Nos. 20-1410 and 20-7934

In the Supreme Court of the United States

XIULU RUAN, PETITIONER

v.

UNITED STATES OF AMERICA

JOHN PATRICK COUCH, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITIONS FOR WRITS 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 district court abused its discretion in declining a requested jury instruction on the ground that it would have required acquittal on charges of the unauthorized distribution of controlled substances, in violation of 21 U.S.C. 841, based on petitioners' own "subjective view" of the "usual course of medical practice."

ADDITIONAL RELATED PROCEEDINGS

United States District Court (S.D. Ala.):

United States v. *Couch et al.*, No. 15-cr-88 (May 26, 2017)

United States Court of Appeals (11th Cir.):

United States v. *Ruan et al.*, No. 17-12653 (July 10, 2020)

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-128a)[*] is reported at 966 F.3d 1101.

JURISDICTION

The judgment of the court of appeals was entered on July 10, 2020. A petition for rehearing en banc was de-

[*] In this brief, citations to the petition appendix are to the petition appendix in No. 20-1410.

nied on November 4, 2020 (Pet. App. 129a). The petitions for writs of certiorari were filed on April 5, 2021 (Monday). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the Southern District of Alabama, petitioners were convicted of racketeering conspiracy, in violation of 18 U.S.C. 1962(d); drug-distribution conspiracies for Schedule II drugs, Schedule III drugs, and fentanyl, 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. In addition, petitioners were individually convicted on multiple counts of drug distribution, in violation of 21 U.S.C. 841(a)(1). Ruan Judgment 1; Couch Judgment 1. Petitioner 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. Petitioner Ruan was sentenced to 252 months of imprisonment, to be followed by four years of supervised release. *Id.* at 2-3. Petitioner 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 to the district court for resentencing. Pet. App. 128a.

1. Petitioners were licensed physicians, ostensibly specializing in pain management, who enriched themselves through a long-running scheme of unlawfully issuing prescriptions for addictive and potent controlled substances, in response to their own financial incentives rather than the legitimate medical needs of their patients. See Pet. App. 5a-30a. They jointly owned and operated a medical clinic and a connected pharmacy in Mobile, Alabama. *Id.* at 5a-6a. The pharmacy's sole business was dispensing drugs prescribed at petitioners' clinic. *Id.* at 6a. Between January 2011 and May 2015, each petitioner made more than $3.7 million from the clinic and more than $550,000 in prescription service fees from the pharmacy. *Id.* at 6a.

Over that same four-year period, petitioners wrote nearly 300,000 prescriptions for controlled substances, the majority of which were Schedule II drugs—"the most powerful and dangerous drugs that can be lawfully prescribed." Pet. App. 7a; see Ruan Presentence Investigation Report (PSR) ¶ 25 (noting that petitioner Ruan, through the clinic's pharmacy, was the top purchaser in the State of Alabama of oxycodone from 2011-2015; of morphine from 2011-2015; and of fentanyl from 2012-2014). In particular, petitioners were among the top prescribers nationwide of a potent and expensive version of fentanyl called transmucosal immediate-release fentanyl (TIRF), which the Food and Drug Administration (FDA) had approved in 2011 to treat "breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy." Pet. App. 8a; see *id.* at 8a-9a. Although no more than 15% of their clinic's patients had been diagnosed with cancer, petitioners prescribed more than 475,000

doses of TIRF drugs to over 1000 patients, "often surpass[ing] the next highest prescriber [in the nation] by more than double." *Id.* at 9a.

Petitioners' outlier prescription practices "tracked financial incentives rather than their patients' medical needs." Pet. App. 9a. For example, between November 2013 and January 2014, petitioners purchased more than $1.3 million of stock in Galena Biopharma, the owner and manufacturer of a TIRF drug marketed as "Abstral." *Id.* at 10a; see *id.* at 8a. Around the same time, petitioners massively increased their prescriptions of Abstral, with petitioner Ruan reaching a peak of more than 2.6 million micrograms per month in March 2014. *Id.* at 11a. Petitioners became so important to Galena's bottom line that the company fired its CEO at their request, and the new CEO made a trip to Mobile to meet with petitioners in person. *Ibid.* And "national Abstral sales dropped significantly" when petitioners' clinic was shuttered in May 2015. *Id.* at 12a (internal quotation marks omitted).

Petitioners' prescription practices also put them in position to collect substantial speaking fees from Insys, the manufacturer of a different TIRF drug marketed as "Subsys." Pet. App. 8a, 13a. Petitioners were paid to host weekly programs promoting Subsys, even though no new prospective prescribers attended those programs. *Id.* at 13a. According to the Insys 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. *Ibid.* The strategy worked: Petitioners' clinic ranked among the top ten prescribers of Subsys, and Insys considered petitioners to be "whales" —*i.e.*, "the top prescribing doctors" for the drug. *Ibid.*

Suspecting that petitioners were operating a "pill mill," the Drug Enforcement Administration (DEA) launched an investigation in 2014. Pet. App. 18a. As part of that investigation, an undercover DEA agent acted as a patient seeking controlled substances from petitioners' clinic. *Ibid.* Clinic staff did not ask the undercover agent about his pain levels, and the agent told clinic employees that he had previously been self-medicating with oxycodone that he had purchased on the street. *Id.* at 18a-19a. Nevertheless, petitioner Couch signed a 90-pill prescription for Roxicodone, a Schedule II controlled substance, after appearing for less than one minute of the agent's initial office visit. *Id.* at 19a. On several subsequent occasions, the undercover agent obtained additional prescriptions for oxycodone, sometimes with an increased number of pills, without seeing either petitioner. *Ibid.* Those prescriptions appeared to have been pre-dated and signed by petitioner Couch. Ruan PSR ¶¶ 49-51. Although the undercover agent was seen by other medical practitioners at the clinic during those visits, none of those practitioners was authorized to prescribe Schedule II controlled substances like oxycodone. See *ibid.*

2. In 2016, a federal grand jury returned an indictment charging petitioners with 22 counts of conspiracy, drug distribution, fraud, illegal kickbacks, and money laundering. See Second Superseding Indictment 13-41. Both petitioners proceeded to trial, which lasted seven weeks. Gov't C.A. Br. 32.

At the close of trial, petitioners proposed that the jury be instructed as follows:

> If 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, and you must return a not guilty verdict for the applicable count. Good faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs. It means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice. If you find that a Defendant acted in good faith in dispensing or distributing a Controlled Substance, as charged in the indictment, then you must return a not guilty verdict.

Pet. App. 102a-103a. Petitioners also urged the district court to instruct the jury that "the Government must prove, beyond a reasonable doubt, that the physician's decisions to distribute or dispense a Controlled Substance were inconsistent with any accepted method of treating a pain patient—that the physician, in fact, operated as a drug pusher." *Id.* at 103a.

While the district court offered to give a different instruction including "good faith language," Pet. App. 136a, it declined to give petitioners' particular proposed instruction, *id.* at 135a. As most relevant here, it determined that the instruction embodied "a subjective view of what is the usual course of professional practice," when "the standard should be an objective one." *Id.* at 134a. The court also concluded that the proposed language requiring proof that a physician operated as a "drug pusher" was legally incorrect. *Id.* at 104a.

The district court subsequently instructed the jury that, "[f]or a controlled substance to be lawfully dispensed by a prescription," the physician must have prescribed the substance "both within the usual course of

professional practice and for a legitimate medical purpose." Pet. App. 104a. The court also offered a good-faith instruction drawn from circuit case law:

> 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 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 139a; accord *United States* v. *Joseph*, 709 F.3d 1082, 1092 (11th Cir. 2013), cert. denied, 571 U.S. 1204 (2014).

The jury found both petitioners guilty of racketeering conspiracy, in violation of 18 U.S.C. 1962(d); three counts of conspiring to distribute Schedule II drugs, Schedule III drugs, and fentanyl, in violation of 21 U.S.C. 841(a)(1) and 846; two counts of conspiring to commit healthcare fraud and mail and wire fraud, in violation of 18 U.S.C. 1347 and 1349; 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); and five counts of drug distribution, in violation of 21 U.S.C. 841(a)(1). Ruan Judgment 1; Couch Judgment 1. The jury also found petitioner Ruan guilty of conspiring to launder the proceeds of illegal activity, in violation of 18 U.S.C. 1956(h), and laundering the proceeds of illegal activity, in violation of 18 U.S.C. 1957. Ruan Judgment 1. The district court sentenced petitioner Ruan to 252 months of imprisonment,

to be followed by four years of supervised release, and petitioner Couch to 240 months of imprisonment, to be followed by four years of supervised release. Ruan Judgment 2-3; Couch Judgment 2-3.

3. The court of appeals largely affirmed petitioners' convictions, reversing only their convictions on one count of conspiring to violate the anti-kickback statute. Pet. App. 1a-128a. The court remanded the cases for resentencing. *Id.* at 128a.

As relevant here, the court of appeals rejected petitioners' arguments that the district court had abused its discretion in declining to issue their proposed "good faith" jury instruction. Pet. App. 102a-113a. The court of appeals agreed with the district court that the proposed instruction had incorrectly stated the law because the question "[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 105a (quoting *Joseph*, 709 F.3d at 1097).

The court of appeals explained that the objective standard best reflected this Court's decision in *United States* v. *Moore*, 423 U.S. 122 (1975), which had established that "physicians can be prosecuted for violating the Controlled Substances Act 'when their activities fall outside the usual course of professional practice.'" Pet. App. 106a (quoting *Moore*, 423 U.S. at 124). The court observed that petitioners' proposed instruction would instead have allowed a physician to escape conviction "as long as a physician subjectively believes that he is meeting a patient's medical needs by prescribing a controlled substance, * * * no matter how far outside the bounds of professional medical practice his conduct falls." *Ibid.* And the court emphasized that a jury in-

struction endorsing "a complete defense" based on subjective "good faith" impermissibly omits "the objective standard by which to judge the physician's conduct." *Ibid.* The court also noted that the rejection of petitioners' preferred instruction did not "seriously impair [petitioners'] ability to present an effective defense" because the district court had provided a good-faith instruction linked to the "standards of medical practice generally recognized and accepted in the United States." *Id.* at 107a.

The court of appeals likewise affirmed the district court's refusal to issue the proposed "drug pusher" instruction, Pet. App. 108a-111a, and its general "instruction at the end of trial defining the criminal standard" applicable to petitioners' conduct, *id.* at 112a; see *id.* at 111a-113a.

ARGUMENT

Petitioners renew their contention (Ruan Pet. 14-36; Couch Pet. 5-11) that the district court abused its discretion in declining to deliver their proposed good-faith instruction to the jury. The court of appeals correctly rejected that contention, and its decision neither contravenes any precedent of this Court nor meaningfully conflicts with any decision of another court of appeals. Even if the district court's instruction could have been worded more precisely, the instruction that petitioners had proposed was inaccurate. This Court has denied review in other cases presenting similar issues. See, *e.g.*, *Sun* v. *United States*, 138 S. Ct. 156 (2017) (No. 16-9560); *Armstrong* v. *United States*, 558 U.S. 829 (2009) (No. 08-9339). It should follow the same course here. In addition, even if the question presented otherwise

warranted this Court's review, this case presents an unsuitable vehicle in which to resolve it. The petitions for writs of certiorari should be denied.

1. a. Federal law prohibits the distribution of controlled substances "[e]xcept as authorized by" the Controlled Substances Act (CSA), 21 U.S.C. 801 *et seq.* 21 U.S.C. 841(a). The CSA authorizes physicians who register with the DEA to dispense controlled substances, but only "to the extent authorized by their registration and in conformity with [the CSA]." 21 U.S.C. 822(b); see 21 U.S.C. 823(f).

In *United States* v. *Moore*, 423 U.S. 122 (1975), this Court held that physicians registered under the CSA may be subject to criminal liability under Section 841 "when their activities fall outside the usual course of professional practice." *Id.* at 124. The Court reasoned that, under the Act's statutory predecessor, physicians "who departed from the usual course of medical practice" had been subject to the same penalties as "street pushers," and "the scheme of the [CSA] * * * reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Id.* at 139-140.

Applying that standard, the Court in *Moore* upheld the prescribing physician's conviction because "[t]he evidence presented at trial" in that case "was sufficient for the jury to find that [his] conduct exceeded the bounds of 'professional practice.'" 423 U.S. at 142. Although the Court did not specifically decide what jury instructions were required, it implicitly deemed sufficient the jury instructions given. Those instructions stated that the physician could be found guilty of violating Section 841 if he dispensed controlled substances "other than in good faith * * * in the usual course of a professional

practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.* at 139 (citation omitted). They also stated that the defendant could not be found guilty if he "made 'an honest effort' to prescribe * * * in compliance with an accepted standard of medical practice." *Id.* at 142 n.20 (citation omitted).

As the court of appeals in this case correctly recognized, this Court's decision in *Moore* contemplates that a defendant physician's conduct "must be evaluated based on an objective standard, not a subjective standard." Pet. App. 105a (citation omitted). The touchstone for liability under *Moore* is whether a defendant acted —or, at a minimum, "made 'an honest effort'" to act— consistently with an objectively "accepted standard of medical practice." 423 U.S. at 142 n.20 (citation omitted). Framed in terms of "good faith," the jury instructions implicitly approved in *Moore* allowed the defendant to argue that he should not be subject to criminal liability if he had made a good-faith attempt to comply with generally accepted medical practice. But *Moore* did not endorse a freewheeling subjective approach, under which the defendant could argue that he had acted in good faith by prescribing controlled substances in any manner that he subjectively viewed as acceptable medical practice.

Petitioners nonetheless asked the district court in this case 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," and the jury "must return a not guilty verdict for the applicable

count." Pet. App. 130a-131a. Petitioners' proposed instruction then supplied two definitions of "good faith": first, that "[g]ood faith in this context means good intentions and the honest exercise of professional judgment as to the patient's needs"; and second, that "[i]t means that the Defendant acted in accordance with what he reasonably believed to be proper medical practice." *Id.* at 131a. The government objected to that instruction on the ground (*inter alia*) that it "would invite confusion." *Id.* at 133a. And the district court agreed that the instruction was improper, finding that petitioners were "proposing * * * a subjective view of what is the usual course of professional practice," when "the standard should be an objective one, not a subjective one." *Id.* at 134a.

The court of appeals correctly determined that the district court acted within its discretion in rejecting petitioners' proposed jury instruction. Like the district court, the court of appeals read petitioners' proposed instruction to articulate a wholly subjective standard, requiring the jury to acquit if it found that petitioners had acted in accordance with either their "professional judgment as to the patient's needs" or their subjective "belie[f]" as to "proper medical practice," Pet. App. 103a—regardless of whether petitioners had in fact attempted to comply with generally accepted medical practice. See *id.* at 106a. As the court explained, "under [petitioners'] proposed instruction, as long as a physician subjectively believes that he is meeting a patient's medical needs by prescribing a controlled substance, then he cannot be convicted of violating the Act no matter how far outside the bounds of professional medical practice his conduct falls." *Ibid.* Because such a formulation "fail[s] to include the objective standard

by which to judge the physician's conduct," *ibid.*, it is inconsistent with this Court's decision in *Moore*. The court of appeals thus correctly affirmed the district court's rejection of petitioners' proposed instruction.

Petitioner Ruan asserts that "[t]he Solicitor General * * * call[ed]" an instruction like the instruction proposed here "a 'model of clarity and comprehensiveness.'" Ruan Pet. 20 (quoting Br. in Opp. at 12, *Volkman* v. *United States*, 574 U.S. 955 (2014) (No. 13-8827)). But the quoted language, which was itself a quotation from a specific court of appeals opinion, was addressed to the combination of various "aspects of the instructions" that had been "tailored to the facts of th[at] case," not all of which appeared in petitioners' proposal here. Br. in Opp. at 6, *Volkman*, *supra* (No. 13-8827); see, *e.g.*, *id.* at 7 (noting that the jury in that case was instructed, *inter alia*, that a "physician's own individual treatment methods do not, by themselves, establish what constitutes a 'usual course of professional practice'") (citation omitted). And when the government later directly addressed the question, the government made clear that Section 841 incorporates an objective rather than a subjective standard for assessing a defendant's compliance with the accepted course of professional practice. See Br. in Opp. at 13, *Sun*, *supra* (No. 16-9560).

b. In his petition for a writ of certiorari, petitioner Ruan principally focuses not on the rejection of his proposed instruction, but instead on the instruction given by the district court. He asserts (Pet. 2-3, 15-16, 25-26) that the jury instructions did not permit *any* good-faith defense by a physician who reasonably believes that he is complying with professional norms, or subjectively intends to do so.

To the extent that the district court's instruction might be parsed in such a way as to exclude any good-faith defense, a reasonable jury would not have understood the given instructions to exclude a good-faith defense altogether. See *United States* v. *Hooshmand*, 931 F.2d 725, 731 (11th Cir. 1991) (noting that, "[w]hen reviewing jury instructions," the court of appeals "determines whether the charges as a whole sufficiently instructed the jury so that it understood the issues involved"). The district court twice mentioned "good faith," including that 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." Pet. App. 104a-105a. And the jury would naturally understand "professional" "medical" practice as including some reasonable degree of individualized physician judgment as to how such practice would translate into individualized treatment of specific patients. Defense counsel argued to the jury—without objection from the government—that the question in the case was not whether petitioners had "committed malpractice" but whether they had in fact been "practicing medicine." D. Ct. Doc. 722-27, at 102 (Dec. 20, 2017). On appeal, the government thus contended that "[a] jury that believed defendants committed only negligent misprescribing and not intentional drug distribution would have acquitted." Gov't C.A. Br. 97. And the court of appeals construed the jury instructions that way, concluding that "the district court instructed the jury that if the [petitioners] acted in good faith, they acted lawfully." Pet. App. 112a.

In all events, any impression in the jury instruction given by the district court would not cast doubt on the court of appeals' rejection of petitioners' argument that

"the district court erred in refusing to give *their* proposed jury instruction," Pet. App. 102a (emphasis added). Petitioner Ruan contends that the Eleventh Circuit has elsewhere determined that "[t]here is no room for good faith mistakes, reasonable or otherwise." Pet. 16; see Pet. 16-17, 23-26. But the decisions on which he relies do not clearly establish such a rule. In both *United States* v. *Tobin*, 676 F.3d 1264 (11th Cir.), cert. denied, 568 U.S. 1026 (2012), and 568 U.S. 1105 (2013), and *United States* v. *Joseph*, 709 F.3d 1082 (11th Cir.), cert. denied, 571 U.S. 1204 (2014), the court of appeals rejected challenges to excluded evidence or jury instructions like the one given here, on the ground that the usual course of professional practice must be evaluated based on an objective rather than a subjective standard. See *Joseph*, 709 F.3d at 1097; *Tobin*, 676 F.3d at 1279, 1281, 1283. And in the unpublished decision in *United States* v. *Enmon*, 686 Fed. Appx. 769 (11th Cir.), cert. denied, 138 S. Ct. 254 (2017), the court concluded that, even if it had "never (unequivocally) held that good faith is irrelevant to the objective standard required for the 'usual course of his professional practice' analysis," a jury instruction to that effect did not amount to plain error. *Id.* at 773; see *Joseph*, 709 F.3d at 1097 ("The law of this Circuit is not even clear that [the defendant] was entitled to a 'good faith' jury instruction at all."). The Eleventh Circuit thus has not directly considered a proposed jury instruction that—in contrast with the instruction petitioners proposed here—links good faith to a defendant's attempt to comply with the objectively accepted professional practice.

2. The court of appeals' rejection of petitioners' proposed jury instruction here is consistent with the uni-

form view of other courts of appeals, which have recognized that "allowing criminal liability to turn on whether the defendant-doctor complied with his own idiosyncratic view of proper medical practices is inconsistent with [this] Court's decision in *Moore*." *United States* v. *Hurwitz*, 459 F.3d 463, 478 (4th Cir. 2006). Every court of appeals to consider the question has concluded that *Moore* calls for "an objective standard" rather than a subjective one, and that an instruction focused on what the doctor "'believed to be proper medical practice'" is "not an accurate statement of the law." *Ibid.* (citation and emphasis omitted); see, *e.g.*, *United States* v. *Smith*, 573 F.3d 639, 648 (8th Cir. 2009) (explaining that liability turns on an objective standard measured by "generally recognized and accepted medical practices" rather than "a doctor's self-defined particular practice"); *United States* v. *Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986) ("To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area."), cert. denied, 479 U.S. 1036 (1987); *United States* v. *Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986) ("[T]he district court carefully modelled its charge after the *Moore* charge and properly directed the jury to consider * * * from an objective standpoint whether the drugs were dispensed in the usual course of a professional practice."); cf. *United States* v. *Ludwikowski*, 944 F.3d 123, 137 (3d Cir. 2019) (observing that "if we were to explicitly rule upon the nature of the 'usual course of professional practice' standard, we would likely agree with our sister Circuits that the plain language of the standard shows it to be an objective one"), cert. denied, 141 S. Ct. 872 (2020).

Nevertheless, petitioners contend (Ruan Pet. 17-27; Couch Pet. 10-11) that the decision below conflicts with decisions of other courts of appeals—and, in petitioner Ruan's view, with two separate alignments of circuits, neither of which purportedly adopts the same approach to Section 841 prosecutions as the Eleventh Circuit. While some variation exists in the case-specific jury instructions that courts of appeals have upheld over the years, no court of appeals has reversed a conviction on the theory that a defendant physician is entitled to a jury instruction like the one that petitioners proposed here. Indeed, most of the decisions on which petitioners rely *affirmed* convictions of physicians under the CSA—a result in accord with the result here.

a. Petitioner Ruan first contends (Ruan Pet. 18) that, "[i]n the Fourth, Second, and Sixth Circuits, physicians are entitled to acquittal if they 'reasonably believe' that their conduct complied with professional norms." His leading authority for that proposition is the Fourth Circuit's decision in *United States* v. *Hurwitz*, *supra*. See Ruan Pet. 18-19; see also Couch Pet. 10 (arguing that "other circuits recognize [that] there are inherently subjective and objective components in the liability of physicians under the Controlled Substances Act," and citing only *Hurwitz*). In that case, however, the Fourth Circuit concluded that the district court had "erred by affirmatively informing the jury that good faith was relevant only to the fraud charges" against the defendant and thus was not relevant in any respect to the Section 841 charges against him. *Hurwitz*, 459 F.3d at 480. This case does not involve any analogous set of instructions. And the Fourth Circuit indicated that a proper good-faith instruction "must reflect an objective rather than subjective standard for

measuring [the doctor's] good faith." *Id.* at 482; see Pet. App. 106a.

The remaining decisions on which petitioner Ruan relies (Ruan Pet. 19-21) are also consistent with the court of appeals' decision in this case. In *United States* v. *Wexler*, 522 F.3d 194 (2008), the Second Circuit rejected a defendant's challenge to a jury instruction that "lacked a 'good intentions' component," stating that, instead, "a jury must be informed that the drug has been legally dispensed if the physician had a good faith belief, based on a standard of objective reasonableness, that his prescription 'was for a legitimate medical purpose and in accord with the usual course of generally accepted medical practice,'" *id.* at 205 (citation omitted). That determination is consistent with the court of appeals' rejection of petitioners' proposed definition of "good faith" to "mean[] good intentions." Pet. App. 131a.

Likewise, in *United States* v. *Volkman*, 797 F.3d 377, cert. denied, 577 U.S. 934 (2015), the Sixth Circuit affirmed a district court's rejection of a proposed instruction stating that, "in order to find the defendant guilty, [the jury] must find that he used his prescription-writing power as a means to engage in the illicit drug-dealing and trafficking as conventionally understood," *id.* at 385. Similarly here, the court of appeals affirmed the district court's rejection of petitioners' proposed instruction that "the Government must prove * * * that the physician, in fact, operated as a drug pusher," observing that "the term 'drug pusher' connotes imagery of back-alley illicit drug deals" that need not be part of a CSA violation. Pet. App. 103a, 108a. Although the *Volkman* court also upheld the lengthier good-faith instruction delivered by the district court in that case, it

did not hold that any particular good-faith formulation was a required component of jury instructions on a Section 841 charge.

b. Petitioner Ruan next contends (Pet. 21) that "[t]he Ninth, First, and Seventh Circuits * * * require the government to prove that a physician *intentionally* exceeded the bounds of professional practice." But again, the decisions on which he relies do not meaningfully differ from the court of appeals' decision here to reject petitioners' proposed jury instruction.

The First Circuit's decision in *United States* v. *Sabean*, 885 F.3d 27 (2018), concerned the distinction between criminal liability under Section 841 and civil liability for medical malpractice. In that case, the district court had instructed jurors that they "may consider * * * evidence regarding ethical standards and the standard of care," but "caution[ed] [them] that this is not a civil case involving medical negligence for which a person may recover monetary damages." *Id.* at 48-49. On appeal, the First Circuit confirmed that "medical negligence alone was insufficient to ground a conviction" for unlawful drug distribution, rejecting the defendant's assertion that his "proposed alternative language * * * would have better illustrated the distinction between criminal distribution of drugs and medical malpractice." *Id.* at 45.

At trial in this case, petitioners were permitted to argue at length that simple negligence—and even malpractice sufficient for civil liability—did not satisfy the standard for criminal liability under the CSA. Petitioner Couch's counsel explained that distinction to the jury:

> There's poor care. Okay. There's neglect care, even. And then there's even malpractice. * * * All of that

> is within the usual course of medicine. It's only when you step outside the practice of medicine or you're outside the usual course of professional practice, that's where the government has to get you. Was Dr. Couch no longer practicing medicine? Had he shed his white coat and decided to become a drug pusher, a drug dealer? That's the question in this case, not whether he committed malpractice, not whether he was negligent, not whether his records were perfect. Was he practicing medicine?

D. Ct. Doc. 722-27, at 101-102.

The government did not object to that line of argument in the district court, and it observed on appeal that a "jury that believed defendants committed only negligent misprescribing and not intentional drug distribution would have acquitted." Gov't C.A. Br. 97. The court of appeals agreed. See Pet. App. 111a-113a. Accordingly, no party to this case and neither of the courts below disputes the First Circuit's holding in *Sabean*—that a defendant's having fallen short of the civil "standard of care" imposed on physicians is not sufficient to convict for intentional drug distribution.

Petitioner Ruan's reliance (Pet. 22-23) on *United States* v. *Kohli*, 847 F.3d 483 (7th Cir.), cert. denied, 138 S. Ct. 204 (2017), is similarly misplaced. In that case—which concerned a defendant's challenge to the sufficiency of the evidence against him rather than any instructional dispute—the Seventh Circuit stated that "the critical inquiry is whether the relevant prescriptions were made for a valid medical purpose and within the usual course of professional practice." *Id.* at 491. Because the defendant's prescriptions were issued neither for a valid medical purpose nor in the usual course

of professional practice, the court of appeals determined that the government had carried its evidentiary burden. See *id.* at 490 ("[T]he government presented ample evidence establishing that Dr. Kohli intentionally abandoned his role as a medical professional and unlawfully dispensed controlled substances with no legitimate medical purpose."). The Seventh Circuit's decision does not indicate that it would have reversed petitioners' convictions here.

Finally, petitioner Ruan's invocation (Pet. 21) of *United States* v. *Feingold*, 454 F.3d 1001 (9th Cir.), cert. denied, 549 U.S. 1067 (2006), does not provide support for petitioners' proposed instruction. In that case, the Ninth Circuit upheld a jury instruction stating that, *inter alia*, a "practitioner may not be convicted of unlawful distribution of controlled substances when he distributes controlled substances in good faith to patients in the regular course of professional practice." *Id.* at 1006. That description of the good-faith defense is substantively identical to the good-faith instruction that the district court delivered in this case. See Pet. App. 104a (explaining that a physician lawfully prescribes a controlled substance "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"). And although the *Feingold* opinion additionally noted that the defendant's "state of mind" is an important consideration in the prosecution of a Section 841 offense, and commended the district court for "compell[ing] the jury to consider whether Dr. Feingold intended to distribute the controlled substances for a legitimate medical purpose and whether he intended to act within the usual course of professional practice," 454

F.3d at 1008-1009, the Ninth Circuit did not hold that a district court would abuse its discretion by declining to give an instruction like the one proffered by petitioners in this case, see Pet. App. 103a.

c. Any minor variation that has developed in the decisions applying *Moore* does not warrant this Court's review. Nor is any such division implicated here: Petitioners have failed to demonstrate that any court of appeals would have found that the district court abused its discretion in declining to give the "good intentions" jury instruction that petitioners proposed. Pet. App. 103a.

Whatever weight might be given to the Eleventh Circuit's statement, in decisions other than this one, that a defendant's entitlement to a good-faith instruction is "not * * * clear," *Joseph*, 709 F.3d at 1097, the lower courts in this case, like all of the courts of appeals, recognized that a defendant's good faith can be relevant to the Section 841 analysis. See Pet. App. 107a, 136a; see also, *e.g.*, *Hurwitz*, 459 F.3d at 477. Like all courts of appeals, however, the lower courts here recognized that "the usual course of professional practice" articulated in *Moore*, 423 U.S. at 124, must be assessed objectively. See, *e.g.*, *Hurwitz*, 459 F.3d at 478. And, like all courts of appeals, the lower courts here recognized that the standard for criminal liability under Section 841 is higher than the standard for civil liability on a medical-negligence or medical-malpractice claim. See, *e.g.*, *id.* at 478-479.

3. Even if petitioners' challenge to the jury instructions otherwise warranted this Court's review, this case would be a poor vehicle in which to consider the question presented.

a. First, any error in the instructions was harmless beyond a reasonable doubt in light of the overwhelming

evidence that petitioners dispensed dangerous and addictive drugs to serve their own financial interests rather than to further any legitimate medical purpose or adhere to any arguable, reasonable, or subjectively perceived professional standard. See Fed. R. Crim. P. 52(a); see generally Pet. App. 5a-30a. As the government detailed before the court of appeals, petitioners routinely signed prescriptions without seeing patients and left blank, pre-signed prescriptions at the office, despite being informed that such a practice was illegal. Gov't C.A. Br. 50. That approach allowed petitioners' clinic to process "upwards of . . . 150 to 200" patients each day, with patients sometimes quadruple-booked for the same appointment slots. *Id.* at 18 (citation omitted). And as exemplified by the experience of an undercover DEA agent, petitioners prescribed drugs based on minimal, unverified complaints of pain. See Pet. App. 18a-19a.

Moreover, petitioners' prescribing habits clearly tracked their financial incentives, including their substantial investments in and payments received from the pharmaceutical companies that manufactured and sold the drugs they were prescribing. Gov't C.A. Br. 50. Petitioners and their staff pressured patients to fill prescriptions at the clinic's in-house pharmacy and prescribed medication based on what the pharmacy had in stock. *Id.* at 15. They also routinely prescribed potent and expensive TIRF drugs, which are approved for opioid-tolerant cancer patients, to patients who did not have cancer and did not need or want the medication. *Id.* at 51. And they ignored evidence of diversion and abuse, see *id.* at 24-25, by, for example, continuing to prescribe opioids for patients who had repeatedly failed

drug tests, *id.* at 17, and disregarding the outright admission of an undercover DEA agent that he had been obtaining oxycodone on the street before seeking a prescription from their clinic, Ruan PSR ¶ 48. See Gov't C.A. Br. 25 (noting that "so many [clinic]-prescribed opioids ended up on the streets of Mobile that the week after [petitioners' clinic] was raided, the street price for those drugs 'almost doubled'") (citation omitted).

The trial evidence thus overwhelmingly demonstrated that each petitioner, like the doctor in *Moore*, "[i]n practical effect * * * acted as a large-scale 'pusher'—not as a physician." 423 U.S. at 143. Accordingly, petitioners would not have benefitted even from their proposed instruction directing the jury to acquit solely upon a finding that petitioners believed that their prescribing practices were "proper." Pet. App. 103a; see, *e.g.*, *Feingold*, 454 F.3d at 1012 (determining that any instructional error in a Section 841 case was harmless because the evidence was "overwhelming" and included proof that the defendant physician prescribed drugs "to undercover law enforcement officials who did little more than tell him they wanted narcotics").

b. Second, the interlocutory posture of this case "alone furnishe[s] sufficient ground for the denial" of the petition for a writ of certiorari. *Hamilton-Brown Shoe Co.* v. *Wolf Bros. & Co.*, 240 U.S. 251, 258 (1916); see *Brotherhood of Locomotive Firemen & Enginemen* v. *Bangor & Aroostook R.R.*, 389 U.S. 327, 328 (1967) (per curiam) (explaining that a case remanded to district court "is not yet ripe for review by this Court"). "[E]xcept in extraordinary cases, [a] writ [of certiorari] is not issued until final decree." *Hamilton-Brown Shoe Co.*, 240 U.S. at 258. That approach promotes judicial efficiency because the issues raised in a petition may be

rendered moot by further proceedings on remand, and because challenges to a criminal defendant's conviction and sentence may be consolidated into a single petition for a writ of certiorari.

Here, the court of appeals vacated one count of conviction as to both petitioners and remanded to the district court for resentencing. Pet. App. 128a. Resentencing has not yet taken place. Following the district court's disposition of the case on remand (and any new appeal taken from the amended judgment), petitioners will be able to reassert the current claim raised in their petitions—together with any other claims that may arise at sentencing—in new petitions for writs of certiorari seeking review of the final judgment against them. See *Major League Baseball Players Ass'n* v. *Garvey*, 532 U.S. 504, 508 n.1 (2001) (per curiam) (noting that the Court "ha[s] authority to consider questions determined in earlier stages of the litigation where certiorari is sought from" the most recent judgment). Petitioners provide no sound reason to depart in this case from the Court's usual practice of awaiting final judgment.

CONCLUSION

The petitions for writs of certiorari should be denied.

Respectfully submitted.

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