No. _____

In the Supreme Court of the United States

DONOVAN DAVE DIXON,
Petitioner,

v.

UNITED STATES OF AMERICA,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Because prescribing controlled substances is a quintessential part of a physician's professional life, when those controlled substances have medical uses, the Controlled Substances Act ("CSA") empowers physicians to do so. But that authority has limits.

Specifically, the CSA "bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood." *Gonzalez v. Oregon*, 546 U.S. 243, 270 (2006). A doctor, therefore, is criminally liable for unlawfully distributing a controlled substance when acting as "a drug 'pusher,'" and "not as a physician." *United States v. Moore*, 423 U.S. 122, 126, 143 (1975).

The practice of instructing juries in the Fourth Circuit, however, strips the CSA, as applied to physicians, of any meaningful *mens rea* component and blurs this clear line between criminal and merely unprofessional or negligent conduct, and allows medical practitioners to be convicted of felony drug trafficking based on malpractice or other disputes about the standard of care.

The question presented is:

Whether juries must be instructed that the government must prove that a physician acted with the *mens rea* of intent as to issuing a prescription outside the usual course of professional practice or not for a legitimate medical purpose and that that action and intent must mean that a physician has abandoned medical practice and engaged in "illicit drug dealing and trafficking as conventionally understood" in order to prevent a criminal conviction for malpractice under the CSA?

PARTIES TO THE PROCEEDING

Donovan Dixon, petitioner on review, was the defendant-appellant below.

The United States of America, respondent on review, was the appellee below.

RELATED PROCEEDINGS

United States Court of Appeals for the Fourth Circuit:

United States v. *Dixon*, No. 18-4936 (4th Cir. Dec. 20, 2019)

United States District Court for the Eastern District of North Carolina:

United States v. *Dixon*, No. 7:16-cr-30-D-1 (E.D.N.C. Aug. 30, 2018).

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PETITION FOR A WRIT OF CERTIORARI

Donovan Dixon respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit.

OPINION BELOW

The Fourth Circuit's opinion is unpublished but available at Pet. App. 3a-4a.

JURISDICTION

The District Court entered on the docket the final judgment on August 30, 2018. The Fourth Circuit had jurisdiction pursuant to 28 U.S.C. § 1291 and entered judgment on December 20, 2019. Pet. App. 7a. On March 19, 2020, this Court extended deadline to file petitions for a writ of certiorari by 150 days from the

date of the lower court judgment due to the ongoing public health concerns relating to COVID-19. This Court has jurisdiction under 28 U.S.C. § 1254(1).

FEDERAL PROVISIONS INVOLVED

The relevant statutory provisions are codified at 21 U.S.C. §§ 802, 829, 841, and 21 C.F.R. § 1306.03, 1306.04, and are set forth fully in the Appendix. *See* Pet. App. 8a-66a.

STATEMENT OF THE CASE

A. Statutory Background

Because this is a physician-prescribing case, it has a unique legal posture under federal drug law.

The Controlled Substances Act (CSA) generally prohibits any person from dispensing or distributing a controlled substance. See 21 U.S.C. § 841(a)(1). But many of the controlled substances covered by the Act have important medical uses, thus the Act exempts physicians and other medical "practitioners" from this prohibition and authorizes them to write prescriptions for certain controlled substances "in the course of professional practice." 21 U.S.C. §§ 802(21), 829.

For a physician's controlled substance prescriptions to be lawful, there are two important conditions.

First, the physician must register with the Attorney General. See 21 U.S.C. §§ 802(19), 822(b); 21 C.F.R. § 1306.03. There is no dispute Dr. Dixon was lawfully registered.

Second, the physician must be acting as a physician, that is, "in the course of professional practice." 21 U.S.C. § 802(19). Regulations promulgated by the Attorney General further provide that to be lawful, a prescription "must be issued for a legitimate medical

purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The regulation does not define the terms "legitimate medical purpose" or "usual course of professional practice," nor does it provide any further explanation about the differences between civil and criminal liability vis a visa a failure to comply with a particular standard of care. It lacks an articulation of the *mens rea* required to convict a physician for prescribing controlled substances, conduct that is at the very core of a physician's responsibilities towards caring for their patients.

This Court has consistently drawn the line between civil and criminal liability. That is, the CSA "bars doctors from using their prescription writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood," *Gonzalez, v. Oregon*, 546 U.S. 243, 270 (2006), and that a doctor, therefore, is criminally liable for unlawfully distributing a controlled substance when acting as "a drug pusher," and "not as a physician." *United States v. Moore*, 423 U.S. 122, 126, 143 (1975).

The Fourth Circuit employs the "legitimate medical purpose" and usual course of professional practice" language of § 1306.04(a) when instructing juries about the elements the government must prove to convict a physician for unlawfully prescribing (that is, for a violation of the common drug crime of distribution of a controlled substance under 21 U.S.C. § 841(a)).

The Fourth Circuit's precedents on jury instructions for applying the CSA to physicians do not contain a *mens rea* element as to the language from § 1306.04(a) and do not inform juries that conduct akin

to civil malpractice is insufficient to sustain a conviction and that acting outside the usual course of professional practice or without a legitimate medical purpose is conduct akin to drug dealing conventionally understood. *See, e.g., United States v. Hurwitz*, 459 F.3d 463, 475-77, 479 (4th Cir. 2006); *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995). Furthermore, the panel in the Fourth Circuit below relied on other circuit decisions, *see United States v. Volkman*, 797 F.3d 377, 385-86 (6th Cir. 2015), to determine that this Court's decision in *Gonzalez* "imposed no new requirements [in jury instructions] to establish a violation of the CSA." Pet. App. 3a-4a.

Thus, juries in the Fourth Circuit are instructed, as the jury in Dr. Dixon's case was, that there are no specific guidelines but that a physician is criminally liable for issuing a prescription for a controlled substance if they determine that prescription "was not for a legitimate medical purpose or was outside the usual course of professional medical practice." Pet. App. 81a. Juries are given a non-binding list of factors tending to show professional regulation violations that they may take into consideration in making the determination of whether the physician's conduct was outside the usual course of professional practice or without a legitimate medical purpose. *Id*. at 82a.

B. Procedural History

1. Dr. Dixon ran a small medical practice in the rural and impoverished area of Robeson County, North Carolina.

In 1998, Dr. Dixon graduated from medical school and afterwards completed residencies in family medicine and OB/GYN. (JA 850-51).[1] In 2005, Dr. Dixon served as an Army physician and treated very seriously injured service members. (*Id.*). He was honorably discharged from the Army and received numerous awards. (*Id.*).

In 2011, Dr. Dixon opened his own clinic, focusing on pain management, in Robeson County, North Carolina, an impoverished rural area outside of the Army base at Fort Bragg. (*Id.* at 841.). The North Carolina Medical Board reprimanded Dr. Dixon in 2014 for failing to comply with professional regulations relating to the dispensing of pain medications, and, after another complaint of inappropriate prescribing, in 2015, Dr. Dixon executed a consent order with the North Carolina Medical Board agreeing not to prescribe controlled substances. (*Id.* at 842). In fact, Dr. Dixon stopped practicing medicine in the United States and moved back to Jamaica, where he was born. (*Id.* at 793).

However, in 2016, the government obtained an indictment against Dr. Dixon for his prescribing practices between 2012 and 2015, conduct constituting professional regulation violations addressed by the North Carolina Medical Board. (*Id.* at 18-21). He was

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[1] Citations are to the record on appeal—the joint appendix—in the Fourth Circuit. The citations are provided for the Court's convenience in the event this Court deems it necessary to review the record to resolve this petition. *See* Sup. Ct. R. 12.7.

arrested while on a visit back to the United States. (*Id*. at 850).

In 2017, the government brought additional charges for the conduct addressed by the North Carolina Medical Board in a superseding indictment, charging Dr. Dixon with conspiracy to unlawfully dispense and distribute controlled substances in violation of 21 U.S.C. § 846 and also with twenty counts of unlawfully dispensing and distributing controlled substances in violation of 21 U.S.C. § 841(a)(1). (*Id*. at 40-44).

2. Consistent with circuit precedent, the district court failed to give a *mens rea* instruction to the jury as to what the government must prove that a physician intended when they wrote prescriptions while allegedly acting outside the usual course of professional practice or without a legitimate medical purpose, or to otherwise delineate the line between medical malpractice and criminal conduct.

There was no dispute at trial that the prescriptions in question were for controlled substances and had been written by Dr. Dixon, i.e., that he had "distributed" or "dispensed" a controlled substance. The only issue was the exercise of his professional judgment, and whether the prescriptions were written for a "legitimate medical purpose" and within his "usual course of professional practice."

The district court failed to instruct the jury on the *mens rea* the government must prove beyond a reasonable doubt than an accused physician acted with in connection with these phrases or otherwise clarify that these phrases create a different and higher

standard than the civil standards for medical malpractice.[2]

Without clarification for the jury, the disposition of this critical issue turned mostly on the testimony of the government's expert, Dr. Greenblatt, a doctor and medical school professor practicing in a large urban hospital, when weighed against the testimony of Dr. Dixon's former spouse, Dr. Baptiste, a doctor with experience in pain management in impoverished rural areas.[3]

Dr. Greenblatt recognized that the North Carolina Medical Board had not adopted the 2014 national guidelines for opioid safety promulgated by the Centers for Disease Control ("CDC") until 2017, well after the allegations in the case occurred. (*Id*. at 518-19). That said, Dr. Greenblatt testified to an unwritten standard of care that, in his opinion, was in effect back in 2012 through 2014, focusing on the need to perform physical examinations and obtaining medical records for the patient generated by other provides. (*Id*.). When asked how a practitioner would know this standard of care during the relevant time frame, Dr. Greenblatt testified that most learn it during their post-medical school residencies. (*Id*. at 520).

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[2] The pertinent instructions ultimately given by the district court appear below in the Pet. App. 81a to 84a.

[3] The Government also relied, in part, on incentivized witnesses, i.e., testimony from people they had charged in the case for obtaining prescriptions from Dr. Dixon, as well as a former employee of Dr. Dixon's clinic who had become an informant for the DEA. (JA 176-196, 247-257, 379-429). No undercover investigative work that could have been audio or video recorded was conducted to corroborate the allegations that these witnesses made against Dr. Dixon.

Furthermore, for example, Dr. Greenblatt himself did not have the medical records for one of the testifying co-defendants, J.F., who had been a patient of Dr. Dixon, and so Dr. Greenblatt's opinions, informed by that former patient's testimony, on when the physician-patient relationship had turned illegitimate was based on the credibility of a person facing criminal prosecution who was an admitted addict. (*Id*. at 529-32). On cross examination, Dr. Greenblatt admitted that when patients have limited financial resources, and they are self-pay without extra funds for radiological studies, etc, it presents a challenge to the physician treating for pain management. (*Id*. at 543).

While Dr. Dixon's former attorneys, who were trial counsel in this case, did not seek to have Dr. Baptiste formally tendered as an expert, she also testified about the relevant standards of care as they applied in the actual communities being served, especially in impoverished rural areas. (*Id*. at 603-628). She was a family medicine physician for the Department of Defense. (*Id*. at 604). She had previously worked for the VA in the area where Dr. Dixon practiced, and described that practice in that rural area as very challenging, especially due to the poverty. (*Id.* at 608-09).

In the area where Dr. Dixon practiced, Dr. Baptiste explained that there is only one hospital in the Pembroke area. (*Id*. at 609). As a result, "[t]here is not a lot of access to physical therapy, x-rays, MRIs, even pain management clinics." *Id*. That affected her medical practice because her patients could not always travel to Fayetteville to get x-rays which, according to Dr. Greenblatt, may have been necessary medical information for a doctor to review before prescribing opiates. *Id*. Dr. Baptiste testified that when a doctor

has no records to refer to, or x-rays to examine, because a patient did not have access to those medical services, the only thing a doctor can use is his or her ability to examine the patient, the doctor's training and the patient's history – or what the patient tells the doctor. (*Id.* at 610-611).

Dr. Baptiste continued by explaining that sometimes a doctor-patient relationship can be formed even when the doctor and patient have never met face-to-face. (*Id*. at 622). She explained, that "there are situations * * * that a doctor might prescribe for a family member [of a patient] because they know that family member, whether it be a husband or wife, whatever, and they choose to write a hand-script for them." (*Id*. at 627-628).

Dr. Baptiste testified that it can be very difficult to differentiate between an addict and a person genuinely in pain. (*Id*. at 613). She said, "when a patient comes in complaining of pain, you don't know if they have pain * * * you're just basically going off what they're telling you. And if they're coming to see you for pain, you're required to address it." *Id*. She explained that people, and addicts in particular, can be very manipulative. (*Id.* at 614). "[Y]ou have to balance your clinical training and your desire to help someone and relieve their pain with trying to see through the fog, and see do they really have pain, how are they walking, what's going on." (*Id*.).

She also testified that, when dealing with patients complaining of pain, some doctors are more aggressive than others. (*Id*.). Furthermore, doctors in combat situations are even more aggressive in pain management treatment because when they are taking on gun fire, they cannot have soldiers "laid up" in pain.

(*Id.* at 614). She said, "[s]o, if someone comes in with – like I see it in my clinic every day, and we're not even a combat zone – but we see people who come back from combat who have injuries that they couldn't have gotten through if they didn't have that pain relief." (*Id.*). Thus, the actual practice of prescribing pain medication varies based on both the doctor's experience and the patient's circumstances. (*Id.*).

Dr. Baptiste testified that the first time she ever wrote a prescription for an opiate, it was after she completed her residency. (*Id.* at 611). Contrary to what Dr. Greenblatt testified was the norm, Dr. Baptiste had not learned how to prescribe opiates in medical school or her residency. (*Id.*). She had to consult the Physician's Desk Reference to learn the appropriate dosages to prescribe her patient. (*Id.*). Dr. Baptiste stated that it has only been in the last few years that doctors have become more versed in the use of pain medications, and opiates in particular. (*Id.* at 612). However, Dr. Baptiste conceded effectively that Dr. Dixon was at least negligent in some of his prescribing practices by saying she would not have engaged in some of those practices. (*Id.* at 626).

The jury ultimately convicted Dr. Dixon on all 21 counts in the indictment. (Id. at 759-774). At the end of the sentencing hearing, the district court sentenced Dr. Dixon to 240 months imprisonment (20 years). *See* Pet. App. 2a.

3. The Fourth Circuit rejected Dr. Dixon's challenge to the jury instructions.

On appeal, despite even the government alleging in the superseding indictment that Dr. Dixon acted with the *mens rea* of intending to act outside the usual course of professional practice and not for a legitimate

medical purpose (but, critically, not instructed on by the district court), the panel in the Fourth Circuit—in an unpublished decision—rejected Dr. Dixon's challenge to the jury instructions, in part citing that other circuits had determined that this Court's decision in *Gonzalez* did not impose any new requirements in the body of law on instructing juries when a physician is prosecuted under the CSA. *See* Pet. App. 3a-4a.

REASONS FOR GRANTING THE WRIT

I. THE FOURTH CIRCUIT'S INSTRUCTIONAL PRACTICE FAILS TO SET OUT A *MENS REA* THE GOVERNMENT MUST PROVE & LEAVES JURIES UNINFORMED ABOUT THE CLEAR LINE THIS COURT HAS DRAWN BETWEEN CIVIL MALPRACTICE AND CRIMINAL LIABILITY RESULTING FROM DRUG DEALING AS CONVENTIALLY UNDERSTOOD

By developing the law of jury instructions in unlawful prescribing trials without instructing on a *mens rea* that the government must prove that a physician acted with in relation to the key terms "legitimate medical purpose" and "usual course of medical practice," and without otherwise instructing about the line between criminal conduct and bad or merely disputed medical practice, the Fourth Circuit is failing to enforce an important line that Congress and this Court have drawn.

Most recently, in discussing the reach of the Controlled Substances Act ("CSA") in *Gonzalez v. Oregon*, this Court emphasized the Act's narrow scope when it comes to the practice of medicine. Specifically, the Court explained the CSA is a statute concerned with

combating recreational drug abuse, and not an attempt (or authorization to the federal government) to regulate medical practice generally. 546 U.S. 243, 272 (2006). This Court explained that the CSA draws a clear and important line between criminal and non-criminal conduct:

> The [CSA] and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.

Id. at 269-70.

This is the same line this Court drew when it upheld the government's prosecution of a physician under the CSA in *United States v. Moore*, the only case where this Court has directly dealt with a physician being prosecuted under the CSA on the merits. 423 U.S. 122, 143 (1975).

In *Moore*, this Court held that physicians were not categorically exempt from criminal prosecution under the CSA's unlawful distribution provisions, i.e., 21 U.S.C. § 841(a). And criminal liability existed in *Moore*, because the doctor "acted as a large scale 'pusher' not as a physician." *Id*. This clear line, where the government must prove that the physician acted with a *mens rea* that they were engaged in drug dealing as conventionally understood effectuates what this Court sought to clarify when deciding *Moore*, which involved a doctor "prescribing as much and as frequently as the patient demanded…not charg[ing] for medical services rendered, but graduat[ing] his fee

according to the number of tablets desired." *Id*. at 142-43.

This clear line—that the accused physician intended (the *mens rea*) to act as a drug dealer as conventionally understood—is also embodied in the same line that this Court drew a century ago in cases interpreting the 1914 Harrison Act (the predecessor to the CSA), and where this Court affirmed convictions from prosecutions where the doctor "[i]n reality [ ] became party to sales of drugs." *Linder v. United States*, 268 U.S. 5, 20-22 (1925); *see, e.g., Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920) (affirming conviction of doctor who prescribed large quantities of morphine, where prescriptions were demonstrably just sales to drug addicts, where doctor, *inter alia*, charged according to the amount of drugs "prescribed"); *Webb v. United States*, 249 U.S. 96, 99 (1919) (affirming conviction where physician and druggist conspired to sell large quantities of morphine under the guise of issuing prescriptions); *United States v. Behrman*, 258 U.S. 280, 288-89 (1922) (affirming conviction where physician "indiscriminate[ly] dol[ed] out narcotics" in such large quantities to a known addict that the "so called prescriptions" could only be for drug use or sale); *compare with Linder*, 268 U.S. at 17, 22 (reversing conviction of a physician because, unlike in *Jin Fuey Moy*, *Webb* or *Behrman*, the physician's distribution of only a small quantity of drugs did not give rise to such clear inference of unlawful actions and failure to comply with professional standards, or in other words a "conscious design to violate the law").

Against this backdrop, the line that has been drawn by this Court, and Congress, is when a physician intends (the *mens rea*) to cease to act as a physician and instead intends to act as a drug dealer that

causes a doctor to face federal criminal prosecution and serve potentially years, or decades, in prison. This Court in *Moore* implicitly approved of a mens rea instruction by acknowledging that subjective good faith by a physician would be a defense to an accusation that a physician acted outside the usual course of professional practice. 423 U.S. at 139.

The lack of a *mens rea* as to the element of prescribing (distributing) controlled substances outside of the usual course of professional practice or without a legitimate medical purpose violated two basic principles of our criminal justice system. That lack ignores the principle that "[t]he existence of a *mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence." *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978). That rule is "universal and persistent in mature systems of law." *Morissette v. United States*, 342 U.S. 246, 250 (1952). Its application is especially critical "where the act underlying the conviction" – here, a doctor prescribing medicine – "is by itself innocuous." *Arthur Andersen LLP v. United States*, 125 S. Ct. 2129, 2134 (2005). This Court has emphasized this principle repeatedly. "*Morissette*, reinforced by *Staples* [*v. United States*, 511 U.S. 60 (1994)], instructs that the presumption in favor of a scienter requirement should apply to each of the statutory elements that criminalize otherwise innocent conduct." *United States v. X-Citement Video, Inc.* 513 U.S. 64, 72 (1994); *see also Rehaif v. United States*, 139 S. Ct. 2191, 2200, 204 L. Ed. 2d 594 (2019) (clarifying that government must prove that in a prosecution for unlawfully possessing a firearm the accused knew they belonged to the relevant category of persons barred from possessing a gun).

Without this *mens rea*, which is the current state of the law in the Fourth Circuit, leaves a realm of conduct up for debate in the jury room that is better suited to medical malpractice proceedings or state medical board or licensing actions. *Cf. Gonzalez*, 546 U.S. at 270-21 (noting traditional reservation to the states of the regulation of the medical profession). Some circuits, recognizing the ambiguity in the concepts of usual course of professional practice and legitimate medical purpose, have cautioned district courts of the perils of lowering the standard for criminal liability. *See, e.g., United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009) (recognizing danger in confusing mere medical malpractice and 21 U.S.C. § 841 standards); *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006) (noting this Court's care in *Moore* to emphasize that the defendant had so wantonly ignored basic protocols of medical profession that he acted as a large-scale pusher and not as a physician); and, the Fourth Circuit has made a similar warning (but is not required in the instruction practice in the district courts), *United States v. McIver*, 470 F.3d 550, 558 (4th Cir. 2006) (noting potential for juries to confuse the civil standard of care applied in medical malpractice cases).

Only the Ninth Circuit has read into its body of law for instructions a *mens rea* requirement as to the concepts of usual course of professional practice and legitimate medical purpose, that is "criminal liability under § 841(a) requires more than proof of a doctor's intentional failure to adhere to the standard of care." *Feingold*, 454 F.3d at 1011. "A practitioner becomes a criminal not when he is a bad or negligent physician, but when he ceases to be a physician at all." *Id*. Other

circuits, recognize the ultimate danger, i.e. convictions for civil malpractice, resulting from a lack of a clear articulation of the *mens rea* that must be proven but fail to make a *mens rea* requirement a core part of their body of law on instructions governing the application of the CSA to physician prescribing practices. *See United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) (noting that a criminal conviction "requires more" than a showing of malpractice); *see also United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978) (stating that there are no specific guidelines concerning what is required to support a conclusion that the accused acted outside the usual course of professional practice).

Telling juries that a doctor must have acted with "a legitimate medical purpose" or within "the usual course of professional practice" to escape criminal liability, gives them a free hand to decide for themselves what the standard of care is, and then convict on any deviation from that standard. It is not at all the same thing as telling them that criminal liability can only attach when a doctor intentionally abandons his or her role as a physician to become a drug dealer as conventionally understood. *Cf. Gonzalez*, 546 U.S. at 258 ("All would agree, we should think, that the statutory phrase 'legitimate medical purpose' is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense.").

Moreover, a "good faith" jury instruction, as was given here is no answer to these concerns. It creates circular logic, because that instruction simply re-incorporates the very same terms, still without defining them, thus allowing a conviction for a species of civil malpractice:

> [i]f a doctor dispenses a drug in good faith, in medically treating a patient, then the doctor has dispensed that drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully. Good faith in this context means good intentions, and the honest exercise of professional judgment as to the patient's needs. It means that the defendant acted in accordance with what he reasonably believed to be a legitimate medical purpose and… in accordance with the usual course of generally accepted medical practice.

See, e.g., Pet. App. 82a. Additionally, the dissent in *Hurwitz* pointed out the logical contradiction between the concept of good faith (the intent of the actor) and an objective inquiry (the act in question) and concluded that good faith should be a subjective standard. 459 F.3d 463, 483 (4th Cir. 2006) (Widener, J., dissenting).

The failure to instruct the jury on a *mens rea* that the government had to prove, as was actually alleged in the counts in indictment, erases the line that Congress and this Court have drawn to separate negligence and malpractice from the realm of intent and conduct that establishes criminality, creating the very real possibility of conviction on grounds broader than "drug dealing and trafficking as conventionally understood."

II. THE FOURTH CIRCUIT'S PRACTICE DEVOID OF A *MENS REA* ELEMENT CRIMINALIZES DISPUTES ABOUT THE PROPER STANDARD OF CARE

By failing to define what is—and what is not—encompassed by the terms "legitimate medical purpose" and "usual course of professional practice," and then also failing to articulate what *mens rea* a physician must have when deviating from those terms in their prescribing practices in order to be lawfully prosecuted under the CSA, the Fourth Circuit's practice effectively criminalizes disputes about the proper standard of care.

Without an instruction on *mens rea* in this context, and further clarification on what is and is not the usual course of professional practice and a legitimate medical purpose, the gravamen of physician-prescribing cases is almost always going to be the physician's exercise of professional judgment.

Not only do juries have a free hand under this legal regime to decide for themselves what the standard of care is in a given case, and then to convict on a deviation from that standard, this legal regime also empowers the government to mold a standard of care through the use of their experts in these trials, even if, as what occurred in the trial below, another doctor testifies in disagreement with the government's expert.

This outcome is in tension with the limits on the federal government's ability to define standards for the proper medical care and treatment of patients. As this Court explained in *Gonzalez*, the CSA evidences no Congressional intent to permit the Attorney General to make such a general definition; in fact, to the

contrary, it affirmatively "conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise." 546 U.S. at 265-66. Yet the government's use of experts to testify in a trial where the jury is ultimately charged without any meaningful principle for distinguishing between negligence or malpractice, on the one hand, and conduct that is outside the "usual course of professional practice" and without "a legitimate medical purpose," i.e., criminal behavior, on the other, and then without a *mens rea* element as to those concepts, is so problematic because bad and outright wrong medical judgments may occur within the usual course of a physician's professional practice.

Here, two doctors with experience in treating chronic pain testified on what was often different sides of the line. Also, Dr. Dixon's interview with the DEA was played to the jury, where there was an effective admission of negligence on his part. The disagreements by the testifying doctors in this case is unsurprising given how fluid and uncertain the concepts of usual course of professional practice and legitimate medical purpose are, and why this Court's articulation in *Moore* and *Gonzalez* of where that line rests makes a great deal of sense. But the practice in the Fourth Circuit, and other circuits, in instructing juries on the application of the CSA to a physician's prescribing practices fails to give effect to where this Court and Congress has identified where that line rests. Physicians are critical to the wellbeing of our society, now more than ever, however, a legal regime that subjects a physician to great ambiguity on where the line rests for criminal prosecution and exposure to what this Court recognized in *Moore* as "severe criminal penalties" is untenable. 423 U.S. at 135.

In contrast, explaining to juries that criminal prosecutions are not evaluating malpractice, and that a doctor intentionally acts outside of "a legitimate medical purpose" and the "usual course of professional practice" only when they intentionally become a drug "pusher" engaging in drug dealing as "conventionally understood," provides a clear and meaningful benchmark to evaluate the expert testimony, and allows juries to serve as a check against unchained prosecution. But failing to expressly delineate these critical boundaries through a *mens rea* element and the clarification of the narrow application of the CSA to physicians that this Court articulated in *Gonzalez*, risks criminalizing the practices of physicians who may be negligent or exercising poor judgment, even engaging in professional norm violations, but are not crossing the line into the behavior of drug dealers conventionally understood.

This Court has repeatedly intervened to rein in the government's overly expansive interpretation and application of criminal statutes. *See, e.g., Kelly v. United States*, 590 U.S. ___ (2020) (reversing convictions of local officials for causing crippling and dangerous traffic jams on the George Washington bridge by holding federal wire fraud statute does not reach all forms of deception through use of the wires but instead only those schemes where the object is obtaining money or property); *Maslenjak v. United States*, 137 S. Ct. 1918, 1927 (2017) (rejecting government's broad interpretation of 18 U.S.C. § 1425(a), which would "give prosecutors nearly limitless leverage" because "Congress…did not go so far as the Government claims"); *McDonnell v. United States*, 136 S. Ct. 2355, 2367-68 (2016) (rejecting government's broad interpretation of

18 U.S.C. § 201(a)(3), which read statutory term "official act" to "encompass nearly any activity by a public official," and instead "adopt a more bounded interpretation of 'official act'"); *Yates v. United States*, 135 S. Ct. 1074, 1081 (2015) (plurality opinion) (rejecting government's broad interpretation of 18 U.S.C. § 1519, which read undersized fish as falling within phrase "any record, document, or tangible object," because it was an "unrestrained reading'"); *Bond v. United States*, 572 U.S. 844, 857-61 (2014) (rejecting government's broad interpretation of 18 U.S.C. § 229(a)(1) and statutory implementation of chemical weapons treaty as including local crime of poisoning a romantic rival).

This Court should rein in the application of the CSA to the prescribing practices of physicians through a *mens rea* element and clarification on the concepts of usual course of professional practice and legitimate medical purpose in order to re-establish the line that this Court has already drawn. Indeed, it has been nearly 46 years since this Court last reviewed the federal government's criminal prosecution of a physician for unlawfully prescribing controlled substances in *Moore*. (*Gonzalez*, while important to this question, arose as an action for injunctive relief by the State of Oregon and others against an interpretive rule issued by the Attorney General indicating that physicians who assisted the suicide of terminally ill patients under state law would be violating the CSA, *see* 546 U.S. at 248, 254.) There is no substitute for reaffirming the line between criminal conduct and negligence or professional malfeasance in an actual criminal prosecution.

III. THE QUESTION PRESENTED ABOUT WHAT THE GOVERNMENT MUST PROVE TO ESTABLISH A PRACTITIONER'S CRIMINAL LIABILITY HAS SIGNIFICANT CONSEQUENCES FOR MEDICAL PRACTICE NATIONWIDE.

Now, especially in an era that has brought us a national emergency and global pandemic due to COVID-19, and rampant debate within the medical community on the efficacy of potential treatments, this is an important time for this Court to intervene and require juries to be instructed more clearly about when a physician is criminally liable for prescribing a controlled substance.

Specifically to this case, in the years since the prescriptions in this case were written back in 2012 through 2014, the national attention on the use, and misuse, of opioids and other prescription drugs has increased drastically. *See, e.g.,* Lenny Bernstein, *White House opioid commission calls for wide-ranging changes to anti-drug policies*, Washington Post, Nov. 1, 2017 (recounting national attention on prescription drug abuses). In 2016, the Centers for Disease Control and Prevention published a guideline for prescribing opioid pain medications in primary care settings. *See* Centers for Disease Control and Prevention, et. al., *Guideline for Prescribing Opioids for Chronic Pain*, J. Pain & Palliative Care Pharmacotherapy, 2016, Jun; Vol. 30(2):138-40; [4] *CDC Guideline for Prescribing*

[4] *Available at,* https://www.ncbi.nlm.nih.gov/pubmed/27301691; https://www.tandfonline.com/doi/full/10.3109/15360288.2016.1173761.

Opioids for Chronic Pain – United States, 2016, Morbidity and Mortality Weekly Report (MMWR), March 15, 2016.[5]

In 2017, the Acting Secretary of Health and Human Services declared the national opioid abuse epidemic a public health emergency, and the President established a commission to study the problem and make recommendations. *See, e.g.*, U.S. Dep't of Health and Human Services, Press Release, *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, Ex. Order 13784 (March 29, 2017) (establishing Presidential Commission).[6]

The government has also responded by prosecuting doctors. *See, e.g.,* Michael Nedelman, *Doctors increasingly face charges for patient overdoses*, CNN, July 31, 2017 (reporting that "[b]etween 2011 and 2016, the number of doctors punished by the DEA jumped more than five times"); Kelly K. Dineen & James M. DuBois, *Between A Rock and A Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 Am. J.L. & Med. 7, 36 (2016) (suggesting that "[t]here are some indications that law enforcement scrutiny of physicians has grown recently in reaction to the rise in prescription drug abuse").

The government has identified prosecutions of physicians under the CSA as a high priority area, thus there is an expectation that these prosecutions will be recurring events with a profound impact on the

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[5] *Available at,* https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[6] *Available at,* https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html.

medical profession. *See* K. Tate Chambers, *A Primer on Investigating Doctors Who Illegally Prescribe Opioids*, 66 U.S. Att'y Bull. (July 2018) at 19-32 (recounting efforts to make the "overprescribing of opioids by health care professionals a top priority of the Department of Justice," and providing guidance on such prosecutions);[7] *see also* U.S. Dep't of Justice, Press Release, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017);[8] U.S. Dep't of Justice, Press Release, Attorney General Sessions Announces New Prescription Interdiction and Litigation Task Force (Feb. 27, 2018).[9]

Accordingly, the courts are likely to continue to grapple with many cases involving physicians charged with unlawfully prescribing controlled substances, and predictably beyond just the opioid crises. Instructing juries with greater specificity, uniformly across the country, will ensure that they can adequately distinguish well-meaning but mistaken doctors (and even bad doctors engaged in professional malfeasance) from drug dealers conventionally understood. Doing so with an emphasis on the *mens rea* that the government must prove to convict a physician (or other qualified practitioner) still protects the government's important efforts to shut down problematic "pill mills" and "pain clinics" that are medical practices in name only, or to prosecute doctors "who sold drugs, not for legitimate purposes, but 'primarily for

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[7] *Available at,* https://www.justice.gov/usao/page/file/1083791/download.

[8] *Available at,* https://www.justice.gov/opa/pr/attorney-general-sessions-announces-opioid-fraud-and-abuse-detection-unit.

[9] *Available at,* https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force.

the profits to be derived therefrom.'" *Moore*, 423 U.S. at 135 (quoting legislative history of the Controlled Substances Act, H.R. Rep. No. 91-1444 at 10).

Adding this clarity to the legal regime governing prosecutions of physicians under the CSA, with a *mens rea* element and further clarification on the concepts of usual course of professional practice and legitimate medical purpose, will curtail the over- criminalization of disputes about the proper exercise of medical judgment, holding the line of criminal liability where Congress and this Court have appropriately set it, at those who "engage in illicit drug dealing and trafficking as conventionally understood." *Gonzalez*, 546 U.S. at 270.

The instructional practice in the Fourth Circuit, and in other circuits, has obscured this clear line and risks convictions and imposing serious penalties, including years or decades in prison, for a species of civil medical malpractice. This Court's intervention is necessary to reaffirm the line and ensure that juries are properly instructed.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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