NO. _____

IN THE

SUPREME COURT OF THE UNITED STATES

JOEL E. MILLER,

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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QUESTION PRESENTED

Because many controlled substances have medical uses, the Controlled Substances Act ("CSA") authorizes doctors and other medical practitioners to issue prescriptions. But as this Court has explained, that authority obviously 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." *Gonzales 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 Tenth Circuit, however, blurs this clear line between criminal and non-criminal conduct, and allows doctors and other medical practitioners to be convicted of felony drug crimes based on malpractice, or even mere disagreements about the appropriate standard of care.

The question presented is:

Whether the phrase "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," as used in 21 C.F.R. § 1306.04 and routinely employed in jury instructions setting forth the elements of an unlawful prescribing charge, must mean that a doctor has abandoned medical practice and engaged in "illicit drug dealing and trafficking as conventionally understood," and whether juries must be so instructed in order to prevent criminal conviction for malpractice or mere disagreements about the appropriate standard of care?

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PETITION FOR A WRIT OF CERTIORARI

Petitioner, Joel E. Miller, respectfully petitions for a writ of certiorari to review the order and judgment of the United States Court of Appeals for the Tenth Circuit entered on June 6, 2018.

OPINION BELOW

The published decision of the United States Court of Appeals for the Tenth Circuit, *United States v. Miller*, 891 F.3d 1220 (10th Cir. 2018), appears in the Appendix at 1.

JURISDICTION

The United States District Court for the District of Colorado had jurisdiction in this criminal action pursuant to 18 U.S.C. § 3231. The Tenth Circuit had jurisdiction pursuant to 28 U.S.C. § 1291 and 18 U.S.C. § 3742. The circuit court entered judgment on June 6, 2018, and it denied rehearing on August 6, 2018. (Appendix at 1, 18.) Justice Sotomayor extended the time in which to petition for certiorari by 60 days, to and including January 3, 2019. (Appendix at 19.) This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

FEDERAL PROVISIONS INVOLVED

The relevant statutory and regulatory provisions, including 21 U.S.C. §§ 802, 829, 841, and 21 C.F.R. §§ 1306.03, 1306.04, are included in the Appendix at pages A21 to A23. *See* Sup. Ct. R. 14.1(f).

STATEMENT OF THE CASE

A. Dr. Miller ran a family medical practice in the small, rural community of Craig, Colorado.

After completing his medical training and spending nearly a decade working as a physician in Texas and along Colorado's Front Range, Joel Miller moved to Craig, Colorado in 2003, to follow his goal of becoming a small-town doctor. (V9 at 2774-75; 3362; V1 at 1014.)[1] He practiced medicine there for almost another decade, first alongside a longtime family practitioner in town, and then, beginning in 2008, in his own practice. (V9 at 2776-81.)

Craig is a small, rural community in the northwest corner of the state—"out in the middle of nowhere," in the words of one lifelong resident. (*Id.* at 2145.) It is a hardscrabble town, driven by boom-and-bust industries like coal mining and ranching. (*Id.* at 2006, 2063, 2140, 2176, 2394, 2456.) Like many rural communities, it has its fair share of poverty. (*Id.* at 2111; V1 at 1015.)

By the time Dr. Miller opened his own practice, he was one of the few doctors left in Craig. The doctor with whom he had worked retired (v9 at 2778-80), and the recession had hit the area hard, leading other doctors to leave (*id.* at 2003-07). The

[1] Citations are to the record on appeal in the Tenth Circuit and the page number at the bottom, right-hand side of each page. 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.

small hospital in town was staffed with a rotating cast of practitioners, who many residents resisted seeing, in part because they couldn't provide continuing care. (*Id.* at 704, 1011, 1459, 2206.) The nearest big city and the main referral area was Grand Junction, Colorado, a city about 3 hours away in good weather, and sometimes unreachable in winter. (*Id.* at 2005, 2174.)

Accordingly, Dr. Miller soon found himself running a vibrant general practice, inheriting some patients from his prior stint, attracting new ones, and ending up with around 2,500 patients whom he saw for a full panoply of medical conditions. (V1 at 198; V9 at 1454, 2096.)[2] He was well-liked in Craig, and regarded as a caring doctor, who never turned someone away because they couldn't pay or because they had complicated conditions or histories that required time to manage. (*Id.* at 1497, 2001.) Indeed, the picture painted in the proceedings below was that of a small-town doctor who took the time to listen to his patients, and become involved not only in their care, but also their lives beyond the examination room; he knew about their families, their troubles, and their lives, in addition to

[2] This practice size was consistent with that for primary-care physicians at the time. *See, e.g.*, Lenny Bernstein, *How many patients should your doctor see each day?*, Washington Post, May 22, 2014 (reporting on studies from 2012 and 2013 demonstrating average patient loads of approximately 2,300 patients for primary-care physicians).

their illnesses. (V1 at 1015, 2917, 2152, 2133.) Many of his patients credited him with saving their lives and those of their loved ones. (V9 at 2120, 2498.)

The principal reason most people go to see their primary-care provider is for pain—something hurts, perhaps something minor like a sore throat, perhaps something major like an injury from working in the mines or on the ranch. (V9 at 2764-65, 3120-22.) The vast majority of Dr. Miller's patients were people he saw for regular conditions or minor pain, some of whom might take a narcotic for just a short period of time while they healed. (*Id.* at 3120-22.) He also saw some people with chronic pain as a small part of his practice. (*Id.* at 2783.)

That he did so is unremarkable. There are millions upon millions of Americans living with significant pain. (*Id.* at 2564.) But because there is a shortage of certified pain management specialists across the country, primary care physicians such as Dr. Miller shoulder most of the responsibility for managing patients' pain. (*Id.* at 2004-05, 2567.) This is particularly true in rural communities like Craig, where access to such specialists is further restricted by geography and economics. Indeed, the only regional pain specialists, some of whom were up to three hours away in Grand Junction, either focused on temporary interventions and not on patients requiring medication management over the long-term (*id.* at 2004-05), or didn't see Medicaid patients or those lacking insurance, or didn't take patients who had been treated extensively with narcotics in the past (*id.* at 2181-82).

Treating chronic pain patients is extremely complex; they are genuinely sick people afflicted by legitimately painful conditions, and often by mental illnesses as well. (*Id.* at 2665-66, 2671.) Moreover, chronic pain tends to coincide with other conditions, like anxiety and sleeplessness—indeed, if you're in pain all the time, you're unlikely to be calm or sleep well. (*Id.* at 2060, 2597.) You're also less likely to be able to work, meaning such patients were often of limited means, and without private insurance. In the words of the district court below, these were "scabrous, almost impossible patients . . . the worst of the worst . . . the untouchables." (*Id.* at 3396-97.) But Dr. Miller saw them, even when others wouldn't, and tried to do his best with them. (*Id.* at 2016, 3027.)

Indeed, it bears stating directly that this is not the type of "pill mill" or "pain clinic" case that have dominated headlines in recent years. Rather, Dr. Miller ran a legitimate family medicine practice, and after a five-week jury trial, even the government conceded that he helped many people in his practice. (V9 at 3223-25.)

Nevertheless, Dr. Miller eventually ended up in the government's crosshairs, accused of improperly prescribing controlled substances to a handful of the thousands of patients that he saw, and of improperly billing government and private insurance for those services. (V1 at 449-57.) The jury rejected the government's theory of the case, however, and acquitted Dr. Miller on all the financial counts; it split, however, on 14 prescription drug counts, ultimately convicting him of seven counts of

unlawfully distributing a controlled substance. (V1 at 840.) One of these counts was reversed by the district court after trial (v1 at 1198), and an additional conviction for making a false statement to the DEA was reversed by the Tenth Circuit. (Appendix at A10-A11.)

Thus, all that remains of the 35-count superseding indictment in this case are six prescription drug convictions. Each concerns a single prescription written between 2009 and 2012, to just five of Dr. Miller's over 2,500 patients—those with complex histories and conditions and whom the district court below described as "the most needy and intractable." (V9 at 3396-97.) The question presented encompasses all of these remaining convictions, each charged as a violation of 21 U.S.C. § 841(a), and which are, briefly recounted:

- Count 20 charged Dr. Miller with prescribing hydrocodone (Schedule III) and zolpidem (Schedule IV) to L.D.[3] on March 3, 2009;

- Count 23 charged Dr. Miller with prescribing fentanyl (Schedule II) to S.K. on April 12, 2010;

- Count 27 charged Dr. Miller with prescribing morphine (Schedule II), oxycodone (Schedule II), and clonazepam (Schedule IV) to C.M. on April 7, 2011;

[3] Consistent with the practice in the proceedings below and the applicable privacy redaction requirements, *see* Sup. Ct. R. 34.6, Fed. R. App. P. 25, 10th Cir. R. 25.5, initials of the patients in each count are used here and in the elements jury instructions reproduced in the Appendix at A24.

- Count 28 charged Dr. Miller with prescribing oxycodone (Schedule II) to L.W. on April 20, 2011;

- Count 31 charged Dr. Miller with prescribing both hydrocodone (Schedule III) and zolpidem (Schedule IV) to S.F. on December 22, 2011;

- Count 32 charged Dr. Miller with prescribing hydrocodone (Schedule III), zolpidem (Schedule IV), and carisoprodol[4] (Schedule IV), again to S.F., on January 18, 2012.

B. Under the Controlled Substances Act, doctors and other medical practitioners are authorized to issue prescriptions for controlled substances, but that authorization is not a license "to engage in illicit drug dealing and trafficking as conventionally understood."

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

The Controlled Substances Act (CSA), of course, generally prohibits any person from dispensing or distributing a controlled substance. *See* 21 U.S.C. § 841(a)(1). But because many of the controlled substances covered by the Act have important medical uses, 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.

[4] Carisoprodol was scheduled as a controlled substance only seven days prior to the prescription charged in Count 32. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330-01, at 77357 (noting effective date of January 11, 2012).

For a physician's controlled substance prescription to be lawful, two principal things must be present.

First, the physician must register with the Attorney General. *See* 21 U.S.C. §§ 802(21), 822(b); 21 C.F.R. § 1306.03. This requirement is not at issue, as Dr. Miller was properly registered at all times relevant here.

Second, the physician must be acting as a physician, that is, "in the course of professional practice." 21 U.S.C. § 802(21). 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) (emphasis added). 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 vis failure to comply with a particular standard of care.

As discussed in greater detail below, however, this Court has drawn that line, clearly and consistently. 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," *Gonzales 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 Tenth 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 doctor for unlawful prescribing (that is, for a violation of the common drug crime of distribution of a controlled substance under 21 U.S.C. § 841(a)). But the Tenth Circuit also has directed district courts *not* to further define these critical terms for the jury. Rather, the circuit has concluded that the question of what constitutes the "usual course of professional practice" in a § 841(a) prosecution (and, by implication, a "legitimate medical purpose") is a question of fact to be left to the jury. *See United States v. Lovern*, 590 F.3d 1095, 1101 (10th Cir. 2009) (citation omitted); *United States v. Bartee*, 479 F.2d 484, 488–89 (10th Cir. 1973).

Thus, juries in the Tenth Circuit are instructed, as the jury in Dr. Miller's case was, only that a physician is criminally liable for issuing a prescription for a controlled substance if that prescription "was not for a legitimate medical purpose or was outside the usual course of professional medical practice." (V1 at 881.)

C. Consistent with circuit precedent, the district court declines to define for the jury what it means for a prescription to be "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 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. Miller, 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."

Dr. Miller requested that the district court instruct the jury with definitions as a matter of law for the terms "legitimate medical purpose" and "usual course of professional practice" as used in 21 C.F.C. § 1306.04, and make clear that an important line exists between civil medical malpractice and criminal conduct. (V9 at 3173-74; *see also* V1 at 640-42 (defense proposed jury instructions), 939 (renewed argument in motion for a new trial).)[5]

The district court declined to define these terms for the jury, however, or to otherwise instruct the jury on how these phrases create a standard different from the civil standards for medical malpractice. Instead, the court pointed to the Tenth Circuit's decision in *Lovern* as foreclosing that argument. The court noted that this

[5] The pertinent instructions proposed by both Dr. Miller and the government below appear in the Appendix at A27 to A36, as do the instructions ultimately given by the district court (at A24 to A26). *See* Sup. Ct. R. 14.1(i)(vi).

authority "[c]ame as a surprise to me," but because of it, the court had to "resist[] that which is almost irresistible, which is to weigh in and provide the jury with definitions as a matter of law." (V9 at 3173-74; *see also* V1 at 1186-87.)

Without clarification for the jury, the disposition of this critical issue turned on the testimony of dueling expert witnesses.

The government's key expert witness was Dr. Theodore Parran, a physician from Cleveland, Ohio, who worked at the medical school at Case Western and practiced medicine with an emphasis in pain management and addiction. (V9 at 1097-1118.) At the time of this case, Dr. Parran previously had testified on behalf of the government in approximately 50 to 60 criminal trials of physicians. (V9 at 1326-27.)

With respect to each of the drug counts, Dr. Parran opined, echoing the language of 21 C.F.R. § 1306.04, that the prescriptions charged in each count were "inconsistent with the usual course of medical practice" and "for other than a legitimate medical purpose." (*Id.* at 1142, 1150-51; 1185-87 (Prescription charged in Count 20); 1192-94 (Counts 31, 32); 1224-25 (Count 23); 1238-40 (Count 27); 1276-77 (Count 28).)

On cross examination, however, Dr. Parran was unable to articulate where the line fell between poor medical practice or malpractice, on the one hand, and criminal conduct, on the other. (*Id.* at 1331-33.) The best he could explain was that it was a matter of degree, and that "[t]he criminal standard . . . is much more stringent in

terms of the problematic behavior on the part of the doctor. That's all I can tell you." (*Id.* at 1331.)

The defense presented expert testimony from Dr. Lynn Webster, a pioneer in the field of pain medicine and a past president of the American Academy of Pain Medicine. (*Id.* at 2522, 2530.) Like Dr. Parran, he too was qualified as an expert in, *inter alia*, pain and addiction medicine. (*Id.* at 2540.)

Dr. Webster testified that, contrary to Dr. Parran's opinion, each of the individual controlled substances prescribed in the counts in question was for a "legitimate medical purpose" and prescribed within the usual course of Dr. Miller's medical practice. (*Id.* at 2563, 2593-94, 2630-31; 2569-71, 2577-78 (Count 20); 2627, 2634-35, (Counts 31, 32); 2674-77 (Count 23); 2610 (Count 27); 2626 (Count 28).)

He also testified extensively regarding the difference between the standard of criminal conduct as opposed to standards for malpractice, explaining the importance of distinguishing between the two, and how in the former there is "no physician-patient relationship" and simply "no standard of care . . . [y]ou're not practicing medicine." (*Id.* at 2549-54.)

Finally, it also came out at trial that the prescriptions at issue in this case all were filled by pharmacists, who have their own duty under the Controlled Substances Act to only fill prescriptions that are for "a legitimate medical purpose." (*Id.* at 1079-82, 1086-87, 1762-64.) Also disclosed was that many of Dr. Miller's patients

continued to receive the same prescriptions they received from Dr. Miller after he stopped seeing them. (*Id.* at 664-67, 1592, 2105-06, 2220-22, 2389-90, 2266.) This was so, explained one doctor who inherited some of Dr. Miller's patients after he was forced to shutter his practice under the weight of the government's investigation (*id.* at 3095), because the prescriptions were for a legitimate medical purpose (*id.* at 2009-10). No pharmacist or other doctor was charged in relation to the prescriptions at issue in this case. (*Id.* at 664-71; 2009-10.)

D. The Tenth Circuit recognizes Dr. Miller's preserved challenge, but declines to consider the issue en banc.

On appeal, Dr. Miller conceded that prior circuit precedent foreclosed the instructional challenge presented in this petition. He acknowledged, therefore, that he would need to present his claim to the en banc court and this Court for review. (Opening Br. at 57-58.) In its published decision, the panel acknowledged Dr. Miller's preservation of this claim. (Appendix at A2 n.1, A14.)

The Tenth Circuit denied Dr. Miller's petition for rehearing en banc on the question presented (Appendix at 18), and this petition follows.

REASONS FOR GRANTING THE WRIT

I. The Tenth Circuit's instructional practice fails to inform juries about the clear line that Congress and this Court have drawn between a doctor's failure to adhere to a particular standard of medical care (a civil matter) and a doctor's complete abandonment of medical practice to engage in drug dealing as conventionally understood (a criminal matter).

By instructing juries in unlawful prescribing trials without defining the key terms "legitimate medical purpose" and "usual course of professional practice," and without otherwise instructing about the line between criminal conduct and bad or merely disputed medical practice, the Tenth Circuit is failing to enforce an important line that Congress and this Court have drawn for nearly a century.

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). Indeed, 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 (emphasis added).

This is the same line this Court drew over four decades ago in *United States v. Moore*, the Court's first—and only—case involving the prosecution of a physician under the CSA for unlawfully distributing controlled substances.

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." 423 U.S. 122, 143 (1975). Indeed, the doctor in *Moore* conceded that he had not observed generally accepted medical practices, and in fact demonstrably engaged in drug dealing as conventionally understood, "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." 423 U.S. at 142-43.

This clear line—drug dealing as conventionally understood—is also the same line that this Court drew a century ago in cases interpreting the 1914 Harrison Act, the predecessor statute to the CSA, and in which this Court affirmed numerous convictions where "[i]n reality, the doctor 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 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).

All told then, the line that Congress and this Court have drawn, clearly and consistently for a century, is simple—it is ceasing to act as a physician, and instead acting as a drug dealer, that causes a doctor to face federal criminal prosecution. Anything else, a fortiori, falls elsewhere, as matters better suited to medical malpractice proceedings or state medical board disciplinary or licensing actions, for example. *Cf. Gonzalez*, 546 U.S. at 270-21 (noting traditional reservation to the states of the regulation of the medical profession).

This simple line, however, is not being enforced in the charging of juries in the Tenth Circuit, as typified by Dr. Miller's trial below. Because 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, is not at all the same thing as telling them that criminal liability only attaches when a doctor abandons his or her role as a physician to become a drug dealer as conventionally understood.

Indeed, the plain meaning of these instructional adjectives ("usual" and "legitimate") suggest liability based on something far broader, such as deviation from a general standard of care. *See, e.g.*, Merriam-Webster Online, *legitimate*, "4 **:** conforming to recognized principles or accepted rules and standards"; *usual*, "1 **:** accordant with usage, custom, or habit **:** normal; 2 **:** commonly or ordinarily used followed his usual route; 3 **:** found in ordinary practice or in the ordinary course of events **:** ordinary."; *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 (v1 at 889), is no answer to these concerns. That's because that instruction simply re-incorporates the very same terms, still without defining them. (*See, e.g.*, V1 at 889 ("A physician does not violate the law when he dispenses a controlled substance to a patient for *a legitimate medical purpose and in the usual course of professional medical practice.* The term 'good faith' means the honest exercise of good professional judgment about the medical needs of a patient. Good faith requires conduct in accordance with what the

physician reasonably believed to be *a legitimate medical purpose and in the usual course of professional medical practice*.") (Emphasis added.).) That's why Dr. Miller sought to have the jury instructed with greater clarity about what is a "*legitimate* medical purpose" and what counts as the "*usual* course of medical practice." The failure to do so erases the line that Congress and this Court have drawn, and, indeed, fails to instruct the jury about what the government must prove to establish criminality, creating the very real possibility of conviction on grounds broader than "drug dealing and trafficking as conventionally understood."

II. The Tenth Circuit's practice criminalizes disputes about the proper standard of care, and turns every physician who prescribes controlled substances into a potential felon.

By failing to define what is—and what is not—encompassed by the terms "legitimate medical purpose" and "usual course of professional practice," the Tenth Circuit's practice effectively criminalizes disputes about the proper standard of care.

After all, the crux of physician-prescribing cases is almost always going to be the physician's exercise of professional judgment—i.e., whether a physician acted with a "legitimate medical purpose" and within the "usual course of professional practice." (Whether a prescription was written, and whether it was for a scheduled controlled substance, are unlikely to be disputed elements.) But without clear definitions of what those terms mean, the jury must rely largely, if not exclusively, on expert opinion. This is deeply problematic.

For one thing, the government's expert in this case, Dr. Parran, has testified on behalf of the government at between 50 to 60 trials. That means that the government, through continued reutilization of this expert, is effectively establishing a de facto standard of care that medical practitioners around the country must follow. Because any physician who does not adhere to Dr. Parran's view of what constitutes a "legitimate medical purpose" or the "usual course of professional practice" risks being hauled into federal court and forced to explain his or her treatment decisions under risk of criminal conviction and imprisonment—even if another expert sees no problem. That is a troubling outcome, to say the least, and one that makes any doctor prescribing controlled substances into a potential felon.

Unsurprisingly, 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. There is no reason why the government should be able to accomplish through the repeated use of a single expert in criminal trials, that which it could never do by regulation. But that is the practical effect of its action, and in a very real sense then, the government is defining the scope of the very crime it is enforcing.

Also troubling is this expert's failure to articulate any 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. In the end, all Dr. Parran could come up with was that it was a matter of degree, and that the criminal standard was "much more stringent." This lack of any meaningful distinction (to say nothing of the vagueness of "stringen[cy]" as a measure to be employed in the criminal law) is so problematic because bad and even outright wrong medical judgments may occur within the usual course of a physician's professional practice.

The very fact that two credentialed experts viewed the evidence here so differently—and as falling on different sides of the line—indicates precisely how fluid and uncertain these concepts are, and why this Court's articulation in *Moore* and *Gonzalez* of where that line rests makes a great deal of sense. Moreover, if, as here, two experts in pain medicine can't agree on the proper standard of care for complex patients, it seems hard to expect a rural family doctor to always strike the right balance. But if those judgments fall along the wrong part of the government expert's stringency scale, that physician risks criminal prosecution and exposure to what this Court recognized in *Moore* were "severe criminal penalties." 423 U.S. at 135.[6]

[6] Indeed, depending on the controlled substance involved, the statutory penalties can range from up to 10 to 20 years' incarceration on each count. *See, e.g.*, 21 U.S.C. §§ 841(a)(1), (b)(1)(C), (b)(1)(E). It does not take much imagination to

In contrast, explaining to juries that criminal prosecutions are not evaluating malpractice, and that a doctor acts outside of "a legitimate medical purpose" and the "usual course of professional practice" only when he becomes 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 unbridled prosecution. But failing to expressly delineate these boundaries risks sweeping up as criminals many physicians who are not engaged in drug dealing as conventionally understood, including those who might just be bad doctors, those who might just be negligent on a particular judgment, or even those whose practice just isn't in accord with the views of the government's preferred practice standard as described by the expert witness of its choosing.

III. Prosecutorial discretion is not an answer to this problem, and only this Court's intervention will ensure that juries are properly instructed about when medical practitioners are criminally liable for prescribing controlled substances.

Failing to instruct juries about this clear line grants the government a dangerously broad power to prosecute, and the exercise of prosecutorial discretion is no answer to this concern.

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envision how just a handful of contested prescriptions quickly could expose a doctor to a potential sentence that effectively amounts to life incarceration. And if a patient misuses a prescribed drug and death results, that physician also may be exposed to a mandatory minimum sentence of 20 years, and up to a maximum of life, on one count alone. *See id.*

As this Court recognized last term, "to rely upon prosecutorial discretion to narrow the otherwise wide-ranging scope of a criminal statute's highly abstract general statutory language places great power in the hands of the prosecutor. Doing so risks allowing 'policemen, prosecutors, and juries to pursue their personal predilections,' which could result in the nonuniform execution of that power across time and geographic location." *Marinello v. United States*, 138 S. Ct. 1101, 1108-09 (2018) (quoting *Smith v. Goguen,* 415 U.S. 566, 575 (1974)).

The government once seemed to recognize the clear line between drug "pushers" who engage in "drug dealing as conventionally understood" and disputes about how to practice medicine. *See, e.g.*, *United States v. Moore*, 74-759, Oral Argument at 59:16 (describing prosecutions in which evidence of medical practitioners' failure to comply with usual course of professional practice was "completely blatant"); *id.* at 1:03 (explaining that "we have been able to distinguish what is legitimate and what is not legitimate, and what is within the scope of legitimacy, *and what is so far beyond the pale that under no interpretation could it be considered legitimate medical practice within the course [of professional practice]*.") (Emphasis added.).[7] But like any principle, the government's view of its own discretion is not immune from "[t]he tendency . . . to expand itself to

[7] *Available at* https://www.oyez.org/cases/1975/74-759. (All links last visited January 3, 2019.)

the limit of its logic." Benjamin N. Cardozo, The Nature of the Judicial Process 51 (1921).

Accordingly, it is unsurprising to witness a certain mission creep over time—from the "completely blatant" drug dealing and undisputed failure to comply with acceptable medical practice in *Moore*; to blatant "pill mill" operations and conduct which even a defense expert concedes was outside the usual course of practice, *see United States v. Feingold*, 454 F.3d 1001, 1005, 1011 (9th Cir. 2006); to increasingly nuanced allegations of physician misconduct like that which split two undisputed experts (as well as the jury) in this case.

In recent terms, however, this Court repeatedly has intervened to rein in the government's overly expansive interpretation and application of criminal statutes. *See, e.g.*, *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[ing]d "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") (emphasis added); *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 with small amounts of chemicals to develop an uncomfortable rash, because such "boundless reading" would "dramatically intrude upon traditional state criminal jurisdiction" and Congress gave no clear indication of an intent to reach such local criminal conduct) (internal quotation marks and citation omitted).

It should do the same here to reestablish the line that Congress and the Court have already drawn. Indeed, it has been nearly 45 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 and non-criminal conduct in an actual criminal prosecution, and this case, with the issue squarely presented as an instructional challenge, presents a compelling vehicle to do so.

IV. Properly instructing juries about what the government must prove to establish medical practitioners' criminal liability is an issue of increasing national importance.

Finally, 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.

In the years since the prescriptions in this case were written back in 2009-12, the national attention on the use, and misuse, of opioids and other prescription drugs has exploded. *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). The government's response to the crisis has varied.

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;[8] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, Morbidity and Mortality Weekly Report (MMWR), March 15, 2016.[9] And in 2017, the Acting Secretary of

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

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

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*[10]; Ex. Order 13784 (March 29, 2017) (establishing Presidential Commission).

But 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").

And there is every indication that such prosecutions will continue apace, with the Department of Justice identifying such cases as a high priority area. *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

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

by health care professionals a top priority of the Department of Justice," and providing guidance on such prosecutions);[11] *see also* U.S. Dep't of Justice, Press Release, Attorney General Sessions Announces Opioid Fraud and Abuse Detection Unit (Aug. 2, 2017);[12] U.S. Dep't of Justice, Press Release, Attorney General Sessions Announces New Prescription Interdiction and Litigation Task Force (Feb. 27, 2018).[13]

Accordingly, the federal courts are likely to continue to see many cases involving physicians charged with unlawfully prescribing controlled substances. 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) from drug dealers. Doing so would have no impact on the government's 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 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). But such instructional clarity will help to stave off the government's

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

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

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

mission creep and prevent criminalizing disputes about the proper exercise of medical judgment, holding the line of criminal liability where Congress and this Court have sensibly set it, at those who "engage in illicit drug dealing and trafficking as conventionally understood." *Gonzalez*, 546 U.S. at 270.

* * *

The line that Congress and this Court have drawn has been clear and consistent for a century: a doctor violates federal drug laws and becomes criminally liable when he engages in "illicit drug dealing and trafficking as conventionally understood," *Gonzalez*, 546 U.S. at 272, acts as a "'pusher and not a physician,' *Moore*, 423 U.S. 143, and "[i]n reality, . . . bec[o]me[s] party to sales of drugs," *Linder*, 268 U.S. at 20. The instructional practice in the Tenth Circuit erases this clear line, and countenances criminal conviction for medical malpractice or mere disputes about the appropriate standard of care. This Court's intervention is necessary to reaffirm the line and ensure that juries are properly instructed.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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