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

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

A physician otherwise authorized to prescribe controlled substances may be convicted of unlawful distribution under 21 U.S.C. § 841(a)(1) if his prescriptions "fall outside the usual course of professional practice." *United States* v. *Moore*, 423 U.S. 122, 124 (1975). To ensure that physicians are not convicted for merely negligent conduct, however, the federal courts generally permit doctors to advance a "good faith" defense.

The question presented is whether a physician alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under Section 841(a)(1) without regard to whether, in good faith, he "reasonably believed" or "subjectively intended" that his prescriptions fell within the usual course of professional practice.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant below, is Dr. Xiulu Ruan.

Respondent is the United States of America, appellee below. Under this Court's Rule 12.6, Dr. John Patrick Couch, defendant-appellant below, is also considered a respondent.

RELATED PROCEEDINGS

United States v. *John Patrick Couch*, No. 16-16361, United States Court of Appeals for the Eleventh Circuit. Judgment entered Aug. 15, 2017.

United States v. *Xiulu Ruan*, No. 19-11508, United States Court of Appeals for the Eleventh Circuit. Judgment entered Jan. 8, 2020.

United States v. *Ling Cui*, No. 19-12661, United States Court of Appeals for the Eleventh Circuit. Judgment entered May 11, 2020.

United States v. *Lori L. Carver*, No. 17-13402, United States Court of Appeals for the Eleventh Circuit. Judgment entered Oct. 17, 2018.

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BRIEF FOR THE PETITIONER

OPINIONS AND RULINGS BELOW

The opinion of the court of appeals is reported at 966 F.3d 1101. Pet. App. 1a-128a. The order of the Eleventh Circuit denying rehearing is unreported. *Id.* at 129a.

JURISDICTION

The court of appeals' judgment was entered on July 10, 2020. The Eleventh Circuit denied rehearing on November 4, 2020. Pet. App. 129a. The petition for a writ of certiorari was filed on April 5, 2021, and granted by this Court on November 5, 2021. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 822(b) of the Controlled Substances Act (CSA), 21 U.S.C. § 822, provides:

> (b) Authorized Activities
>
> Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

Section 829 of the CSA, 21 U.S.C. § 829, provides in relevant part:

> (a) Schedule II substances
>
> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner . . . .
>
> (b) Schedule III and IV substances
>
> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription . . . .
>
> (c) Schedule V substances
>
> No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.
>
> * * *
>
> (e) Controlled substances dispensed by means of the Internet
>
> * * *
>
> (2) As used in this subsection:
>
> (A) The term "valid prescription" means a prescription that is issued for a legitimate

> medical purpose in the usual course of professional practice by—
>
> (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or
>
> (ii) a covering practitioner.

Section 841(a)(1) of the CSA, 21 U.S.C. § 841 provides:

> (a) Unlawful acts
>
> Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> (1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance[.]

21 C.F.R. § 1306.04(a) provides:

> Purpose of issue of prescription.
>
> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription

> within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

INTRODUCTION

The Controlled Substances Act (CSA) makes it unlawful for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense" a controlled substance, "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). The subchapter requires physicians to "obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him." *Id.* § 822(a)(1)-(2). One of those rules provides that an "effective" prescription is one that is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a).

To ensure that licensed medical professionals do not risk criminal prosecution and felony conviction based on simple malpractice, nearly all courts, construing the CSA and the implementing regulations, require that the government prove that the physician lacked a good faith basis for her prescription. See Pet. 4-5, 18-27. But not the Eleventh Circuit. According to the court of appeals, a doctor may be convicted under the CSA if her prescription fell outside of professional norms—*without regard* to whether she believed in good faith that the prescription served a bona fide medical purpose. That outlier position, if sustained, would

result in the kind of "sweeping expansion of federal criminal jurisdiction" that this Court has repeatedly condemned. *Kelly* v. *United States*, 140 S. Ct. 1565, 1574 (2020) (quoting *Cleveland* v. *United States*, 531 U.S. 12, 24 (2000)); see also *Bond* v. *United States*, 572 U.S. 844, 862-865 (2014). It would also chill medical progress, disrupt the doctor-patient relationship, and criminalize prescriptions whenever a lay jury is persuaded that the physician exceeded the "usual" practice of medicine.

Petitioner's judgment of conviction should be reversed.

STATEMENT

1. Petitioner Dr. Xiulu Ruan practiced medicine as a board-certified interventional pain specialist in Mobile, Alabama. Together with his partner Dr. John Patrick Couch, Dr. Ruan owned and operated a pain clinic (Physicians' Pain Specialists of Alabama (PPSA)) and an affiliated pharmacy (C&R Pharmacy). Pet. App. 5a-6a. As of May 2015, the two physicians had 57 employees and served more than 8,000 patients. *Ibid.*

In April 2016, a grand jury indicted Petitioner and his partner on substantive and conspiracy charges of unlawful distribution of controlled substances under 21 U.S.C. § 841(a)(1), racketeering conspiracy, health care fraud conspiracy, mail and wire fraud conspiracy, and anti-kickback conspiracy. Pet. App. 3a-4a. Dr. Ruan (but not Dr. Couch) was also charged with money laundering and conspiracy to commit money laundering. Pet. App. 4a. The indictment included the Section 841(a)(1) violations as predicate offenses for the majority of these

additional charges. See J.A. 52-54, 63-64, 80-83. The doctors pleaded not guilty and were tried together.

2. At trial, the government acknowledged "that there were certainly instances where Dr. Ruan and Dr. Couch did a really good job for their patients," and that, "[b]y and large, their patients were legitimate patients." Pet. App. 84a. One government witness described PPSA as "one of the best, well-rounded pain centers in this area." J.A. 174. It was "undisputed" that PPSA was not a "sham practice"; it accepted only patients with insurance (and thus accepted those insurers' oversight), refused cash payments, and used a variety of sophisticated "[d]iagnostic tools" to discover the source of patient pain. Pet. App. 84a-85a.

The government alleged, however, that some of Dr. Ruan's prescriptions fell outside a "usual course of professional practice." To sustain that allegation, the government devoted much of the trial to proof that, taken separately or together, was indistinguishable from simple negligence.

For example, the government presented medical experts who testified at length that Petitioner and his partner had prescribed medication "outside [the] standard of care." Tr. 2357:10-11 (Jan. 24, 2017); see also Tr. 661-1061 (Jan. 12-13, 2017) (Dr. Greenberg); Tr. 2246-2542 (Jan. 23-24, 2017) (Dr. Vohra); Tr. 4328-4520 (Feb. 6, 2017) (Dr. Aultman). One such witness opined that the defendants too frequently "jumped to an opioid medication first" when there are "a lot of other things that you can do for patients with chronic pain." Tr. 4437:4-5, 16-22 (Feb. 6, 2017). The experts identified patients who, by their lights, should have been referred to a psychiatrist, a detox facility, or a physical therapist. See Tr. 731:10-11 (Jan. 12,

2017); Tr. 743:11-14 (Jan. 12, 2017) (detox facility would have been "ideal"); see also Tr. 730:24-731:2 (Jan. 12, 2017) (physical therapy "would have been perfect").

The government's expert witnesses also chided Dr. Ruan for not having identified or acted upon "red flags." See Tr. 749:16-750:9 (Jan. 12, 2017); Tr. 4407:19-4408:15 (Feb. 6, 2017). For example, although the defendants regularly tested patients to confirm that they had taken their prescriptions (and not diverted them to the black market), one government expert, Dr. Greenberg, characterized a particular test as "inadequate," criticizing "the doctor's [un]willingness to spend the tiny bit more money" to "protect his patients the best that he can." Tr. 923:1-4 (Jan. 13, 2017).[1]

This platonic notion of the "standard of care" suffused the entire trial. The government's medical experts claimed that Dr. Ruan had mismanaged his medical practice through recordkeeping failures, *e.g.*, Tr. 746:5-6 (Jan. 12, 2017), and excessive reliance on nurse practitioners and other staff to help provide care for his large population of patients, *e.g.*, Tr. 681:12 (Jan. 12, 2017). Even for the non-narcotics charges, the government's case hinged on whether the

[1] Shortly after Dr. Greenberg's testimony, the government alerted the district court that Greenberg "thought he had early-onset dementia and was consulting a neurologist." Pet. App. 40a. The government stated that it would investigate to determine whether a jury instruction was warranted, see Tr. 1068:13-24; Tr. 1070:16-1071:6 (Jan. 17, 2017), but never presented any further information to the court, Pet. App. 41a. At closing arguments, the government admitted that "at times" Dr. Greenberg was "confused about small matters," "had some mistakes and . . . forgot some things." J.A. 232-233.

physicians reasonably exercised their professional judgment. See Tr. 6303:15-22 (Feb. 16, 2017) ("the doctor should have known" not to write fentanyl prescriptions; "[t]hey are trained to notice that"); Tr. 6152:23-6153:1 (Feb. 16, 2017) (on healthcare fraud, Dr. Ruan is "billing through C&R Pharmacy drugs that were being prescribed outside the usual course of professional practice and that's being paid by healthcare providers").[2]

3. Dr. Ruan and Dr. Couch sharply disputed the government's allegations. They called medical experts of their own, who testified that the defendants complied with (indeed, exceeded) relevant professional standards of care. See Tr. 4763-4914 (Feb. 8, 2017) (Dr. Warfield); Tr. 6034-6078 (Feb. 15, 2017) (Dr. Gharibo); Tr. 5205-5341 (Feb. 10, 2017) (Dr. Gudin). Dr. Gharibo, for instance, reviewed patient files and "found Dr. Ruan's treatment in many ways exemplary." J.A. 226. He also testified that Dr. Ruan's patient care was "multi-modal and multi-disciplinary" and "clearly in the higher end of the standard of care." J.A. 230. Similarly, Dr. Gudin testified that for "each and every patient chart" he had reviewed, Dr. Ruan's "prescribing seemed appropriate and certainly within the course of legitimate medical practice." J.A. 203-204. Even one of the government's witnesses allowed that "doctors can in good faith

[2] The government did put on some evidence that may have transcended simple malpractice, including evidence that defendants prescribed products of a company in which they held stock and of another company for which they served as speakers. Pet. App. 13a; see *id*. at 10a-11a, 17a. But that evidence was strongly contested by defendants, see, *e.g.*, Tr. 4878:11-20 (Feb. 8, 2017), 4906:3-9 (Feb. 8, 2017), 5798:13-5799:7 (Feb. 14, 2017), and it was over-matched by proof of ordinary malpractice.

disagree with each other about the application of guidelines" and the "appropriate treatment for a particular patient in a particular situation." Tr. 4458:2-11 (Feb. 6, 2017) (Dr. Aultman).[3]

Petitioner himself took the stand to explain how he at all times believed his prescribing was for a legitimate medical purpose. He testified that he always made an "individualized decision" as to "[w]hat medication to use" and did so "based on the patient's best interest," J.A. 209-210. He further explained that his treatment decisions were always motivated by "caring for [his] patients." J.A. 223; 225 (similar). He would prescribe only for "[p]atient need, that's all there is." J.A. 209; 208 (similar); 211 ("I tried to use [abuse-deterrent features] whenever my

[3] Dr. Ruan also sought to introduce videos showing that he had declined to prescribe opioids to patients who turned out to be undercover DEA agents. Dr. Ruan explained to one such "patient" that "it was not appropriate to prescribe controlled substances because of better alternatives." Pet. App. 85a. Dr. Ruan also sought to call several patients not identified by the government to confirm that his treatment had been exceptional and to explain why controlled substances comprise the only effective treatment for certain chronic forms of pain. See Pet. App. 80a-89a. This evidence would have gone directly to the question of whether Dr. Ruan prescribed for a legitimate medical purpose and whether he "primarily practiced good medicine." Status Conf. Tr. 16:13-15 (Jan. 3, 2017). All of this evidence was excluded as "not relevant," because it would be "wasted time" to show the jury "legitimate medical patients" or "legitimate prescriptions," despite the fact that the district court recognized the government was seeking to prove "the criminal nature of the practice." *Id.* at 17:3-13. See Pet. App. 19a-20a, 27a. See also Pet. App. 84a (in affirming convictions, the court of appeals stated that this evidence was "not necessary" to "complete the picture").

patient get[s a] benefit."); 216 ("the decision" what to prescribe "is still based on the need of the patient").

Dr. Ruan emphasized, for example, that he had prescribed especially potent fentanyl medications only for "very severe breakthrough pain," and that he would not prescribe it for "regular breakthrough pain." J.A. 206-207. He also testified that the medication was a "lifesaver" for patients who would otherwise "have to go to [the] ER" during such an episode. J.A. 207. And, with respect to patients exhibiting "red flags," Dr. Ruan testified that he would "terminate the relationship" once he "decide[d] [he] can no longer help" the patient. J.A. 217. Dr. Ruan saw "[e]very patient who comes to the clinic, if there's an issue," and was "involved in every decision making, medications, [and] procedures." J.A. 221.

4. At the close of evidence, Dr. Ruan requested that the district court give the jury a good faith instruction to explain "the terms 'usual course of professional practice' and 'legitimate medical purpose.'" J.A. 102. Dr. Ruan's proposed instruction stated:

> 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.

J.A. 102.

Dr. Ruan also requested an additional instruction to give context to this good faith definition. He asked that the district court instruct that "[i]n making a medical judgment concerning the right treatment for an individual patient, physicians have wide discretion to choose among a wide range of options. No single national standard exists." *Ibid.* He also requested that the district court instruct the jury that "[t]o prove a violation of the Controlled Substances Act in this case, 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*" J.A. 103 (emphasis added), to underscore the difference between a charge under the CSA and mere medical malpractice or negligence.

The district court refused to give any of these instructions. Agreeing only to "throw[] a bone to your good faith language," and emphasizing that this was "as far as I'm willing to go" Pet. App. 136a, the district court gave the following jury instruction over Dr. Ruan's objection (*ibid.*; Status Conf. Tr. 42:3-6 (Jan. 3, 2017)):

> 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).

In short, although the district court mentioned "good faith" in passing, it told the jury, in the very next breath, that, *regardless* of Dr. Ruan's good faith, the jury could convict if it found that he had acted "outside the usual course of professional medical practice."

5. Dr. Ruan was convicted on all but two counts in the second superseding indictment. Pet. App. 2a-3a.[4] He was sentenced to 252 months' imprisonment, to be followed by four years of supervised release, and ordered to pay more than $15 million in restitution and more than $5 million in forfeiture. *Ibid.* Seven of the counts on which he was convicted were controlled substances charges. Save for the two Anti-Kickback charges,[5] every count of conviction either explicitly

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[4] He was acquitted on one count of unlawful distribution of controlled substances, Pet. App. 5a; the government dismissed one count under the Anti-Kickback statute at trial, Tr. 4524:24-4525:8 (Feb. 6, 2017).

[5] Even the Anti-Kickback charges, though, related to the government's theory that Dr. Ruan did not prescribe for a legitimate medical purpose. See, *e.g.*, J.A. 71 (alleging Dr. Ruan was induced to "prescrib[e] high volumes of Subsys," and that "nearly all of [those prescriptions]" were prescribed for off-label

relied on the controlled substances offenses as a predicate or implicitly relied on the facts underlying those offenses and the allegation that Dr. Ruan did not prescribe for legitimate purposes for the theory of wrongdoing.[6] Sentencing for all counts relied on the controlled substances offenses to calculate the base level offense range. Couch Sentencing Tr. 37:23-38:4 (May 25, 2017); Pet. App. 32a-34a; PSR ¶ 64.[7]

6. The court of appeals affirmed on the jury instruction. Pet. App. 106a-107a. It first rejected Dr. Ruan's proposed good faith instruction as "an incorrect statement of the law." Pet. App. 105a (citing *United States* v. *Joseph*, 709 F.3d 1082, 1097 (11th Cir. 2013)). Although the requested instruction expressly focused on what Dr. Ruan "reasonably

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use). Moreover, one of the Anti-Kickback convictions (Count 16) was reversed on appeal for insufficient evidence, Pet. App. 60a, and on the other (Count 17), Dr. Ruan has already served his term of imprisonment.

[6] See Tr. 6330:5-11 (Feb. 17, 2017) (racketeering conspiracy); Tr. 6344:3-13 (Feb. 17, 2017) & J.A. 63-64 (health care fraud conspiracy); J.A. 71; Tr. 6163:21-25 (Anti-Kickback statute); Tr. 6349:19-6351:6 (Feb. 17, 2017) (money laundering conspiracy and substantive money laundering); J.A. 76-77 (wire and mail fraud conspiracy based on selecting patient prescriptions for reasons other than "the needs of the patient").

[7] For these reasons, reversal of the controlled-substances charges would require vacatur of the sentence on all counts. See PSR ¶ 64 (grouping all counts as to Ruan under USSG § 3D1.2(d) as closely related for purposes of sentencing); Dkt. 642, Gov't Sentencing Mem. 2 ("The guidelines for these convictions is driven largely by the drug quantities associated with these conspiracies."). For example, the wire and mail fraud conspiracy count sentence was calculated based on the drug quantities underlying the CSA counts. See Dkt. 642, Gov't Sentencing Mem. 3 & n.1; Ruan Sentencing Tr. 61:3-5 (May 26, 2017).

believed," the panel held that the instruction would wrongly permit an acquittal based only on Dr. Ruan's "subjective[] belie[f]." Pet. App. 106a.

The panel next held that the district court's good faith instruction was correct. In the panel's view, 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 (emphasis added). The court did not explain what purpose a good faith defense serves if it is available only to physicians whose prescriptions *already* fall within professional norms.

On November 4, 2020, the Eleventh Circuit denied Dr. Ruan's petition for rehearing without comment (Pet. App. 129a), and on November 5, 2021, this Court granted Dr. Ruan's petition for a writ of certiorari.[8]

SUMMARY OF THE ARGUMENT

I.A. The CSA's text, structure, history, and implementing regulations all confirm that a physician otherwise authorized to prescribe controlled substances may not be convicted under Section 841(a)(1) unless she acts without a good faith medical purpose. A "medical purpose" standard—which is substantially identical to the "subjective" good faith

[8] The court of appeals also reversed one of the Anti-Kickback convictions for insufficient evidence. Pet. App. 60a. On remand from the vacatur of that conviction, the district court re-sentenced Petitioner to the same term as before. J.A. 259-270. That judgment was appealed to the court of appeals on July 27, 2021 (11th Cir., Case No. 21-12521), but the appeal has been stayed pending the disposition of this case. See Order, No. 21-12521 (11th Cir. Nov. 19, 2021).

standard embraced by three circuits—means that a physician who believes in good faith that her prescription serves a valid medical purpose may not be convicted simply because her belief proves to be unpopular. This standard honors the fundamental premise in our criminal law that "the essence of an offence is the wrongful intent, without which it cannot exist." 1 J. Bishop, *Commentaries on the Criminal Law* § 227, at 198-199 (1st ed. 1856).

Any more restrictive good faith standard—including the so-called "objective" standard applied in several circuits—inevitably exposes doctors to draconian prison sentences for conduct better suited to state administrative sanctions and civil litigation. Such diluted conceptions of good faith also raise serious federalism concerns, chill the doctor-patient relationship, and, more generally, stifle the very progress of science, whose lifeblood depends on dissent and outlier opinions. The CSA was never intended to "impede legitimate research" or curtail physicians' "reasonable discretion in treating patients and testing new theories." *United States* v. *Moore*, 423 U.S. 122, 143 (1975).

B. At the very least, any "objective" good faith standard must afford some breathing room for error. Convicting a doctor because a lay jury finds her beliefs "unreasonable" results in little more than malpractice actions parading as prosecutions. At a minimum, therefore, a doctor should be acquitted under Section 841(a)(1) if she *honestly sought* to comply with a reasonable professional standard of care.

II. Even if this Court subscribes to the "objective" good faith standard adopted in some circuits, it should still vacate all of Petitioner's

convictions. The trial court, sustained by the Eleventh Circuit, instructed Dr. Ruan's jury that it could convict him if it found that he had exceeded professional norms, *regardless* of his state of mind. In the Eleventh Circuit, a physician's "good faith belief that he dispensed a controlled substance in the usual course of his professional practice is *irrelevant*." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (2017) (per curiam) (emphasis added). The government itself, though it chose not to confess error in this case, has sensibly declined to defend that standard. Because Petitioner may therefore have been convicted (and, given the nature of the evidence, likely *was* convicted) for conduct that was not unlawful, his convictions should be reversed even under the (erroneous) "objective" good faith standard.

ARGUMENT

I. PETITIONER'S CSA AND CSA-DEPENDENT CONVICTIONS SHOULD BE REVERSED BECAUSE A PHYSICIAN AUTHORIZED TO PRESCRIBE CONTROLLED SUBSTANCES MAY NOT BE CONVICTED UNLESS SHE ACTS WITHOUT A GOOD FAITH MEDICAL PURPOSE.

A conviction under the CSA requires that the defendant act "knowingly or intentionally." 21 U.S.C. § 841(a)(1). The statute's text, structure, history, and implementing regulations all confirm that this *mens rea* requirement insulates physicians with a good faith belief that their prescription serves a medical purpose. Any lower standard—whether "objective" good faith (an oxymoron, in our view) or the entirely contentless rule adopted by the Eleventh Circuit—fails to distinguish ordinary malpractice from federal

criminal conduct. Because Petitioner was convicted under instructions that deprived him of *any* good faith protection, the judgment below should be reversed.

A. The CSA's Text, Structure, And History Show That Prescribing Physicians Must Be Permitted To Assert A Defense Of Good Faith Medical Purpose.

1. The CSA's text and implementing regulations are dispositive: a prescription is criminal *only* when dispensed without a good faith medical purpose.

a. "Part of a fair reading of statutory text is recognizing that Congress legislates against the backdrop of certain unexpressed presumptions." *Bond* v. *United States*, 572 U.S. 844, 857 (2014) (cleaned up). Among the "traditional legal concepts," *United States* v. *United States Gypsum Co.*, 438 U.S. 422, 437 (1978), against which Congress enacted the CSA is the well-settled principle that "a 'vicious will'" is required "to establish a crime," *Staples* v. *United States*, 511 U.S. 600, 616-617 (1994) (quoting 4 W. Blackstone, *Commentaries* *21). See also 3 E. Coke, *Institutes of the Laws of England* 107 (1809 ed.) ("*Actus non facit reum nisi mens sit rea*": The act does not make one guilty unless the mind is also guilty).

To effectuate this "firmly embedded" requirement, *Staples*, 511 U.S at 605, this Court presumes that a statute's *mens rea* requirement (whether it is express or unstated) extends to "each of the statutory elements that criminalize otherwise innocent conduct." *Rehaif* v. *United States*, 139 S. Ct. 2191, 2195 (2019). See *United States* v. *X-Citement Video, Inc.*, 513 U.S. 64, 70 (1994); *Morissette* v.

United States, 342 U.S. 246, 248 n.2, 271 (1952). This *mens rea* presumption is "a sturdy background principle against which Congress legislates"—and it governs "unless Congress has plainly indicated otherwise." *United States* v. *Burwell*, 690 F.3d 500, 531, 537 (D.C. Cir. 2012) (en banc) (Kavanaugh, J., dissenting). See *Morissette*, 342 U.S. at 254 n.14 (requiring a "clear command" from Congress); *Torres* v. *Lynch*, 578 U.S. 452, 467 (2016) (courts presume that "the defendant must know each fact making his conduct illegal" "absent an express indication to the contrary").

Honoring this *mens rea* presumption is all the more essential when a statute uses imprecise standards to impose criminal liability on activity that is often entirely innocuous. The Court addressed such a statute in *Gypsum*. The Sherman Act criminalizes "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce." 15 U.S.C. § 1. Although the statute does not expressly impose any *mens rea* requirement, this Court held that intent is an element of criminal price-fixing. 438 U.S. at 443-444.

The Court began with the traditional presumption of *mens rea*, "reinforced" by considerations that apply with equal or greater force in the present case.[9] As the Court explained, the

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[9] The Court grounded the *mens rea* presumption in a common law tradition that made intent a "critical factor," 438 U.S. at 437, and in the rule of lenity—a rule "perhaps not much less old than construction itself," *United States* v. *Wiltberger*, 18 U.S. (5 Wheat.) 76, 95 (1820) (Marshall, C.J.). See *Gypsum*, 438 U.S. at 437. The rule of lenity is based on the importance of

Sherman Act "does not, in clear and categorical terms, precisely identify the conduct which it proscribes." *Id.* at 438. As a practical matter, therefore, "open-ended and fact-specific standards" end up being "applied [by juries] to broad classes of conduct." *Ibid.* Because "the behavior proscribed by the Act is often difficult to distinguish from the gray zone of socially acceptable and economically justifiable business conduct," imposing criminal liability without regard to intent would improperly threaten a federal conviction for "even a good-faith error of judgment." *Id.* at 440-441. "[T]he use of criminal sanctions in such circumstances would be difficult to square with the generally accepted functions of the criminal law." *Id.* at 442 (citing Henry M. Hart, Jr., *The Aims of the Criminal Law*, 23 Law & Contemp. Probs. 401, 422-425 (1958)). Moreover, ignoring a defendant's intent (and thus "simply . . . regulat[ing] business practices," *ibid.*) would risk chilling commercial activity with social utility.

b. Only the strongest textual evidence to the contrary could overcome the presumption that the CSA likewise requires proof that the physician *intended* to prescribe beyond his "authoriz[ation]." But far from overcoming that presumption, the text and structure of the CSA strongly confirm the conclusion that a physician otherwise authorized to prescribe controlled substances may not be treated as

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"provid[ing] fair warning concerning conduct rendered illegal," *Yates* v. *United States*, 574 U.S. 528, 548 (2015) (plurality opinion) (quoting *Liparota* v. *United States*, 471 U.S. 419, 427 (1985)), and on "the plain principle that the power of punishment is vested in the legislative, not in the judicial department." *Wiltberger*, 18 U.S. at 95.

a "drug dealer" unless he lacks a good faith belief in the medical purpose of the prescription.

Section 841(a)(1) provides that "[e]xcept as authorized by this subchapter," it is "unlawful for any person knowingly or intentionally . . . to manufacture, distribute, or dispense . . . a controlled substance." 21 U.S.C. § 841(a)(1). True, Section 841(a)(1)'s *mens rea* requirement comes only *after* the "except as authorized" clause. But "far more than the simple omission of the appropriate phrase from the statutory definition is necessary to justify dispensing with an intent requirement." *Gypsum*, 438 U.S. at 438. After all, for physicians otherwise authorized to prescribe controlled substances, "the crucial element separating legal innocence from wrongful conduct," *Elonis* v. *United States*, 575 U.S. 723, 737 (2015), is whether prescribing is "authorized by this subchapter," 21 U.S.C. § 841(a)(1). It is not improper—much less "unlawful"—for a physician merely to knowingly or intentionally "distribute" controlled substances. See *id.* § 841(a)(1); *id.* § 822(b); 21 C.F.R. § 1306.04(a). Were it otherwise, we would not have pharmacies. "The mental state requirement must therefore apply" to the fact that a prescription is not "authorized." *Elonis*, 575 U.S. at 737. Indeed, to apply Section 841(a)(1)'s *mens rea* requirement only to whether a physician *distributed* or *dispensed* a controlled substance would protect only those physicians who prescribe in their sleep.[10] Not even the government makes that argument. See BIO 11.

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[10] That distinguishes *United States* v. *Yermian*, which addressed the question whether a *mens rea* requirement applied to the statutory section's preceding jurisdictional hook. 468 U.S.

Nor could it. This Court considered a similar scheme in *Liparota* v. *United States*, 471 U.S. 419 (1985). There, a food-stamp fraud statute provided that "whoever knowingly uses, transfers, acquires, alters, or possesses coupons or authorization cards in any manner not authorized by [the statute] or the regulations" would be subject to fine and imprisonment. *Id.* at 420. The government urged that "knowingly" did not modify the "not authorized" element; the defendant countered that this interpretation, "by dispensing with *mens rea*, dispenses with the only morally blameworthy element in the definition of the crime." *Id.* at 423. Siding with the defendant, the Court held that the statute "requires a showing that the defendant knew his conduct to be unauthorized by statute or regulations." *Id.* at 425.

So, too, here. As in *Liparota*, Section 841(a)(1) requires proof that the defendant-physician knew or intended that her prescribing was "unauthorized."[11]

63, 68-69 (1984). "Jurisdictional language need not contain the same culpability requirement as other elements of the offense." *Id.* at 68. See *Torres*, 578 U.S. at 468.

[11] This is not affected by 21 U.S.C. § 885(a)(1), which provides that the government need not "negative any exemption or exception set forth in this subchapter" and places "the burden of going forward with the evidence with respect to any such exemption or exception . . . upon the person claiming its benefit." That provision merely assigns a *prima facie* burden to the defendant; "[o]nce a defendant presents a claim that he falls within the exemption, the government must prove beyond a reasonable doubt that the accused does not fall within it." *United States* v. *Rosenberg*, 515 F.2d 190, 199 (9th Cir. 1975). See *United States* v. *Outler*, 659 F.2d 1306, 1309-1310 & n.3 (5th Cir. 1981); *United States* v. *Murray*, 618 F.2d 892, 901 (2d Cir. 1980);

And under the text of the CSA, only a prescription lacking a good faith medical purpose is unauthorized. As the CSA expressly finds, "[m]any of the drugs included within this subchapter have a *useful and legitimate medical purpose* and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. § 801(1) (emphasis added). Not surprisingly, therefore, the CSA repeatedly uses "medical purpose" to separate lawful from unlawful prescriptions. See, *e.g.*, *id.* § 829(c) (requiring a "medical purpose" for dispensing the least controlled substances, those in Schedule V); *id.* § 830(b)(3)(A)(ii) (CSA's reporting provision defining a "valid prescription" as one "issued for a legitimate medical purpose"); *id.* § 829(e)(2)(A) ("The term 'valid prescription' means [for Internet-prescription provision] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice"); *id.* § 829(a) (prescription provision that "ensures patients use controlled substances under the supervision of a doctor," and, "[a]s a corollary, . . . bars

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United States v. *Hooker*, 541 F.2d 300, 305 (1st Cir. 1976). See also, *e.g.*, *United States* v. *Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (listing § 1306.04(a)'s "medical purpose" and "usual course" requirements as elements that the government must prove under § 841(a)(1)); *United States* v. *Varma*, 691 F.2d 460, 462 (10th Cir. 1982) (same). But cf. *United States* v. *Steele*, 147 F.3d 1316, 1319-1320 (11th Cir. 1998) (en banc) (holding that "the course of professional practice" "need not be negated in the indictment," but declining to address "who bears the burden of persuasion"). To hold otherwise would impermissibly shift to physician-defendants the burden of proof on a defense that "negate[s] an element of the crime"—*mens rea*. *Smith* v. *United States*, 568 U.S. 106, 110 (2013). See *Outler*, 659 F.2d at 1309 (the "lack of a legitimate medical reason" "embodies the culpability of the offense").

doctors *from peddling to patients who crave the drugs for those prohibited uses*." *Gonzales* v. *Oregon*, 546 U.S. 243, 274 (2006) (emphasis added)).

c. Nearby provisions confirm that Congress granted physicians robust *mens rea* protection when the government prosecutes them as drug dealers. For example, the relatively modest administrative penalties in Section 842 lack any *mens rea* element, except in narrow enumerated circumstances. See, *e.g.*, 21 U.S.C. § 842(a)(2) (unlawful for any person "who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration"). One such exception: where Section 842 imposes misdemeanor liability, it requires a "knowing" *mens rea*. See *id.* § 842(c)(2)(A) (violators subject to "imprisonment of not more than one year or a fine" if "a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed"). It is unthinkable that Congress intended no meaningful *mens rea* protection for physicians at risk of life in prison under Section 841—and yet carefully excepted Section 842's *misdemeanor* penalty from the section's general lack of *mens rea* requirements.

Likewise, Section 842(a)(12)(B) forbids regulated sellers "to knowingly *or recklessly* sell at retail" certain substances. (emphasis added). When Congress wanted to impose liability for reckless distribution, it did so expressly—and it made the penalties less severe than under Section 841(a)(1).

See 21 U.S.C. § 842(c)(1)(A) (violators "subject to a civil penalty of not more than $25,000"). The clear implication: a higher standard of *mens rea* than recklessness is necessary to convict doctors as "drug pushers." Indeed, Section 841(a)(1)'s "severe penalt[ies]" themselves suggest that Congress intended a robust *mens rea* requirement. See *Staples*, 511 U.S. at 618. Compare *Gypsum*, 438 U.S. at 442 n.18 (penalty of "imprisonment for up to three years" bolstered presumption of *mens rea*), with 21 U.S.C. § 841(b)(1)(C) (unauthorized distribution of Schedule II substances punishable by "not more than 20 years" imprisonment, with life sentence authorized "if death or serious bodily injury results from the use of such substance").

Having expressly lowered the *scienter* standard for lower-level drug offenses elsewhere in the CSA, Congress clearly intended to reserve the harsh penalties of Section 841(a)(1) for cases in which physicians "us[e] their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Oregon*, 546 U.S. at 269-270.

d. The good faith "medical purpose" standard we are urging the Court to adopt is confirmed by the plain language of the CSA's implementing regulations.

The CSA delegates to the Attorney General the power to authorize physicians to prescribe controlled substances unless "inconsistent with the public interest." 21 U.S.C. § 823(b), (e). Once authorized, doctors may "possess, manufacture, distribute, or dispense such substances or chemicals . . . to the extent authorized by their registration and in

conformity with the other provisions of this subchapter." *Id.* § 822(b). But the CSA was also clear that regulations could not give federal officials the power "to exercise supervision or control over the practice of medicine or the manner in which medical services are provided." *Id.* § 823(g)(2)(H)(i).

The Attorney General exercised that delegated authority by promulgating 21 C.F.R. § 1306.04(a). See *Oregon*, 546 U.S. at 257 (Section 1306.04(a) "does little more than restate the terms of the statute itself."). Section 1306.04(a) defines a "prescription" as one "issued *for a legitimate medical purpose* by an individual practitioner acting in the usual course of *his* professional practice." (emphasis added).

Section 1306.04(a) strongly supports the "medical purpose" test in two related ways. First and most obviously, it expressly defines a "prescription" as one "issued for a legitimate medical purpose." Reinforcing that first pillar is the second: only a prescription outside the "individual practitioner['s]" *own* practice—"*his* professional practice," not the norms of the profession as a whole—is proscribed. (emphasis added). These requirements are really just two sides of the same coin: when a prescribing physician acts without a good faith medical purpose, he has also abandoned his individual practice and is no longer "prescribing" within the meaning of the CSA.[12]

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[12] Consolidated case No. 21-5261 presents the question "Should the 'usual course of professional practice' and 'legitimate medical purposes' prongs of C.F.R § 1306.04(a) be read in the conjunctive or the disjunctive?" Because § 1306.04(a) sets forth a single standard, these two phrases must be read in the conjunctive.

2. The CSA's statutory and legislative history confirm that prescribing physicians must be permitted to advance a robust good faith defense based on the physician's medical purpose.

a. The CSA's predecessor statute, the Harrison Narcotics Act, closely tracked the language that delineates the scope of a physician's "authorization" under the CSA. In particular, it regulated the distribution of narcotic drugs, excepting "dispensing or distribution . . . *to a patient by a physician* . . . regularly registered under this act *in the course of his professional practice* only." *United States* v. *Doremus*, 249 U.S. 86, 91 (1919) (quoting Harrison Act § 2(a), 38 Stat. 785) (emphasis added).

This Court's precedents construing the Harrison Act underscore that physicians may not be convicted as federal felons unless they act without a medical purpose. Soon after the Harrison Act's passage in 1914, this Court interpreted Section 2's general prohibition to apply to physicians who prescribed without a medical purpose. In assessing one physician's sufficiency-of-the-evidence challenge, the Court explained that a physician could be convicted if he prescribed to addicts "for the mere purpose, as the jury might find, of enabling such persons to continue the use of the drug, or to sell it to others." *Jin Fuey Moy* v. *United States*, 254 U.S. 189, 193 (1920). The Court also rejected as a "perversion of [the] meaning" of "a physician's prescription" (and therefore outside Section 2(a)'s exemption) a prescription issued not "in the course of professional treatment in the attempted cure of the habit, but . . . for the purpose of providing the user with morphine sufficient to keep him

comfortable by maintaining his customary use." *Webb* v. *United States*, 249 U.S. 96, 99 (1919).

Five years later, in *Linder* v. *United States*, 268 U.S. 5 (1925), the Court reinforced the point. Although the "[m]ere pretense" of bona fide medical purpose could not insulate a physician from prosecution, *id.* at 18, the Court vacated Dr. Linder's conviction because a physician who prescribes "in good faith" and without a "conscious design to violate the law" may not be convicted. *Id.* at 17.

Linder's holding is especially notable for two reasons. First, a separate section of the Act—Section 8, covering possession of narcotics—*expressly* provided for a good faith defense, whereas Section 2 did not, *id.* at 14. That distinction did not deter the Court from applying a robust good faith standard in Dr. Linder's favor. Second, the Court had previously held that Section 2's general prohibition was a strict-liability offense. See *United States* v. *Balint*, 258 U.S. 250, 253-254 (1922). That, too, did not dissuade the Court from setting aside Dr. Linder's drug trafficking conviction because he lacked a "conscious design to violate the law."[13]

b. In 1970, Congress enacted the CSA in an effort to "devise a more flexible penalty structure than that used" previously, *Moore*, 423 U.S. at 132, while also "strengthen[ing] . . . existing law enforcement

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[13] *Linder*'s holding was reinforced in *Boyd* v. *United States*, 271 U.S. 104 (1926), in which "[t]he disputed question was whether the defendant issued the prescriptions in good faith." *Id.* at 105. The Court affirmed the convictions because the jury instructions had appropriately advised the jury to acquit if the physician had acted "honestly and in good faith" in an "effort to cure disease." *Id.* at 108.

authority in the field of drug abuse," *ibid.* (quoting Pub. L. No. 91-513, 84 Stat. 1236 (1970) (preamble)). But Congress gave "no indication" that the new statute brought a "sharp departure," *Moore*, 423 U.S. at 132, from the longstanding good faith defense endorsed by *Linder* and its progeny. For one, if Congress had wanted to eliminate this important *mens rea* protection, it would have spoken clearly;[14] it did the opposite, requiring that unauthorized prescribing be "knowing or intentional," 21 U.S.C. § 841(a)(1). And as this Court explained in *Moore*, the CSA also embodies the policy that "physicians be allowed reasonable discretion in treating patients and testing new theories." 423 U.S. at 143. Consistent with that principle, Dr. Moore's jury instructions (implicitly approved by the Court) provided that Dr. Moore could be convicted only if he acted "other than in good faith" and did not make at least "'an honest effort' to prescribe . . . in compliance with an accepted standard of medical practice." *Id.* at 139, 142 n.20.

Since *Moore*, this Court has confirmed that Section 841(a)(1)'s application to physicians is narrow and targeted; it is not a tool for regulating medical practice by punishing doctors who practice bad medicine in good faith. In assessing the federal government's attempt to define the phrase "legitimate medical purpose," the Court explained that "[t]he statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Oregon*,

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[14] See *Morissette*, 342 U.S. at 254 n.14 (presumption of *mens rea* may be overcome by a "clear command" from Congress).

546 U.S. at 269-270. But the CSA "manifests no intent to regulate the practice of medicine," *id.* at 270, beyond prohibiting doctors from acting "as a drug 'pusher' instead of a physician." *Id.* at 269 (quoting *Moore*, 423 U.S. at 143).

* * *

The proper standard, then, is one that separates physicians operating at the fringes of medical innovation from those who abandon medicine entirely to engage in "conventional[ ]" "drug dealing and trafficking," *Oregon*, 546 U.S. at 270. A physician may not be convicted if she believes in good faith that her prescription has a legitimate medical purpose. This good faith defense must look only to the physician's subjective belief—eschewing both constructive knowledge and reference to general professional norms. No other standard is up to the task of "separat[ing] wrongful conduct from otherwise innocent conduct." *Elonis*, 575 U.S. at 736 (quoting *Carter* v. *United States*, 530 U.S. 255, 269 (2000)). Requiring a physician's good faith belief to be "reasonable" imposes negligence liability—criminalizing and federalizing malpractice. See *infra* Part I.B. And measuring good faith by reference to objective standards is both inconsistent with the statute and regulation and insufficiently protective of physicians' "traditional[ ]" and "widely accepted," *Staples*, 511 U.S. at 612, discretion in treating patients and "testing new theories," *Moore*, 423 U.S. at 143. See *infra* Part I.B-C.

To be sure, a physician's claim that he prescribed with a good faith medical purpose may not be credible. But that is a question to be resolved by the jury, which is free "not [to] believe him," *Moore*, 423 U.S. at 143.

See *Morissette*, 342 U.S. at 263 ("The purpose and obvious effect of doing away with the requirement of a guilty intent is to ease the prosecution's path to conviction, to strip the defendant of such benefit as he derived at common law from innocence of evil purpose, and to circumscribe the freedom heretofore allowed juries.").

B. The "Good Faith Medical Purpose" Standard Accords With The "Subjective" Good Faith Standard Adopted By The First, Seventh, And Ninth Circuits.

1. The "medical purpose" test we propose is not meaningfully different from the so-called "subjective" good faith standard adopted by the First, Seventh, and Ninth Circuits.

a. *United States* v. *Feingold* is the leading articulation of the subjective standard. There, the Ninth Circuit, relying on *Moore*, held that the government is required to prove "that the practitioner *intentionally* has distributed controlled substances for no legitimate medical purpose *and* outside the usual course of professional practice." 454 F.3d 1001, 1010 (2006) (emphasis added); *id.* at 1011 ("standard for criminal liability under § 841(a) requires more than proof of a doctor's intentional failure to adhere to the standard of care"). This standard asks whether a doctor's prescription conforms to what *she* believes is a generally accepted standard of medical practice *and* is serving what *she* believes to be a legitimate medical purpose. Failure to prove either of those requirements beyond a reasonable doubt requires acquittal. Were it otherwise, the Ninth Circuit has said, juries could convict "solely on a finding that [a physician] has committed malpractice," *id.* at 1010,

rather than convicting only when a physician "ceases to be a physician *at all*," *id.* at 1011.

The Seventh Circuit takes the same view, holding that the government must prove a physician "deliberately made the prescriptions outside the ordinary scope of professional practice *and* with no acceptable medical justification." *United States* v. *Kohli*, 847 F.3d 483, 490 (2017) (emphasis added); see *id.* at 491 (affirming conviction where evidence proved that physician "intentionally and knowingly prescribed controlled substances outside the usual course of professional medical practice and without a legitimate medical purpose"); *United States* v. *Chube*, 538 F.3d 693, 698 (2008) ("[T]he jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional." (quoting *Feingold*, 454 F.3d at 1008)).

The First Circuit likewise focuses on the physician's subjective intent. See *United States* v. *Sabean*, 885 F.3d 27, 45-46 (2018) (affirming instruction that government must prove defendant "was aware to a high probability the prescription was not given for a legitimate medical purpose in the usual course of professional practice" because that "luminously clear language" "elucidated the distinctions between intentional and negligent misconduct").

The "medical purpose" test we propose is not meaningfully different from the standard adopted in the First, Seventh, and Ninth Circuits. Each of those circuits requires the government to prove that the doctor intended to prescribe without a proper medical purpose. *E.g.*, *Feingold*, 454 F.3d at 1008 ("[T]he jury

must look into a practitioner's mind to determine whether he prescribed the pills for what he thought was a medical purpose."). The only point of departure is that those circuits *also* require the prosecutor to show that the physician intended to exceed professional norms.[15] But the two inquiries are really just two ways of saying the same thing. See, *e.g.*, *United States* v. *Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975) ("The two phrases . . . have essentially the same meaning.").

b. By contrast, the Second, Fourth, and Sixth Circuits have articulated an "objective standard" of good faith. *United States* v. *Hurwitz*, 459 F.3d 463, 475, 477-478 (4th Cir. 2006). Accord *United States* v. *Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States* v. *Singh*, 390 F.3d 168, 186 (2d Cir. 2004); *United States* v. *Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986); *United States* v. *Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981). In those circuits, it does not suffice that the physician "acted according to what he believed to be proper medical practice." *Hurwitz*, 459 F.3d at 478. Instead, because the good faith inquiry "must be an objective one," a physician acts in good faith only if he prescribes "in accordance with what he *reasonably* believed to be proper medical practice." *Id.* at 478-480 (emphasis added); see *Wexler*, 522 F.3d at 205-206; *United States* v. *Volkman*, 797 F.3d 377, 387-388 (6th Cir. 2015).

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[15] It is not altogether clear whether the First Circuit views Section 1306.04(a)'s "legitimate medical purpose" and "usual course of his professional practice" prongs as separate standards. See *Sabean*, 885 F.3d at 45.

2. The circuits adopting a subjective standard have the better of the argument.

a. "Good faith," by its nature, is a subjective concept. It asks about the state of the defendant's mind, not the objective nature of his conduct. By contrast, a requirement that the doctor's good faith be "reasonable" is, at bottom, a negligence standard—which is not the level of "culpability . . . we usually require in order to impose criminal liability." *Arthur Andersen LLP* v. *United States*, 544 U.S. 696, 706 (2005). The traditional rule is that a defendant must "*know* the facts that make his conduct fit the definition of the offense." *Elonis*, 575 U.S. at 735 (emphasis added) (quoting *Staples*, 511 U.S. at 608 n.3). By contrast, a "reasonableness" qualifier converts good faith into *constructive* knowledge—and in the process disregards our law's traditional "belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil," *Morissette*, 342 U.S. at 250. It is also incompatible with other CSA provisions that impose a *higher* standard (recklessness) yet impose far less drastic penalties. See *supra* pp. 23-24.

As this Court explained in rejecting a similar "reasonableness" construction of the federal-threats statute, a "'reasonable person' standard is a familiar feature of civil liability in tort law, but is inconsistent with 'the conventional requirement for criminal conduct—*awareness* of some wrongdoing.'" *Elonis*, 575 U.S. at 737-738 (quoting *Staples*, 511 U.S., at 606-607). "Having liability turn on" whether a physician's good faith belief in her medical purpose is "reasonable"—"regardless of what the [physician] thinks—reduces culpability on the all-important

element of the crime to negligence." *Id.* at 738 (quotation marks omitted).

Nor is *Elonis* the only case that rejects a "reasonable belief" standard. Just such a standard was implicitly rejected in *Staples*—a case in which, unlike here, the statute lacked any express *mens rea* requirement. There, the Court held that "to be criminally liable a defendant must know that his weapon possessed automatic firing capability so as to make it a machinegun" (and thus fit the definition of the offense). *X-Citement Video*, 513 U.S. at 71 (discussing *Staples*). It was not enough that an owner *should reasonably* have believed that the firearm was unlawful. See *Staples*, 511 U.S. at 609-610 (rejecting argument that guns "should alert their owners to the probability of regulation").

An "objective" good faith standard is also difficult to square with the CSA's implementing regulation, which focuses, not on the "usual course of professional practice," but instead on the course of *the physician's own practice*. 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of *his* professional practice.") (emphasis added). The AG's formulation appropriately recognizes that a physician who sincerely believes that her medical purpose is legitimate should not be charged as a federal drug dealer merely because she should have known that most other doctors would prescribe differently. Using felony prosecutions to yoke physicians to objective professional norms dishonors physicians' "traditional[ ]" and "widely accepted," *Staples*, 511 U.S. at 612, discretion in treating

patients and "testing new theories," *Moore*, 423 U.S. at 143. See also *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 351 n.5 (2001) (off-label prescribing "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine").

b. In the cauldron of actual Section 841(a)(1) prosecutions, a "reasonable belief" requirement cannot be distinguished from a civil malpractice lawsuit. Whether a physician's good faith is "reasonable" is typically determined by calling competing experts who offer warring opinions on whether the defendant followed the "usual course of professional practice." This case is an object lesson. Evidence of simple malpractice suffused the government's case in chief. For example, the government put on medical experts who testified that Dr. Ruan prescribed "outside [the] standard of care, . . . outside the usual practice." Tr. 2357:10-11 (Jan. 24, 2017); see also Tr. 661-1061 (Jan. 12-13, 2017) (Dr. Greenberg); Tr. 2246-2542 (Jan. 23-24, 2017) (Dr. Vohra); Tr. 4328-4520 (Feb. 6, 2017) (Dr. Aultman). One government expert testified that in her opinion "[t]he ideal thing for the doctor to have done would have been to transfer the patient for detoxification at a licensed detoxification facility," or have patients "referred to a psychiatrist" rather than prescribing opioids as a first step of treatment. Tr. 731:10-11 (Jan. 12, 2017); Tr. 743:11-14 (Jan. 12, 2017). Another expert opined that Dr. Ruan excessively relied on nurse practitioners, which, in the expert's view, fell outside "the usual practice of practicing medicine *in the state of Arizona*." Tr. 688:17-21 (Jan. 12, 2017) (emphasis added); Tr. 681:12 (Jan. 12, 2017) ("I normally [examine the

patient] by myself."); Tr. 2375:20-24 (Jan. 24, 2017) (similar). Yet another hired government expert testified that certain of Petitioner's drug-testing practices were "inadequate" and demonstrated "the doctor's [un]willingness to spend the tiny bit more money and go ahead and protect his patients the best that he can." Tr. 923:1-4 (Jan. 13, 2017). Such testimony would barely be admissible in a *civil* case (in Alabama, anyway); it hardly showed that Petitioner "completely betrayed any semblance of legitimate medical treatment," as required for a felony conviction under Section 841(a)(1). *Feingold*, 454 F.3d at 1010.[16]

But this is what CSA prosecutions invariably devolve to in "objective good faith" jurisdictions. In the *Volkman* prosecution in the Sixth Circuit, the government's expert witnesses testified at length to the appropriate "standard of care," 797 F.3d at 388-390. In the Second Circuit's *Wexler* case, government experts claimed that defendant's skin excisions were unreasonable because "people don't have that much skin to spare," 522 F.3d at 198. And in the *Hurwitz* prosecution in the Fourth Circuit, the government's

[16] In fact, prosecutors may produce expert witnesses in criminal CSA trials who would not meet the standards required for expert witnesses in state malpractice cases. Alabama, recognizing the difficulty of establishing a standard of care and the deleterious impact of the "continuing and ever increasing threat of legal actions for alleged medical injury" on patient care, requires that expert witnesses in civil cases against physicians be "similarly situated" to the physician on trial, defined as someone who is licensed, trained in the same specialty as the defendant-physician, and who has practiced in the specialty during the year prior to the alleged breach of the standard of care. Ala. Code §§ 6-5-548(b)-(d), 6-5-549.1.

lead expert repeatedly contrasted Dr. Hurwitz's prescriptions with the typical quantities for high dose opioid therapy, 459 F.3d at 467-468 (citing *Hurwitz* J.A. at 2456). See *United States* v. *Tran Trong Cuong*, 18 F.3d 1132, 1135 (4th Cir. 1994) (government expert testimony that defendant's prescriptions "were totally unreasonable and not appropriate care for a family physician").

c. A "reasonable belief" requirement is also unfair and unworkable given the indeterminacy of the bounds of professional practice. No physician can predict whether a lay jury will decide, after hearing competing expert testimony (and there's always a competing expert available), that her course of treatment was "unreasonable." By unmooring Section 841(a)(1) from the doctor's subjective intent, CSA prosecutions almost inevitably fail to give "fair warning . . . of what the law intends to do if a certain line is passed." *Arthur Andersen*, 544 U.S. at 703. Indeed, given the protean and rapidly changing landscape of medical science, a robust, subjective good faith defense is critical lest the CSA become a "trap for those who act in good faith," *Gonzales* v. *Carhart*, 550 U.S. 124, 149-150 (2007).

It was precisely such concerns that prompted this Court in *Gypsum* to adopt a presumption of *mens rea*. As in that case, the CSA and its implementing regulation do not "in clear and categorical terms, precisely identify the conduct which [they] proscribe[]"—lawful behavior is often "difficult to distinguish" from unlawful, and, in practice, "open-ended and fact-specific standards" end up being clarified only *after* they are "applied" by juries "to broad classes of conduct." 438 U.S. at 438, 440-441.

This Court's "traditional[ ] . . . restraint in assessing the reach of a federal criminal statute" is therefore especially appropriate—and a subjective good faith standard mitigates notice concerns and leaves criminal lawmaking to Congress. *Arthur Andersen*, 544 U.S. at 703. A legal standard that gives physicians fair warning has the additional benefit of avoiding a chilling effect on "salutary . . . conduct lying close to the borderline of impermissible conduct [that] might be shunned by [physicians] who chose to be excessively cautious." *Gypsum*, 438 U.S. at 441.

d. Adopting an "objective" good faith standard would also present serious federalism concerns. "It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there"—indeed, that is "a vital part of a state's police power." *Barsky* v. *Board of Regents*, 347 U.S. 442, 449 (1954). This is particularly true with respect to physicians, "whose relations to life and health are of the most intimate character." *Hawker* v. *New York*, 170 U.S. 189, 194 (1898). It is thus "well settled that the State has broad police powers in regulating the administration of drugs by the health professions." *Whalen* v. *Roe*, 429 U.S. 589, 603 n.30 (1977) (collecting cases).

Interpreting the CSA to "regulate[ ] medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician," *Oregon*, 546 U.S. at 269, would vastly expand federal regulation of medicine. And a regime that imposes criminal liability based on simple negligence (or, as in the Eleventh Circuit, what amounts to strict liability) would do just that. Nothing in the CSA suggests an intent to replace medical boards and damages awards

with United States Attorneys and prison terms. Indeed, far from displacing the States' regulation of medicine, "[t]he structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." *Id.* at 270. Confirming the point: Congress *did* specifically displace State standards in one discrete area—the treatment of addicts. See *id.* at 271-272 (discussing 42 U.S.C. § 290bb-2a). When Congress wants to regulate medical practice, rather than punish conventional "drug dealing and trafficking," it "does so by explicit language in the statute." *Id.* at 270, 272.

Beyond seriously altering the relationship between the States and the federal government, extending Section 841(a)(1) sanctions to doctors who act "unreasonably" would threaten a "fundamental[ ] chang[e]" in "the relation between the citizen and the Federal Government," *NFIB* v. *Sebelius*, 567 U.S. 519, 555 (2012) (opinion of Roberts, C.J.). Physicians' autonomy is only one side of the coin. There is also the freedom of citizens to choose among physicians and treatment options, subject to local regulation of medical practice. The *in terrorem* effect of overzealous CSA prosecutions has already disrupted this balance, depriving chronic pain patients of medical choice and affecting their quality of life. See Pet. 32-33. Deference to the traditional doctor-patient relationship is especially important for sufferers of chronic pain—pain is by nature unusually subjective and often cannot be assessed using scans or diagnostic tests.

C. A Subjective Good Faith Standard Is Essential To The Practice And Progress Of Medicine.

1. In enacting the CSA, "Congress understandably was concerned that the drug laws not impede legitimate research and that physicians be allowed reasonable discretion in treating patients and testing new theories." *Moore*, 423 U.S. at 143. While seeking to place "some limits on free experimentation with drugs," Congress was also mindful not to constrain "legitimate research and experimentation." *Ibid.*

Limiting criminal liability to circumstances in which physicians lack a good faith medical purpose balances the need to deter and punish drug pushing with the need for innovative medical research and effective patient care. In order to preserve "reasonable discretion" for physicians, *Moore*, 423 U.S. at 143, doctors must have "latitude" in "trying to determine the current boundaries of acceptable medical practice." *Hurwitz*, 459 F.3d at 477. A subjective good faith defense preserves this latitude, and makes space for both legitimate medical research and individualized patient care.

Medical practice, after all, is an iterative and highly individualized process. There are numerous valid reasons why doctors may take divergent approaches to treatment of specific patients or in treatment philosophy more generally, including prescribing controlled substances for uses not yet recognized by the FDA (so-called "off-label" use). As scholars have recognized, there are differences of opinion "in the medical community over whether certain patterns of prescribing for pain treatment are

appropriate." Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 St. Louis U. J. Health L. & Pol'y 231, 291 (2008). The "standard of care in the treatment of non-malignant chronic pain patients," for instance, "is an area of medical practice in which the boundaries and contours are in flux and one in which the boundaries may differ significantly from patient to patient." *Ibid.*

Giving physicians the freedom to tailor their treatment, including the "freedom to prescribe drugs off-label," therefore "carries important advantages." Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 New Eng. J. Med. 1427, 1427 (2008). Off-label prescribing permits "innovation in clinical practice, particularly when approved treatments have failed," gives patients "earlier access to potentially valuable medications," and allows physicians to respond to "'orphan' conditions" that would otherwise lack treatment. *Ibid.* Indeed, doctors routinely prescribe controlled substances for off-label use. See, *e.g.,* Agency for Healthcare Research and Quality, "Off-Label Drugs: What You Need to Know" (Sept. 2015), https://perma.cc/6M65-AHXR ("one in five prescriptions written today are for off-label use").[17]

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[17] As but a few examples, methylphenidate (*i.e.*, Ritalin), an approved ADHD medicine for children over age five, is routinely prescribed off-label for children under five; the anti-anxiety drug Ativan is often used off-label as an anti-nausea drug during cancer treatment; and naltrexone, an addiction treatment medication, is used to treat cancer and autoimmune diseases. See Shannon G. Panther et al., *Off-label Prescribing Trends for ADHD Medications in Very Young Children*, 22 J. Pediatric

Federal drug trafficking cases against doctors "are the only realm in which juries are tasked with applying complicated medical concepts to vague elements in order to determine if a physician should be convicted and sentenced to decades in prison due to a medical disagreement." Ronald W. Chapman II, *Defending Hippocrates: Representing Physicians in the Wake of the Opioid Epidemic*, 43 Champion (Nat'l Ass'n of Crim. Defense Law.) 40, 41 (2019). And asking juries to shoulder that task under an "objective" standard of good faith only compounds the challenge. Given the differences of opinion even among medical practitioners and the continually developing understanding of various drugs and their uses, a subjective good faith defense provides an essential buffer for doctors to make reasoned prescription decisions without fear that a jury may later regard those decisions to be too unorthodox—and thus punishable by decades in prison.

Here, as elsewhere, "a page of history is worth a volume of logic." *New York Trust Co.* v. *Eisner,* 256 U.S. 345, 349 (1921). Dissent has always been essential to medical progress. As the aphorism goes, "[a]ll truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident." When Dr. William Harvey discovered that blood circulates continually throughout the body, disproving the then-prevailing 17th century theory that blood was produced by the

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Pharmacology and Therapeutics 423, 426 (2017); American Cancer Society, "Off-label drug use" (Mar. 2015), https://perma.cc/HW96-RFWR; S.M. Drogovoz et al., *Experience and Prospects for the Use of Off-Label Drugs in Oncology*, 43 Experimental Oncology 1, 4 (2021).

liver and absorbed into the body's tissue, he "was attacked viciously" as his findings "set off a storm in medical and philosophical circles." Roberto Bolli, *William Harvey and the Discovery of the Circulation of the Blood—Part III*, 124 Circulation Research 1428, 1428 (2019). Louis Pasteur's 19th century publication of germ theory was initially "met with ridicule by the medical establishment." Theodore H. Tulchinsky & Elena A. Varavikova, *A History of Public Health*, The New Public Health, Oct. 10, 2014, at 19. These days, germs are regarded with disfavor.

More recently, Dr. Robin Warren and Dr. Barry Marshall's discovery that gastric ulcers are caused by H. pylori bacteria was met with "skepticism and a lot of criticism" by a medical community that had long linked ulcers to stress, spicy foods, and other lifestyle choices. Niyaz Ahmed, *23 years of the discovery of Helicobacter pylori: Is the debate over?*, Annals of Clinical Microbiology and Antimicrobials, Oct. 31, 2005. Dr. Charles Dotter's invention of angioplasty, now used extensively in the treatment of heart disease, was "[i]nitially met with hostility and skepticism in the United States." Oregon Health & Science University, "History, Charles Theodore Dotter," https://perma.cc/B955-SAEM. And Dr. James Allison, who pioneered the use of immunotherapy as a treatment for cancer, contended with "doubt from his peers" for more than fifteen years before the FDA approved an immuno-oncology drug in 2011. Timothy Bella, *A Texas scientist was called 'foolish' for arguing the immune system could fight cancer. Then he won the Nobel Prize*, Wash. Post (Mar. 25, 2019), https://perma.cc/LVU5-4JMS.

Doctors should not have to risk felony liability whenever they choose unpopular treatments. Such a construction of the CSA would disserve both the development of medicine generally, and the individual needs of patients for whom medical trials or other novel treatments may present the only possibility of recovery. Indeed, physicians' guiding principle—to "do no harm"—may in some instances *require* them to prescribe unorthodox treatment.

It is no exaggeration to say that CSA prosecutions of physicians have already impaired the treatment of chronic pain. In response to the opioid crisis, fear of prosecution has increasingly prompted pain management doctors to avoid or reduce opioid prescriptions, even when those decisions leave chronic pain patients without recourse. See, *e.g.,* Maia Szalavaitz, *The Pain Was Unbearable. So Why Did Doctors Turn Her Away?*, WIRED (Aug. 11, 2021), https://perma.cc/J5E4-ZNYG (describing how fear of prosecution can leave "patients who have chronic pain but do not have addictions . . . cut off from medication that could help them"); Joel Achenbach & Lenny Bernstein, *Opioid crackdown forces pain patients to taper off drugs they say they need*, Wash. Post (Sept. 10, 2019), https://perma.cc/9S6U-2Q75 (explaining that some chronic pain patients "have the kind of pain that's unbearable," and "their doctors are terrified"); Wesley J. Smith, *Pain Doctors Face Greater Scrutiny Than Death Doctors*, National Review (May 3, 2018), https://perma.cc/84R5-S5W9 ("Legitimate pain patients are being abandoned to agony that could be relieved because the responsible are being swept up with the dysfunctional and criminal."). Fear of unwarranted prosecution has also resulted in other adverse outcomes, as forced tapering "without

providing effective alternative care is associated with nearly triple the risk of overdose death." Szalavaitz, *Unbearable*, *supra* p.44. As "fear of false accusation drives those physician behaviors that do not prioritize patient well-being," the good faith defense is an essential safeguard for both physicians and their patients. Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 Am. J.L. & Med. 7, 39 (2016).

2. Taking good faith seriously will not be a get-out-of-jail-free card for physicians who truly act as drug pushers. While juries may not be best suited to assess evolving medical standards, they *are* able to evaluate subjective intent, and can look to evidence concerning a physician's practice in assessing the veracity of a physician's claim to have acted in good faith.

Indeed, juries are routinely asked to evaluate subjective intent by drawing inferences from objective facts. In *Linder*, for instance, the Court explained that an "enormous quantity of drugs ordered, considered in connection with the recipient's character, without explanation" could indicate "prohibited sales" and "exclude the idea of bona fide professional action" under the CSA's predecessor statute. 268 U.S. at 22. Likewise, in *Liparota*, the Court explained that requiring proof that the defendant *knew* his conduct was unauthorized would "not put an unduly heavy burden on the Government in prosecuting violators" because, "as in any other criminal prosecution requiring *mens rea*, the Government may prove by reference to facts and

circumstances surrounding the case that petitioner knew that his conduct was unauthorized or illegal." 471 U.S. at 433-434. And while a defendant may seek to avoid criminal tax liability by proving she did not act "willfully," "the more unreasonable the asserted beliefs or misunderstandings are, the more likely the jury will consider them to be nothing more than simple disagreement with known legal duties," rather than a lack of *mens rea*. *Cheek* v. *United States*, 498 U.S. 192, 203-204 (1991). Factors such as the extent of deviation from generally accepted medical practice may appropriately inform the scienter determination under Section 841(a)(1). See, *e.g.*, *Feingold*, 454 F.3d at 1007 ("Knowing how doctors generally ought to act is essential for a jury to determine whether a practitioner has acted not as a doctor, or even as a *bad* doctor, but as a 'pusher' whose conduct is without a legitimate medical justification.").

Moreover, the CSA is not the sole bulwark against physician misconduct. Far from it: numerous federal and state laws impose criminal and civil liability for a wide range of improper acts. State level medical practice statutes allow state medical boards to regulate and discipline medical providers for unprofessional conduct, including conduct that violates medical ethics or exceeds professional norms. Individuals may bring civil malpractice lawsuits against doctors for injuries suffered in treatment. And at the federal level, a network of laws including the Health Insurance Portability and Accountability Act and the Anti-Kickback Act preclude doctors from violating patient confidentiality and engaging in healthcare fraud. Recognizing subjective good faith as a defense to CSA liability will not undercut the regulation of physicians or give doctors a free pass to

engage in unchecked medical experimentation. It will, however, ensure that States, as the primary regulators of health professionals and the administration of drugs, are able to effectively regulate physician conduct.

D. At A Bare Minimum, Any "Objective" Good Faith Standard Must Afford Physicians Breathing Room For Honest Departures From Professional Norms.

At the close of trial, Petitioner asked the district court to instruct the jury that it should acquit him if the government failed to prove that he had "good intentions" and displayed "the honest exercise of professional judgment" in conforming to "what he reasonably believed to be proper medical practice." J.A. 102. Although we believe that a purely subjective good faith standard best accords with the text and history of the CSA, at the very least a doctor must be acquitted if he *honestly tried* to meet reasonable professional standards. Indeed, the Solicitor General conceded the point in its brief in opposition. See BIO 11 ("[t]he touchstone for liability under *Moore* is whether" "at a minimum, [defendant] 'made "an honest effort"' to act" according to professional norms (quoting *Moore*, 423 U.S. at 142 n.20)). Unlike the purely objective standard embraced by the Second, Fourth and Sixth Circuits—which requires that the physician's intent be "reasonable"—this standard asks only whether the doctor's intent is "honest."

In the present case, of course, Petitioner was deprived of *any* good faith standard. For that reason, as we next explain, Dr. Ruan's convictions should be reversed under *any* plausible formulation of the good faith defense.

II. EVEN UNDER AN "OBJECTIVE" GOOD FAITH STANDARD—INDEED, UNDER *ANY* CIRCUIT'S LAW BUT THE ELEVENTH'S—PETITIONER'S CONVICTIONS SHOULD BE REVERSED.

1. The district court told Petitioner's jury that it could convict him under the CSA if it found that he had exceeded professional norms. Full stop. Although the court purported to "throw[] [Petitioner] a bone" by adverting to his good faith defense, in the very next breath it rendered good faith irrelevant:

> *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 Eleventh Circuit agreed. In its view, good faith is a defense only "as long as the appellants' conduct *also* was in accordance with the standard of medical practice generally recognized and accepted in the United States." Pet. App. 107a (emphasis added). That ruling reflected the Eleventh Circuit's idiosyncratic notion that a physician's "good faith belief that he dispensed a controlled substance in the usual course of his professional practice is *irrelevant*." *United States* v. *Enmon*, 686 Fed. Appx. 769, 773 (2017) (per curiam) (emphasis added); *see also United States* v. *Tobin*, 676 F.3d 1264, 1283 (11th Cir. 2012) (exclusion of "evidence of good faith" is "consistent with [this circuit's] holdings").

The Eleventh Circuit's treatment of good faith saps the defense of any actual content. By reserving the defense only for physicians whose prescriptions already fall within professional norms, the Eleventh Circuit ensures that good faith may be invoked only by defendants who don't need it. That is the kind of defense only Joseph Heller's Major Major could appreciate.[18]

Needless to say, the Eleventh Circuit's rule is a complete outlier. Every other circuit to pass on the question has endorsed *some* kind of good faith defense as essential to "explain[] to the jury a critical difference between" civil and criminal liability. *Sabean*, 885 F.3d at 45 (quoting *United States* v. *Smith*, 573 F.3d 639, 650 (8th Cir. 2009) (quoting in turn *United States* v. *McIver*, 470 F.3d 550, 560 (4th Cir. 2006))).

2. It follows that even if the Court adopts the "objective" good faith standard embraced by the

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[18] "What shall I say to the people who do come to see you while you're here?

"Tell them I'm in and ask them to wait."

"Yes, sir. For how long?"

"Until I've left."

"And then what shall I do with them?"

"I don't care."

"May I send them in to see you after you've left?"

"Yes."

"But you won't be here then, will you?"

"No."

Joseph Heller, *Catch 22* 100 (S&S Classic ed. 1999) (1961).

Second, Fourth, and Sixth Circuits, it should reverse Petitioner's convictions.

By directing the jury to focus only on whether Dr. Ruan exceeded professional norms, the district court authorized the jury to disregard the abundant evidence of Petitioner's subjective good faith. So instructed, Dr, Ruan's jury had no reason to consider the government's concession that he "did a really good job for [his] patients," and that "[b]y and large, [his] patients were legitimate patients." Pet. App. 84a. Nor did the jury need to assess Dr. Ruan's testimony that he always made an "individualized decision" as to "[w]hat medication to use" "based on the patient's best interest." J.A. 209-210.

Instead, Petitioner's case devolved into a battle of experts, much like any run-of-the-mill malpractice lawsuit. Experts may well differ about best practices, or even "the usual course of professional practice," *Moore*, 423 U.S. at 124. But a lay jury's assessment of the cut of an expert's jib should not spell the difference between guilt or innocence. And here, the jury was especially at a loss because, guided by the Eleventh Circuit's idiosyncratic views, the district court excluded critical evidence that Petitioner refused to prescribe to undercover DEA agents and evidence that Petitioner's treatments were lifesaving for certain patients. See *supra* pp. 9-10 & n.3. That evidence bore directly on Petitioner's good faith and "would have rebutted the government's evidence that [Petitioner's] prescriptions lacked a legitimate medical purpose." *United States* v. *Arny*, 831 F.3d 725, 734, 736 (6th Cir. 2016).

By depriving Petitioner of *any* substantive good faith defense—even one as diluted as the "objective"

standard adopted by the Second, Fourth, and Sixth Circuits—the district court, sustained by the court of appeals, invited the jury to convict Petitioner based on a strict liability standard. Nothing in the CSA or its implementing regulations authorizes that wholesale disruption of medical practice and scientific progress.[19]

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment of the court of appeals.

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[19] The error was not harmless. 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). "By concluding that good faith was not applicable to the § 841 charges," the district court "effectively deprived the jury of the opportunity to consider [Petitioner's] defense." *Hurwitz*, 459 F.3d at 482. "In a criminal appeal where a mens rea-related jury instruction issue may have made a difference to the conviction and sentence, it is critically important to ensure that the jury had a correct understanding of the relevant law." *United States* v. *Williams*, 836 F.3d 1, 20 (D.C. Cir. 2016) (Kavanaugh, J., concurring). For its part, the government has never claimed that Dr. Ruan was not entitled to a good faith instruction.

Respectfully submitted.

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