No. 20-1410

In the Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

REPLY BRIEF FOR THE PETITIONER

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REPLY BRIEF FOR THE PETITIONER

"There you go again." October 28, 1980 Presidential Debate (then-candidate Ronald Reagan). Just as it did in its brief in opposition, the government strategically truncates the good-faith instruction Dr. Ruan actually received at trial. It fails even to mention that Dr. Ruan's jury was authorized to convict him on the mere finding that he had prescribed "outside the usual course of professional medical practice." Pet. App. 139a.

The government is equally misdirecting when it recounts the Eleventh Circuit's decision. To read the government's brief, one would never learn that the court of appeals affirmed because of its longstanding belief that a doctor's good faith is "irrelevant." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (2017) (per curiam); *United States* v. *Tobin*, 676 F.3d 1264, 1283 (2012). On that indefensible premise, the Eleventh Circuit held, in language the government completely elides, that a physician may assert good faith only "as long as [his] conduct also was in accordance with the standards of medical practice generally recognized and accepted in the United States." Pet. App. 107a.

All of which is to say that, in the Eleventh Circuit, a doctor may assert a good faith defense only when his prescriptions are already lawful.

It's not hard to see why the government declines to mention, much less defend, that standard. The fact is, under *any* intelligible conception of good faith—the "medical purpose" standard we endorse; the "honest effort" standard the government sometimes endorses

(Br. 31, 33, BIO 11); the "objective honest-effort" standard the government sometimes endorses (Br. 17); or even the "objectively reasonable attempt" standard the government sometimes endorses (Br. 16, 24, 26)—Dr. Ruan's convictions cannot be sustained. On remand, the court of appeals should be directed either to dismiss the case outright (in light of the government's newly announced statement that Alabama law is the source of the relevant professional standards), or at a minimum to grant a new trial governed by the correct standard for a good faith defense.

I. EVEN UNDER THE GOVERNMENT'S (ERRONEOUS) GOOD FAITH STANDARD, PETITIONER'S CONVICTIONS SHOULD BE REVERSED.

A. Here is the good faith instruction Dr. Ruan's jury actually received:

> A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States. The defendants in this case maintain at all times they acted in good faith and in accordance with [the] standard of medical practice generally recognized and accepted in the United States in treating patients.
>
> *Thus* a medical doctor has violated section 841 when the government has proved beyond a reasonable doubt that the doctor's actions were

> either not for a legitimate medical purpose or were outside the usual course of professional medical practice.

Pet. App. 139a (emphasis added).

The government assiduously avoids defending that instruction, and with good reason. The instruction confined the good faith defense only to physicians whose prescriptions were already lawful. Driving the point home, the jury was authorized to convict so long as Dr. Ruan's treatment was outside the "recognized and accepted" standard of medical practice, regardless of his state of mind. *Ibid.* On appeal, the Eleventh Circuit sustained that instruction precisely because it "told the jury that good faith was a defense to a Controlled Substances Act violation as long as the appellants' conduct *also* was in accordance with the standards of medical practice generally recognized and accepted in the United States." Pet. App. 107a (emphasis added).

In other words, in the Eleventh Circuit, the good faith defense is available only to those defendants who don't need it. That's no defense at all.

B. In keeping with every other circuit to address the issue, the government acknowledges that *something* more is needed to constitute an appropriate good faith instruction. But the government is not altogether clear what that something should be.

The government first floats an "honest effort" standard. Br. 31, 33. That's a good start. Indeed, this Court in *United States* v. *Moore* approved a similar instruction, making clear that "honest effort" is a subjective inquiry and only the *goal* of that effort—"compliance with an accepted standard of medical

practice"—should be objectively defined. See 423 U.S. 122, 142 n.20 (1975); BIO 11. See also Webster's New Twentieth Century Dictionary 871 (2d ed. 1962) (defining "honest," in the sense of "an *honest* effort," as "showing fairness and sincerity; straightforward; free from deceit").[1]

But Petitioner's jury was not asked to assess his subjective honesty, nor does the government think it should have. Rather, as reinforced by the government's two alternative formulations—"objective honest effort," and "objectively reasonable attempt"—the government advances a purely objective test, which inquires only whether the physician has hewed sufficiently closely (in the eyes of a lay jury) to the evolving norms of the medical community.

So, for example, the government explains that its standard requires the defendant to make an "objectively reasonable attempt to ascertain and act within the bounds of professional medicine," Br. 16, while "reasonably trying to situate himself within the medical community," Br. 17. Put differently, the government proposes to treat the *mens rea* element of a serious felony as something akin to a federalized continuing-professional-education requirement. The government is not bashful about this: it declares that a physician who has not "educate[d] himself about

[1] If *Moore* had endorsed an objective-reasonableness standard, then the Court would not have found it significant (as it did) that the "jury did not believe" Dr. Moore's claim to be experimenting with a new detoxification method. 423 U.S. at 143.

current medicine" is a "drug dealer, plain and simple." Br. 26. That is remarkable.[2]

What is an "objectively honest effort," anyway? Or, murkier still, an "objectively reasonable attempt"? And how are those standards different from a simple negligence standard, which the government turns cartwheels to disclaim (Br. 35, 41-42)? The difference, the government suggests, is that its standard looks to the "broader picture of a physician's decisions," Br. 35, and that isolated mistakes are not culpable, as they might otherwise be in a civil malpractice case, Br. 41-42. But the government's "broader picture" distinction is one without a difference. Expanding the lens through which "reasonableness" is viewed does not create a standard different from negligence. It merely creates a panoramic negligence standard.

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[2] The government's standard cannot plausibly be compared to "deliberately shielding [oneself] from clear evidence of critical facts that are strongly suggested by the circumstances," *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 563 U.S. 754, 766 (2011), or "aware[ness] of a high probability of [a culpable fact's] existence," *Leary* v. *United States*, 395 U.S. 6, 46 n.93 (1969). See Br. 35. To put it mildly, the doctrine of willful ignorance would balloon if it embraced a physician's failure to keep abreast of academic literature, or to survey the field before using treatments at the cutting edge of medical practice. A physician who fails to reasonably "respect[ ] the profession," Br. 35, is nothing like a smuggler who agrees to transport baggage in suspicious circumstances while intentionally avoiding knowledge of the contents. See *United States* v. *Jewell*, 532 F.2d 697 (9th Cir. 1976) (en banc). See also *United States* v. *Hale*, 857 F.3d 158, 168 (4th Cir. 2017) (applying *Global-Tech* and noting that "willful blindness instructions should be handled with caution because of the risk that the instruction could mislead a jury into believing that it could convict the defendant for his mere negligence or recklessness with respect to a key fact making his conduct illegal" (cleaned up)).

Indeed, evaluating whether mistakes are "unreasonable" often turns on the "broader picture." See, *e.g.*, *Trimarco* v. *Klein*, 56 N.Y.2d 98, 106 (1982) ("when proof of a customary practice is coupled with a showing that it was ignored and that this departure was a proximate cause of the accident, it may serve to establish liability"). Cf. *Elonis* v. *United States*, 575 U.S. 723, 738-739 (2015) ("The Government is at pains to characterize its position as something other than a negligence standard" but "negligence standards often incorporate 'the circumstances known' to a defendant.").

C. The government's proposed negligence standard is untenable. As we have explained, a negligence *mens rea* is insufficient to separate innocent from wrongful conduct in Section 841(a)(1) prosecutions of doctors. See Pet. Br. 33-35. See also *United States* v. *Houston*, 792 F.3d 663, 668 (6th Cir. 2015) (Sutton, J.) (finding plain instructional error in part because of "the oddity of permitting a criminal conviction to stand based on a reasonable-person—which is to say, negligence—standard").

Tellingly, however, even under the government's negligence standard, Dr. Ruan's convictions should be reversed. The instruction given to Dr. Ruan's jury rendered his state of mind, negligent or otherwise, irrelevant. After "throw[ing] a bone to [Dr. Ruan's proposed] good faith language," Pet. App. 136a, the district court made clear that good faith plays no role in the jury's analysis, concluding that a doctor violates Section 841(a)(1) if "the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice," Pet. App. 139a. This language foreclosed *any* possible

defense based on Dr. Ruan's "honest effort" or "good faith."

D. This fundamental instructional error was not harmless, particularly in a sharply contested case like this one. By foreclosing any actual good faith defense, the jury instructions "provided no assurance that the jury reached its verdict after finding those questions or matters." *McDonnell* v. *United States*, 136 S. Ct. 2355, 2374 (2016). Where, as in *McDonnell*, the jury instructions "lacked important qualifications, rendering them significantly overinclusive," a reviewing court need not parse the record to assess the harmfulness of the instructional error. *Ibid.* "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." *Id.* at 2374-2375. Faced with this possibility, a court "cannot conclude that the errors in the jury instructions were 'harmless beyond a reasonable doubt.'" *Id.* at 2375 (quoting *Neder* v. *United States*, 527 U.S. 1, 16 (1999)).

If the Court nevertheless accepts the government's invitation to parse the record, there is no basis to find this fundamental instructional error to be harmless. To carry its heavy burden, the government must show that it is "clear beyond a reasonable doubt that a rational jury would have found the defendant guilty absent the error." *Neder,* 527 U.S. at 18. The evidence cited by the government comes nowhere close to meeting that standard.

Indeed, much of that evidence is (if anything) evidence of mere malpractice—a far cry from a showing that Dr. Ruan "decided no longer to act recognizably as a doctor." Br. 42. For instance, the

government points to expert testimony regarding when and how physicians may delegate certain tasks and sign prescriptions. Br. 47-48. Rather than suggest that Dr. Ruan abdicated his role as a physician—or even "sharply departed" from professional standards, Br. 47—that testimony reveals a wide range of professional views on such practices. Compare, *e.g.*, Tr. 2483 (Dr. Vohra) (a physician's "do[ing] an exam to assess the patient's clinical condition" before prescribing is "certainly standard of care"), with Tr. 4837-4838 (Dr. Warfield) ("[T]here are many, many different ways of doing things."); Tr. 4844 (Dr. Warfield) (it is "common practice across the country for someone else to be able to give the patient informed consent"); Tr. 6052 (Dr. Gharibo) ("Most of us use nurse practitioners or physician extenders. It's very common.").

The government also takes liberties when it asserts that the record "overwhelmingly demonstrated that [Dr. Ruan] acted as [a] drug dealer[ ]." Br. 47. For example, while the government correctly notes that Drs. Ruan and Couch's clinic issued close to 300,000 controlled-substance prescriptions between January 2011 and May 2015, Br. 5, the government fails to mention that this number breaks down to fewer than one prescription per month per patient, Tr. 61; that the clinic took patients only by referral, Tr. 70, 977 (describing one patient referral to Dr. Ruan from the U.S. Surgeon General); that Dr. Ruan took only patients with insurance, accepting insurers' oversight, Pet. App. 85a; and that more than 90% of these patients already had active opioid prescriptions when they came to the clinic, Tr. 70, 5843 ("That's when people come to the interventional pain practice[.]"). The government also

contends that the "evidence showed 'that Ruan and Couch treated approximately three dozen' patients" in violation of the Controlled Substances Act, Br. 8, but neglects to clarify that Dr. Ruan was convicted of improperly prescribing to only *four* individual patients.[3] And the record is replete with testimony from medical experts, former clinic employees, and Dr. Ruan himself showing that Dr. Ruan's practice complied with professional norms and guarded against the risk of opioid abuse, even as to these four patients. See Tr. 5227-5231, 5282 (Dr. Gudin) (describing review of patient charts and concluding that "the prescribing seemed appropriate and certainly within the course of legitimate medical practice"); Tr. 6035, 6042-6056 (Dr. Gharibo) (describing review of patient charts and confirming that "each of the prescriptions were proper"); Tr. 5512-5513 (Harville) (describing how Dr. Ruan "developed an opioid risk tool" for the clinic); J.A. 209 (Dr. Ruan) (prescription decisions were based on "[p]atient need, that's all there is"); Tr. 5821-5822 (Dr. Ruan) (describing use of an "abuse-deterrent formulation drug" when he "see[s] the indication [for abuse] in [a] patient"); J.A. 223 (Dr. Ruan) (treatment decisions were always motivated by "caring for [his] patients"). Indeed, the government itself conceded at trial that Dr. Ruan's clinic was not a "pill mill," see Pet. App. 27a n.6, and that "[b]y and large, their patients were legitimate patients," Pet. App. 84a.

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[3] The government states that Dr. Ruan was convicted on five counts of unlawful distribution, Br. 2, failing to account for his acquittal on Count 10 of the Superseding Indictment. See J.A. 260.

In this hard-fought case, the district court's erroneous jury instruction was anything but harmless. This Court has repeatedly held that a jury "instruction 'may not be judged in artificial isolation,' but must be considered in the context of the instructions as a whole." *Estelle* v. *McGuire*, 502 U.S. 62, 72 (1991) (quoting *Cupp* v. *Naughten*, 414 U.S. 141, 147 (1973)); see also *Waddington* v. *Sarausad,* 555 U.S. 179, 191 (2009) (same). Here, the district court's brief reference to "good faith"—shoehorned in passing into the instruction's description of an authorized prescription—was followed by an unqualified instruction to convict if "the government has proved beyond a reasonable doubt that the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice." Pet. App. 139a. The "bone" thrown Petitioner's way was all gristle and no meat.

True, defense counsel tried to clarify that (empty) standard during their summations to the jury. But "[a]rguments of counsel cannot substitute for instructions by the court." *Carter* v. *Kentucky*, 450 U.S. 288, 304 (1981) (quoting *Taylor* v. *Kentucky*, 436 U.S. 478, 488-489 (1978)). And counsel's arguments certainly cannot overcome the *incorrect* jury instruction given in this case.[4] Jurors, after all, are

[4] The government contends that these deficiencies in the instructions are evident only if the instructions are "parsed after the fact." Br. 44. Exactly the converse is true: it is the government that cherry-picks snippets to improve upon the good faith instruction actually given. Nor is Petitioner identifying errors only "after the fact"; as the government does not dispute, defendants objected contemporaneously to the district court's vacuous good faith instruction.

presumed to follow the instructions they are given. See *Richardson* v. *Marsh*, 481 U.S. 200, 206 (1987).[5]

II. ON REMAND, THE COURT OF APPEALS SHOULD BE DIRECTED EITHER TO DISMISS DR. RUAN'S CASE OUTRIGHT OR, AT A MINIMUM, TO ORDER A NEW TRIAL ON ALL COUNTS.

Because Dr. Ruan's case should be reversed and remanded, the question arises what directions should be given to the court of appeals on remand. We turn to that question next.

A. In Light Of The Government's Concession Regarding Alabama Law, The Court Of Appeals Should Be Directed To Dismiss The Case On Remand.

In its response brief, the government contends for the first time that "limits of [physicians'] federal registrations" under the CSA should "look to *state* practices for their definition." Br. 40 (emphasis in original). Accordingly, says the government, "the question of whether a physician acted outside the

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[5] The government offers the fanciful suggestion that perhaps the district court's passing "mention[ ]" of the words "good faith," "professional," and "medical" would have prompted the jury to give Dr. Ruan room "for considerable individualized physician judgment." Br. 45. Even if the jury were that clairvoyant, it would still have foundered on the district court's explicit invitation to convict if "the doctor's actions were either not for a legitimate medical purpose or were outside the usual course of professional medical practice," regardless of his state of mind. Pet. App. 139a. See also Tr. 6322:12-13 (district court expressly reminded the jury that it must "follow the law as [the court] explain[s] it").

course of his professional practice, and therefore outside the scope of his DEA registration, is determined by reference to the relevant standards governing the practice of medicine set by the State and the state medical board." *Ibid.*

This concession is dispositive. At Dr. Ruan's trial, the government did not even attempt to present qualified testimony about Alabama's standards for controlled-substance prescriptions, focusing instead on (nebulous) national practice standards. See, *e.g.*, Tr. 4567 (government counsel arguing that there is "no written national standard," but "through experience and through what various state board rules are and general practices of medicine, doctors do have an idea of what is within the usual course of professional practice and what is outside the usual course of professional practice"). In light of the government's newly minted (but binding) assertion that individual state standards should govern professional obligations under the CSA, Dr. Ruan's case, once remanded, should be dismissed for want of sufficient evidence.

The government claims that "[e]xperts provided extensive testimony confirming that [Dr. Ruan's] practices sharply departed from the professional standards of Alabama doctors." Br. 47. But that contention is not borne out by the record. First of all, *not one* of the government's experts was even an Alabama-licensed physician. Rather, Dr. David Greenberg was licensed in Arizona and California (Tr. 662); Dr. Rahul Vohra was licensed in Mississippi and Texas (Tr. 2247); and Dr. Tricia Aultman was

licensed in Mississippi (Tr. 4445).[6] None of those experts was even *proffered* as an expert in Alabama pain management practices, nor were they qualified to provide such testimony. If, as the government now maintains (Br. 43), the pertinent question is "whether a defendant's activities are recognizable to the state medical community as the activities of a doctor," then the trial evidence was woefully insufficient. The jury never even heard from a member of "the state medical community."

Nor did any of these putative experts provide what the government calls "extensive testimony" (Br. 47) showing that Dr. Ruan's conduct abridged Alabama practice standards. True, government experts were asked to confirm that they had reviewed the Alabama Board of Medical Examiners' Administrative Code and that the Code contained rules governing when physicians could delegate certain tasks to assistants and how physicians should sign and date prescriptions. See Br. 47-48 (citing 1/24/17 Ruan Tr. 144-150, 203-204; 2/8/17 Ruan Tr. 77-84; 2/10/17 Ruan Tr. 94-97; 2/15/17 Ruan Tr. 162-168). Notably absent, however, was *any* testimony about Alabama's actual treatment standards, or whether Dr. Ruan's prescription decisions fell within the course of professional practice in Alabama.

It may well be that the Alabama Code contains "well-worn, objective standards for controlled-substance prescriptions." Br. 23. But the government

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[6] Nor were any of the defense experts Alabama-qualified doctors. See Tr. 4764 (Dr. Carol Warfield, licensed in Massachusetts); Tr. 5211 (Dr. Jeffrey Gudin, licensed in New Jersey); Tr. 6036 (Dr. Christopher Gharibo, licensed in New York).

offered no expert testimony—qualified or otherwise—on the content of those standards, or whether Dr. Ruan's treatment choices complied with Alabama pain management practices.[7] And while the government notes, generically, that some States require physicians to "participate in regular continuing education on the responsible prescribing of controlled substances," Br. 23-24, the government is unable to identify any trial testimony concerning *Alabama's* continuing education requirements, or whether Dr. Ruan attended (or failed to attend) such courses.

In short, the government is hoist with its own petard. Having insisted at trial that there is a *national* standard for pain management, the government is bereft of proof meeting the Alabama-law standard it now advances. Indeed, at trial the prosecutors *objected* to defense counsel's suggestion that the Alabama Medical Board's rules "would be a good place for a doctor in Alabama to look." Tr. 829 (objecting "to that line of questioning, because it is the federal rules that they are operating under for the DEA license and the DEA prescribing of controlled substances"); see also *ibid.* ("[A]gain we object. They

[7] To the extent that the government now attempts to point to *defense* experts' testimony concerning Alabama's standards, this testimony (which did not come from Alabama-licensed physicians and did not purport to establish the Alabama standards for professional practice) explained that Dr. Ruan's prescription decisions *complied* with Alabama's rules. See, *e.g.,* Tr. 5245, 5282 (Dr. Gudin) (confirming that he reviewed the Alabama Board of Medical Examiners' Administrative Code and opining that Dr. Ruan's prescription decisions were appropriate, in the course of professional medical practice, and made for a legitimate medical purpose); Tr. 6042-6056 (Dr. Gharibo) (same).

are not charged with violating any of the rules of the Alabama Board. They are charged with violating criminal violations of the United States."). Because there is insufficient evidence regarding Petitioner's compliance with Alabama medical standards, the court of appeals should be directed to dismiss the case on remand.[8]

B. At A Minimum, The Court Should Remand For A New Trial At Which The Correct Good Faith Instruction Will Be Given.

In the event this Court declines to direct the court of appeals to dismiss (or to consider dismissal) on remand, it should order the court of appeals to require a new trial on all charges. At that new trial, the jury should be instructed that Dr. Ruan may not be convicted under Section 841(a)(1) unless his prescriptions lacked a medical purpose.

1. The government opposes our "medical purpose" test because, in its view, the "knowing or intentional" requirement in Section 841(a)(1) applies only to the act of *prescribing*, and not to the opening clause "[e]xcept as authorized by this subchapter." That is untenable. Even when a statute is otherwise unclear, this Court ordinarily applies the statutory *mens rea* to "each of the statutory elements that criminalize otherwise innocent conduct." *Rehaif* v. *United States*, 139 S. Ct. 2191, 2195, 2197 (2019). In

[8] As with the question of harmless error, see *supra* pp. 7-11, the Court may wish to leave the sufficiency question to the Eleventh Circuit in the first instance. If the Court takes that route, the court of appeals should be directed, if it declines to dismiss, to order a new trial on all counts under the correct good faith standard.

physician cases, culpability turns on whether prescribing was "authorized," and so a physician-defendant must know the facts that make a prescription "[un]authorized." That is, she must know that her prescriptions lack a good faith medical purpose. See Pet. Br. 19-23.

The government asserts (Br. 24-25, 34) that *United States* v. *Yermian*, 468 U.S. 63 (1984), counsels otherwise, but that case is readily distinguishable. *Yermian* held that a statutory *mens rea* requirement did not extend to an antecedent *jurisdictional* element. *Id.* at 69-70. But for several reasons, that holding does not apply to Section 841(a)(1).

First, there is the strong background presumption of scienter for *non-jurisdictional* elements, requiring a "plain[ ] indicat[ion]" that Congress intends otherwise. Pet. Br. 18 (collecting cases). For jurisdictional elements like that in *Yermian*, "the default rule flips" because Congress views such elements as "distinct from, and subject to a different rule than, the elements describing the substantive offense." *Luna Torres* v. *Lynch*, 578 U.S. 452, 468 (2016). Lack of authorization under Section 841(a)(1) doesn't just "describ[e] the substantive offense" in physician prosecutions—it is the *only* element that separates culpable from innocent conduct. See Chamber of Commerce Amicus Br. 5-6.

Second, the government fails to address the structural features of the CSA that confirm that "knowing or intentional" applies to the "except as authorized" element. See Pet. Br. 23-24; *United States Nat'l Bank of Or.* v. *Independent Ins. Agents of Am., Inc.*, 508 U.S. 439, 455 (1993) ("Statutory

construction 'is a holistic endeavor,' and, at a minimum, must account for a statute's full text, language as well as punctuation, structure, and subject matter." (quoting *United Sav. Ass'n of Tex.* v. *Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)). Had the government reckoned with the text as a whole, it could not have come up with its "objective honesty" standard. For example, the government says that the failure to keep up with the latest professional developments may convert mere negligence into something worthy of felony conviction. But that "educate thyself" standard for felony liability is hard to square with 21 U.S.C. § 842(a)(17), which requires "registered manufacturer[s] [and] distributor[s] of opioids" to "review the most recent information made . . . available by the Attorney General," punishing the "knowing[ ]" failure to review that information merely with a criminal fine "not to exceed $500,000." *Id.* § 842(c)(2)(A), (D).

Finally, even if the analysis in *Yermian* were otherwise applicable, the absurdity of the consequences would refute it. After all, if "knowingly or intentionally" applied only to the verbs "manufacture, distribute, or dispense," the only doctors who could be exonerated would be those who prescribed medicine in their sleep. Pet. Br. 20. See *United States* v. *X-Citement Video, Inc.*, 513 U.S. 64, 69 (1994) (rejecting grammatically sounder construction that produced "positively absurd" results in favor of interpretation that extended *mens rea* across statutory subsections and to entirely separate clauses); see also *Green* v. *Bock Laundry Mach. Co.*, 490 U.S. 504, 527-529 (1989) (Scalia, J., concurring in the judgment) (applying absurdity canon).

2. In opposing the "medical purpose" test, the government also misapprehends the relevant statutory history.

Section 841 was enacted against the background of its antecedent Harrison Act provision, Section 2(a), 38 Stat. 785, which employed "course of his professional practice" language similar to that found throughout the CSA—language construed by this Court to require a robust good faith instruction. See Pet. Br. 26-27. See also *Taggart* v. *Lorenzen*, 139 S. Ct. 1795, 1801 (2019) ("When a statutory term is obviously transplanted from another legal source, it brings the old soil with it." (cleaned up)). As we explained in our opening brief (at 27), the Court's construction of the Harrison Act in *Linder* v. *United States*, 268 U.S. 5 (1925), is especially compelling. There, the Court held insufficient an indictment that "d[id] not question the doctor's good faith nor the wisdom or propriety of his action according to medical standards"; that did not "allege that he dispensed the drugs otherwise than to a patient in the course of his professional practice or for other than medical purposes" and that "indicate[d] no conscious design to violate the law." *Id.* at 17; Pet. Br. 27.

Not surprisingly, the government has little to say about *Linder*. It relies, instead, on *United States* v. *Behrman*, but that case is cold comfort. For one thing, the dispute in *Behrman* involved the quite distinct question whether courts could rule entire practices (there, prescribing to addicts) outside the bounds of "the regular course of practice," see 258 U.S. 280, 287, 289 (1922); see also CATO Institute Amicus Br. 4-8. For another, Justice Holmes' dissent in that case, joined by Justices Brandeis and McReynolds, carried

the day only three years later in *Linder*. See *Behrman*, 258 U.S. at 290 (Holmes, J., dissenting) (it is "wrong to construe the statute as creating a crime . . . without a word of warning" by criminalizing prescriptions—"however foolish"—"given honestly in the course of a doctor's practice").

As for *Jin Fuey Moy* v. *United States*, the government quotes (Br. 31) the part of one sentence that it likes—*i.e.*, the Harrison Act was intended to confine doctors "strictly within the appropriate bounds of a physician's professional practice"—but omits the rest of the sentence: ". . . and not to extend it to include a sale to a dealer or a distribution *intended to cater to the appetite or satisfy the craving of one addicted* to the use of the drug." 254 U.S. 189, 194 (1920) (emphasis added). "A 'prescription' issued for either of the latter *purposes*"—*i.e.*, *intentionally* catering to drug addiction—is what the CSA forbids, said the Court. *Ibid.* (emphasis added). The Court then enumerated objective indicia by which "the jury might find" that the defendant prescribed for such an unlawful "purpose." *Id.* at 193. That is precisely the role our "medical purpose" test would reserve for juries.

3. As between the "medical purpose" standard that we endorse and the "objective honest effort" standard proffered by the government, only the former comports with the role of lay juries in assessing the guilt of a prescribing physician. Our standard requires the jury to consider circumstantial evidence bearing on whether the doctor lacked a good faith medical purpose (and that his DEA authorization was thus a "[m]ere pretense," *Linder*, 268 U.S. at 18). That task is familiar to juries; "[i]nferring the existence or

nonexistence of intent from objective facts and circumstances is a familiar process in our criminal justice system." *Oregon* v. *Kennedy*, 456 U.S. 667, 675 (1982).[9]

The government's standard, by contrast, takes juries onto treacherous terrain. A jury must first determine the metes and bounds of "accepted" "medical practice," Br. 17, on competing expert testimony. The very notion of "accepted medical practice" is fraught, especially in the area of pain management. See *infra* pp. 22-23 (discussing CDC revisions to its overzealously applied opioid-prescribing guidelines). The jury must then decide whether the physician made an "objectively honest" attempt to comply with that nebulous standard, which it will be told is satisfied if the physician made a "reasonable attempt" to ascertain and comply with it. In sum: a physician's liberty is made to depend on a jury's definition of the bounds of "accepted practice" and its assessment whether the physician's conduct was "reasonable." Such complex, inexact, and unpredictable judgments should not spell the difference between simple malpractice (or less) and decades in prison (or more).

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[9] In assessing this sort of circumstantial evidence of good faith, evidence of the "broader picture" (U.S. Br. 35) of a physician's practice is certainly relevant. Thus, the fact that Dr. Ruan's practice was concededly not a "pill mill," see Pet. App. 27a n.6, and that "[b]y and large, their patients were legitimate patients," Pet. App. 84a, bears on the question of good faith. In like fashion, testimony from the many patients who found Dr. Ruan's treatment exemplary should be permitted on remand. See Pet. Br. 9 n.3.

Dr. Ruan's case illustrates the point. There can be no question that Dr. Ruan made an objectively reasonable attempt to *ascertain* the bounds of the practice of interventional pain medicine. At the time of Dr. Ruan's arrest he held eight active board certifications, and his numerous academic publications in the field still help define the ever-evolving practice of pain medicine. See, *e.g.*, Xiulu Ruan et al., *Revisiting Oxycodone Analgesia: A Review and Hypothesis*, 35 Anesthesiology Clinics 163 (2017); Paul J. Christo et al., *Urine Drug Testing in Chronic Pain*, 14 Pain Physician 123 (2011).

Under the government's standard, the jury would be tasked with deciding whether Dr. Ruan made an "objectively reasonable honest effort" to comply with "accepted practice" (as defined by the jury). But the bounds of "accepted practice" are simply too dynamic and uncertain—especially at the cutting edge of practice—to anchor the *mens rea* element of a serious felony. Compare, *e.g.*, Tr. 753:11-16 (government-expert testimony that it was "outside the usual course of professional practice to prescribe [a patient] a Narcan [naloxone] injector"), with Draft CDC Clinical Practice Guideline for Prescribing Opioids–United States, 2022 (Draft CDC Guidelines) at 4 ("During ongoing opioid therapy" clinicians should "incorporate relevant strategies to mitigate risk, including offering naloxone.").

4. The "medical purpose" standard is also best suited to the federalism concerns posed by Section 841(a)(1) prosecutions of doctors. The government gives such concerns the back of the hand (Br. 40-41), contending that state regulatory interests will be fully vindicated by drawing the professional norms from

the pertinent State's medical standards. That is a fairly rich suggestion in this case, given that the government advanced a *national* standard at trial. See Tr. 829:20-23 ("Your Honor, again we object. They are not charged with violating any of the rules of the Alabama Board. They are charged with violating criminal violations of the United States.")). In any event, it is not consistent with principles of federalism to borrow the State's professional norms, but then displace the State's system of penalties and enforcement with the blunt force of federal prosecution and hefty criminal sentences.

5. Our "medical purpose" standard is better calibrated to safeguard patient access to needed treatment. As the CDC recently recognized in revising its opioid-prescription guidelines, overzealous application of the prior guidelines "contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior." Draft CDC Guidelines at 12; see 87 Fed. Reg. 7838 (Feb. 10, 2022). There is a manifest need to avoid "overdeterrence," *United States* v. *United States Gypsum Co.*, 438 U.S. 422, 441 (1978), especially in the profession of pain management: "It is estimated that approximately 1 in 5 U.S. adults had chronic pain in 2019." Draft CDC Guidelines at 6.

A "good faith medical purpose" standard balances concerns about overdeterrence against the need to deter physicians from abusing their prescription pads. By contrast, because of the uncertainty inherent in "accepted standards of practice," the government's "objective honesty" standard would chill the practice

of pain management—leading to needless suffering. The importance of case-by-case flexibility is precisely why the CDC found it necessary to issue the Draft CDC Guidelines. The Guidelines attempt to correct course by warning physicians "not [to] abandon patients" and to avoid "us[ing] this clinical practice guideline to set rigid standards related to dose or duration of opioid therapy." Draft CDC Guidelines at 114.

6. Finally, the "medical purpose" test does not, as the government alleges, authorize every physician to be a profession unto himself. Juries can be trusted to disbelieve (and convict) doctors whose pretextual claims of sincere medical purpose run up against stronger evidence that they were everyday "drug deal[ers] and traffick[ers]." *Gonzales* v. *Oregon*, 546 U.S. 243, 269-270 (2006). In making such determinations, juries may look to all of the objective benchmarks touted by the government: is the prescription supported by the professional literature; did the physician conduct bona fide exams; are the patients' claims of pain contravened by evidence of drug-seeking behavior; etc. Juries make such scienter determinations in nearly every criminal case, and they do so based on circumstantial evidence of exactly the sort that the government identifies.

In short, the "medical purpose" standard permits juries to do their job. Petitioner's jury was not given that chance.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the court of appeals and remand with direction either to entertain dismissal of

the case or else to order a new trial using a correct definition of "good faith."

Respectfully submitted.

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