No. _____

IN THE SUPREME COURT OF THE UNITED STATES

FRANK PURPERA,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether a physician alleged to have acted outside the "lawful course of professional practice" is entitled to a good faith instruction defining good faith based on his subjective state of mind.

LIST OF PARTIES TO PROCEEDINGS

Petitioner, defendant-appellant below, is Dr. Frank Purpera.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

Fourth Circuit Court of Appeals:

United States v. Frank Craig Purpera, Jr., No. 19-4158, United States Court of Appeals for the Fourth Circuit. Judgment entered Feb. 5, 2021. *United States v. Purpera*, 844 F. App'x 614, 617 (4th Cir. 2021)

United States District Court for the Western District of Virginia:

United States v. Purpera, No. 17 CR 79. Judgement and conviction entered February 20, 2019.

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The opinion of the court of appeals is reported at *United States v. Purpera*, 844 F. App'x 614, 617 (4th Cir. 2021)

JURISDICTION

The court of appeals' judgment was entered on February 5, 2021. On November 4, 2020, the Court issued guidance reflecting that the 150-day extension "from the date of the lower court judgment, order denying discretionary review, or order denying a timely petition for rehearing," directed by the Chief Justice on March 19, 2020, remains in effect. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution prohibits any person from being deprived of his or her liberty without due process of law:

> "No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

U.S.S.C. AMND V.

21 U.S. Code § 843(4)(a) in tandem with 21 U.S. Code § 827 and 21 C.F.R. § 1304.03 criminalizes a physician's failure to keep a dispensing log indicating any controlled substances distributed outside the course of the physician's legal medical practice:

21 U.S. Code § 843(4)(a) provides:

"It shall be unlawful for any person knowingly or intentionally—

(a)(4)(A) to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter or subchapter II, …"

21 U.S.C. § 843(4)(a).

21 U.S. Code § 827 describes when medical practitioners must keep a log of the controlled substances they distribute:

"(a) Inventory Except as provided in subsection (c)—

…(3) "on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual"

21 U.S.C. § 827.

Then federal regulation regarding when a medical practitioner must keep a distribution log is 21 C.F.R. § 1304.03:

> "(b) A registered individual practitioner is required to keep records, as described in § 1304.04, of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.
>
> …
>
> (d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual."

21 C.F.R. §1304.03.

STATEMENT

Medical practitioners are generally entitled to a good faith instruction when charged with distributing controlled substances outside the scope of professional practice under §841. At present, the Courts of Appeal have adopted at least three different good faith instructions, each articulating a different mens rea. While Dr. Purpera is charged with violating §843(a)(4)(A), the question at issue in his case is identical to the more commonly charged §841 cases and provides this court an opportunity to resolve what has become an untenable split among the circuits. In the absence of a good faith instruction requiring that a doctor actually know he is acting outside lawful medical practice, §827 would be fatally vague. The statute does not define what constitutes lawful practice of medicine.

FACTS

At the time relevant this petition, Dr. Purpera was a doctor registered and licensed to distribute controlled substances with the DEA. 1/30/18 Tr. 65. Dr. Purpera owned and operated

the Virginia Vein Institute, a vascular clinic operating in Western Virginia. 1/3018 Tr. 84. Henry Schein is a national drug distribution company operating around the nation. 1/3018 Tr. 84. Starting in April of 2014, the Virginia Vein Institute began ordering controlled substances from Henry Schein. R.3 at 5-7. *See*, *generally*, 1/30/18 Tr. 217 – 1/31/18 Tr. 15-65. Counts 1-68 of the indictment charged Dr. Purpera with obtaining those controlled substances from Henry Schein by fraud in violation of 21 USC §843(a)(3). R.3 at 1-7. The forms submitted by the Virginia Vein Institute to Henry Schein denied that any of the controlled substances were being used to treat family or friends. R. 3 at 1-5. At trial, the government admitted a letter from Purpera to Virginia Department of Health Professionals. In that letter, Purpera indicated while he did administer controlled substances in office to a very small percentage of his patients for post-surgical pain, "the vast majority of medications were administered to his wife for immediate in office use." 01/22/20 Tr. 288-291.

Dr. Purpera's wife, Rebecca Mosig, worked as an office manager at the Virginia Vein Institute. Mosig suffered from a Factor V Leiden mutation, a bona fide painful condition. 1/29/18 Tr. 113-14. Purpera had been treating Ms. Mosig for this condition for a number of years prior to the establishment of the Virginia Vein Institute. 1/30/18 Tr. 82, 170-72; 2/1/18 Tr. 16-42; 1/31/18 Tr. 138-42. It was undisputed at trial that Mosig suffers from a painful medical condition. Two subsequent doctors continued to treat Ms. Mosig with opioids. The government presented no evidence that the controlled substances were diverted, abused, or administered other than in an attempt to treat a bona fide medical condition. 1/30/18 Tr. 148.

The subject of Purpera's instant petition is his conviction on Count 69 under 21 U.S.C §843(a)(4)(A) for failing to keep a log documenting the distribution of the controlled substances ordered from Henry Schein. R. 3 at 8. Purpera did not, in fact, keep a log cataloguing the

substances he administered to Ms. Mosig. Under 21 U.S.C. § 827 and 21 C.F.R. § 1304(b) medical practitioners are *not* required to maintain a dispensing log *if* they are administering medication in "the lawful course of professional practice." 21 C.F.R. § 1304(b). Therefore, if Dr. Purpera was administering the Henry Schein controlled substances to his wife in "the lawful course of professional practice" he did not have an obligation to keep an administration log and could not be guilty of omitting material information under §843(a)(4)(A).

The government's expert witness Dr. Burton did not testify regarding the propriety of the treatment Purpera was providing to his wife; but rather, as an expert on the laws of Virginia and whether the fact of Purpera's treatment of his wife was in keeping with those laws. *See, e.g.,* 1/25/18 Tr. 118-9 (But the main issue is whether or not a physician who is prescribing in violation of a regulation of the state of Virginia is acting outside the usual course of professional Practice… We do not expect this trial to get involved into vein ablation issues … This is more as to whether or not Virginia law was complied with and to whether or not -- potentially, depending upon the course of the trial, whether or not the pain medications were appropriately administered and/or prescribed"). Burton identified a Virginia Medical regulation regarding the treatment of family and friends. 1/31/18 Tr. 131; 1/31/18 Tr. 117-18. On direct examination, Dr. Burton testified that it was his understanding of that statute that a doctor was not allowed to distribute controlled substances to a spouse with the exception of a limited number of inapplicable exceptions. 1/31/18 Tr. 117-18. However, as the district court acknowledged, the Virginia Medical regulations only prohibit *prescribing* to family members not *administering* to family members. 1/31/18 Tr. 129-131; R. 109 at 30 (Instruction No. 26).

The district court instructed the jury that practitioners do not have to maintain a dispensing log if they are "administering controlled substances in the lawful course of

professional practice, unless (1) The practitioner regularly engages in the dispensing or administering of controlled substances, and (2) The practitioner charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered." R. 109 at 28. The government did not argue that the exceptions apply. The sole question was whether Purpera was acting in the lawful scope of professional practice. The district court did not define what was or was not within the lawful scope of professional practice Instead, the district court instructed the jury: "In determining whether his actions were within the lawful course of professional practice, you may consider whether the defendant complied with state laws or regulations. A violation of a state medical law or regulation, however, does not, in and of itself, establish a violation of criminal law. In other words, violations of state laws or regulations or professional norms, alone, are not sufficient to convict the defendant." R. 109 at 29.

Dr. Purpera requested an instruction indicating that a defendant acts within the lawful scope of professional practice if he is treating his patients in good faith. In pertinent part, Dr. Purpera's proposed instruction read.

> "If a physician prescribes or administers a drug in good faith, then he has done so within the lawful course of professional practice. A physician prescribes or administers a drug in good faith in medically treating a patient when he does so for a legitimate medical purpose in the usual course of medical practice. Good faith means good intentions and the honest exercise of best professional judgment as to the patient's needs. It means that the doctor acted in accordance with (what he reasonably believed to be) the standard of medical practice generally recognized and accepted in the United States."

R.60 at 22-23 (Defense Inst. B-6). The trial court denied Purpera's request for a good faith instruction. Purpera was convicted of all counts at trial and sentenced to 20 months. R.184 at 5-6.

LOWER COURT RULING

On appeal Purpera argued that the district court erred in denying his request for a good faith instruction. The Fourth Circuit "assumed without deciding" that good faith is a defense to § 843(4)(a) charges. *United States v. Purpera*, 844 F. App'x 614, 629 n.13 (4th Cir. 2021). The Fourth Circuit nonetheless held that the district court did not abuse its discretion in rejecting the defendant's proffered good faith defense because his instruction was not an accurate statement of the law in the Fourth Circuit. *United States v. Purpera*, 844 F. App'x 614, 626 (4th Cir. 2021). Specifically, the Fourth Circuit indicated that Purpera's proposed instruction directed the jury to consider what the defendant "reasonably believed." The Fourth Circuit indicated that this imposed a subjective standard whereby a doctor would be allowed "to decide for himself what constitutes proper medical treatment." *United States v. Purpera*, 844 F. App'x 614, 627 (4th Cir. 2021). Instead, the Fourth Circuit found that the jury should have been instructed to determine what a "physician *should have* believed." *Id*.

As argued below, removing all consideration of a doctor's mental state from the equation is inconsistent with the concept of good faith and the Court's practice of inferring a mental state requirement even where one is not explicitly stated. *United States v. Purpera*, 844 F. App'x 614, 627 (4th Cir. 2021) ("The instruction in *Voorhies* defined good faith as 'an observance of conduct in accordance with what the physician *should* reasonably believe to be proper medical practice.' That definition of good faith is meaningfully different from one that is based on what the physician *actually* believed. A jury tasked with assessing what a physician *should have* believed must apply an objective standard. In contrast, determining what a doctor *actually* believed requires a jury to assess the doctor's subjective point of view.") (*quoting United States v. Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981)).

REASONS FOR GRANTING REVIEW

I. REVIEW IS NECESSARY TO RESOLVE A NUMBER OF CIRCUIT SPLITS CENTERING AROUND THE CENTRAL QUESTION OF WHAT LEVEL OF INTENT IS NECESSARY FOR CONVICTION OF A LICENSED PHYSICIAN UNDER THE CONTROLLED SUBSTANCES ACT.

This case presents a vehicle for this Court to address a split among the Courts of Appeal as to what form of good faith instruction a doctor is entitled to where his conviction is dependent upon the question of whether he was acting in the "course of professional practice." The most common charges that turn on whether a doctor operates in the course of professional practice involve medical practitioners charged under §841 for distribution of controlled substances outside the usual course of professional practice. The circuits are split as to what type of good faith instruction is appropriate where doctors are charged with violating §841. The Tenth, Eleventh, and Fifth Circuits have explicitly held that a defendant is strictly liable for acting outside the scope of professional practice; *United States v. Kahn*, No. 19-8051, 2021 WL 732348, at *13 (10th Cir. Feb. 25, 2021) ("We hold that § 841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant … issued a prescription that was objectively not in the usual course of professional practice."); *United States v. Tobin*, 676 F.3d 1264, 1283 (11th Cir. 2012); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986). The Seventh and the Ninth Circuits allow for subjective good faith instructions. *United States v. Kohli,* 847 F.3d 483, 490 (7th Cir. 2017); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006).

The Second, Sixth, and Eighth Circuits require good faith instructions that effectively require the government to establish negligence by asking what a doctor reasonably believed or should reasonably believe. *United States v. Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986); *United States v. Godofsky*, 943 F.3d 1011, 1026 (6th Cir. 2019); *United States v. King*, 898 F.3d 797, 807–08 (8th Cir. 2018). In this case, the Fourth Circuit indicated that concentrating on what a

doctor "reasonably believed" imposes too subjective of a standard. Instead, the Fourth Circuit embraced a standard for good faith based on what a doctor "should believe." It is unclear whether that standard would allow for a "reasonable" mistake.

The Fifth, Tenth, and Eleventh Circuits explicitly hold that there is no *mens rea* requirement when a doctor is charged with acting outside the scope of professional practice. Every other circuit to have considered the matter has held either explicitly or implicitly that the government must prove that a defendant at least *knew* that a given prescription was issued outside the scope of professional practice. *United States v. Hurwitz,* 459 F.3d 463, 478, 481 (4th Cir. 2006) ("attorney's statement therefore cannot be viewed as a clear and unambiguous admission that [the defendant] knowingly acted outside the bounds of accepted medical practice."); *United States v. Jones,* 825 F. App'x 335, 339 (6th Cir. 2020) (unpublished) ("Accordingly, to have convicted [the defendant] under § 841(a)(1), the jury must have found that Jones filled prescriptions for Schedule II substances knowing that the prescriptions were outside the scope of professional practice and that they were not for a legitimate medical purpose."); *United States v. Kohli,* 847 F.3d 483, 490 (7th Cir. 2017) ("In other words, the evidence must show that the physician not only intentionally distributed drugs, but that he intentionally 'act[ed] as a pusher rather than a medical professional.'"); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006) ("[T]he government must prove … that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice. In other words, the 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."); United *States v. Garrison*, 888 F.3d 1057, 1064 (9th Cir. 2018); *United States v. Sabean,* 885 F.3d 27, 45 (1st Cir. 2018) ("It stressed that the government had to

prove, at a minimum, that the defendant "was aware to a high probability the prescription was not given for a legitimate medical purpose in the usual course of professional practice" and that the defendant "consciously and deliberately avoided learning that fact."); *United States v. Li*, 819 F. App'x 111, 118 (3d Cir. 2020) (unpublished) ("It is settled law that 'a district court does not abuse its discretion in denying a good faith instruction where the instructions given already contain a specific statement of the government's burden to prove the elements of a 'knowledge' crime.' Here the District Court instructed the jury on the requirements to prove knowledge. Thus, it acted within its discretion.").

While the Second and Eighth Circuits have not explicitly held that knowledge as to usual course of professional practice is an element of § 841 offenses, both have issued opinions indicating that a mistake in treatment, "however gross," is not sufficient to establish a defendant's guilt. *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States v. Smith*, 573 F.3d 639, 649–50 n.4 (8th Cir. 2009) (noting that instruction conflating civil standard of care with usual course of professional practice was cured, in part, by good faith instruction which noted that "unreasonable belief sincerely held is good faith."); *see also United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018) ("So it is here: although a physician's failure to adhere to an applicable standard of care cannot, by itself, form the basis for a conviction under section 841(a), such a failure is undeniably relevant to that determination."); *United States v. Alerre*, 430 F.3d 681, 691 (4th Cir. 2005) (malpractice not sufficient); *Feingold,* 454 F.3d at 1007 ("A practitioner becomes a criminal not when he is a *bad* or *negligent* physician, but when he ceases to be a physician *at all*.").

Even among those circuits requiring *knowledge* that a doctor acts outside the scope of professional practice, a split has developed as to what constitutes "good faith." *See* Deborah

Hellman, *Prosecuting Doctors For Trusting Patients*, 16 GEO. MASON L. REV. 701, 715 (2009). The consensus view in the circuits is that medical practitioners charged with violating §841 are entitled to some form of good faith instruction.

The Seventh and Ninth Circuits allow for instructions that define good faith "subjectively." That is, that ask the jury to consider the defendant's "honest efforts" without requiring that a defendant's belief be "reasonable."

> "[T]he Defendant may not be convicted if he dispenses or causes to be dispensed controlled substances in good faith to patients in the usual course of professional medical practice. Only the lawful acts of a physician, however, are exempted from prosecution under the law. The Defendant may not be convicted if he merely made an honest effort to treat his patients in compliance with an accepted standard of practical practice.... Good faith in this context means good intentions and the honest exercise of good professional judgment as to the patient's medical needs."

United States v. Kohli, 847 F.3d 483, 489 (7th Cir. 2017).

> "[G]ood faith means an honest effort to prescribe for a patient's condition in accordance with the standard of medical practice generally recognized and accepted in the country. Mistakes, of course, are not a breach of good faith.... You need not agree with or believe in a standard practice of the profession, but must only be concerned with a good faith attempt to act according to them. Good faith is not merely a doctor's sincere intention towards the people who come to see him, but, rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country."

United States v. Hayes, 794 F.2d 1348, 1351 (9th Cir. 1986). It is important to note that these instructions both include an objective element. In both circuits, what *actually* constitutes the usual course of professional practice is an objective question. The subjective aspect requires that the doctor *know* he is acting outside the scope of what is objectively accepted medical practice.

The Second, Sixth, Eighth, and previously the Fourth, Circuits require varying degrees of "objective" good faith instructions. *States v. Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986); *United States v. Godofsky*, 943 F.3d 1011, 1026 (6th Cir. 2019); *United States v. King*, 898 F.3d 797,

807–08 (8th Cir. 2018). This is consistent with the track taken by the Fourth Circuit at least prior to the instant appeal. The Fourth Circuit previously indicated that an instruction indicating that good faith should be determined by what a defendant-doctor actually believed to be appropriate medical practice was impermissibly subjective, and thus an incorrect statement of law. The Fourth Circuit indicated that any good faith instruction must be based on what a defendant-doctor "reasonably believed" to be within the scope of professional practice. *United States v. Hurwitz,* 459 F.3d 463, 478, 481 (4th Cir. 2006). The Fourth Circuit, in the case at bar, held that even asking what a doctor "reasonably believed" is too subjective. *United States v. Purpera*, 844 F. App'x 614, 626 (4th Cir. 2021). Instead, the Fourth Circuit now explicitly requires that the government prove only what the defendant *should have* believed. *United States v. Purpera*, 844 F. App'x 614, 626 (4th Cir. 2021).

It is not entirely clear from the Fourth Circuit's opinion whether they intended to impose strict liability. The Fourth Circuit only asks what a doctor "should have believed." A literal reading of the opinion, therefore, would suggest that even reasonable mistakes are subject to prosecution. In that sense, the Fourth Circuit's good faith instruction is close to the Eleventh Circuit's, which explicitly takes all consideration of a doctor's mental state out of consideration. The Eleventh Circuit instruction defines good faith as a doctor actually acting in accordance with a standard of medical practice generally recognized in the United States. *United States v. Ruan*, 966 F.3d 1101, 1167 (11th Cir. 2020) ("A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.").

II. REQUIRING THAT THE GOVERNMENT PROVE THAT A MEDICAL PRACTITIONER *KNOW* A GIVEN PRESCRIPTION IS OUTSIDE THE SCOPE OF PROFESSIONAL PRACTICE IS

NECESSARY TO SAVE § 843(A)(4)(A) FROM BEING VOID FOR VAGUENESS AS APPLIED TO MEDICAL PRACTITIONERS.

"[T]he Government violates [the due process] guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 135 S.Ct. 2551, 2556 (2015). "As generally stated, the void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited, and in a manner that does not encourage arbitrary and discriminatory enforcement." *Kolender v. Lawson*, 461 U.S. 352, 357 (1983). The "doctrine guards against arbitrary or discriminatory law enforcement by insisting that a statute provide standards to govern the actions of police officers, prosecutors, juries, and judges." *Sessions v. Dimaya,* 138 S. Ct. 1204, 1212 (2018); *United States v. U.S. Gypsum Co.,* 438 U.S. 422, 442 (1978) ("criminal sanctions would be used, not to punish conscious and calculated wrongdoing at odds with statutory proscriptions, but instead simply to *regulate* business practices regardless of the intent with which they were undertaken.").

Neither the CFR nor the statute defines what it means for a doctor to be acting in the lawful course of professional practice. Presumably, a single violation of a regulation or ethical provision would not be enough to render a doctor's conduct criminal. *See*, *United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006); *United States v. Miller*, 891 F.3d 1220, 1227–28 (10th Cir. 2018). At least one common sense way of reading the statute is to say that so long as the doctor is licensed and registered with the DEA he is acting in the lawful practice of medicine. However, this Court rejected a similar reading of § 841in *United States v. Moore* ("This limitation is emphasized by the subsection's heading 'Authorized activities,' which parallels the headings of ss 841-843 'Unlawful acts.' We think the statutory language cannot fairly be read to

support the view that all activities of registered physicians are exempted from the reach of s 841 simply because of their status."). An ordinary doctor reading the statutes and regulations could not understand whether he is or is not required to keep a distribution log. "It is common ground that this Court, where possible, interprets congressional enactments so as to avoid raising serious constitutional questions." *Cheek v. United States*, 498 U.S. 192, 203 (1991); *Skilling v. United States*, 561 U.S. 358, 408–09 (2010). "This Court has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of *mens rea*." *Colautti v. Franklin*, 439 U.S. 379, 395 (1979).

This Court has "repeatedly held that 'mere omission from a criminal enactment of any mention of criminal intent should not be read as dispensing with it.'" *Elonis v. United States*, 135 S. Ct. 2001, 2008 (2015). Where an intent element is missing from some aspect of an offense, the Court will read the statute "to include *broadly applicable* scienter requirements." *Id.* "[W]rongdoing must be conscious to be criminal.' ... [T]his principle is 'as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.'" *Id.*

"[A] defendant generally must 'know the facts that make his conduct fit the definition of the offense,'" *Id. at* 2009. *See* P*osters 'N' Things, Ltd. v. United States,* 511 U.S. 513 (1994) (Finding the government must also prove that the defendant "knew that the items at issue [were] likely to be used with illegal drugs."); *Rehaif v. United States*, 139 S. Ct. 2191, 2197 (2019) ("Without knowledge of that status, the defendant may well lack the intent needed to make his behavior wrongful. His behavior may instead be an innocent mistake to which criminal sanctions normally do not attach.")

The fact that makes a medical practitioner's conduct unlawful is not administering controlled substances without keeping a log, but administering a controlled substance outside of lawful medical practice and not keeping a log. The Court includes a "*broadly applicable* scienter requirement[]" even where the fact that renders a defendant's conduct illegal is derived from a CFR. *See Liparota v. United States*, 471 U.S. 419, 425 (1985) (interpreting a statute criminalizing "knowingly possess" or "use" food stamps in an unauthorized manner as requiring knowledge that the use is unauthorized.). Issuing prescriptions outside the scope of professional practice "is the 'crucial element' separating innocent from wrongful conduct." *Rehaif v. United States*, 139 S. Ct. 2191, 2197 (2019) (*quoting X-Citement Video*, 513 U.S. at 73, 115 S.Ct. 464.

The CDC and FDA guidelines on treating chronic pain are explicitly not mandatory. There is no professional body or authority a doctor can go to in an effort to determine whether a given prescription runs afoul of the usual course of professional practice. Removing any requirement that the government prove a medical professional is knowingly acting outside the scope of professional practice subjects a wide range of well-intentioned medical practitioners, who issue prescriptions that in fact serve a legitimate medical purpose, to the threat of incredible penalties. This court does not "construe a criminal statute on the basis that the government will use it reasonably." *McDonnell v. United States*, 136 S. Ct. 2355, 2372-73 (2016) (quoting *United States v. Stevens*, 559 U.S. 460, 480 (2010)). " [A]a statute ... that can linguistically be interpreted to be either a meat axe or a scalpel should reasonably be taken to be the latter."). *Id*.

CONCLUSION

For the foregoing reasons, Petitioner respectfully prays that the Court will grant his Petition for Certiorari.

Respectfully Submitted,

July 6, 2021_
DATE

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