In the Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

The government evidently believes that this Court won't read the Eleventh Circuit's opinion before acting on the petition. The court of appeals held, in language the government omits from its opposition, that a physician may assert a good faith defense only "as long as [his] conduct also was in accordance with the standards of medical practice." Pet. App. 107a. The court therefore sustained an instruction that told the jury—in language the government lops off entirely, see, e.g., BIO 7—that a doctor may be convicted, regardless of his good faith, if his prescriptions "were outside the usual course of professional medical practice." Pet. App. 139a. The Eleventh Circuit's refusal to accord good faith any independent force reflects its longstanding view that "whether [a physician] had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice is irrelevant" to criminal liability. United States v. Enmon, 686 Fed. Appx. 769, 773 (2017) (per curiam) (emphasis added); *United* States v. Tobin, 676 F.3d 1264, 1283 (2012).

Tellingly, the government does not defend that idiosyncratic position. Indeed, it concedes that a physician who "ma[kes] 'an honest effort' to act[] consistently with" professional standards should not be convicted. BIO 11 (quoting *United States* v. *Moore*, 423 U.S. 122, 142 n.20 (1975)). Nor does the government dispute that the question presented is important and recurring. Good faith, after all, is the defense in every single physician prosecution under the CSA, spelling the difference between felony distribution and simple malpractice.

The government's concession should have prompted it to confess error in this case. Instead, the government engages in misdirection, starting by recasting the challenged ruling as only a *discretionary refusal to grant* an instruction, rather than the *giving* of a legally erroneous instruction. The government uses the same feint to reformulate the question presented and to minimize the 3-3-1 circuit conflict over the scope of the good faith defense. The government also makes two of the usual "vehicle" objections, but neither is well taken.

1. Because the government's brief conspicuously avoids doing so, we reiterate the district court's actual instruction. Purporting to "throw[]" Petitioner "a bone," Pet. App. 136a, the court agreed to *mention* "good faith," but then immediately told the jury that the defense has no independent force:

Thus a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions ... were outside the usual course of professional medical practice.

Pet. App. 139a (emphasis added). The court of appeals upheld this instruction because it believed that good faith is a CSA defense "as long as the [defendants'] conduct also was in accordance with the standards of medical practice," Pet. App. 107a (emphasis added)—that is to say, as long as the doctor's conduct is already lawful. On that basis, the Eleventh Circuit also

¹ For that reason, the government's suggestion (at 9) that the petition raises the same issue as those in *Sun* and *Armstrong* is mistaken. As best we can tell, neither case presented a challenge to an affirmatively erroneous good faith instruction.

rejected (Pet. App. 105a) Petitioner's proposed "reasonable belief" instruction—even though the Fourth, Second, and Sixth Circuits have approved that identical instruction, see Pet. 18-21, and the Solicitor General has endorsed it as a "model of clarity and comprehensiveness," U.S. BIO at 12-13, *Volkman* v. *United States*, No. 13-8827 (July 11, 2014).²

The government suggests (at 14), fancifully, that the jury may have "naturally" intuited a good faith defense because the district court used the words "professional" and "medical." Even if the jurors were that clairvoyant, their imaginations would not overcome the district court's explicit instruction that a departure from professional norms is enough to And the Eleventh Circuit affirmed, not because the jury would somehow intuit a genuine good faith defense, but precisely because the instruction "told the jury" that good faith may be claimed only by doctors whose conduct falls within professional See Pet. App. 107a. The court of appeals likewise rejected Petitioner's attempt to give the good faith defense some meaning as an "incorrect statement of the law." Pet. App. 105a.

Not to worry, the government says (at 14). The district court at least "mentioned" (*ibid.*) the words "good faith," so perhaps Petitioner wasn't deprived of a good faith defense after all. Not even the Eleventh

² The government seeks to diminish its *Volkman* concession (BIO 13), but fails to identify any pertinent distinction between the instruction in that case and the one Petitioner unsuccessfully requested. And *Sun* sheds no light on the issue, as the petitioner there sought a purely subjective "belief" instruction that omitted the modifier "reasonably." U.S. BIO at 12-13, *Sun* v. *United States*, No. 16-9560 (Aug. 2017).

Circuit subscribed to that canard. Yes, the trial court "thr[ew]" Petitioner "a bone" by mentioning good faith, but it immediately sapped it of any actual content. Pet. App. 139a. That was "as far as [the court was] willing to go, given the state of the law on this issue." Pet. App. 136a.

And under Eleventh Circuit precedent, the district court's conclusion was undoubtedly correct. That court has squarely held that the "appropriate focus" is "whether the physician prescribes medicine in accordance with a standard of medical practice." United States v. Abovyan, 988 F.3d 1288, 1305 (2021) (quoting United States v. Merrill, 513 F.3d 1293, 1306 (2008)). It had previously rejected a "reasonable belief" instruction as "incorrect" (United States v. Joseph, 709 F.3d 1082, 1097 (2013)), and concluded that the CSA "holds practitioners" to the standard of care. Tobin, 676 F.3d at 1283 & n.10. Put simply, in the Eleventh Circuit, good faith is "irrelevant." Enmon, 686 Fed. Appx. at 773.3

2. In an understatement worthy of P.G. Wodehouse, the government acknowledges (at 17) "some variation" among the circuits in the content of a permissible good faith defense. In truth, the "variation" is gaping. Three circuits (the Fourth,

³ The government claims (at 15) that the Eleventh Circuit has never "directly considered" a proposed jury instruction that "links good faith to a defendant's attempt to comply with the objectively accepted professional practice." Even if that were so (and it isn't; Petitioner's proposed instruction meets that made-up standard), it would still not diminish the fact that the Eleventh Circuit has repeatedly rejected as "incorrect," Pet. App. 105a; Joseph, 709 F.3d at 1097, the *very* instruction that three other circuits have approved, see Pet. 18-21, 24.

Second, and Sixth) forbid conviction if the doctor "reasonably believed" that her prescription fell within professional norms. See Pet. 18-21. Three (the Ninth, Seventh, and First) require the government to prove that the physician *intended* to exceed the bounds of the profession. See Pet. 21-23. But the Eleventh Circuit permits *neither* such defense.⁴

a. The government says that the Fourth Circuit's decision in *Hurwitz* is not truly conflicting because the jury in that case was "affirmatively" told that good faith is not a defense to prescribing beyond professional norms. BIO 17. Exactly—and so was Petitioner's jury. As the Eleventh Circuit explained in affirming, the district court told the jury that a doctor's good faith is relevant only if her "conduct also was in accordance with the standards of medical practice." Pet. App. 107a. Dr. Hurwitz's jury was effectively told the same thing, and on that very basis the Fourth Circuit reversed.⁵

⁴ It is scarcely surprising that only one circuit, the Fourth in *Hurwitz*, has found it necessary to reverse a verdict based on an instruction like the one below. District courts in other circuits—following their respective circuit precedent, this Court's decisions (see Pet. 27-29; *Moore*, 423 U.S. at 139, 142 n.20), and common sense—never tell juries that exceeding professional norms is a sufficient basis to convict.

⁵ The government notes that the Fourth Circuit has rejected a "subjective standard for measuring . . . good faith." BIO 17-18. That's true enough, but irrelevant. For one thing, Petitioner did not request a "subjective standard"; he asked that the jury be told it should acquit if he "reasonably believed" his prescriptions comported with professional standards. Pet. App. 131a (emphasis added). Moreover, the question presented centers on the decision to give an erroneous instruction, not just the failure

The government's treatment of the Second Circuit's case law is equally baffling. As the government recognizes, in the Second Circuit "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 ... in accord with the usual course of generally accepted medical practice." BIO 18 (quoting *United States* v. Wexler, 522 F.3d 194, 205 (2008) (emphasis added) (quotation marks omitted)). Petitioner asked for exactly that instruction, but the Eleventh Circuit held that the jury need not "be informed" of that defense unless the physician's conduct falls within professional norms. See Pet. App. 105a-107a.

As for the Sixth Circuit, the government is in an especially tough spot because its brief in opposition in *Volkman* endorsed precisely the instruction that the opinion below rejected as an "incorrect statement of the law." Pet. App. 105a. See supra pp. 2-3 & n.2. So the government directs this Court's attention (BIO 18) to the *Volkman* court's rejection of a separate "drug pusher" instruction. But the petition—and the circuit district court's split—concern the good faith instruction, not the drug pusher instruction. Compare Pet. App. 105a-107a (discussing the "Good Faith Instruction"), with Pet. App. 108a-111a (discussing the "Drug Pusher Instruction"). On that issue—the one that actually matters—the government has nothing to say.

to give the correct instruction Petitioner sought. That erroneous instruction would not be countenanced in any of the conflicting circuits.

b. The government's treatment of the Ninth, Seventh, and First Circuit cases is downright misleading. To hear the government tell it (at 21), the instruction in *United States* v. *Feingold*, 454 F.3d 1001 (9th Cir. 2006), was "substantively identical" to the instruction given in this case. Not so—not even close.

Dr. Feingold's jury was told that it could not convict him of drug dealing if he acted in good faith, where "good faith . . . means an honest effort to prescribe . . . in accordance with the standard of medical practice generally recognized." Id. at 1006 (emphasis added). The Ninth Circuit sustained that instruction because it "compelled the jury to consider whether Dr. Feingold . . . intended to act within the usual course of professional practice." Id. at 1009 (emphasis added). As the Ninth Circuit explained, "a practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) only if he does so intentionally." Id. at 1007 (emphasis added). That, of course, is the very proposition that the Eleventh Circuit rejected.

The government misdirects the eye again when it addresses *United States* v. *Kohli*, 847 F.3d 483 (7th Cir. 2017). *Kohli*, the government tells the Court (at 20), "concerned a defendant's challenge to the sufficiency of the evidence against him rather than any instructional dispute." You might reach that conclusion if you stopped reading the opinion on page 493. On page 494, the court rejected defendant's *instructional* challenge precisely because the jury was told that it could not convict Dr. Kohli if he prescribed in good faith. 847 F.3d at 494. See also *id*. at 489 (noting that instructions directed the jury to acquit if

the physician acted with "good intentions and the honest exercise of good professional judgment"). The Eleventh Circuit has held the opposite.

Most baffling of all is the government's contention (at 19-20) that there is no conflict with the First Circuit because $Dr.\ Couch's\ counsel$ argued to the jury that malpractice is an insufficient basis to convict. The question, of course, is whether $Eleventh\ Circuit\ law\ conflicts\ with\ that\ of\ other\ circuits,\ not\ whether\ Couch's\ closing\ statements\ did.\ And,\ here,\ Eleventh\ Circuit\ law\ exposes\ physicians\ to\ felony\ conviction\ based\ on\ nothing\ more\ than\ a\ departure\ from\ the\ "state\ standard\ of\ professional\ practice."\ <math>Tobin,\ 676\ F.3d\ at\ 1283\ n.10.$

- 3. Finally, the government raises two standard vehicle objections, but each lacks merit.
- a. First, advancing an argument that it did not make below, the government contends that "any error in the instructions was harmless beyond a reasonable doubt." BIO 22-24.

Even if this argument had merit, it would not present a vehicle problem. This Court's "usual practice" is to grant certiorari, resolve the legal issue, and reserve disputes over harmless error "for resolution on remand." *Maslenjak* v. *United States*, 137 S. Ct. 1918, 1931 (2017); see *McFadden* v. *United States*, 576 U.S. 186, 189 (2015) (doing so in a case concerning an instruction that "did not accurately convey th[e] knowledge requirement" for a CSA prosecution); see also, *e.g.*, *Rehaif* v. *United States*, 139 S. Ct. 2191, 2200 (2019); *Kingsley* v. *Hendrickson*, 576 U.S. 389, 404 (2015); *Skilling* v. *United States*,

561 U.S. 358, 414 (2010); *Black* v. *United States*, 561 U.S. 465, 474 (2010).

In any event, the harmless error argument is meritless. Because "the jury was not correctly instructed on the meaning of [the good faith defense], it may have convicted [Petitioner] for conduct that is not unlawful." *McDonnell* v. *United States*, 136 S. Ct. 2355, 2375 (2016). That alone precludes any finding that the "errors in the jury instructions were harmless beyond a reasonable doubt." *Ibid.* (quotation marks omitted).

The risk of prejudice is especially severe because, as the petition explained (Pet. 5-10 & n.6), with no discernible response from the government, substantial portions of the trial were consumed by evidence of simple malpractice, thereby inviting the jury to convict on that basis alone. As for the purportedly "overwhelming" evidence of criminal intent the government invokes (at 22-23), the proof was anything but.⁶

⁶ Delegation to physician extenders, allegedly improper (though facially legal, see Pet. App. 9a) off-label prescribing, relations with pharmaceutical companies, and allegedly insufficient attentiveness to prophylactic drug tests hardly overcome (much less beyond a reasonable doubt) an affirmatively erroneous instruction on Petitioner's core defense. See BIO 23-The government also draws on "the experience of an undercover DEA agent" to argue that "petitioners prescribed drugs based on minimal, unverified complaints of pain." BIO 23 (emphasis added). But Dr. Ruan, the only *petitioner* we represent, never prescribed opioids to an undercover agent: he turned agents away three times, telling one that prescription drugs were "not appropriate" for him. Pet. 9 n.3; Pet. App. 85a; cf. BIO 5, 24 (describing an instance in which "Couch signed" a prescription for an undercover agent (emphasis added)).

Indeed, the government was constrained to concede at trial that Petitioners did not operate a "pill mill," see Pet. App. 27a n.6, and that "[b]y and large, their patients were legitimate patients," Pet. App. 84a. In a closely fought case such as this one, an erroneous instruction on the central defense easily made all the difference.⁷

b. The government's appeal (at 24-25) to the case's "interlocutory" posture is less persuasive still. "[T]here is no absolute bar to review of nonfinal judgments of the lower federal courts[.]" *Mazurek* v. *Armstrong*, 520 U.S. 968, 975 (1997) (per curiam). And this case is not "interlocutory" in any sense that counsels deferring review.

For one, since the government filed its brief in opposition, Petitioner was resentenced to the same term as he had previously been sentenced. Amended Judgment, Dkt. 917 (July 14, 2021). That resentencing on a single, non-CSA count did not "moot" the "issues raised in [the] petition." BIO 24-25. Nor could it possibly have done so: The question presented was definitively decided by the court of appeals and has nothing to do with the vacated Anti-Kickback Statute count. See Pet. 13 (noting that the

⁷ The government also suggests that defense counsel's argument to the jury cured any error in the jury instructions. BIO 14. But it is the instructions that constitute the "definitive and binding statements of the law," and juries are presumed to follow them. *Boyde* v. *California*, 494 U.S. 370, 384 (1990); *Richardson* v. *Marsh*, 481 U.S. 200, 211 (1987). Here, moreover, the court expressly reminded the jury that it must "follow the law as [the court] explain[s] it," Tr. 6322:12-13; that "anything the lawyers say . . . is not binding on you," Tr. 6323:11-12; and that "arguments . . . by the lawyers are not evidence," Tr. 9:17-19.

AKS counts were independent of the narcotics charges).8

On the other side of the ledger, two medical doctors now sit in federal prison, convicted by a jury that was told that good faith is not a real defense. All the while, the Eleventh Circuit's erroneous rule continues to govern an untold number of other prosecutions of medical providers. And federal courts' "divergent, conflicting, and, frankly, confusing approaches" continue to deter medical professionals from prescribing to patients suffering from chronic pain, "causing needless suffering and death." Br. of Health Law Professors 6-7, 14.

CONCLUSION

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

⁸ Count 16 (the vacated conviction) and Count 17 (the other AKS conviction) together yielded a 120-month sentence that had originally been ordered to run concurrently with Petitioners' 240-month sentences for the narcotics violations. Sentencing Tr. 65:12-23.

Respectfully submitted.

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