No. 21-5261

In The
Supreme Court of the United States

SHAKEEL KAHN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

BRIEF OF PETITIONER

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QUESTIONS PRESENTED

1. Where the government prosecutes a medical practitioner under the Controlled Substances Act for issuing a prescription "outside the usual course of professional practice," is the government required to prove that the doctor *knew* or *intended* that the prescription be outside the scope of professional practice?

2. Does a "good faith" defense in the context of a licensed medical practitioner prosecuted under the Controlled Substances Act protect doctors who have an honest but mistaken belief that they have issued the charged prescription in "the usual course of professional practice"; and, if so, must that belief be objectively reasonable?

3. Should the "usual course of professional practice" and "legitimate medical purposes" prongs of 21 C.F.R. § 1306.04(a) be read in the conjunctive or the disjunctive?

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OPINION BELOW

United States v. Kahn, 989 F.3d 806 (10th Cir. 2021).

JURISDICTION

The court of appeals' judgment was entered on February 25, 2021. Pet. App. 40. Petitioner filed a timely petition for writ of certiorari on June 26, 2021, which this court granted on November 05, 2021. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

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."

18 U.S.C. § 841(a)(1) states:

> "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally – 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 the requirements for lawful prescription by a physician:

> "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."

STATEMENT OF THE CASE

As applied to medical practitioners charged under § 841, the government must prove not only that a defendant-doctor knowingly issued the charged prescriptions, but also that he did not do so "for a legitimate medical purpose . . . acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Generally, the circuits hold that this provision outlines two distinct elements, which the government may prove in the alternative. Under that view, a defendant is guilty if he issues a prescription without a legitimate medical purpose *or* outside the usual course of professional practice. *Id*. The consensus view among the circuits is that "legitimate medical purpose" poses a subjective question regarding whether the defendant believed his prescription served a legitimate medical purpose.

The central question before this Court today is what level of scienter, if any, must the government establish where a physician is accused of acting outside the "usual course of professional practice." The second question presented by petitioner is whether these two requirements should be read disjunctively. Can a doctor be convicted as a drug dealer under § 841 if he has a sincere belief that a charged prescription is serving a legitimate medical purpose?

A. Factual Background And Evidence Presented At Trial

Shakeel Kahn is a medical doctor registered with the DEA to issue prescriptions for controlled substances under the Controlled Substances Act. R. 356 at 1. The Third Superseding Indictment charged Kahn with conspiracy to distribute controlled substances, operating a continuing criminal enterprise, and multiple substantive counts of distributing controlled substances including one resulting in death. R. 356. There is no dispute that Dr. Kahn issued the charged prescriptions. Rather, the question at trial was whether he had a legitimate medical purpose for doing so and if he was acting in good faith in the usual course of professional practice.

Dr. Kahn's medical practice did not live up to the model of consistency and caution that one might hope for in a practice specializing in long term pain management. His physical examination of patients was (while varying in length) sometimes cursory. R. 912 at 43-44, 206-08, 230-37; R. 913 at 216; R. 914 at 36. Depending upon the patient, he implemented urine screens, but often did so sporadically. R. 912 at 198; R. 915 at 61; R. 918 at 48. He kept medical records, but they were often not as thorough as one would hope. The government successfully established that several of Dr. Kahn's patients were diverting or abusing their medication. R. 912 at 107; R. 912 at 243; R. 913 at 104; R. 913 at 194; R. 914 at 63; R. 914 at 161; R. 918 at 48; R. 920

at 197. Dr. Kahn testified that he would not have issued prescriptions to individuals that he knew to be selling their medication. R. 923 at 51, 193

1. Testimony Of Patient-Witnesses

Each patient witness called by the government presented petitioner with evidence of a medical condition capable of causing real and significant pain. R. 911 at 145 (herniated disc); R. 912 at 200 (multiple sclerosis and optic neuritis); R. 912 at 230 (endometriosis); R. 912 at 254-56 (real pain helped by medication); R. 913 at 12-13 (neurological records regarding back injury and migraines); R. 913 at 199-200 (thyroid condition and degenerative disc disease); R. 914 at 23 (significant back pain); R. 915 at 74-75 (lengthy medical history including back pain); R. 918 at 47 (testifying she wouldn't refer any patient to Petitioner if they could not prove an underlying medical condition). Petitioner requested and received (if sometimes incomplete) medical records or MRI's supporting those conditions. R. 913 at 13, at 201; R. 918 at 99; R. 912 at 101-02. Patients filled out pain contracts and informed consent documents detailing the risk of opioids at every visit and disclosed any change in their pain or use of the prescriptions. R. 911 at 138, 163; R. 914 at 23-24, 98-99, 214; R. 913 at 12-13, 221. In many cases, similar medications were prescribed by previous or

subsequent doctors. R. 912 at 148-49, 254; R. 913 at 141, 198; R. 914 at 26; R. 915 at 126.

In order to obtain the charged prescriptions, each of the patient-witnesses who testified admitted that they lied to Dr. Kahn either about the degree of pain they experienced or whether they suffered an underlying medical condition. R. 911 at 144; R. 912 at 190-92, 219-20; R. 912 at 240; R. 913 at 12; 32-33; R. 913 at 266; R. 914 at 104-05; R. 914 at 197, 238; R. 915 at 135-36; R. 921 at 9; R. 918 at 48. This often involved more than a simple exaggeration of pain levels or denial of bad intent in seeking the medication. For example, in order to circumvent the routine urinalysis tests and prevent Petitioner from learning that she was not taking, but rather selling, her medication, patient Antelope would save a pill to take the day of her visit. R. 918 at 48. Another patient covered his track marks with make-up in order to hide detection of his heroin use when his blood pressure was taken. R. 912 at 122. A third patient sought the advice of a nurse practitioner regarding how to answer questions in order to optimize his chances of securing a prescription for opioids. R. 920 at 195. In order to explain a lack of complete medical records, patient Vargas, as well as the undercover agent acting as a patient, indicated that they were previously treated by a local doctor whose practice had closed. R. 913 at 119; R. 920 at 202-03; R. 919 at 35-38. The undercover agent testified that the purpose of his scheduling an appointment with was to trick Dr. Kahn by convincing him that

the agent suffered from pain when he really did not. R. 919 at 53.

With one exception, each of the witnesses testified that they did not have an agreement with Dr. Kahn to abuse or divert their medication and/or believed that, if Dr. Kahn learned they were abusing or diverting medication, they would be discharged as a patient. R. 912 at 141-43, 257; R. 913 at 100, 126, 197, 290-91, 297-98; R. 914 at 65, 112, 256; R. 921 at 15-16.[1]

2. Testimony Of The Government's Expert

Dr. Jed Shay testified as the government's expert on pain management. R. 910 at 4-257; R. 913 at 164-91. Dr. Shay reviewed 22 of Dr. Kahn's patient files. Dr. Shay analyzed these files by comparing them to the Federation of State Medical Boards model guidelines for pain treatment, the CDC guidelines, the Wyoming chronic pain management tool kit, and the guidelines imposed by various insurance companies. R. 910 at 22, 70. Dr. Shay testified that each of the files he reviewed were outside the scope of professional practice. Dr. Shay acknowledged that none of these guidelines are mandatory and, indeed, that the fact that they are sometimes thought of as mandatory has caused problems in the pain management field. R. 910 at 255. Dr. Shay could not say that Dr. Kahn knew of the medical

[1] The one exception is Ms. Antelope. R. 918 at 37-40. Her consistency and credibility on this point was in serious doubt. R. 918 at 86-98, 108-11.

regulations, but he did say that he "should have known." R. 913 at 175.

None of the guidelines referenced in Dr. Shay's testimony provide specific or detailed procedures that a doctor must follow before issuing a prescription. The Federation of State Medical Board Model Guidelines direct medical boards evaluating the sufficiency of a doctor's pain practice to analyze whether there was (1) "inadequate monitoring," (2) "inadequate attention" to informed consent, (3) "unjustified dosage increases," (4) "excessive" reliance on opioids and (5) failure to make use of available tools for risk mitigation. R. 910 at 20-22.

Under the guidelines, there is no specific requirement on how long a physical examination must take. (Dr. Shay himself sees 50 patients per day, the majority of whom are on opioids). *Id.* 67-68. Physical examinations are unable to detect a patient's pain level. *Id.* 40. There is no specific time period for how long a patient may receive a prescription without having an appointment. *Id.* 98. Nor is there any mandatory timeframe as to how often a patient must see a doctor. *Id.* 232. There is no specific upper limit on opioid prescriptions. Vol 4. Tr. 98. Serious disagreement exists in the medical community about the efficacy of high dosage opioid treatments. *Id.* 254. There is no mandatory prohibition on the prescription of certain drug combinations. Prescribing even potentially dangerous combinations of drugs may be appropriate. *Id.* 65, 229. Dr. Shay testified that patients can and do go out of their way to lie to doctors, and that even if a doctor asks all the right

questions, patients may still fool them. *Id.* 250; R. 913 at 172. No tools can detect addiction. R. 910 at 251. There are no mandatory rules requiring the use of drug screening or urinalysis and, in fact, there is disagreement in the medical community as to the efficacy of urinalysis. *Id.* 226. Finally, even where a patient violates a pain contract, cutting off a patient's medication is outside the scope of professional practice because it subjects them to withdrawal. *Id.* 76-77.

Dr. Shay's testimony highlights the ambiguity in determining when and by what degree a defendant must violate medical board guidelines before he is rendered "outside the scope of professional practice." Dr. Shay testified repeatedly that medicine was both an "art and a science." *Id.* 88; 99. R. 913 at 185. Dr. Shay indicated that he generally examines medical records for an overall "impression" as to whether a physician is in compliance with the Model Guidelines. R. 910 at 81 ("but I can nitpick"). Dr. Shay appeared to agree that a single instance of malpractice or sloppy record keeping was insufficient to render a doctor criminal or outside the "usual course of professional practice" and that analysis should be conducted with review of a doctor's overall practice. *Id.* 237, 248.

Many of the forms used by Dr. Kahn were similar to those used by Dr. Shay and were, "on paper," sufficient to establish informed consent. *Id.* 107-74. Nevertheless, Dr. Shay determined that failure to document in his medical records that he had verbally gone over the drug addiction statement and the informed consent with his patients rendered the prescriptions

outside the scope of professional practice. *Id.* 65-66, 107. This is true, in Dr. Shay's assessment, even if there were good and legitimate reasons to issue the charged prescriptions. *Id.* 114, 206. Similarly, Dr. Shay testified that in order to be within the scope of professional practice a doctor must determine a treatment plan, and that failure to specifically document a comprehensive treatment plan in medical records rendered the prescriptions outside the scope of professional practice. *Id.* 119, 218. Even where a doctor obtains and reviews medical records or tests, failure to document that review in a patient's medical file renders the prescription outside the "usual course" of professional practice. *Id.* 89, 181-82.

B. Jury Instructions

The district court instructed the jury that "good faith on the part of Defendant Shakeel Kahn would be inconsistent with knowingly and intentionally distributing and/or dispensing controlled substances outside the usual course of professional practice and without a legitimate medical purpose which is an essential part of the charges." However, the district court went on to instruct the jury that " 'Good faith' connotes an attempt to act in accordance with *what a reasonable physician should believe* to be proper medical practice," and that "[t]he good faith defense requires the jury to determine whether Defendant Shakeel Kahn acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." R. 741 at 58-59. Petitioner

argued that the government must prove *both* that the instant prescriptions were written "outside the usual course of the medical practitioner's profession" and without a "legitimate medical purpose." R.729 at 8-9; R. 925 at 7.

C. Decision Below

Dr. Kahn was convicted of all counts and sentenced to 25 years in prison. On appeal, the Tenth Circuit held that the elements of legitimate medical purpose and usual course of practice should be read in the disjunctive, and that while medical purpose required the government to prove that the defendant "subjectively knew a prescription was not issued for a legitimate medical purpose," usual course required only that the government prove that a prescription was "objectively not in the usual course of professional practice." *United States v. Kahn*, 989 F.3d 806, 825 (10th Cir. 2021) ("[t]hus, the only relevant inquiry under that second prong is whether a defendant-practitioner objectively acted within that scope, regardless of whether he believed he was doing so."). The Tenth Circuit found the "good faith" instruction does not define the defendant's mental state, but rather "the scope of professional practice, and thus the effectiveness of the prescription exception and the lawfulness of the *actus reus*." *Id.* 826.

SUMMARY OF ARGUMENT

Section 841 has never been interpreted by this court as a public welfare statute. *McFadden v. United States*, 576 U.S. 186, 188-89 (2015). Under the Controlled Substances Act, every criminal sanction explicitly imposed on registrants requires knowledge. 21 U.S.C. § 843. In interpreting congressional statutes, this Court has long imposed a presumption of favor of scienter. *Rehaif v. United States*, 139 S. Ct. 2191, 2195 (2019). Generally, the presumption in favor of scienter applies to each element that describes the "evil Congress seeks to prevent." *Id.* 2196.

The consensus view among the circuits is that a doctor can be prosecuted under § 841 if she acts outside the "usual scope of professional practice" by prescribing medication not "in accordance with a standard of medical practice generally recognized and accepted in the United States." *United States v. Merrill*, 513 F.3d 1293, 1306 (11th Cir. 2008). That element is essential to guilt and essential to blameworthiness. Therefore, under this Court's case law presuming scienter, in order for a defendant to be guilty under § 841, she must act knowingly as to that element: that is, she must issue a prescription knowing it to be outside the usual course of professional practice.

A good faith instruction based on negligence is inconsistent with a knowing *mens rea*. *Cheek v. United States*, 498 U.S. 192, 201 (1991). The district court in this case issued a good faith instruction indicating that "Good faith connotes an attempt to act in accordance

with *what a reasonable physician should believe* to be proper medical practice." R. 741 at 58-59. The good faith instruction in this case provided the jury with an "objective" *mens rea* element. A *knowing mens rea* is necessarily a subjective one. Therefore, if knowledge, or even recklessness, is required to convict a registrant under § 841, the jury instructions in this case were in error.

The consensus view among the circuits is that a medical practitioner can be convicted if she either (1) acted outside the usual course of professional practice or (2) without a legitime medical purpose. Historically, the "course of professional practice" was defined by whether a doctor issued a prescription for a legitimate medical purpose. The phrase "usual course of professional practice," when unmoored from "medical purpose," is unconstitutionally vague. It suffers from a dual "indeterminacy" problem. *Johnson v. United States*, 135 S. Ct. 2551, 2558 (2015). It does not define the standard by which a given practitioner's decisions should be judged. Nor does it identify the degree of deviation from the standard that renders a give prescription or practice criminal.

ARGUMENT

I. The Language And Framework Of The CSA And This Court's Caselaw Imposing A Presumption In Favor Of Scienter Requires That The Government Prove A Medical Practitioner Charged Under § 841 Knowingly And Intentionally Acted "Outside Of The Usual Course Of Professional Practice."

A. This Court's Long-Standing Case Law Imposing A Presumption In Favor Of Scienter Requires The Government Prove That A Practitioner Knew That Charged Prescriptions Were Outside The "Usual Course Of Professional Practice."

This Court has repeatedly held that "[i]n determining Congress's intent," it starts "from a longstanding presumption, traceable to the common law, that Congress intends to require a defendant to possess a culpable mental state regarding 'each of the statutory elements that criminalize otherwise innocent conduct.'" *Rehaif*, 139 S. Ct. at 2195; *Elonis v. United States*, 575 U.S. 723, 734 (2015); *Morissette v. United States*, 342 U.S. 246, 250 (1952); *United States v. X-Citement Video, Inc.*, 513 U.S. 64 (1994); *Posters 'N' Things, Ltd. v. United States*, 511 U.S. 513, 522 (1994). Every circuit court recognizes that "usual course of professional practice" and "legitimate medical purpose" are elements (albeit elements that may be proven in the disjunctive) of § 841 when violation

is charged against a medical professional.[2] While the CSA did not specifically articulate a *mens rea* as to those elements, this Court's case law presuming scienter requires that a doctor issue a prescription knowing it to be outside the "usual course" of professional practice in order to be guilty of a criminal offense.

The CSA does not articulate a minimum standard of care necessary to deprive a doctor of her authorization to issue prescriptions under § 841 and is silent as to what *mens rea* the government must prove in order to obtain a conviction of a medical practitioner under § 841.

The Controlled Substances Act ("CSA") is an omnibus Act creating "a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006); 21 U.S.C. § 801 *et seq*. The CSA includes two different types of provisions, the general prohibition on unauthorized distribution

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[2] *United States v. Limberopoulos*, 26 F.3d 245, 249-50 (1st Cir. 1994); *United States v. Wexler*, 522 F.3d 194, 206 (2d Cir. 2008); *United States v. Li*, 819 F. App'x 111, 118 (3d Cir. 2020) (unpublished); *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006). *See United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004); *United States v. Armstrong*, 550 F.3d 382, 395-401 (5th Cir. 2008), *overruled on other grounds by United States v. Guillermo Balleza*, 613 F.3d 432, 433 n.1 (5th Cir. 2010); *United States v. Godofsky*, 943 F.3d 1011, 1017 (6th Cir. 2019); *United States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007); *United States v. Joseph*, 709 F.3d 1082, 1094 (11th Cir. 2013).

(§ 841(a)) and penalty provisions targeted specifically at doctors and other registrants. *See*, *e.g.*, § 842, § 843.

The petitioner in this case was charged under 21 U.S.C. § 841(a):

> "*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 the intent to manufacture, distribute, or dispense, a controlled substance."

21 U.S.C. § 841 (emphasis added).

Section 822 indicates that "persons registered by the Attorney General under this subchapter to . . . distribute . . . controlled substances . . . are authorized to possess, manufacture, distribute, or dispense such substances . . . *to the extent authorized by their registration and in conformity with the other provisions of this subchapter*." 21 U.S.C. § 821 (emphasis added). Under the CSA, different registration requirements apply to medical practitioners depending upon the class of substance they are prescribing and the purpose of the prescriptions. *See, e.g.*, 21 U.S.C. § 823 (describing different obligations and registrations for doctors dispensing as part of a detoxification program).

As the Court recognized in *Moore*, there is something of a circularity to the scope of a doctor's authorization. *United States v. Moore*, 423 U.S. 122, 124 (1975) ("Section 822(b) defines the scope of authorization under the Act in circular terms."). Unlike the 1914 Harrison Anti-Narcotics Act ("Harrison Act"), the CSA does

not explicitly state that the scope of a registrant's prescription authority is limited to the "usual course of professional practice." *Id*. 139-40 ("The difficulty arises because the CSA, unlike the Harrison Act, does not spell out this limitation in unambiguous terms."); Harrison Narcotics Act, 38 Stat. 785, 786 (Comp. St. §§ 6287g-6287q) (1914).[3] Section 802(21) defines practitioner as "a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance *in the course of professional practice* or research." 21 U.S.C. § 802(21) (emphasis added). The CSA provides no guidance defining the limits of the "course of professional practice."

The "legitimate medical purpose" and "usual course of professional practice" language is derived from 21 C.F.R. § 1306.04.

> "A prescription for a controlled substance to be effective must be issued for a legitimate

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[3] "[I]t shall be unlawful for any person to sell, barter, exchange, or give away any of the aforesaid drugs except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Commissioner of Internal Revenue. . . . Nothing contained in this section shall apply—

(*a*) To the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon registered under this act in the course of his professional practice only . . . " 38 Stat. 785, 786 Sec. 2(a).

> medical purpose by an individual practitioner acting in the usual course of his professional practice."

21 C.F.R. § 1306.04.

In *Moore*, this Court reasoned that exempting all doctors from liability under § 841, even when not acting in the scope of professional practice, "would constitute a sharp departure" from the previous Harrison Act standard and that "there is no indication that Congress had any such intent." *Moore*, 423 U.S. at 132.

The Circuits now recognize "usual course of professional practice" ("usual course prong") and "legitimate medical purpose" ("medical purpose prong") to represent two distinct elements (which may be charged and proven in the alternative), one of which the government must prove in order to secure the conviction of a medical practitioner under § 841.

Because the CSA itself does not explicitly require that a prescription be issued within the "usual course of practice" or "for a legitimate medical purpose," it is unsurprising that it is silent as to what *mens rea* is required to establish those elements. However, Congress's silence on this point cannot be taken as evidence that it intended to subject doctors to strict liability under § 841 for any prescription that falls outside the "usual course of professional practice" or was issued "without a medical purpose." "[F]ar more than the simple omission of the appropriate phrase from the statutory definition is necessary to justify dispensing with an intent requirement." *United States Gypsum*

Co., 438 U.S. at 438. "[S]ome indication of congressional intent, express or implied, is required to dispense with *mens rea* as an element of a crime." *Staples v. United States*, 511 U.S. 600, 605 (1994).

1. The Presumption In Favor Of Scienter Requires That The Government Prove That A Defendant-Practitioner Issued A Prescription Knowing It To Be Outside The "Usual Course" Because "Usual Course" Is The Element That Distinguishes Between An Innocent And Guilty Act.

"The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It 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." *Morissette*, 342 U.S. at 250; *United States Gypsum Co.*, 438 U.S. at 436-37 ("The existence of a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence.").

This presumption in favor of scienter applies to each element that describes the "evil Congress seeks to prevent." *Rehaif*, 139 S. Ct. at 2196 ("The presumption of scienter should be applied to all elements necessary to "separate those who understand the wrongful nature of their act from those who do not.") (*quoting Torres v. Lynch*, 578 U.S. 452, 467 (2016)); *X-Citement Video*, 513 U.S. at 72 (" . . . should apply to each of the

statutory elements that criminalize otherwise innocent conduct."); *Staples*, 511 U.S. at 610 (applying the presumption of scienter "to avoid construing a statute to dispense with *mens rea* where doing so would 'criminalize a broad range of apparently innocent conduct.' ") (*Liparota v. United States*, 471 U.S. 419, 426 (1985)).

For most people, knowingly distributing a controlled substance is blameworthy conduct, and a significant crime under § 841. For a registered medical professional, however, knowingly issuing a prescription for a controlled substance is not blameworthy. To the contrary, it is her job. As applied to a medical professional, issuing a prescription is, at least on its face, "apparently innocent conduct." *Id.* 426.

A fundamental conceit of the CSA's structure is that the distribution of controlled substances by a medical practitioner is, by itself, entirely legitimate. Therefore, it is not the act of issuing the prescription that was the "evil Congress [sought] to prevent." *Rehaif*, 139 S. Ct. at 2196. Rather, the evil Congress sought to prevent was issuing a prescription *outside the scope of practice without a legitimate medical purpose*. That is the " 'crucial element' separating innocent from wrongful conduct." *Id.* (*quoting X-Citement Video*, 513 U.S. at 73).

In the absence of some clear expression of Congressional intent, "usual course of professional practice" must require *some* scienter. To hold otherwise would be to subject a broad range of well-intentioned

doctors, who (even if wrongly) believed that they were issuing medically necessary prescriptions in keeping with the current standards of medical practice, to draconian sentences. One would expect that if Congress truly sought to allow medical professionals to face decades-long mandatory minimum sentences and potential life imprisonment for errors in judgement, they would have spoken more clearly—or at all.

Nor can § 841 be construed as a public welfare statute. This Court has recognized that in "limited circumstances," the presumption of scienter is not appropriate. *United States Gypsum Co.*, 438 U.S. at 437. Typically, these statutes involve regulatory violations in heavily regulated industries involving "potentially harmful or injurious items." *Staples*, 511 U.S. at 607; *United States v. Int'l Mins. & Chem. Corp.*, 402 U.S. 558, 565 (1971); *Morissette*, 342 U.S. at 257.

"Historically, the penalty imposed under a statute has been a significant consideration in determining whether the statute should be construed as dispensing with *mens rea*." *Staples*, 511 U.S. at 616; Sayre, *Public Welfare Offenses*, 33 Colum. L. Rev. 55, 72 (1933) ("cardinal principle" of public welfare offenses that the penalty not be severe); Rollan M. Perkins, *The Civil Offense*, 100 U. Pa. L. Rev. 832, 845-46 (1952) ("On the other hand the penalty for a civil offense should never be severe. The maximum should be a moderate fine or something of a comparable nature. It should never include imprisonment."). The length of the sentences at issue in these cases is, by itself, dispositive evidence that § 841 is not a public welfare offense. *Gypsum*

involved a potential three-year statutory *maximum*. There, this court held that, "[t]he severity of these sanctions provides further support for our conclusion that the [Act] should not be construed as creating strict-liability crimes." *Gypsum*, 438 U.S. at 442, n.18. This Court has repeatedly held that statutes imposing a 10-year statutory *maximum* should not be construed as "public welfare offenses." *Staples*, 511 U.S. at 616*; X-Citement Video, Inc.*, 513 U.S. at 72; *Rehaif*, 139 S. Ct. at 2197. Where defendants are charged under § 841, they are often subject to decades-long mandatory minimums and the possibility of life imprisonment.

Petitioner does not contend that controlled substances are not potentially dangerous and heavily regulated items. However, application of the public welfare exception to the presumption in favor of scienter is not automatic whenever a statute concerns a dangerous item. This Court has rejected application of the public welfare exception in cases involving firearms. *See, e.g.*, *Rehaif*, 139 S. Ct. at 2196; *Staples*, 511 U.S. at 609. Firearms are no doubt dangerous and subject to significant regulation. However, as noted in *Staples*, the fact that "an item is 'dangerous,' in some general sense, does not necessarily suggest . . . that it is not also entirely innocent." 511 U.S. at 611.

Nor does the fact that the offense turns on the violation of a federal regulation automatically render the statute a public welfare offense. In *Liparota*, 471 U.S. at 421, this Court rejected application of the public welfare exception to a statute which criminalizes the knowing use of food stamps "in any manner

not authorized by . . . the regulations." This Court held that, under the statute, in order to be guilty, the defendant must know "that he was acting in a manner not authorized by statute or regulations." *Id.* The Court reasoned that specific intent was "particularly appropriate where, . . . to interpret the statute otherwise would be to criminalize a broad range of apparently innocent conduct." *Id*. 426.

The Court's holding in *United States v. Balint*, 258 U.S. 250, 251 (1922) does not compel a contrary result. In *Balint*, the defendants were charged with violating Section 2 of the Harrison Narcotics Act, by selling of opium without obtaining a written order from the Commissioner of Internal Revenue. *Id*. The Defendants in that case argued that the indictment was insufficient because it did not allege that they had knowledge that the drugs being distributed were subject to the regulation at issue. *Id*. At the time, the Harrison Act was interpreted by the Court as primarily a taxing act, which (contrary to the modern rule) did not require intent. *United States v. Doremus*, 249 U.S. 86, 94 (1919); *United States v. Jin Fuey Moy*, 241 U.S. 394 (1916). The Court found that proof of the defendant's knowledge that the drug he was selling is one that falls under the ambit of the statute is not necessary. *Balint*, 258 U.S. at 254. The Court reasoned that the purpose of the act was to "require every person dealing in drugs to ascertain at his peril whether that which he sells comes within the inhibition of the statute, and if he sells the inhibited drug in ignorance of its character, to penalize him." *Id.*

The Harrison Act is not § 841. First, Section 2 of the Harrison Act does not have an explicit *mens rea*. Rather, that Act simply declared that distributing certain narcotics without an order from the Internal Revenue service was "unlawful." 38 Stat. 785, 786. By contrast, § 841 explicitly requires proof of the knowing distribution of a controlled substance. 21 U.S.C. § 841. This Court has interpreted § 841 to require, if not knowledge of the law, at least either knowledge of the actual substance being possessed, or knowledge that the substances was some controlled substance. *McFadden*, 576 U.S. at 188-89 ("We hold that § 841(a)(1) requires the Government to establish that the defendant knew he was dealing with "a controlled substance.").

Where Congress is explicit in applying a particular *mens rea* to some element of a statute, this Court imposes a "broadly applicable" scienter requirement imposing that same *mens rea* on every material element of the offense. *X-Citement Video, Inc.*, 513 U.S. at 70; *Rehaif*, 139 S. Ct. at 2195 ("[Presumption of scienter] applies with equal or greater force when Congress includes a general scienter provision in the statute itself.") (*quoting* ALI, Model Penal Code § 2.02(4), p. 22 (1985)); *Elonis*, 575 U.S. at 723 ("broadly applicable scienter requirements"); *X-Citement Video, Inc.*, 513 U.S. at 79 (J. Stevens, concurring) ("Surely reading this provision to require proof of scienter for each fact that must be proved is far more reasonable than adding such a requirement to a statutory offense that contains no scienter

requirement whatsoever."). This Court has "interpreted statutes to include a scienter requirement even where 'the most grammatical reading of the statute' does not support one." *Rehaif*, 139 S. Ct. at 2197; *X-Citement Video*, 513 U.S. at 70 ("Our reluctance to simply follow the most grammatical reading of the statute is heightened by our cases interpreting criminal statutes to include broadly applicable scienter requirements.").

In addition, regardless of whether the Harrison Act imposed strict liability as to whether a substance fell under the ambit of the statute, at least as applied to the question of whether a *doctor* was acting outside the scope of professional practice, the Harrison Act *did not* impose strict liability. Rather, under the Harrison Act, defendants were often given the benefit of *subjective* good faith defenses, focusing on the doctors' *subjective* beliefs and intent in issuing the charged prescriptions. *See* Sec. III infra.

The second, and perhaps more important difference between the Harrison Act and the section 841 is the sheer length of sentences available. The Harrison Act imposed a maximum sentence of five years for the offense. Five years and life imprisonment are very different outcomes. This Court has never held that application of the public welfare exception to the presumption of scienter turns exclusively on the nature of the item Congress seeks to regulate.

B. The Structure And Legislative History Of The CSA Suggest That Congress Intended To Shield Medical Practitioners From Criminal Liability In The Absence Of Knowledge.

"Whether a criminal statute requires the Government to prove that the defendant acted knowingly is a question of congressional intent." *Rehaif*, 139 S. Ct. at 2195; *Staples*, 511 U.S. at 605 ("[S]ome indication of congressional intent, express or implied, is required to dispense with *mens rea* as an element of a crime."). The CSA, read as a whole, suggests that Congress intended to protect doctors from criminal sanctions for accidental and even negligent violations. Sections 842 and 843 list several requirements to which medical practitioners must adhere when issuing prescriptions.[4] Congress was explicit in limiting liability for unintentional violations of § 842 to civil penalties. *See* 21 U.S.C. § 842(c)(1)(A) ("[A]ny person who violates this section shall, with respect to any such violation, be subject to

[4] While these provisions are sometimes described as "technical violations" some of the potential missteps constitute serious misconduct necessarily requiring reckless or negligent behavior. For example, § 842(2) makes it unlawful for registrants "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.*" § 842(2) (emphasis added). Similarly, § 842(11) makes it unlawful for a registrant "to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this subchapter or subchapter II, *with reckless disregard for the illegal uses to which such a laboratory supply will be put.*" § 842(11) (emphasis added).

a civil penalty of not more than $25,000."). It is only where the violation is committed intentionally or knowingly that criminal sanctions (of one year) can attach. 21 U.S.C. § 842(c)(2)(A); 21 U.S.C. § 843 ("Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense."). Similarly, even where a medical professional obtains a registration through *fraud* or obtains a controlled substance through *fraud*, knowledge is required. 21 U.S.C. § 843 (West) (four-year statutory maximum).

It would be incongruous to assume that Congress, which was so careful and explicit in protecting doctors from the possibility of criminal sanctions for unintentional violations of these statutes, would have intended to subject doctors to far more draconian penalties under § 841 based on some lesser *mens rea*.

Nothing in the legislative history suggests that Congress intended the CSA to permit the prosecution of doctors for *unknowingly* stepping outside the scope of professional practice. The House Interstate and Foreign Commerce Committee report suggests that Congress did not intend to regulate the *methods* of medical practice at all. The report suggests that drafters of the CSA were "Concerned about the appropriateness of having federal officials determine the appropriate *method* of the practice of medicine." H.R.Rep.No. 91-1444, pp. 14-15 (emphasis added). The House Report

noted that "There is no doubt that a physician may prescribe narcotic drugs for a patient suffering acute pain or from a painful and incurable disease. But a controversy has existed for 50 years over the extent to which narcotic drugs may be administered to an addict solely because he is an addict."). *Id.* (*quoting* Report of the President's Advisory Commission on Narcotic and Drug Abuse 56-57 (1963)). The Committee noted that these controversies and ambiguities in the case law had a chilling effect on the practice of medicine. *Id.* ("The practicing physician has thus been confused as to when he may prescribe narcotic drugs for an addict. Out of fear of prosecution many physicians refuse to use narcotics in the treatment of addicts . . . in most instances they shun addicts as patients."). That Congress did not have the intent to limit the methods of the practice of medicine is codified in 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

There is no clear intent, either on the face of the CSA or in the legislative history, to hold medical practitioners liable under § 841 for unintentional deviations from the standard of care. In the absence of clear congressional intent to the contrary, this court's case law imposing a presumption of scienter requires that the government prove that the defendant knowingly acted outside the scope of professional practice.

II. Where A Medical Professional Is Charged With Acting Outside The Scope Of His Professional Practice, Good Faith Instructions Must Be Subjective.

Instructions defining "good faith" as acting within the scope of what a doctor "reasonably believes" or "should reasonably believe" to be legitimate medical practice create, at best, a negligence standard that permits conviction under § 841 if a doctor negligently acts outside the usual course of medical practice even if he does not do so intentionally. As the Tenth Circuit recognized below, an "objective" good faith instruction is not a good faith instruction, at least as generally understood. *Kahn*, 989 F.3d at 825 ("Unlike other criminal offenses, good faith does not go to *mens rea* for § 841 offenses involving practitioners."). Good faith is a complete defense because it negates the *mens rea* element of an offense. *Cheek*, 498 U.S. at 201. Where a crime requires scienter greater than negligence, limiting a good faith defense to only those defendants whose beliefs are "objectively reasonable" effectively negates that element. *Id.*

In *Cheek*, this Court vacated the defendant's conviction where, in a tax case requiring willfulness, the district court instructed the jury that good faith required that the defendant's beliefs be "objectively reasonable." *Id.* 202. In order to establish willfulness, the government was required to prove that the defendant knew of his legal duty. This Court found that limiting good faith to instances where the defendant's

belief was "objectively reasonable" was not consistent with the statute's requirement that the defendant act with actual knowledge of his legal duty. *Id*. ("In the end, the issue is whether, based on all the evidence, the Government has proved that the defendant was aware of the duty at issue, which cannot be true if the jury credits a good-faith misunderstanding and belief submission, whether or not the claimed belief or misunderstanding is objectively reasonable."). The error in *Cheek* was not cured simply because the elements instruction articulated the correct *mens rea*. *Id.*

The same logic applies to the case at bar. As argued above (*see* Sec. I supra), § 841 requires that medical practitioners issue a prescription knowing it to be outside the usual course of professional practice. Like "willfulness," "knowledge" is a subjective standard. A person acts knowingly when "'he is aware that [a] result is practically certain to follow from his conduct,' whatever his affirmative desire." *Borden v. United States*, 141 S. Ct. 1817, 1823 (*quoting Bailey*, 444 U.S. at 404). "A person who injures another knowingly, even though not affirmatively wanting the result, still makes a deliberate choice *with full awareness* of consequent harm." *Borden*, 141 S. Ct. at 1823 (emphasis added). Whether a defendant knows he is acting outside the scope of professional practice is a subjective question.

As this Court has recognized, "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 737-38 (emphasis added) (*quoting Staples*, 511 U.S. at 606-07). This Court has "long been reluctant to infer that a negligence standard was intended in criminal statutes." *Id.* 737-38 (quotations omitted); *id.* 745 (J. Alito, *concurring*) ("Whether negligence is morally culpable is an interesting philosophical question, but the answer is at least sufficiently debatable to justify the presumption that a serious offense against the person that lacks any clear common-law counterpart should be presumed to require more.").

It does not appear that any of the Circuit Courts impose a recklessness standard. Nor is a recklessness standard consistent with the intent of the CSA. "When interpreting federal criminal statutes that are *silent* on the required mental state [this Court reads] into the statute only that *mens rea* which is necessary to separate wrongful conduct from 'otherwise innocent conduct.'" *Id.* at 736 (*quoting Carter v. United States*, 530 U.S. 255 (2000)); *X-Citement Video,* 513 U.S. at 72. The CSA is not entirely silent as to the *mens rea* required under § 841. Section 841 imposes a general knowledge requirement. *McFadden,* 576 U.S. at 188-89. Applying this scienter "broadly" requires that the government prove the defendant issued the prescription with knowledge that the prescription is outside the usual course of professional practice. *X-Citement Video*, 513 U.S. at 70.

Regardless, "recklessness" is directed at the defendant's *subjective* state of mind. "A person acts

recklessly, in the most common formulation, when he 'consciously disregards a substantial and unjustifiable risk.'" *Borden*, 141 S. Ct. at 1824 (*quoting* Model Penal Code § 2.02(2)(c)). Even in recklessness cases, the defendant's subjective beliefs—whether reasonable or not—are still dispositive. The defendant must *actually* and subjectively believe, if not the certitude of the fact, at least the fact's probable likelihood. That is with actual "*knowledge* that the proscribed effects would most likely follow." *Posters 'N' Things,* 511 U.S. at 523 (emphasis added). Even in recklessness cases, the defendant's subjective beliefs—whether reasonable or not—are still dispositive. The defendant must *actually* comprehend, if not the certitude of the fact, at least the fact's probable likelihood.

The instructions in this case, like the instructions in *Cheek*, limited good faith to what the defendant "reasonably should have believed." R. 741 at 58-59. This sets forth, and is intended to set forth, an *objective* standard. *Kahn*, 989 F.3d at 825. The purpose and effect of this language is to make clear to the jury that any consideration of the defendant's purpose or knowledge is entirely irrelevant if he acts negligently—*i.e.*, if a reasonable practitioner should know a prescription would be outside the "usual course," the defendant's intent or knowledge does not matter. *Id*. If this Court finds that § 841 requires the government to prove any *mens rea* above negligence when charging registered practitioners, the good faith instruction issued in Petitioner's case was in error.

III. The "Usual Course" And "Medical Purposes" Prongs Must Be Read In The Conjunctive. When Unmoored From The Purpose For Which A Prescription Was Issued, "Usual Course" Becomes Unconstitutionally Vague.

As applied today, whether a doctor is acting "outside the scope of professional practice" and whether a doctor is acting "without a legitimate medical purpose" are two very distinct and separate questions. First, even those circuits finding that the "usual course" prong carries no scienter hold that the "medical purpose" prong requires the government to prove actual knowledge. *Kahn*, 989 F.3d at 825; *United States v. Tobin*, 676 F.3d 1264, 1283 (11th Cir. 2012); *United States v. Norris*, 780 F.2d 1207, 1209 (5th Cir. 1986). Second, the "usual course" prong does not consider whether the prescriptions were actually helping to treat a patient's pain. While "legitimate medical purpose" focuses on (1) a doctor's intent in issuing the prescription, and (2) whether the prescription was beneficial to the patient, "usual course of professional practice" focuses on the manner in which the prescription was issued, and the procedures employed: Did the doctor conduct only cursory physical examinations? Does the doctor provide patients with pain contracts? Does the doctor keep sufficiently complete medical records? *United States v. Ruan*, 966 F.3d 1101, 1139 (11th Cir. 2020) (*cert. granted*, and consolidated with the instant case, 142 S. Ct. 457 (2021) (U.S. Nov 5, 2021) (No. 20-1410)); *United States v. Naum*, 832 F. App'x 137, 142 (4th Cir. 2020) (petition pending before this Court, *Naum v.*

United States, No. 20-1480). Defining "usual course" based exclusively on the procedures a doctor employs without any reference to "medical purpose" renders the phrase indeterminant as to both how the standard should be measured and the degree of compliance required. This dual indeterminacy is exactly the type of indeterminacy this court has found to be unconstitutionally vague. *Johnson*, 135 S. Ct. at 2558 ("By combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony, the residual clause produces more unpredictability and arbitrariness than the Due Process Clause tolerates.").

A. Historically "Medical Purpose" And "Usual Course" Were Considered Related Or Identical Concepts.

The trend in recent decades has been to divorce legitimate medical purpose from usual course of professional practice. In all circuits to have decided the question, save arguably the Ninth (*United States v. Feingold*, 454 F.3d 1001, 1007 (9th Cir. 2006)), "legitimate medical purpose" and "usual course of professional practice" represent two distinct elements that the government may prove in the disjunctive. *See Nelson*, 383 F.3d 1227; *Armstrong*, 550 F.3d at 395-401, *overruled on other grounds by United States v. Guillermo Balleza*, 613 F.3d 432, 433 n.1 (5th Cir. 2010); *Bek*, 493 F.3d at 798; *Limberopoulos*, 26 F.3d at 249-50; *McIver*, 470 F.3d at 559; *Joseph*, 709 F.3d at

1094.[5] The Fourth Circuit appears to have recently interjected an additional iteration of the test indicating that "the Government may meet its burden by establishing that the physician's actions were not for legitimate medical purposes in the usual course of professional medical practice *or* were beyond the bounds

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[5] In *United States v. Boettjer*, 569 F.2d 1078, 1081 (9th Cir. 1978), the Ninth Circuit held that "A close look at the pertinent regulation reveals that the requirements of 'legitimate medical purpose' and 'usual course' both must be met in order for a prescription to be validly issued. The absence of either would support a conviction under 21 U.S.C. § 841." The Ninth Circuit's reasoning was based on the conclusion that the "'usual course' standard itself imports considerations of medical legitimacy and accepted medical standards." *Id.* 1081 (*citing Moore*, 423 U.S. at 138-143). "Proof beyond a reasonable doubt that the prescriptions were not issued pursuant to a legitimate medical purpose suffices to place them beyond the activities authorized by the Controlled Substances Act." *Id.* The Ninth Circuit clarified that, as written, the jury instructions could be read to permit "a conviction where the doctor's conduct in issuing the prescriptions failed either to be 'in good faith for a legitimate medical purpose' or 'in accordance with medical standards generally recognized and accepted in the medical profession' . . . thereby condemning all conduct which fails to satisfy both tests." Such a reading "would theoretically permit a conviction where a practitioner had merely fallen below the standards 'generally recognized and accepted in the medical profession,' i.e., merely upon a showing of malpractice." As the *Boettjer* court recognized, that "result would clearly be contrary to the letter and spirit of the statute, and, to the extent the given instruction countenanced this result, it was deficient." *Id.* 1082. *See Feingold*, 454 F.3d at 1008 ("Simply put, to convict a practitioner under § 841(a), the government must prove . . . (2) that the distribution of those controlled substances was outside the usual course of professional practice and without a legitimate medical purpose, and (3) that the practitioner acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice.*") (emphasis added).

of professional medical practice." *Naum*, 832 F. App'x at 142.

While admittedly sparce and not entirely uniform, published Harrison Act cases generally defined whether a defendant was acting in the "course of his professional practice" as being dependent upon whether the doctor honestly believed that he was issuing a prescription in a sincere attempt to treat a medical condition. For example, in *Linder v. United States*, 268 U.S. 5, 22 (1925) this Court reversed a defendant's conviction because "the facts disclosed [in the indictment] indicate[d] no conscious design to violate the law, no cause to suspect that the recipient intended to sell or otherwise dispose of the drugs, and no real probability that she would not consume them." *Id*. In *Boyd v. United States*, 271 U.S. 104, 105 (1926), the good faith instruction issued by the district court defined good faith as "whether or not the defendant in prescribing morphine to his patients was honestly seeking to cure them of the morphine habit, while applying his curative remedies, it is not necessary for the jury to believe that defendant's treatment would cure the morphine habit, but it is sufficient if *defendant honestly believed his remedy was a cure for this disease*." *Id.* 107-08 (emphasis added). That instruction was "in accord with what this court said in *Linder.*" *Id*.

Ten years later, a district court presiding over a bench trial issued a somewhat lengthy written opinion analyzing *Linder*. *United States v. Anthony*, 15 F. Supp. 553, 556 (S.D. Cal. 1936). The district court acquitted a physician-defendant who issued large amounts of

narcotics to known addicts based on the government's failure to prove intent. "We would have a situation where the courts would arbitrarily say that, irrespective of the belief of the physician that he is effecting a cure or properly prescribing narcotics, the amount is excessive and is *ipso facto* a violation of the law." The Court indicated that under then-existing Supreme Court precedent, "What the law punishes is not bad judgment in a physician, but bad faith." *Id*. 559. The district court found that a judge's prior instructions in the same case were an accurate statement of the law. Those instructions read, in part, "Good faith on the part of the accused is an all-important element in the offenses charged—good faith according to fair or reasonable medical standards *as understood by him*." *Id*. (emphasis added).

The district court in *Anthony* did not appear to be alone in determining a defendant's good faith based on whether the doctor subjectively believed the charged prescriptions were issued for a medical purpose. *See DuVall v. United States*, 82 F.2d 382, 384 (9th Cir. 1936) ("But if the prescriptions were not issued in good faith, but were issued to enable such person to obtain morphine sulphate to satisfy his appetite and cravings for such drugs only, and not in the treatment of his patient, then the issuance of such prescriptions would not be in good faith nor in the course of the defendant's professional practice as a physician, and the sale and dispensing upon such prescriptions would not be lawful."); *Towbin v. United States*, 93 F.2d 861, 865-66 (10th Cir. 1938) ("The fact that he made the record as

to the date of the first dispensing, when the woman's pain was first relieved, indicates absence of any unlawful design."); *Workin v. United States*, 260 F. 137, 141 (2d Cir. 1919) ("Proof is ample to justify the conclusion that the plaintiffs in error conspired to violate this statute and used Dr. Corish to write prescriptions for narcotics without any relation to the prospect of curing the disease or its alleviation. The evidence is ample that the plaintiffs in error conspired that the prescriptions should not be issued in good faith."); *United States v. Bush*, 6 F.2d 303, 304 (W.D. La. 1925), *aff'd*, 16 F.2d 709 (5th Cir. 1927) ("In other words, in my opinion, under the *Linder* Case, it would be lawful for a practicing physician, in treating a bona fide patient who had applied to him for that purpose, to prescribe what, in his professional opinion, in good faith was necessary for the alleviation of the pain and suffering incident to addiction, and, unless there appeared some lack of good faith or ulterior purpose calculated to defeat the collection of the tax, the courts would not be justified in condemning and regulating that discretion."); *Heller v. United States*, 104 F.2d 446, 447 (4th Cir. 1939) ("Without reviewing it in detail, we think there can be no doubt that it furnishes sufficient basis for a finding by the jury that Dr. Heller was giving prescriptions to drug addicts, not in the treatment of disease in the bona fide practice of his profession, but to enable them to secure the drug to gratify the cravings of their appetites; *that Kuhn filled the prescriptions with knowledge of their fraudulent character.*") (emphasis added); *Teter v. United States*, 12 F.2d 224, 225 (7th Cir. 1926) ("In the case at bar,

while the quantity shown to have been sold was not large, nevertheless there was evidence tending to indicate that the sales were not in good faith *from a physician's standpoint*, and were for no other purpose than to enable this addict to further indulge her unfortunate propensities.") (emphasis added); *Strader v. United States*, 72 F.2d 589, 592 (10th Cir. 1934) ("Expert testimony . . . was admissible because of its bearing upon the intent and purpose with which the prescriptions were issued. . . . If appellant issued the prescriptions in good faith as a physician, believing [the receiver] to be a bona fide patient, for the purpose of curing disease or relieving suffering, he was not guilty.").[6]

[6] Indeed, many cases defined good faith as dependent upon whether a medical practitioner was acting for the purpose of catering to and maintaining a patient's addiction for profit. *DuVall*, 82 F.2d at 384 ("If the prescriptions were issued in good faith and according to fair medical standards, in the curing of disease, and not merely to satisfy the cravings of the said persons for such drug, then they may be said to have been issued in the course of the defendant's professional practice only; but if the prescriptions were not issued in good faith, but were issued to enable such person to obtain morphine sulphate to satisfy his appetite and cravings for such drugs only, and not in the treatment of his patient, then the issuance of such prescriptions would . . . not be lawful."); *White v. United States*, 399 F.2d 813, 817 (8th Cir. 1968) (" . . . but who peddles prescriptions without regard to the health or safety of the individual to whom the prescription is given, and with profit as a motive, is not acting within the course of professional practice.").

Similarly, in early CSA cases, the Circuits interpreted the phrases "usual course" and "medical purpose" as meaning approximately the same thing.[7] Where circuit courts first held that the "usual course" prong and "medical purpose" prong could be proved in the disjunctive, they recognized that there was little to no difference in meaning between the two.[8]

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[7] *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975) ("The language clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes.") (*cited with approval in United States v. Plesons*, 560 F.2d 890, 896-97 (8th Cir. 1977)); *United States v. Jackson*, 576 F.2d 46, 48 (5th Cir. 1978) ("Although the indictment does not state that Dr. Jackson acted outside the scope of professional practice, it does allege a more specific activity, i.e., that he dispensed drugs unlawfully 'under the guise and artifice of operating' his clinic. Even a casual reading of the indictment makes clear that Dr. Jackson was alleged to have utilized his clinic as a "front" for dealing drugs, and the language obviously embraces an activity lacking legitimate medical purpose."); *United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978) ("[T]here is no difference in the meanings of the statutory phrase, 'In the usual course of professional practice' and the regulations' phrase, 'legitimate medical purpose.' ").

[8] *Nelson*, 383 F.3d at 1231 ("We note initially that there is considerable room to doubt whether this dispute is of any importance."); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) ("A criminal prosecution requires more—that is, proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e., the personal profit of the physician."); *Armstrong*, 550 F.3d at 395-398 ("This language describes lawful conduct as including a doctor's intentional effort to prescribe for the

Early CSA cases found that the phrase "usual course of professional practice" was not unduly vague. They did so, however, in the context of case law which tied "usual course of professional practice" with the doctor's intent in issuing prescriptions for a legitimate medical purpose. *Rosenberg*, 515 F.2d at 197 ("Here we think that the statute does give such fair notice. This language has been in the statute books since 1914 and no one has ever had problems with its interpretation. The language clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes."); *United States v. Jobe*, 487 F.2d 268, 269 (10th Cir. 1973) ("[T]he statute is not a model of clarity in this respect, but we decided this issue in a recent decision, *United States v. Bartee*, 479 F.2d 484 (10th Cir. 1973), where it was said that it is clear and inescapable 'that when a medical practitioner issues a prescription which is not for a legitimate medical purpose and is not in the usual course of his professional practice,' then he does violate the statute."); *id.* 489 ("in our view permit the inference that [the defendant] in thus prescribing was not acting for a legitimate medical purpose and as such was not within the usual

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purpose of treating a patient's condition. As such, the district court essentially defined conduct 'in the usual course of professional practice' as conduct that is intended 'for a legitimate medical purpose.' "); *Boettjer*, 569 F.2d at 1082 ("Although it is difficult to imagine a situation in which a prescription could be found issued for a legitimate medical purpose, but yet not in accordance with medical standards.").

course of his professional practice."); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) ("Similarly here the physician must make a professional judgment as to whether a patient's condition is such that a certain drug should be prescribed.").

When divorced from "medical purpose" it is not entirely clear what "usual course" means, or that it has any definitive meaning at all. If, as this Court said in *Moore*, Congress did not intend to lessen the obligations of medical practitioners in enacting the CSA, it also serves to reason that they did not intend to expand them. *See Moore*, 423 U.S. at 132.

B. Absent Medical Purpose "Usual Course" Is Unconstitutionally Vague.

When divorced from "legitimate medical purpose," the "usual course" prong becomes hopelessly vague. This is especially true if doctors can be held strictly liable for acting outside the scope of professional practice. *Colautti v. Franklin*, 439 U.S. 379, 395 (1979) ("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*.").

"[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*, 135 S. Ct. at 2556. "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).

The "usual course" prong suffers from two different forms of indeterminacy. It is indeterminate as to how it should be measured because there is no clear way to determine the standard by which "usual course of professional practice" is to be determined. *Gonzales*, 546 U.S. at 257 ("Who decides whether a particular activity is in 'the course of professional practice' or done for a 'legitimate medical purpose?' "). It is also indeterminate as to degree, because it is not clear how "usual" or by what percentage of physicians a practice must be "generally accepted" before deviation becomes criminal.

1. When Unmoored From Medical Purpose, The "Usual Course" Prong Becomes Unconstitutionally Vague Because It Provides Little To No Guidance To Juries Or Prosecutors In Determining How "Usual Course" Should Be Measured.

The circuits recognize that "[t]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice." *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992); *Kirk*, 584 F.2d at 784. The phrase "usual course of professional practice" is not amenable to precise definition. *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995).

However, there is generally consensus that a violation of state or federal laws, regulations, or ethical standards, while certainly relevant to the question of a doctor's good faith, is not sufficient, by itself, to render a defendant guilty under § 841.[9] Further, the Circuit

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[9] *See, e.g.*, *United States v. Abovyan*, 988 F.3d 1288, 1305 (11th Cir. 2021) (acknowledging that prescribing buprenorphine without an X Number as required by 21 U.S.C. § 823(g)(2)(E)(i) is not a "*per se* violation of § 841(a), and, more importantly, this alone does not support a § 841(a) conviction."). *United States v. Goldstein*, 695 F.2d 1228, 1233 (10th Cir. 1981) (pharmacist dispensing from unregistered location not automatically guilty under § 841); *United States v. Temeck*, No. 1:17CR050, 2018 WL 3609503 at *11 (S.D. Ohio July 27, 2018) ("Moreover, the Government has not provided, and the Court has not found, any cases where an unknowing violation of the DEA registration requirement formed the basis of a violation of the Controlled Substance

Courts generally agree that, whatever "usual course of professional practice" means, it requires *more* than even an intentional deviation from the civil duty of care.[10]

A given practitioner is acting in the "course of professional practice" only when "the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." *Merrill*, 513 F.3d at 1306; *see also Feingold*, 454 F.3d at 1011 n.3; *Norris*, 780 F.2d at 1209; *United States v. Hurwitz*, 459 F.3d 463, 480 (4th Cir. 2006); *United States v. Vamos*, 797 F.2d 1146, 1153 (2d Cir. 1986); *United States v. Smith*, 573 F.3d 639, 647-48 (8th Cir. 2009). No circuit has articulated how "generally recognized and accepted in the United States" can possibly serve to distinguish criminal from civil standards. Sandra H. Johnson, *Customary Standards of Care*, 43 HASTINGS CTR. REP. 6 (2013).

Act."); *Joseph*, 709 F.3d at 1102 ("Although we agree with Green and Mack that a violation of section 1306.05 does not constitute a *per se* violation of section 841. . . ."); *Naum*, 832 F. App'x at 145 ("the state regulations were just one factor in determining the legitimacy of prescriptions."); *Humphreys v. Drug Enf't Admin.*, 96 F.3d 658, 662 (3d Cir. 1996). Conversely, a defendant's *adherence* to state regulations does not necessarily constitute a defense. *United States v. Leal*, 75 F.3d 219, 227 (6th Cir. 1996), *abrogated by United States v. Kennedy*, 107 F. App'x 518 (6th Cir. 2004) (unpublished).

[10] *Sabean*, 885 F.3d 27; *Wexler*, 522 F.3d at 206; *Feingold*, 454 F.3d at 1007; *Tran Trong Cuong*, 18 F.3d at 1137; *United States v. Stump*, 735 F.2d 273, 276 (7th Cir. 1984).

As a result, the "usual course" prong tends to focus on procedural failures such as incomplete medical records or failure to conduct sufficiently thorough physical examinations.[11] In *Naum*, for example, the Fourth Circuit held that where the government charges only the "scope of professional practice" element, evidence of the defendant's intent, or even the medical efficaciousness of the prescriptions, is irrelevant. 832 F. App'x at 142 ("Because the issue of whether [the defendant's] treatment was for a legitimate medical purpose was not an element in this case, [the defendant's] contention that he acted with a legitimate medical purpose was not a viable defense. In fact, there was no dispute at trial that [the defendant's] patients suffered from addiction and required

[11] Of course, whether a doctor keeps medical records, or employs pain contracts, or conducts a thorough physical examination is certainly relevant to determining the doctor's intent. *McBride v. United States*, 225 F.2d 249, 252 (5th Cir. 1955) ("Evidence of the failure to follow standard medical practices shows a lack of good faith. So also, as bearing on good faith is the evidence on appellant's unorthodox attitude toward narcotics and addiction."); *Boettjer*, 569 F.2d at 1082 ("Evidence which tended to show that Dr. [defendant's] methods and consultation procedures fell short of acceptable medical standards was not offered to establish malpractice, but rather to support the absence of any legitimate medical purpose in his prescription of controlled substances."); *Stump*, 735 F.2d at 275-76 ("The sheer number of prescriptions written to any one of several individuals in this case were themselves substantial evidence that the defendant *knew* that he was prescribing drugs improperly.") (emphasis added); *Tran Trong Cuong*, 18 F.3d at 1140; However, these types of facts, by themselves, should not render a doctor definitionally guilty of being a drug dealer.

treatment."); *Ruan*, 966 F.3d at 1139 ("And even if [the testifying patient] felt that she benefitted from the medications [the defendant] prescribed, a reasonable jury could nonetheless conclude *that the manner in which* [the defendant] prescribed them was outside the usual course of professional practice.") (emphasis added).

The circuit court law is unclear as to what group or by what standards a physician's procedures should be judged. Should whether a given prescription is consistent with medical practices "generally recognized throughout the United States" be measured by the standards advocated by professional medical organizations, adherence to advisory state or federal guidelines for the treatment of pain, compliance with state medical boards, or perhaps by what most physicians actually do in practice?

Pain management is not an area where medical professionals are in unanimous agreement as to the correct method of treating patients. Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 Geo. Mason L. Rev. 701, 710 (2009) ("what constitutes standard or accepted practice in the treatment of patients in chronic pain is evolving at great speed."). PBS News Hour, "A 'civil war' over painkillers rips apart the medical community," available at https://www.pbs.org/newshour/health/painkillers-controversy-doctors) (Jan. 21, 2017); Anna Lembke, *Why Doctors Prescribe Opioids to Known Opioid Abusers*, 367 NEW ENG. J. MED. 1580, 1580-82 (2012); Rima J. Oken, *Curing Healthcare*

Providers' Failure to Administer Opioids in the Treatment of Severe Pain, 23 Cardozo L. Rev. 1917, 1984 (2002). As the expert in Dr. Kahn's case recognized, the CDC guidelines as to prescription amount and best practices are not mandatory and have been heavily criticized in the medical community. R. 910 at 255.

Uncertainty as to how "usual course" ought to be measured is sufficient to give rise to significant vagueness concerns. In *Johnson*, this Court held that the residual clause of the of the ACCA was unconstitutionally vague because of "grave uncertainty about how to estimate the risk posed by a crime." 576 U.S. at 597. With the substitution of just a couple of words, the Court's reasoning in *Johnson* is equally applicable here: "How does one go about deciding what kind of conduct is within the [usual course of professional practice]? "A statistical analysis [of doctors]? A survey? Expert evidence? Google? Gut instinct?" *Id*. Similarly, in *Colautti*, this Court held a statute criminalizing abortion to be unconstitutionally vague because it did not indicate whether "sufficient reason" should be judged from the perspective of the treating physician or a "cross-section of the medical community." 439 U.S. at 393-94. Unless one can identify the standards by which a doctor is to be judged, it is difficult to understand how a physician has "'fair notice' of the conduct" that renders a prescription criminal. *Papachristou v. Jacksonville*, 405 U.S. 156, 162 (1972).

2. Defining The "Usual Course" Prong Exclusively Based On The Procedures A Doctor Utilizes Renders The Standard Indeterminant As To The Degree Of Compliance Necessary.

Even if one could identify some universal set of procedures agreed on by all pain specialists, the phrase "usual course" would still be indeterminate because it does not establish a degree of compliance necessary before a prescription becomes criminal. The expert testimony in petitioner's trial illustrates this problem. Dr. Shay relied heavily on the Federation of State Medical Boards Model Guidelines For Pain Treatment. R. 910 at 22, 70. The Federation of State Medical Boards Model Guidelines direct medical boards evaluating the sufficiency of a doctor's pain practice to analyze whether there was (1) "inadequate monitoring," (2) "inadequate attention" to informed consent, (3) "unjustified dosage increases," (4) "excessive" reliance on opioids and (5) failure to make use of available tools for risk mitigation. *Id.* 20-22. Dr. Shay seemed to acknowledge that a single deviation from this standard would not render a doctor outside the "usual course." Rather he looks for a general "impression" of a doctor's compliance based on the medical records. *Id.* 81. The guidelines recommended by the Federation of State Medical Boards do not indicate how much attention to informed consent or monitoring is required for a doctor's prescriptions to be "adequate," or how much reliance on opioids is "excessive." Which risk mitigation

procedures must a doctor employ, how often, and to what degree are also not indicated by these guidelines.

As in *Johnson* and *Dimaya*, measuring "usual course" by a practitioner's compliance with general models of conduct leaves "unclear what threshold level" of compliance is required. *Dimaya*, 138 S. Ct. at 1214. Without some basis for determining the threshold level of compliance necessary, nearly every doctor is at risk of prosecution. This "impermissibly delegate[s] basic policy matters" to prosecutors and juries for "resolution on an ad hoc and subjective basis." *Grayned v. City of Rockford*, 408 U.S. 104, 108-09 (1972). Unmoored from "medical purpose," the "usual course" prong allows "criminal sanctions . . . [to 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." *Gypsum Co.*, 438 U.S. at 442.

It is the inability of doctors to determine when their conduct falls inside or outside the scope of medical practice that has led to a chilling effect well documented in the literature. Rima J. Oken, Curing Healthcare Providers' Failure to Administer Opioids in the Treatment of Severe Pain, 23 Cardozo L. Rev. 1917, 1944 (2002); MM. Reidenberg & O. Willis, Prosecution of Physicians for Prescribing Opioids to Patients, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 903 (2007). ("When doctors must continually be suspicious of patients claiming to be in pain because being deceived can lead to criminal prosecution, their

willingness to treat patients in pain with opioids diminishes."); Kelly K. Dineen, Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems, 40 Law & Psychol. Rev. 1, 51 (2016); Steven E. Stark, Bio-Ethics and Physician Liability: The Liability Effects of Developing Pain Management Standards, 14 St. Thomas L. Rev. 601, 638 (2002) ("If that trend continues, however, the emerging standards on pain management will come increasingly from legislatures and regulators on a state and national level, and not the medical profession itself."). Without any mooring, the "usual course" prong allows prosecutors to choose which practices a doctor must follow without any regard to the medical efficaciousness or the intent of the physicians being prosecuted.

Obviously, there are doctors who knowingly abuse their registration status to issue prescriptions to addicts knowing that those prescriptions serve no legitimate medical purpose. Petitioner is not advocating a standard that will prohibit the government from prosecuting those individuals. As noted by the Fifth Circuit, willful blindness instructions are common in prosecution of medical professionals. *United States v. Lee*, 966 F.3d 310, 323 (5th Cir. 2020). Doctors may not intentionally blind themselves to patients' abuse of medication. However, in the absence of any tie to legitimate medical purpose, the usual course prong allows doctors who intended no harm, and provided prescriptions that successfully aided their patients, to be subjected to the threat of significant criminal sanctions for

failing to abide by a standard of care that is both evolving and ambiguous.

CONCLUSION

Wherefore, Petitioner Shakeel Kahn respectfully requests that this Court reverse the judgment of the United States Court of Appeals for the Tenth Circuit.

Respectfully submitted,

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