No. _____

IN THE SUPREME COURT OF THE UNITED STATES

SHAKEEL KAHN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

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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 C.F.R § 1306.04(a) be read in the conjunctive or the disjunctive?

LIST OF PARTIES TO THE PROCEEDINGS

Petitioner, defendant-appellant below, is Dr. Shakeel Kahn.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

Tenth Circuit Court of Appeals:

United States v. Shakeel Kahn, No. 19-8054, United States Court of Appeals for the Tenth Circuit. Judgment entered Feb. 25, 2021. *United States v. Kahn,* 989 F.3d 806 (10th Cir. 2021).

United States District Court for the District of Wyoming:

United States v. Kahn, No. 2:17-cr-00029. Judgement and conviction entered August 29, 2019.

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United States v. Gambler, 662 F.2d 834 (D.C. Cir. 1981)..... 26

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Adam H. Kurland, *Prosecuting Ol' Man River: The Fifth Amendment, the Good Faith Defense, and the Non-Testifying Defendant*, 51 U. Pitt L. Rev. 841 (1990). 26

Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81 (2004). 33

Daniel S. Jonas, *The Circuit Split Over Instructing The Jury Specifically On The Good Faith Defense: A Consequence of Superlegislation By Courts Or The Standards Of Appellate Review*, 46 SYRACUSE L. REV. 61 (1995) 25

Deborah Hellman, *Prosecuting Doctors For Trusting Patients*, 16 GEO. MASON L. REV. 701 (2009) 20

Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 Law & Psychol. Rev. 1 (2016) 33

Lagisetty, Pooja, *et al*., "*Assessing reasons for decreased primary care access for individuals on prescribed opioids*," PAIN. 2021 May; Vol 162. Issue 5. p 13 33

MM. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients,* 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903 (2007) 33

Powell D, Tamara M, Chou, Roger. CDC guideline for prescribing opioids for chronic pain—United States, 2016. JAMA 2016;315:1622 30

Other

Fuqua, Anne, *The other opioid crisis: pain patients who can't access the medicine we need*, THE WASHINGTON POST (March 9, 2018) 36

Goodnough & Hoffman, *Good News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say,* THE NEW YORK TIMES (March 6, 2019) 36

McCoy & Mount, *Unintended Consequences: Inside the fallout of America's crackdown on opioids*, THE WASHINGTON POST (May 31, 2018) 36

O'Donnell & Alltucker, *Pain patients left in anguish by doctors 'terrified' of opioid addiction, despite CDC change*, USA TODAY (June 24, 2019) 36

Rider, Travis, *What Chronic-Pain Patients Are Deeply Afraid Of,* THE NEW YORK TIMES (Oct. 31, 2019) 36

OPINIONS AND RULINGS BELOW

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

JURISDICTION

The court of appeals' judgment was entered on February 25, 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).

CONSITUTIONAL 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."

18 U.S.C.A § 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

This case presents a clear and unambiguous vehicle for the Court to address increasingly divergent inter- and intra-circuit splits pertaining to the *mens rea* the government must establish to secure the conviction of a licensed medical practitioner under the Controlled Substances Act (CSA). Currently, there are at least three different *mens rea* requirements recognized by the Courts of Appeal. Three circuits unequivocally impose strict liability on practitioners who prescribe outside the usual course of professional practice; two (arguably three) impose a knowing or intentional scienter; and the remainder impose varying degrees of negligence. Confusion on this point has led to a number of inter- and intra-circuit splits regarding what constitutes a "good faith" defense for doctors charged under §841. A valid defense in one circuit amounts to an admission of guilt in another.

Relying on this court's holding in *United States v. Moore*, 423 U.S. 122 (1975), and language from C.F.R § 1306.04(a), the circuits universally agree that, in order to convict a licensed medical practitioner under §841, the government must establish that the charged prescriptions were not issued either (1) for "a legitimate medical purpose" or (2) "by an individual practitioner acting in the usual course of his professional practice." The Tenth Circuit (and every other circuit except the Ninth Circuit) interprets this language as allowing for conviction under two different theories. The government must prove either: (1) that the prescription was not written for a legitimate medical purpose; or (2) that the prescription was outside the usual course of professional practice "generally recognized throughout the United States." *United States v. Nelson*, 383 F.3d 1227, 1233 (10th Cir. 2004).

The Eleventh, Tenth, and Fifth Circuits hold that, while the government must prove that a defendant *knew* she was issuing a prescription for no legitimate medical purpose, a doctor charged under the "usual course" prong is strictly liable for any prescriptions she writes that are, in fact, outside the scope of professional practice regardless of whether she knew that they were outside said scope. *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 First, Second, Third, Fourth, Sixth, Seventh, Eighth, and Ninth Circuits have each issued decisions explicitly or implicitly requiring the government to prove that the defendant *knowingly* or *intentionally* acted outside the scope of professional practice. *United States v. Sabean,* 885 F.3d 27, 45 (1st Cir. 2018); *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. Hurwitz,* 459 F.3d 463, 478, 480 (4th Cir. 2006); *United States v. Jones,* 825 F. App'x 335, 339 (6th Cir. 2020); *United States v. Kohli,* 847 F.3d 483, 490 (7th Cir. 2017); *United States v. Smith*, 573 F.3d 639, 649–50 n.4 (8th Cir. 2009); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006).

Despite the majority of circuits' consensus that a doctor must *intentionally or knowingly* issue a prescription outside the scope of professional practice, jury instructions in the Second, Fourth, Sixth, and Eighth Circuits define good faith "objectively." In those circuits, a defendant acts in good faith only when she acts within what she *reasonably should have* believed or "reasonably believed" to be the usual course of professional practice. *United States v. Vamos*, 797 F.2d 1146, 1152 (2d Cir. 1986); *Hurwitz,* 459 F.3d at 478 (4th); *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). The effect of these instructions is to allow a jury to convict based on a *mens rea* of

negligence rather than knowledge or intent. In those circuits, a defendant who holds a sincere belief about what prescription practices are permissible and writes prescriptions based on that belief can still be convicted under the CSA.

The Seventh and Ninth Circuits allow for a good faith instruction directing the jury to consider the defendant's *subjective* good faith. *Kohli,* 847 F.3d at 489; *United States v. Hayes*, 794 F.2d 1348, 1351 (9th Cir. 1986). In those circuits, a defendant who holds a sincere belief about what prescription practices are permissible and writes prescriptions based on that belief is not guilty of intentionally writing prescriptions outside the usual course of professional practice.

The Eleventh Circuit jury instruction on good faith defines good faith as acting within the scope of professional practice, without any reference to the defendant's beliefs. *United States v. Ruan*, 966 F.3d 1101, 1167 (11th Cir. 2020); *United States v. Joseph*, 709 F.3d 1082, 1097 (11th Cir. 2013) ("The law of this Circuit is not even clear that [the defendant] was entitled to a "good faith" jury instruction at all.").

This Court last considered any case involving the prosecution of a medical practitioner under §841 in 1975. *United States v. Moore*, 423 U.S. 122 (1975). The increase of prosecutions against medical practitioners under the CSA over the last decade has not worked to clarify circuit court law but instead has birthed an exponential *increase* in inter- and intra- circuit inconsistency. This case presents a clear opportunity to resolve these inconsistencies precisely because the holding of the Tenth Circuit unambiguously imposes strict liability on doctors acting outside the scope of professional practice. *United States v. Kahn*, 989 F.3d 806, 825 (10th Cir. 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.").

Statutory Framework

The Controlled Substances Act makes it unlawful for any person "knowingly or intentionally to distribute or dispense a controlled substance." 21 U.S.C. §841(a). Medical practitioners are exempt from this prohibition. *See* 21 U.S.C. §§ 821–23. In *Moore*, this Court recognized that a doctor's scope of authority as defined in the CSA is somewhat circular. 423 U.S. at 124. ("Section 822(b) defines the scope of authorization under the Act in circular terms. 'Persons registered . . . under this subchapter . . . are authorized (to dispense controlled substances) . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.") *Id*. The defendant in *Moore* challenged his conviction arguing that he could not be prosecuted under §841 because he was duly licensed and registered under the CSA. *Id*. This Court reasoned that the CSA could not have intended to exempt all practitioners from liability under §841. *Id*. Thus, the Court found that a physician remains criminally liable when he ceases to distribute or dispense controlled substances as a medical professional and acts instead as a "pusher." *Id.* at 138.

Under authorization of the CSA, *see* 21 U.S.C. § 821, the Attorney General issued CFR § 1306.04 indicating the conditions under which registrants are authorized to dispense controlled substances:

> "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."

FACTS

Shakeel Kahn is a medical doctor licensed at the times relevant to the indictment to issue prescriptions in Arizona and Wyoming. R. 356 at 1. The Third Superseding Indictment charged Kahn with 22 counts related to his issuance of prescriptions (primarily opioids) between 2011 and 2016. R. 356.[1] The evidence presented at trial showed that a number of Dr. Kahn's patients were diverting or abusing their medications. Petitioner did not contest that he wrote the charged prescriptions. At trial Dr. Kahn argued that he did not intend or know that the charged prescriptions were written outside the scope of professional practice. *See*, *e.g.,* 05/21/19 Tr. 61, 128.

Dr. Kahn did not accept insurance. Dr. Kahn's patients paid via cash, personal check, credit, or debit card. 05/14/19 Tr. 22. Prior to the instant charges, Kahn was investigated on two different occasions (in 2010 and 2012) by the Arizona Medical board. 05/08/19 Tr. 290. On both occasions, Kahn was cleared of wrongdoing, thus suggesting to him that his practices were valid. 05/09/19 Tr. 22-23. In 2014, Kahn and his wife began moving his practice from Arizona to Casper, Wyoming. 5/14/19 Tr. 73-4.

Kahn argued that he did not know his patients were abusing or selling their medication. One of Kahn's patients (Ms. Burch) passed away after consuming the same substances Kahn had prescribed. 10/14/19 Tr. 257-8; 261-2. Medical records suggest that Ms. Burch lied to several physicians, including Kahn, about her medical history and had been given the same prescription as that issued by Kahn by a previous doctor. 05/10/19 Tr. 111, 115-121.

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[1] Those charges included conspiracy to distribute narcotics, continuing criminal enterprise, possession of a firearm in furtherance of a drug trafficking offense (18 U.S.C. § 924(c)(1)), eleven counts of illegal distribution or aiding and abetting illegal distribution, five counts of use of a communications facility in furtherance of a drug trafficking offense 21 U.S.C. § 843(b) and two money laundering counts 18 U.S.C. § 1957. R. 365.

The principal argument was that Kahn acted outside the scope of professional practice by issuing prescriptions without conducting sufficient investigation or examination, and increased patients' dosages without sufficiently documenting the need for those increases. The government further argued that Kahn's practice of charging more to patients at higher risk due to their dosage amount was outside the scope of professional practice.

The government's expert witness, Dr. Shay, was asked to review 22 of Kahn's patient files. 4/30/10 Tr. 68-70. Kahn's medical records established that patients were required to sign both a drug addiction statement and an informed consent document and pain management contract. 4/30/10 Tr. 259-261; 05/01/19 Tr. 108. Shay indicated that "[o]n paper" the documents provided by Kahn adequately established informed consent. *Id*. 101-03; 106-07. Nevertheless, Shay testified that Kahn's medical records deviated from the usual course of professional practice because Kahn did not properly document sufficient monitoring of patients. *Id.* 101-03.

Dr. Kahn testified as to his theory of pain management. 05/17/19 Tr. 44-45. Kahn admitted to sloppy record keeping. *Id.* 73. Kahn testified that he believed he had a legitimate medical purpose for the discussed prescriptions. *Id.* 298. Kahn testified that he would not have issued prescriptions to individuals that he knew to be selling their medication. *Id.* 51, 193.

A jury convicted Kahn on all counts and he was sentenced to twenty-five years in prison R. 848.

The original good faith instruction proposed by Kahn read:

> "The good faith of a defendant, whether or not objectively reasonable, is a complete defense to the crimes charged, because good faith on the part of a defendant is inconsistent with specific intent, which is an essential part of the charges. A defendant who acts upon an opinion honestly held by him or her at the

time of the alleged acts, or pursuant to a belief honestly entertained by him or her at the time of the alleged acts, cannot be found guilty even though his or her opinion is erroneous or his or her belief is mistaken or wrong.

A defendant's good faith must have existed at the time the alleged unlawful acts were committed. One cannot assert good faith as a defense if the opinions or beliefs advanced as justifications for the good faith defense were formulated after the commission of criminal acts. If you find that the defendant lied about some aspect of the charged conduct, you may consider that, in addition to other evidence presented, in determining whether the defendant acted in good faith.

While the term "good faith" has no precise definition, it means, among other things, a belief or opinion honestly held, an absence of malice or ill will, and an intention to avoid taking unfair advantage of another.

In the practice of medicine, good faith means the honest exercise of good professional judgment as to a patient's medical needs. Good faith connotes an honest effort to treat patients in compliance with generally recognized and accepted standards of medical practice.

The burden of proving good faith does not rest with a defendant because a defendant does not have any obligation to prove anything in this case. It is the government's burden to prove to you, beyond a reasonable doubt, that a defendant acted knowingly and intentionally.

In determining whether or not the government has proven that a defendant acted intentionally, you the jury should consider all of the evidence in the case bearing on that defendant's state of mind."

R. 694 at 10-11. The instruction issued by the district court read:

> "The good faith of Defendant Shakeel A. Kahn is a complete defense to the charges in Count One (conspiracy to commit a federal drug crime) as well as the charges in Counts Four, Six, Seven, Eleven, Fourteen, Sixteen, Nineteen and Twenty (knowingly and unlawfully dispensing and/or distributing Oxycodone outside the usual course of professional practice and without a legitimate medical purpose), because 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. "Good faith" connotes an attempt to act in accordance with *what a reasonable physician should believe* to be proper medical practice.
>
> The 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.
>
> A defendant's good faith must have existed at the time the alleged unlawful acts were committed. One cannot assert good faith as a defense if the opinions or beliefs advanced as justifications for the good faith defense were formulated after the commission of criminal acts. If you find that a defendant lied about some aspect of the charged conduct you may consider that, in addition to other evidence presented, in determining whether the defendant acted in good faith.

> The burden of proving good faith does not rest with a defendant because a defendant does not have any obligation to prove anything in this case. It is the Government's burden to prove to you, beyond a reasonable doubt, that a defendant knowingly or intentionally acted unlawfully.
>
> In determining whether or not the Government has proven that a Defendant intentionally or knowingly violated the law, you should consider all of the evidence in the case bearing on the Defendant's state of mind."

R. 741 at 58-9 (emphasis added). Petitioner argued that the government must prove *both* that the instant prescriptions were written outside "usual course of the medical practitioner's profession" and without a "legitimate medical purpose." R.729 at 8-9; 5/21/19 Tr. 7.

A. The Court of Appeals' Decision

Petitioner appealed to the Tenth Circuit, arguing that the good faith instruction issued by the district court effectively reduced the *mens rea* required to one of negligence. The Tenth Circuit affirmed. *United States v. Kahn*, 989 F.3d 806, 825 (10th Cir. 2021). The Tenth Circuit declined to revisit its precedent that a medical practitioner could be convicted under §841 for issuing a prescription outside the scope of professional practice even if said prescription was written for a legitimate medical purpose. *Id.* at 822. Furthermore, the Tenth Circuit held that a different *mens rea* attached to each prong of CFR § 1306.04(a):

> "We hold that §841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant either: (1) subjectively knew a prescription was issued not for a legitimate medical purpose; or (2) issued a prescription that was objectively not in the usual course of professional practice."

Id. at 825. The Tenth Circuit explicitly held that a doctor faced strict liability under §841 for any prescription that was outside the scope of professional practice: "[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." *Id.* (*quoting United States v. Schneider*, 704 F.3d 1287, 1303 (10th Cir. 2013) (Holmes, J., concurring)).

The Tenth Circuit reasoned that, uniquely as applied to medical practitioners charged under §841, "good faith" instructions are not articulations of the *mens rea* of the offense but rather definitions of the *actus reus*:

> "Kahn's assertion that "good faith is a defense because it negates the *mens rea* element of the offense" is without merit. … Unlike other criminal offenses, good faith does not go to *mens rea* for §841 offenses involving practitioners. Rather, as numerous other circuits have recognized, good faith defines the scope of professional practice, and thus the effectiveness of the prescription exception and the lawfulness of the *actus reus*."

Id. at 826. The Tenth Circuit, thus, asserted that a doctor's actual intentions or beliefs are irrelevant. According to the Tenth Circuit's decision, a doctor who unintentionally writes a prescription negligently is guilty of a crime under the CSA. The Tenth Circuit has imposed strict liability on doctors who act outside the usual course of professional practice even if they do so unintentionally.

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 CSA.

The Tenth Circuit, in the case at bar, as well as the Eleventh and Fifth Circuits, have explicitly held that a defendant is strictly liable for acting outside the scope of professional practice. *Tobin*, 676 F.3d at 1283; *Norris*, 780 F.2d at 1209. In those circuits, a doctor acting outside the scope of professional practice is culpable under §841 even if she intended to comply with what she believed to be the usual course of professional practice and the charged prescriptions were actually serving a legitimate medical purpose. Having a mistaken view about what the standards of medical practices are or what most doctors actually do (depending upon one's interpretation of "usual course of professional practice") is not a defense.

The Ninth and Seventh Circuits are the most explicit in holding that the government must prove that a medical practitioner intentionally acted outside the usual scope of professional practice and/or issued a prescription knowing it served no legitimate medical purpose. *Kohli,* 847 F.3d at 490 ("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.'"); *Feingold*, 454 F.3d at 1008 ("[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).

Other Courts of appeal have issued decisions that either implicitly or explicitly required a finding of knowledge. *See Hurwitz,* 459 F.3d 463 (4th) ("attorney's statement [admitting that his client acted outside the scope of professional practice] therefore cannot be viewed as a clear and unambiguous admission that [the defendant] knowingly acted outside the bounds of accepted medical practice."); *Jones,* 825 F. App'x at 339 (6th) ("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.") (unpublished); *Sabean,* 885 F.3d at 45 (1st) ("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."); *Li*, 819 F. App'x at 118 (3rd) ("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.") (unpublished); *Wexler*, 522 F.3d at 206 (2nd) (mistake "however gross" insufficient); *Smith*, 573 F.3d at 649–50 n.4 (8th) (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.").

Even among those circuits requiring that a doctor *knowingly* act 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. However, the good faith instructions approved of by the courts of appeals are often inconsistent with the circuit's proffered view on the level of intent required to prove a practitioner's guilt.

The Seventh and the Ninth Circuits' good faith instructions are largely (though not entirely) consistent with the view that a doctor must knowingly act outside of the scope of professional practice:

The Seventh, and Ninth, and First Circuits allow for instructions that define good faith "subjectively." That is, instructions that ask the jury to consider the defendant's "honest efforts" without requiring that a defendant's belief regarding the usual course of professional practice 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 medical practice.... Good faith in this context means good intentions and the honest exercise of good professional judgment as to the patient's medical needs."

Kohli, 847 F.3d at 489 (7th).

> "[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."

Hayes, 794 F.2d at 1351 (9th). In both the Seventh and Ninth 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 First Circuit, similarly, has language suggesting that knowledge is required. *Sabean*, 885 F.3d at 45 ("After all, the further that a defendant strays from accepted legal duties, the more likely that a factfinder will find him to be in *knowing* disregard of those duties.") (emphasis added). *Id*. 44 ("We also agree that even a negligent physician is inoculated against criminal liability under Section 841(a) as long as he acts in good faith"). The good faith instructions were not directly challenged in *Sabean*, however, the good faith instruction in that case explicitly stated that good faith connotes "a sincere effort to act in accordance with proper medical practice." *Id*.

On the other side of the spectrum, the Eleventh Circuit's good faith instruction is consistent with its view that a doctor is strictly liable and 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. *Ruan*, 966 F.3d at 1167 ("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.").

Even while, at times, implicitly suggesting that *knowledge* that a prescription is outside the usual course of professional practice is a requirement, the Second, Sixth, Eighth, and Fourth Circuits authorize varying degrees of "objective" good faith instructions.

In *Wexler*, 522 F.3d at 206, the Second Circuit recognized that a mistake "however gross" is not sufficient find a defendant guilty under §841. *Id*. Nevertheless, the court, in the same case, approved of a good faith instruction that defined good faith as what the defendant "*should have reasonably believed* to be proper medical practice." *Id*. The good faith instruction issued explicitly allowed for conviction based on an *unreasonable* mistake. If one can be convicted based on an unreasonable mistake, then one *can* be convicted for a "gross mistake" and without knowledge that she acted outside the usual course of professional practice.

In *Godofsky*, 943 F.3d at 1017, the Sixth Circuit engages in a lengthy discussion of the distinction between objective and subjective good faith. In relevant part, the Sixth Circuit finds that "Without explicitly saying it this way, the court appears to have drawn a distinction between *subjective* good faith ("well, I did what I thought was best"), which it rejected, and *objective* good faith (do "what you believe complies with [the rules and regulations]"), which it accepted." Id. However, the Sixth Circuit reiterated that any mistake on the doctor's part as to the scope of professional practice must be judged from the perspective of a *reasonable* physician. *Id.* at 1026; *United States v. Voorhies*, 663 F.2d 30, 34 (6th Cir. 1981) (approving of good faith instruction that reads "It connotes an observance of conduct in accordance with what the physician should reasonably believe to be proper medical practice."). If the standard a practitioner is held to is based on what a reasonable physician should believe, then that practitioner can be convicted for negligence and knowledge is not actually required.

In *King*, 898 F.3d at 808, the Eighth Circuit upheld the district court's refusal to issue the defendant's proffered good faith instructions, finding (1) that the defendant's good faith instruction was erroneous because it was not "objective" and (2) that the district court properly required the jury to find knowledge. *But see Smith*, 573 F.3d at 649–50 (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."). A good faith instruction that is purely objective is inconsistent with a requirement that the jury find subjective knowledge or intent.

The Fourth Circuit has case law suggesting that knowledge is required to obtain a conviction. *Hurwitz*, 459 F.3d at 468–69. Nevertheless, in *United States v. Purpera*, 844 F. App'x 614, 617 (4th Cir. 2021), the Fourth Circuit indicated that the defendant's proffered good faith instruction was insufficiently "objective." There, the defendant's proffered instruction defined good faith as a doctor acting in conformity with what he "reasonably believed" to be the scope of professional practice. *Id.* The Fourth Circuit indicated that the defendant's instruction by even referencing what the defendant actually believed, even while qualifying that it must be reasonable, was too close to a "subjective" instruction. *Id*. On its face, the Fourth Circuit's opinion allows for conviction even in the case of *reasonable* mistakes. Thus, again, based on an objective good faith instruction, a defendant can be convicted without knowledge in the Fourth Circuit despite the fact that the Fourth Circuit has indicated that knowledge is required.

In each of these circuits, it is sufficient for the government to prove that the doctor acted unreasonably, even if honestly, and still obtain a conviction.

As a practical effect, therefore, there are at least three different versions of the *scienter* requirements that the government must prove to convict a licensed practitioner under §841.

Three circuits impose strict liability (Fifth, Eleventh, and Tenth), two require actual intent or knowledge (Seventh and Ninth), and the remainder of circuits require some degree of negligence.[2] The difference is not insignificant. What are very plausible and sometimes successful defenses in one circuit are admissions of guilt in others. *Cf. Hurwitz,* 459 F.3d at 480 (reversing despite counsel's admission that his client was acting outside the scope of professional practice because said admission did not necessarily concede that defendant knew he was acting outside the usual scope of professional practice) *with Kahn*, 989 F.3d at 825 ("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.").

[2] Clarification from this Court as to the elements the government must prove to secure the conviction of a medical practitioner under §841 would also provide much needed guidance on other inconsistencies among the circuits. For example, even in circuits where knowledge is not a requirement, the issuance of a willful blindness instruction is commonplace. *See, e.g., United States v. Lee*, 966 F.3d 310, 323 (5th Cir.) ("The instruction "should rarely be given," ... but what seems rare is a health care prosecution without the instruction."); *Sabean,* 885 F.3d at 45; United *States v. Leonard*, 738 F. App'x 7, 11 (2d Cir. 2018); *Hurwitz*, 459 F.3d at 481; *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006). The only logical reason to issue the willful blindness instruction is if knowledge is an element of the offense. If a defendant's *knowledge* of acting outside the scope of professional practice is *not* an element of the offense, it seems incongruous to issue a willful blindness instruction. Furthermore, even in those circuits where medical practitioners are subject to a negligence or strict liability standard, the conviction of *other* medical practitioners (such as nurses or technicians) for dispensing medication outside the scope of professional practice under *the same statute* requires proof of actual knowledge. *See, e.g., United States v. Lovern,* 590 F.3d 1095, 1105 (10th Cir. 2009) (finding insufficient evidence that technician knew prescriptions were outside the scope of professional practice); *United States v. Lawson*, 682 F.2d 480, 482 (4th Cir. 1982) ("[t]he question, then, in any case where a pharmacist is charged with illegal distribution of controlled substances, is whether he knew that the purported prescription was not issued for a legitimate medical purpose or in the usual course of medical practice. *But see Sabean* at 45 (allowing good faith instruction as to nurse practitioner that referenced the nurse's "reasonable belief").

Section 841 is not a minor or technical criminal statute. It imposes significant penalties on those convicted. It is difficult to find a similar statute with such wide-ranging disagreement as to the basic *mens rea* elements of the offense.

II. ISSUANCE OF "OBJECTIVE" GOOD FAITH INSTRUCTION IS INCONSISTENT WITH THE *MENS REA* OF KNOWLEDGE REQUIRED BY THE COURT'S CASE LAW.

As the Tenth Circuit recognized, the "objective" good faith instruction is not a "good faith" instruction as commonly understood. Generally, good faith is not a "defense" as such. Rather, it is an articulation of a defendant's theory of the case. Good faith is inconsistent with conviction precisely because a person acting in good faith does not have the required *mens rea.* Daniel S. Jonas, *The Circuit Split Over Instructing The Jury Specifically On The Good Faith Defense: A Consequence of Superlegislation By Courts Or The Standards Of Appellate Review*, 46 SYRACUSE L. REV. 61, (1995) (collecting appellate cases indicating that a good faith instruction need not be issued if the jury is adequately instructed on the intent element of the offense); Adam H. Kurland, *Prosecuting Ol' Man River: The Fifth Amendment, the Good Faith Defense, and the Non-Testifying Defendant*, 51 U. Pitt L. Rev. 841, 856 (1990). Therefore, good faith instructions are tailored to the *mens rea* of the offense. The understanding that good faith is a negation of a knowing or intentional *mens rea* is so ingrained that a plurality of appellate courts will not reverse a conviction for failure to give a good faith instruction if the jury instructions otherwise properly defined the knowledge and intent elements of the offense. *United States v. Nivica*, 887 F.2d 1110, 1125 (1st Cir. 1989); *United States v. McElroy*, 910 F.2d 1016, 1026 (2d Cir. 1990); *United States v. Gross*, 961 F.2d 1097, 1103 (3rd Cir. 1992), *United States v. Dorotich*, 900 F.2d 192, 193-94 (9th Cir. 1990); *United States v. Gambler*, 662 F.2d 834, 837 (D.C. Cir. 1981).

This Court has held that defining a defendant's good faith as being dependent upon whether his (mistaken) belief was "objectively reasonable" effectively reduces the *mens rea*. *Cheek v. United States*, 498 U.S. 192, 197 (1991).

The inconsistency between the "objective" good faith instructions applied to doctors charged under §841 and the "subjective" good faith instructions given in cases involving other criminal charges is well illustrated by the Fourth Circuit's decision in *United States v. Hurwitz*. In *Hurwitz*, the defendant was charged both with distributing outside the scope of professional practice under §841 and healthcare fraud. 459 F.3d at 468–69. The jury was read a subjective good faith instruction as to the fraud counts. *Id*. at 477. However, the Fourth Circuit held that the district court *properly* rejected the defendant's proffered "subjective" good faith instruction as to the §841 counts. *Id*. Although the Fourth Circuit found that the defendant's proffered good faith instruction was not a correct statement of law, it reversed because the district court instructed the jury that good faith was not a defense to the §841 counts. If conviction under §841 requires that the government prove that a defendant intentionally issue a prescription outside the scope of professional practice, there does not seem to be any rational justification for issuing a materially different good faith instruction than would be required for any other specific intent offense.

An objective "Good Faith" instruction is inconsistent with this Court's decision in *Moore* and this court's pre-CSA case law. Prior to the enactment of the CSA, the distribution of narcotics was governed by the Harrison Act, 38 Stat. 785. Under the Harrison Act, distribution of controlled substances by registered medical professionals was permitted "in the course of his professional practice only." *Linder v. United States*, 268 U.S. 5, 13 (1925). In *Moore*, this Court considered the question of whether a registered medical practitioner was "exempted from prosecution under s 841 by virtue of his status as a registrant" under the CSA. 423 U.S. at 124.

The Court found that, were the CSA construed to authorize all prescriptions "thereby exempting them from other constraints, it would constitute a sharp departure from other laws." *Id*. 132-33 ("It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act…"). However, the standard as articulated in *Moore* did not allow for a conviction simply because the doctor happened to step outside of the usual course of professional practice. The jury in *Moore* was instructed that the defendant "could not be convicted if he merely made 'an honest effort' to prescribe for detoxification in compliance with an accepted standard of medical practice." *Id*. at 143 n. 20. The defendant testified that he knew he was acting outside the scope of accepted medical standards. *Id.* at 144. Nothing in *Moore* suggested that a medical professional could be convicted as a drug dealer if he held mistaken beliefs about the practices that most medical professionals employ.

The fact that doctors charged under the Harrison Act were entitled to a good faith defense was well established in the Court's Harrison Act Cases. In *Linder*, the Court reversed because the indictment failed to articulate facts that the defendant doctor had any "conscious design to violate the law." 268 U.S at 17. In *Boyd* the "disputed question was whether the defendant issued the prescriptions in good faith." *Boyd v. United States*, 271 U.S. 104, 105 (1926). The instruction in *Boyd* read in part: "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.* at 107–08. Hence, the need to prove more than a practitioner's failure to comply with objective standards in the medical field finds its origin in this Court's pre-CSA case law and in *Moore*. *Moore, Linder,*

and *Boyd* all required knowledge and provided subjective standards for judging good faith.[3] The Tenth Circuit's opinion in *Kahn* is, consequently, inconsistent with this Court's precedent.

III. REQUIRING THAT THE GOVERNMENT PROVE THAT A MEDICAL PRACTITIONER *KNOW* A GIVEN PRESCRIPTION IS OUTSIDE THE SCOPE OF PROFESSIONAL PRACTICE IS NECESSARY TO SAVE §841 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

[3] Dr. Kahn does not object to an objective definition of "usual course of professional practice." What constitutes usual course of professional practice may be an objective question. A defendant is not entitled to knowingly issue a prescription outside of what he knows to be the usual course of professional practice. Rather, Dr. Kahn argues that in addition to proving that a given prescription was outside the scope of the usual course of professional practice, the government must prove that the defendant *knew* the prescription was outside the scope of professional practice. The latter is a subjective question. "Of course, the more unreasonable the asserted beliefs or misunderstandings are, the more likely the jury will consider them to be nothing more than simple disagreement with known legal duties imposed". Cheek v. United States, 498 U.S. 192, 203–04 (1991).

calculated wrongdoing at odds with statutory proscriptions, but instead simply to *regulate* business practices regardless of the intent with which they were undertaken.").

The Courts of Appeal recognize that the phrase "outside the scope of professional practice" is not susceptible to precise definition. *United States v. Singh,* 54 F.3d 1182, 1187 (4th Cir.1995); *United States v. August,* 984 F.2d 705, 713 (6th Cir.1992) ("There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice."). Indeed, juries are instructed that there is no precise definition.

Additionally, the Courts of Appeal appear to agree that acting outside the "usual course of professional practice" requires something more than failure to abide by the civil duty of care. *Sabean*, 885 F.3d 27 (1st); *Wexler*, 522 F.3d at 206 (2nd); *Feingold,* 454 F.3d at 1007(9th); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994); *United States v. Stump,* 735 F.2d 273, 276 (7th Cir. 1984). On the other hand, whether a given prescription falls within the usual course of professional practice is dependent upon "whether the physician prescribes medicine 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). *See also*, *Feingold,* 454 F.3d at 1011 n. 3 ("The term 'professional practice' implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."); *Norris,* 780 F.2d at 1209 (5th); *Hurwitz,* 459 F.3d at 480 (4th); *Vamos,* 797 F.2d at 1153 (2nd); *Smith*, 573 F.3d at 647–48 (8th). While the courts of appeal are emphatic that the "duty of care" and "practice generally recognized and accepted in the United States" are not the same thing, none provide a meaningful method of distinguishing between the two. There is general agreement that

a "mistake however, gross" is not sufficient to constitute a breach of generally accepted medical practice. *Wexler*, 522 F.3d at 206. That statement is facially inconsistent with allowing the conviction of doctors who make unreasonable but honest mistakes.

The phrase "usual course of medical practice" could be read to mean a violation of state medical regulations. Alternatively, it could mean deviation from the norms adhered to by most physicians in the field even where those norms do not conform with medical regulations. *See, e.g., Humphreys v. Drug Enf't Admin*., 96 F.3d 658, 662 (3d Cir. 1996) (reversing administrative decision to revoke doctor's registration where the administrator failed to "discuss the one and only defense raised … that prescribing antidepressants and other such drugs for a famous patient in the name of another individual in order to preserve the privacy of the patient was, in fact, the 'usual course' of medical practice in circumstances such as these."). One might expect that a doctor could turn to CDC or AMA guidelines on the prescription of opioids to determine what constitutes the "usual" course of professional practice. However, the CDC guidelines on the use of opioids are advisory. Powell D, Tamara M, Chou, Roger. CDC guideline for prescribing opioids for chronic pain—United States, 2016. JAMA 2016;315:1624–45.1622p.

The "usual course of professional practice" 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. 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. *See 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.").

"It is common ground that this Court, where possible, interprets congressional enactments so as to avoid raising serious constitutional questions." *Cheek*, 498 U.S. at 203; *Skilling v. United States*, 561 U.S. 358, 408–09 (2010).

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 simply distributing a controlled substance, but rather distributing a controlled substance *outside the scope of professional practice*. 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*, 139 S. Ct. at 2197.

Requiring that the government prove a defendant doctor knew he was prescribing outside the scope of professional practice could save the statute from fatal vagueness problems and eliminate the circuit splits and uncertainties noted above. "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).

The CDC and FDA guidelines on treating chronic pain are explicitly not mandatory. Removing any requirement that the government prove that 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). "[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*.

IV. THE PRESENT ISSUE IS OF SIGNIFICANT NATIONAL IMPORTANCE.

The absence of any clear mechanism for determining whether a given prescription falls inside or outside of generally recognized medical practice has led to a fear of prosecution and an increasing number of doctors withholding medication from patients suffering from chronic pain. 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); Amy J. Dilcher, *Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain*, 13 ANNALS HEALTH L. 81, 85 (2004). MM. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients,* 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 903 (2007) (fear of prosecution resulting in reduced opioid prescriptions).

It is the fact that an ordinary doctor cannot "understand what conduct is prohibited" by §841 that has led to this chilling effect. "Vague laws threaten to transfer legislative power to police and prosecutors, leaving to them the job of shaping a vague statute's contours through their enforcement decisions." *Sessions v. Dimaya*, 138 S. Ct. 1204, 1227–28 (2018); *See also*, *Grayned v. City of Rockford,* 408 U.S. 104, 108–109 (1972) ("A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis"). One recent study found that of 452 responding clinics in nine states, 43% indicated that they would not prescribe opioids to new patients.
Lagisetty, Pooja, *et al*., "*Assessing reasons for decreased primary care access for individuals on prescribed opioids*," PAIN. 2021 May; Vol 162. Issue 5. p 1379-1386 (*Available at*, DOI: 10.1097/j.pain.0000000000002145 (last visited, July 22, 2021)). If family practitioners are no longer willing to prescribe opioids to new patients out of fear of prosecution, than in one sense, doing so is outside what doctors generally do, and perhaps outside the usual course of professional practice. That does not, however, mean that the prescriptions are being withheld because of medical decision making or the doctor's best medical judgment.

Press reports in recent years document numerable instances, if anecdotal, of patients in desperate need of legitimate pain medication who are unable to find a doctor willing to prescribe to them or who are abruptly cut off from needed medication. McCoy & Mount, *Unintended Consequences: Inside the fallout of America's crackdown on opioids*, THE WASHINGTON POST (May 31, 2018), https://www.washingtonpost.com/graphics/2018/local/impact-of-americas-opioid-crackdown/; Rider, Travis, *What Chronic-Pain Patients Are Deeply Afraid Of,* THE NEW YORK TIMES (Oct. 31, 2019), https://www.nytimes.com/2019/10/31/opinion/opioid-crisis-addiction.html: Goodnough & Hoffman, *Good News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say,* THE NEW YORK TIMES (March 6, 2019), https://www.nytimes.com/2019/03/06/health/opioids-pain-cdc-guidelines.html?smid=nytcore-ios-share; O'Donnell & Alltucker, *Pain patients left in anguish by doctors 'terrified' of opioid addiction, despite CDC change*, USA TODAY (June 24, 2019), https://www.usatoday.com/story/news/health/2019/06/24/pain-patients-left-anguish-doctors-who-fear-opioid-addiction/1379636001/; Fuqua, Anne, *The other opioid crisis: pain patients who can't access the medicine we need*, THE WASHINGTON POST (March 9, 2018), https://www.washingtonpost.com/outlook/the-other-opioid-crisis-pain-patients-who-cant-access-the-medicine-they-need/2018/03/09/5ad83b24-2301-11e8-badd-7c9f29a55815_story.html.

V. THE REQUIREMENTS OF "LEGITIMATE MEDICAL PURPOSE" AND "USUAL COURSE OF PROFESSIONAL PRACTICE" SHOULD BE READ IN THE CONJUNCTIVE, NOT THE DISJUNCTIVE.

As argued above, the term "usual course of professional practice" is subject to multiple different interpretations and leaves little guidance to juries and prosecutors in deciding whether a doctor's actions have crossed the line between malpractice and criminality. The vagueness problem is exacerbated, in part, because the courts of appeal (with the exception of the Ninth

Circuit, *Feingold*, 454 F.3d at 1008) have divorced "usual course of professional practice" from "legitimate medical purpose." *See Nelson,* 383 F.3d 1227 (finding government can prove either that the defendant was acting "outside the scope of professional practice" or "without a legitimate medical purpose"); *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. Bek*, 493 F.3d 790, 798 (7th Cir. 2007); *United States v. Limberopoulos*, 26 F.3d 245, 249-50 (1st Cir. 1994); *United States v. McIver*, 470 F.3d 550, 559 (4th Cir. 2006); *United States v. Joseph*, 709 F.3d 1082, 1094 (11th Cir. 2013). That is, doctors can be convicted even if the prescriptions issued served a legitimate medical purpose, if the procedures used were inconsistent with the procedures "generally recognized throughout the United States." *Nelson*, 383 F.3d at 1233.

In early cases following the passage of the CSA, courts tended to interpret the phrase "usual course of professional practice" and "legitimate medical purpose" to mean approximately the same thing. *United States v. Kirk,* 584 F.2d 773, 784 (6th Cir. 1978) (citing authority that "[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.'*"); United States v. Plesons*, 560 F.2d 890, 897 (8th Cir. 1977); *United States v. Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975). This view made sense in the context of the *Moore* and the prior Harrison Act cases requiring that a doctor *intentionally* act not as a medical professional but as a drug dealer. *Moore*, 423 U.S. at 143 (defendant acted not as a doctor but a drug "pusher"); *Linder*, 268 U.S at 17 (reversing for failure to establish that doctor had "conscious design to violate the law."). In that context, it makes sense to think of acting outside the scope of medical practice as coextensive with acting without a legitimate medical purpose.

In all but the Ninth Circuit, that is no longer the case today. Juries are informed that doctors can be convicted *either* for acting outside the scope of professional practice *or* for issuing a prescription without a legitimate medical purpose. By instructing the jury in the disjunctive, courts explicitly tell the jury that whatever the "usual scope of professional practice" means, it does *not* have the same meaning as "legitimate medical purpose." Indeed, according to at least the Eleventh, Tenth, and Fifth Circuits, different *mens rea* attach to the two standards.

Kahn candidly acknowledges that several courts have held that the "usual scope of professional practice" standard is not unconstitutionally vague. *United States v Jobe*, 487 F2d 268 (10th Cir. 1973); *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973); *Rosenberg,* 515 F2d at190.

However, in several of the circuits, including the Tenth Circuit, the case law has moved a great distance from what was generally considered required to convict at the time of *Moore* and under the Harrison Act. By entirely detaching "usual course of professional practice" from any reference to either the defendant's intent *and* whether a charged prescription was actually helping the patient (*i.e.* not for a legitimate medical purpose), the Tenth Circuit has effectively allowed doctors to be convicted of a criminal offense for issuing prescriptions that (1) a doctor may honestly believe are helping a patient and (2) are actually helping the patient. Under the disjunctive interpretation of the CFR, doctors are not shielded from prosecution even if their prescriptions are actually helping their patients. Requiring the government to prove both that a practitioner intentionally issued a prescription not for a legitimate medical purpose *and* outside the usual course of medical practice would help to prevent that result.

CONCLUSION

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

Respectfully Submitted,

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DATE

s/Beau B Brindley
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