; see *id.* at 12a-17a.

2. Petitioners do not dispute any aspects of the court of appeals' reasoning. Nor do they claim that the actual analysis in the decision below implicates any

disagreement among the courts of appeals. Petitioners instead contend (Pet. 31) that the district court's jury instructions improperly "substituted the language of 21 C.F.R. § 1306.04(a) for the text of the CSA," and assert (Pet. 34-37) that the court of appeals was required to vacate all convictions whose instructions incorporated that regulatory language. But petitioners did not raise that argument in the court of appeals, and that court never considered it. It is therefore not properly preserved for this Court's review.

As discussed above, see pp. 5-6, *supra*, at trial petitioners requested jury instructions that incorporated the language of Section 1306.04(a) to describe the jury's inquiry into whether petitioners' drug-dispensing practices were "authorized" within the meaning of the CSA's core criminal provision, 21 U.S.C. 841(a). The district court similarly incorporated the regulatory standard into its instructions. See pp. 6-7, *supra*. And petitioners admit that, when this case previously came to this Court, "the parties * * * all agreed that some version of 21 C.F.R. § 1306.04(a) should be the basis for a CSA instruction." Pet. 15 (emphasis omitted).

This Court accepted that consensus in *Ruan*, "assum[ing] * * * that a prescription is 'authorized' and therefore lawful if it satisfies [the Section 1306.04(a)] standard." 142 S. Ct. at 2375. And on remand, petitioners continued to equate "authorization" with acting within "'the usual course of professional practice'" and with a "'legitimate medical purpose.'" Ruan C.A. Supp. Br. 13-14 (citation omitted); see *id.* at 9 (stating that one of the "crucial * * * element[s]" was "whether Dr. Ruan issued an *unauthorized* prescription (because it lacked a legitimate medical purpose and fell outside professional norms)"); Couch C.A. Supp. Br. 1

("adopt[ing]" Ruan's arguments "in full" and stating that "a physician otherwise authorized to prescribe controlled substances may be convicted of unlawful distribution under 21 U.S.C. § 841(a)(1) only if his or her prescriptions 'fall outside the usual course of professional practice'") (citation omitted). Even in seeking rehearing en banc in the court of appeals, petitioners did not try to draw a distinction between a physician's "authoriz[ation]," 21 U.S.C. 841(a), and the regulatory language that defines that authorization, as they now do in seeking further review in this Court. See Ruan C.A. Reh'g Pet. 4-15; Couch C.A. Reh'g Pet. 3-5. The court of appeals therefore had no occasion to address such a claim.

This Court is "a court of review, not of first view," *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005), and it traditionally does not grant a writ of certiorari "when 'the question presented was not pressed or passed upon below,'" *United States* v. *Williams*, 504 U.S. 36, 41 (1992) (citation omitted). That principle should preclude a writ of certiorari here. At most, petitioners' claim would be reviewable for plain error—a demanding standard that they do not discuss and could not satisfy for the reasons set forth below.

3. Even if petitioners had preserved their new claim, it would not warrant this Court's review. The regulation at issue provides that a prescription for controlled substances is valid, and accordingly "authorized" for purposes of 21 U.S.C. 841(a), only if "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," as defined in 21 C.F.R. 1306.04(a). And this Court "h[e]ld" in *United States* v. *Moore*, 423 U.S. 122 (1975), "that registered physicians can be prosecuted under § 841

when their activities fall outside the usual course of professional practice." *Id.* at 124. That regulatory standard does not, as petitioners suggest (Pet. 3), "create a criminal offense," but instead has defined practitioners' authority to prescribe controlled substances since the CSA's inception, is a valid limit on that authority, and was not called into question by this Court's decision in *Ruan*.

a. As described above, see p. 3, *supra*, Section 841(a) of the CSA prohibits the knowing or intentional distribution of controlled substances "[e]xcept as authorized by" the Act. 21 U.S.C. 841(a). The CSA's exceptions to the drug-distribution prohibition include an exception for DEA-registered physicians who issue written prescriptions for controlled substances—but only "to the extent authorized by their registration and in conformity with the other provisions" of the Act. 21 U.S.C. 822(b); see 21 U.S.C. 829(a).

The CSA accordingly authorizes the Attorney General "to promulgate rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. 821; see 21 U.S.C. 871(b). "Persons registered by the Attorney General * * * to * * * dispense controlled substances * * * are authorized to * * * dispense such substances * * * to the extent authorized by their registration and in conformity with the other provisions of this subchapter." 21 U.S.C. 822(b). The regulation at issue, 21 C.F.R. 1306.04(a), defines the scope of the authorization for purposes of physicians who write prescriptions for controlled substances.

It has done so throughout the five-decade history of the CSA. The Attorney General promulgated the current text of Section 1306.04(a) less than a year after

the CSA was enacted. 36 Fed. Reg. 7776, 7799 (Apr. 24, 1971) (21 C.F.R. 306.04 (1971)); see *Gonzales* v. *Oregon*, 546 U.S. 243, 250 (2006). Since that time, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment" has been deemed "not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829)." 21 C.F.R. 1306.04(a). As a result, dispensing a covered controlled substance pursuant to such an order is unauthorized. See 21 U.S.C. 822(b), 829(a). And it violates Section 841(a) if done knowingly or intentionally. See 21 U.S.C. 841(a).

Section 1306.04(a)'s terms mirror the CSA itself, which employs the same terminology in multiple different provisions. See *Gonzales*, 546 U.S. at 257; *Moore*, 423 U.S. at 137 n.13, 140-142. For example, Section 829 generally defines a "'valid prescription'" as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by" a qualifying practitioner. 21 U.S.C. 829(e)(2)(A); see, *e.g.*, 21 U.S.C. 830(b)(3)(A)(ii) (similar definition of "valid prescription" applicable to certain reporting requirements). Similarly, the CSA defines "'practitioner'" to include a physician who is "registered" to "distribute [or] dispense * * * a controlled substance in the course of professional practice," 21 U.S.C. 802(21), and allows doctors to prescribe only drugs that have "currently accepted medical use[s]," 21 U.S.C. 812(b).[1]

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[1] See 21 U.S.C. 802(56)(C) (defining "'filling new prescriptions for controlled substances in schedule III, IV, or V'" as including the requirement that "the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription"); 21 U.S.C. 844(a)

The Court thus correctly "h[e]ld" in *Moore* "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." 423 U.S. at 124; see *id.* at 135 (observing that Section 841 applies to those who "s[ell] drugs, not for legitimate purposes, but 'primarily for the profits to be derived therefrom'") (citation omitted). "Under [the Court's] reasoning in *Moore*, writing prescriptions that are illegitimate under § 829 is certainly not 'in the usual course of professional practice' under § 802(21) and thus not 'authorized by this subchapter' under § 841(a)." *Gonzales*, 546 U.S. at 285 (Scalia, J., dissenting) (brackets and citation omitted). And petitioners' current claims cannot be squared with the reasoning and holding of *Moore*.

Petitioners' assertion (Pet. 32) of a nondelegation problem with the regulation is particularly misplaced. As this Court observed in *Gonzales* v. *Oregon*, Section 1306.04(a) "does little more than restate the terms of the statute itself"; the relevant language "comes from Congress, not the Attorney General." 546 U.S. at 257. It was therefore validly incorporated into the jury instructions as defining the scope of petitioners' limited "authoriz[ation]" to distribute controlled substances. 21 U.S.C. 841(a).

(forbidding possession of controlled substances except "pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice"); see also *Webb* v. *United States*, 249 U.S. 96, 99-100 (1919) (finding, under the CSA's statutory predecessor, that it would be a "plain * * * perversion of meaning" to call an order for morphine, issued to an addict outside "the course of professional treatment," a "prescription" at all); accord *Jin Fuey Moy* v. *United States*, 254 U.S. 189, 194 (1920), overruled in part on other grounds by *Funk* v. *United States*, 290 U.S. 371 (1933).

b. The Court's decision in *Ruan* did nothing to upset the long-held understanding that Section 1306.04(a) defines the scope of practitioners' prescribing authority. Instead, the Court "assume[d], as did the courts below and the parties here, that a prescription is 'authorized' and therefore lawful if it satisfies th[e] standard" in Section 1306.04(a). Pet. App. 21a.

Petitioners nevertheless read *Ruan* as holding that practitioners may not be convicted even if "they knew that their prescriptions were *objectively* outside the usual course of professional practice or not for a legitimate medical purpose" but they "themselves believed the prescriptions were appropriate." Pet. 35. That reading is unsound. *Ruan* did not make every registered prescriber of controlled substances a law unto himself. Instead, the Court's conclusion that the government must "prov[e] that a defendant knew or intended that his or her conduct was unauthorized" was informed by an understanding that "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'"—and that a defendant's subjective mindset would be "measured against objective criteria." 142 S. Ct. at 2382 (citation omitted). The Court's discussion of the objective criteria would have been unnecessary if, as petitioners contend (see Pet. 3, 7, 35), a defendant's personal beliefs could always override them, granting him carte blanche to knowingly violate them.

Petitioners highlight (Pet. 2, 9, 16-17, 34) the Court's statement in *Ruan* that "the regulatory language defining an authorized prescription is, we have said, 'ambiguous,' written in 'generalities, susceptible to more precise definition and open to varying constructions.'" 142

S. Ct. at 2377 (quoting *Gonzales*, 546 U.S. at 258) (brackets omitted). But that was simply a reference to a portion of the Court's opinion in *Gonzales*—which, as discussed above, found that Section 1306.04(a) mirrors the CSA's statutory requirements—that was itself describing the original "statutory phrase 'legitimate medical purpose'" that the regulation incorporates. 546 U.S. at 258. Furthermore, the fundamental point in *Ruan* was that a potential to misinterpret the regulation's objective criteria supported a more stringent mens rea, see 142 S. Ct. at 2377—a point that would make no sense if the Court in fact viewed the regulatory criteria as irrelevant.

The Court has thus already addressed petitioners' concerns (Pet. 3; see Pet. 3-4, 22-25) about "chill[ing]" practitioners from providing "outlying" forms of medical treatment. Although petitioners ask the Court to go further and leave the distribution of dangerous controlled substances entirely up to individual practitioners' subjective judgment, the Court has recognized and respected the balance struck by the CSA and Section 1306.04(a) between concerns about "the diversion of drugs * * * to illegitimate channels" and practitioners' need for "reasonable discretion in treating patients and testing new theories." *Moore*, 423 U.S. at 135, 143. And petitioners err in suggesting (Pet. 14) that *Ruan* "smuggles a quasi-negligence standard through the back door." To the contrary, *Ruan* makes clear that a practitioner who knew or intended that he was acting without a legitimate medical purpose and outside the usual course of professional practice can be convicted.

4. Petitioners assert (Pet. 15-22, 25-31) that the decision below, and decisions of other courts of appeals that continue to approve CSA jury instructions based

on Section 1306.04(a), conflict with the Tenth Circuit's remand decision in Kahn's case, *United States* v. *Kahn*, 58 F.4th 1308 (2023). As a threshold matter, as already discussed the decision below did not address the arguments that petitioners now make in their petition, and therefore cannot be viewed as part of any circuit conflict on the question presented.

In any event, the Tenth Circuit's decision in *Kahn* does not provide a sound basis for concluding that it has foreclosed conviction for violating Section 841(a) based on an instruction that defines "authoriz[ation]," 21 U.S.C. 841(a), by incorporating Section 1306.04(a) and requires the jury to find that the defendant knowingly or intentionally acted outside its scope. In *Kahn*, the court found fault with jury instructions that "treated the inquiry under the first 'prong' [of the regulation] as wholly subjective, considering 'why a defendant-practitioner subjectively issued that prescription, regardless of whether other practitioners would have done the same'" and "treated the inquiry under the second prong as wholly objective, considering 'whether a defendant-practitioner objectively acted within that scope, regardless of whether he believed he was doing so.'" 58 F.4th at 1316 (citation omitted). The Tenth Circuit concluded that the instructions were flawed for "two reasons," *ibid.*, neither of which clearly adopts the approach that petitioners now urge.

First, the Tenth Circuit recognized that "*Ruan* expressly disallows conviction under § 841(a)(1) for behavior that is only objectively unauthorized," and instead requires proof that the "defendant 'knowingly or intentionally acted in an unauthorized manner.'" *Kahn*, 58 F.4th at 1316 (quoting *Ruan*, 142 S. Ct. at 2376). Second, it viewed *Ruan* as "treat[ing] 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." *Ibid.* (quoting *Ruan*, 142 S. Ct. at 2382). And it deemed Kahn's jury instructions "erroneous because they allowed the jury to convict Dr. Kahn after concluding either that Dr. Kahn subjectively knew a prescription was issued not for a legitimate medical purpose, or that he issued a prescription that was objectively not in the usual course of professional practice." *Ibid.*

Although petitioners read that passage as adopting an approach under which a defendant may lack knowledge or intent to act in an unauthorized manner even if he knows or intends to prescribe drugs not for a medical purpose and outside the usual course of professional practice, that reading is questionable. Instead, the Tenth Circuit's ultimate conclusion seems to have been that whereas *Ruan* requires knowledge or intent to violate objective criteria, neither of the "prong[s]" in Kahn's jury instructions included both the objective and subjective components. *Kahn*, 58 F.4th at 1316. Instead, the first was "wholly subjective" and the second "wholly objective." *Ibid.*; see *id.* at 1319 ("[T]he government is correct that the Supreme Court has acknowledged that 'the scope of a doctor's prescribing authority' remains tethered 'to objective criteria such as legitimate medical purpose and usual course of professional practice.'") (quoting *Ruan*, 142 S. Ct. at 2382) (some internal quotation marks omitted). And, consistent with this Court's decision in *Ruan*—and the legal regime itself—the Tenth Circuit may have been using the regulatory language and the term "authorization" interchangeably.

Accordingly, petitioners have not demonstrated a circuit conflict.[2] Petitioners insist (Pet. 21) that a division must exist because the Eleventh Circuit upheld most of their convictions after *Ruan*, whereas the Tenth Circuit vacated all of Kahn's convictions, *Kahn*, 58 F.4th at 1321-1322. On remand in *Kahn*, however, the government did not defend the convictions on the merits, instead staking the continued viability of all of Kahn's convictions on harmless error. See Gov't C.A. Supp. Br. at 4-20, *Kahn*, *supra* (No. 19-8054). And the government focused on Kahn's Section 841(a) convictions—and did not make separate harmless-error arguments in support of Kahn's other convictions, such as for conspiring to unlawfully distribute controlled substances. See *ibid.* The Tenth Circuit was never prompted to consider whether, as the Eleventh Circuit determined here (Pet. App. 10a-17a), the instructions for that conspiracy count or other counts avoided the mens rea error found in *Ruan*. The Tenth Circuit therefore engaged in little analysis and vacated all of Kahn's convictions because "the instructions pertaining to [his] charges [were] predicated, at least in part, on one or more of the erroneous § 841(a)(1) instructions." *Kahn*, 58 F.4th at 1322.

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[2] The Tenth Circuit's unpublished order in *United States* v. *Henson*, No. 19-3062, 2023 WL 2319289 (Mar. 2, 2023), see Pet. 13, 21, accepted without analysis the "parties[']agree[ment] that the appropriate course of action for us is to order the vacatur of all of Dr. Henson's counts of conviction, except for" two counts. 2023 WL 2319289, at *1. *Henson* therefore does nothing to establish a circuit conflict.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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