NO. 20-1480

ORIGINAL

IN THE

SUPREME COURT OF THE UNITED STATES



GEORGE P. NAUM III,

Petitioner-Appellant,

v.

UNITED STATES OF AMERICA,

Respondent-Appellee.

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 FOR REVIEW

Justice Potter Steward's concerns raised at oral argument in *United States v. Moore,* 423 U.S. 122 (1975) over 40 years ago have become a reality.

> And is it not true that historically most, if not all of the great breakthroughs and advances in medical science are made by people who did not follow the conventional way of doing things. They followed a new way, their way, and most of the conventional physicians of their day would have disagreed with them because this is not the way it has always been done . . . it bothers me that this kind of evidence . . . is the basis for criminal liability. This man was a physician, he was not a fraud.

*United States v. Moore,* 423 U.S. 122 (1975); Oral Argument in *United States v. Moore,* Oyez, https://www.oyez.org/cases/1975/74-759 (last visited Jan 27, 2021).

As a result of what this Court has declared as ambiguous language in 21 U.S.C. §841 and 21 C.F.R. §1306.04, physicians in the United States are being convicted for professional disagreements and violations of the "standard of care" when prescribing opioids. *United States v. Moore,* 423 U.S. 122, 135; 96 S. Ct. 335, 345 (1975). The Circuits are widely split on their interpretation of 21 U.S.C. §841 and 21 C.F.R. §1306.04 and it is time for this Court to revisit *United States v. Moore.*

Petitioner-Appellant, George P. Naum III was convicted of violations of 21 U.S.C. §841(a)(1) and 21 U.S.C. §846 for prescribing Suboxone, a drug used to treat opioid use disorder. The central issue at trial was his use of nurses to expand the availability of patient care consistent with SAMHSA regulations. At trial, the trial court held that the elements of 21 U.S.C. §841(a)(1) as applied to a physician can be applied in the disjunctive thereby permitting the Government to procced on a theory that prescriptions were issued either "beyond the bounds of professional practice" or

"for other than a legitimate medical purpose." This permitted the Government to prosecute and convict Dr. Naum solely for violating professional standards. Further, the trial court prohibited expert testimony regarding the medical legitimacy of the prescriptions and hospital programs that operated in the same manner as Defendant.

The question presented is: Can the elements of 21 U.S.C. §841(a)(1) as defined in *United States v. Moore,* 423 U.S. 122 (1975) requiring the Government to prove unlawful distribution of a controlled substance "outside the usual course of professional practice" and "for other than a legitimate medical purpose" be applied in the disjunctive permitting the Government to prove only that a prescription was prescribed "outside the usual course of professional practice" or "outside the bounds of professional practice" solely for violation of a professional standard without regard to the medical legitimacy of the medication?

## LIST OF PARTIES

All parties to the proceeding are identified in the style of the case.

## CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Petitioner-Appellant, George P. Naum III discloses the following. There is no parent or publicly held company owning 10% or more of Petitioner-Appellant's stock.

## LIST OF PROCEEDINGS

**Trial Court**
*United States of America, Plaintiff, v. George P. Naum III, Defendant*
United States District Court for the Northern District of West Virginia
Case No.: 1:18-cr-00001
Date of Judgment: February 11, 2020

**Direct Appeal**
*United States of America, Plaintiff-Appellee, v. George P. Naum III, Defendant-Appellant*
United States Court of Appeals for the Fourth Circuit
Case No.: 20-4133
Date of Judgment: October 13, 2020

**Petition for Rehearing and Rehearing *En Banc***
*United States of America, Plaintiff-Appellee, v. George P. Naum III, Defendant-Appellant*
United States Court of Appeals for the Fourth Circuit
Case No.: 20-4133
Date of Judgment: November 24, 2020

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## PETITION FOR A WRIT OF CERTIORARI

Petitioner-Appellant, Dr. George P. Naum III, respectfully prays that a writ of certiorari be issued to review the judgment below of the Fourth Circuit Court of Appeals.

## OPINION BELOW

The opinion of the U.S. Court of Appeals for the Fourth Circuit appears in the Appendix to this Petition and can be found at *United States v. Naum,* 2020 U.S. App. LEXIS 32248 (4th Cir. 2020).

## JURISDICTION

On October 13, 2020, a three-judge panel of the Fourth Circuit Court of Appeals entered its opinion in *United States v. Naum,* 2020 U.S. App. LEXIS 32248 (4th Cir. 2020). Defendant filed a Petition for Panel Rehearing, or alternatively, for En Banc Rehearing, and this rehearing was denied. *United States v. Naum,* 2020 U.S. App. LEXIS 37150 (4th Cir., Nov. 24, 2020). This Court has jurisdiction pursuant to 28 U.S.C. §1254(1).

## STATUTES, ORDINANCES AND REGULATIONS INVOLVED

"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 U.S.C. §841(a)(1).

"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." 21 C.F.R. §1306.04.

"The term 'practitioner' means a physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to distribute, dispense, . . . , administer, or use . . . a controlled substance in the course of professional practice . . . ." 21 U.S.C. §802(21).

## STATEMENT

Defendant was a registered practitioner with the Drug Enforcement Administration and authorized to prescribe controlled substances per 21 U.S.C. §802(6). Defendant was indicted for violations of 21 U.S.C. §841(a) and §846 for knowingly and willfully distributing and dispensing controlled substances outside the usual course of medical practice and for other than a legitimate medical purpose.

Prior to trial, the Government filed a motion *in limine* seeking to clarify its standard of proof, arguing its burden of proof is to show that Defendant prescribed controlled substances "for other than a legitimate medical purpose ***or*** not within the bounds of professional practice." U.S.'s Motion *in Limine* at 3, *United States v. Naum,* No. 18-cr-00001 (N.D. W.Va. filed Apr. 15, 2019), ECF No. 273; *see United States v. Hitzig,* 63 Fed. Appx. 83 (4th Cir. 2003). The trial court granted the Government's motion. Order Following Motion Hearing, *United States v. Naum,* No. 18-cr-00001 (N.D. W.Va. filed Apr. 23, 2019), ECF No. 299. The court's order permitted the Government to sever the standard outlined in 21 C.F.R. §1306.04 and proceed only on the theory that Defendant's prescriptions were issued not within "the bounds of professional practice."

Defendant was charged with unlawful distribution of Suboxone. Suboxone is regulated differently than other medications because it can be used to treat patients suffering from opioid-use disorder. The Federal Government pre-empted the field of Opioid Treatment Standards and delegated the creation of treatment standards to Health and Human Services. 42 U.S.C. §290bb-2a. This statute specifically pre-

empted state governance of addiction treatment and the creation of methods of professional practice. *See Gonzales v. Oregon,* 56 U.S. 243, 271 (2006) (holding that 42 U.S.C. §290bb-2a is the only area in which Congress set general uniform standards of medical practice). In *Gonzales,* the Court noted: "[t]his provision strengthens the understanding of the CSA [Controlled Substances Act, 21 U.S.C. §801] as a statute combating recreational drug abuse, and also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute." *Id.* at 272. The reason Congress sought to pre-empt state regulation of addiction treatment is exactly why the type of prosecution levied against Defendant should be disfavored for very strong public policy considerations:

> The practicing physician has ... been confused as to when he may prescribe narcotic drugs for an addict. Out of a fear of prosecution many physicians refuse to use narcotics in the treatment of addicts except occasionally in a withdrawal regimen lasting no longer than a few weeks. In most instances they shun addicts as patients.

*United States v. Moore,* 423 U.S. 122, 143-44 (1975) (internal citations omitted). The Court found that this Congress-created national standard "was designed to clarify for the medical profession ... the extent to which they may safely go into treating narcotic addicts as patients." *Id.* at 144 (quoting H.R. Rep. No. 91-1444, at 14). Under this scheme, "[t]hose physicians who comply with the recommendations made by the Secretary will no longer jeopardize their professional careers ... ." *Id.* (quoting H.R. Rep. No. 91-1444, at 15).

Traditionally, patients could only be treated for addiction in a traditional "methadone clinic setting." However, in 2000, providers were permitted to treat patients in an office-based setting but were required to obtain a separate DEA

registration in accordance with 21 U.S.C. §823(g)(2). In an effort to expand addiction treatment and make it more widely available to areas suffering from the opioid epidemic, the Federal Government later increased patients' limit from 100 to 275. 42 C.F.R. §8.610 and 42 C.F.R. §8.2.

Given the unique application of medications like Suboxone for treating addiction, and to aid providers in how they may safely expand their reach to treat addiction medicine patients, the Substance Abuse and Mental Health Services Administration ("SAMHSA") created publications and training designed to assist doctors with "best practices." Unlike traditional medicine, nurses play a larger role in medication-assisted therapy so that patients can receive more access to care. Exhibit 2 to United States' Motion *in Limine* on Standards Governing Prescriptions for Suboxone at 41, *United States v. Naum,* No. 18-cr-00001 (N.D. W.Va. filed Jan. 29, 2019), ECF No. 166-2. In its 140-page guide for assisting nurses in this new role, SAMHSA permitted a nurse to perform all follow-up care and relapse prevention functions. *Id.* ("Nurses must continuously monitor urine drug testing or other toxicology testing, the number of pills in the patient's supply, medication dosage, and pharmacy checks to help prevent relapse").

At trial, Defendant called Dr. Sandiford Helm, a board-certified addiction medicine and pain management physician and past president of the American Society of Interventional Pain Physicians. Helm testified that Suboxone is a drug designed to block the effects of opioid withdrawal; patients suffering from opioid use disorder should be put on a long-term, stable dose of Suboxone indefinitely until patient and

provider agree the patient is ready to "wean" off it. A central issue at trial was Defendant's using a registered nurse to see patients after initial induction and to refill prescriptions for Suboxone without Defendant's presence. Defendant would review the treatment of each patient and provide notes for subsequent follow-up, instructing the nurse to increase, decrease, or keep the dose the same upon next visit. Helm testified that after a patient has seen a provider for initial intake, subsequent monitoring and follow-up can be delegated to nurses, but the physician must determine how much medication the patient gets. Transcript of Trial Testimony by Dr. Standiford Helm at 14, *United States v. Naum,* No. 18-cr-00001 (N.D. W.Va. Apr. 29, 2019). Helm described Defendant's process: "The nurse would go in and perform the follow-up exam and — as I described it, and get the appropriate monitoring and then would issue the prescription, based upon the previous order provided by the physician." *Id.* at 24.

Helm testified that he believed Defendant established a physician-patient relationship with patients treated at his clinic during initial intake, and it was medically appropriate to assign follow-up care to a nurse under SAMHSA Guidelines. *Id.* at 19. He also testified that Defendant ensured compliance and properly prevented diversion in accordance with "best practices" by requiring frequent urinalysis tests and prescription drug monitoring report checks. *Id.* at 21. Helm opined it being permissible for a physician to simply review the care of a nurse in a Suboxone program by signing off on the charts. *Id.* at 23.

Helm was then asked by Defendant's counsel if he had seen other examples of Defendant's treatment model being used, which was met by the trial court's sua sponte objection. *Id.* at 27. In a subsequent sidebar proceeding, the court refused to permit Helm to testify about a model similar to the treatment model used by Defendant, permitting nurses to treat patients upon follow-up and call-in physician-issued medication orders. "And to the extent that there are other models out there that are not relevant to this because they've been permitted by special regulation in the states and are funded by state funds, that is not this model. It will confuse the jury. We are not doing it." *Id.* at 27.

After preventing Defendant from introducing evidence about a state-funded model permitting nurses to provide follow-up care (in accordance with SAMHSA guidelines) and call-in prescriptions, the court, sua sponte, instructed the jury as follows:

> Ladies and gentlemen, I just want to make clear to you that we've had a discussion at the bench about anticipated testimony from Dr. Helm regarding a state-approved and funded model in Massachusetts that is a very different approach protocol-wise in the office, and, actually, in the kind of team put together, than what was utilized at Advance Healthcare. That doesn't mean one is right and one is wrong. But it's been my prior ruling in this case, and during this case, that that is — that model is not a relevant discussion to what happened here and the questions that are before you here.

*Id.* at 27-28.

Later during testimony, Helm began to explain that a prescription for a particular patient was written in the bounds of professional practice because the patient had a legitimate medical need. Prosecution objected, saying the Government

need only prove a prescription was written "outside the bounds of professional practice" and therefore the medical legitimacy of the prescription is not relevant. *Id.* at 37. In open court, the trial judge stated:

> I don't think the question of whether it was for a legitimate medical practice has ever been raised by the Government. It's not part of the case-in-chief. And it's not an issue in this case and, therefore, is not helpful to the jury in determining the issues in the case. So his opinion is, it's not outside the bounds of medical practice. You asked him why. He's explaining. And that's that.

After excluding the medical purpose of a medication from the inquiry into whether a prescription was issued "in the bounds of professional practice," the court offered no guidance about its definition of "bounds of professional practice."

The jury convicted Defendant of conspiracy to distribute Suboxone "outside the bounds of professional medical practice" from 2008-2016 in violation of 21 U.S.C. §841(a)(1) and §846, and four counts of aiding and abetting distribution of Suboxone outside the bounds of professional medical practice in violation of 21 U.S.C. §841(a) and 18 U.S.C. §2. The court sentenced Defendant to six months' incarceration followed by six months' home detention.

Section 841(a) of Title 21 of the U.S. Code provides, in relevant part: "(a) ... it shall be unlawful for any person knowingly or intentionally — (1) to ... distribute, ... a controlled substance ...." 21 U.S.C. §841(a)(1). Thus, to secure a conviction under this section, the Government must prove beyond a reasonable doubt that a defendant knowingly or intentionally distributed the controlled substance alleged in the indictment, and at the time of such distribution, the defendant knew the substance distributed was a controlled substance under the law. There is no dispute that the

prescriptions written by Defendant were controlled substances under the CSA and therefore could not be lawfully distributed other than as provided by law.

In 1971, the Attorney General promulgated a regulation requiring every controlled substance prescription "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *See Gonzales* (citing 21 C.F.R. §1306.04(a) (2005)). In 1975, this Court gave its only guidance on what it means for a practice to issue a prescription for a legitimate medical purpose in the usual course of professional practice: "the scheme of the [CSA], viewed against the background of the legislative history reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice.'" *Moore*, 423 U.S. at 140. Therefore, a licensed physician who prescribes controlled substances outside the bounds of his professional medical practice is subject to prosecution and is no different than "a large-scale 'pusher.'" *Id.* at 143. The *Moore* court was careful to emphasize that Moore had so wantonly ignored the basic protocols of the medical profession, "he acted as a large-scale 'pusher' — not as a physician." *Id.* The court further described §841(a) as prohibiting "the significantly greater offense of acting as a drug 'pusher.'" *Id.* at 138. These statements show that the *Moore* court based its decision not merely on the fact that a doctor committed malpractice, or even intentional malpractice, but rather that his actions betrayed any semblance of legitimate medical treatment.

The only other opportunity this Court has had to analyze the conduct required of a physician to be convicted of a violation of 21 U.S.C. §841(a)(1) mirrored the

language of *Moore*, again emphasizing that Federal Jurisdiction under the CSA is not triggered upon a showing of malpractice, which is left up to the states. *Gonzales*. In explaining that the CSA did not authorize the U.S. Attorney General to bar dispensation of controlled substances for assisted suicide in the face of a state medical regime permitting such conduct, this Court said:

> The Controlled Substances Act (CSA), 21 U.S.C. §801 et seq., and 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.

*Gonzales,* 546 U.S. at 269-70.

Since *Moore* and *Gonzales*, Circuit decisions have varied widely in interpreting the limited language in both cases. In the instant case, the Fourth Circuit upheld the trial court's ruling that prevented Defendant from presenting evidence that his treatment of patients was "for a legitimate medical purpose." *Naum* at *11. The Fourth Circuit held that the "Government may meet its burden by establishing that the physician's actions were not for legitimate medical purposes in the usual course of professional medical practice or were beyond the bounds of professional medical practice." *Naum* at *10. *United States v. Singh,* 54 F.3d 1182, 1187 (4th Cir. 1995); *see also United States v. Tran Trong Cuong,* 18 F.3d 1132, 1141 (4th Cir. 1994). The Fourth Circuit also held that the Government is not required to prove "both prongs" (*i.e.,* no legitimate purpose and beyond the bounds of medical practice). The court conceded that Defendant's treatment was for a legitimate medical purpose: "there was no dispute at trial that Naum's patients suffered from addiction and required

treatment." *Naum* at 11. The Fourth Circuit therefore presumes the possibility for a physician to prescribe a medication for a "legitimate medical purpose" but still "beyond the bounds of professional medical practice." *Id.*

In the instant case, the Fourth Circuit did not further explain the meaning of "beyond the bounds of professional medical practice" and why that standard can be met without analyzing whether there was a legitimate medical purpose for a prescription. Its cited cases (*Singh*, *Tran Trong Cuong*) do not shed light on the Fourth Circuit's holding that a physician can be held criminally liable for a medically appropriate prescription other than: "there are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice." *Singh* at 1187. *Tran Trong Cuong*. Without sufficient explanation in prior Fourth Circuit holdings, the only reasonable conclusion is that the Fourth Circuit interprets "bounds of professional practice" to reference professional norms the medical community generally accepts. This is in direct conflict with two holdings of this Court and several circuits. Moreover, such a holding expands the CSA's prohibition on unlawful prescribing to questions of the quality or legitimacy of medical treatment which, per *Gonzales*, is outside the CSA's purview. *Gonzales* at 269-70.

## REASONS FOR GRANTING THE PETITION

### A. The Fourth Circuit has decided an important federal question in a way that conflicts with this Court's holdings in *Moore* and *Gonzales*.

#### a. Overview

Per the Fourth Circuit, a physician can be convicted of unlawful distribution even where both the Government and this Court concede that the prescription was issued for a legitimate medical purpose. *United States v. Naum,* 2020 U.S. App. LEXIS 32248 at *11 (4th Cir. 2020). The court permitted the Government to prove only that Defendant's prescriptions were "beyond the bounds of professional medical practice." *Id.* However, the Fourth Circuit did not explain how a prescription issued by a physician can be for a legitimate medical purpose but still outside the bounds of medical practice. A common sense reading of the opinion suggests that the Fourth Circuit interprets "outside the bounds of professional medical practice" as conduct violating a medical standard. Such a holding exceeds the CSA's intent and preempts states' rights to regulate the practice of medicine. "It comes as little surprise, then, that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug pusher instead of a physician." *Gonzales.*

**b. Circuit Court interpretations of *Moore* have shifted significantly since the decision**

Under 21 U.S.C. §841(a), "[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally (1) to manufacture distribute or dispense or possess with intent to manufacture, distribute, or dispense, a controlled substance...." In order to permit controlled substances to be used when appropriate, the Attorney General may "promulgate rules and regulations ... relating to the

registration and control of the manufacture, distribution and dispensing of controlled substances ...." 21 U.S.C. §821.

Doctors "registered" by the Attorney General are authorized to write controlled substance prescriptions so long as they comply with registration requirements. 21 U.S.C. §822(b); *United States v. Hurwitz,* 459 F.3d 463, 475 (4th Cir. 2006). Pursuant to 21 U.S.C. §821, the Attorney General adopted 21 C.F.R. §1306.04(a): "A prescription for controlled substances 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 only case decided by this Court in the CSA's 40-year existence directly interpreting the standard under 21 U.S.C. §841(a)(1) is *Moore.* Moore was charged in a 639-count indictment alleging that he knowingly distributed methadone in violation of 21 U.S.C. §841(a)(1). He contended that the CSA prohibition on unlawful distribution and the severe penalties associated with distribution cannot be applied to physicians. *Id.* at 126. Instead, he argued, the provision of the CSA prohibiting "technical" violations is the provision Congress intended to apply to physicians. *Id.* The Government argued that §841(a)(1) applies to physicians when they prescribe "without any medical justification at all." *Id.* at 138. At oral argument, Justice Potter Stewart was quick to note that prosecuting physicians based on professional disagreements rests on dubious grounds when the government bases a prescription's legitimacy on whether the practice is generally accepted. *Id.* Oral Argument in *Moore,* Oyez, https://www.oyez.org/cases/1975/74-759 (last visited Jan. 27, 2021). This Court

held that Moore could be prosecuted under 21 U.S.C. §841(a)(1) because he was not acting in any way as a physician but instead was a large-scale drug "'pusher.'" *Id.*

In deciding that 21 U.S.C. §841(a)(1) could be applied to physicians, this Court was clear to recognize that Moore could be subject to criminal liability, not for violating a standard of care, but because he ceased becoming a physician at all. It is here where this Court first used the phrase "bounds of professional practice" and used it to demark the line between the practice of medicine and unlawful drug dealing.

Particularly important to this Court's decision: the CSA was created to prevent distribution to illegitimate channels, *i.e.*, "drug diversion." *Id.* at 135-36. "The legislative history indicates that congress was concerned with the nature of the drug transaction, rather than with the status of the defendant." *Id.* at 134. Both bills and committee reports show that the CSA's prohibition on unlawful dispensing and prescribing was to ensure that drugs are only prescribed and dispensed within the legitimate distribution chain. *Id.* As such, the potential for diversion from this legitimate distribution chain weighed heavily in this Court's decision to hold that a physician could be prosecuted for a violation of 21 U.S.C. §841(a)(1). "Although this language is ambiguous, the most sensible interpretation is that the penalty to be imposed for a violation was intended to turn on whether the transaction falls within or without legitimate channels." *Id.* at 135.

The *Moore* Court specifically avoided the notion that a violation of medical practice guidelines or standards could form the per se basis of a conviction under 21 U.S.C. §841(a)(1).

However, that is not to say that violations of medical practice guidelines, standards of care, or even state regulations constitute per se violation of 21 U.S.C. §841(a). Congress was concerned about unlawful drug diversion, not with enforcing medical standards, which is left solely to the states. *Id.* at 135.

> 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. The silence is understandable given the structure and limitations of federalism, which allow the States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.

*Gonzales.*

In *Moore,* this Court refused to permit federal courts to be medical standards enforcers. In the only other case addressing the CSA's scope, this Court reiterated *Moore*'s language and again held that a physician only runs afoul of the CSA when he/she ceases being a physician. In *Gonzales*, this Court addressed whether the Attorney General could issue a regulation declaring the Oregon Death with Dignity Act a violation of the CSA and 21 U.S.C. §841(a)(1). In holding that the CSA cannot be used to enforce standards of practice, this Court maintained that the CSA explicitly contemplates a role for the states in regulating controlled substances as evidenced by its preemption provision: "No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates ... to the exclusion of any State law on the same subject matter which would otherwise be within the authority or the State." *Id.* at 251.

In *Gonzales*, this Court again clarified that the CSA cannot apply to prescriptions issued for a medical purpose: "[It] allows prescription drugs only if they have a 'currently accepted medical use.'" However, the Court noted that "legitimate medical purpose" is a generality susceptible to more precise definition and open to varying constructions and thus ambiguous. *Id.* at 258. Regardless, this Court determined that the statute cannot be interpreted to attempt to define standards of medical practice: "[t]he structure of the CSA, then, conveys unwillingness to cede medical judgments to an Executive official who lacks medical expertise." *Id.* This court was concerned that if the Attorney General had the authority to declare the use of a particular drug, "he could decide whether any particular drug may be used for any particular purpose, or indeed whether a physician who administers any controversial treatment could be deregistered." *Id.* at 268.

After clarifying that the CSA cannot be interpreted as regulating the practice of medicine generally or permitting the Attorney General to create a "standard of care," the *Gonzales* Court re-affirmed its *Moore* holding: the CSA does not regulate the "medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician." *Id.* at 269.

> The statute and our case law amply support the [*270] 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. The silence is understandable given the structure and limitations of federalism, which allow the States "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."

*Gonzales.*

Since *Gonzales*, Circuits have split widely in interpreting 21 U.S.C. §841(a)(1)'s ambiguous language and its accompanying regulations. In the instant case, the Fourth Circuit determined that "legitimate medical purpose" and "bounds of professional practice" carry two different meanings, creating a dual standard from which the prosecution can pick a theory. *Naum* at 11.

**c. The Fourth Circuit's holding in *Naum* is not grounded in the CSA, *Moore*, OR *Gonzales*, creating further ambiguity disruptive to the state's right to regulate the practice of medicine**

In the instant case, the Fourth Circuit determined that "legitimate medical purpose" and "bounds of professional practice" creates a disjunctive standard from which the prosecution may convict on either theory. *Naum* at 11. Moreover, the panel determined that if the prosecution chooses the "bounds of professional practice" standard, the medication's medical purpose is irrelevant. *Naum* at 11. The Fourth Circuit does not: define "bounds of professional practice;" define how it is different from "legitimate medical purpose;" or state how the medical need for a particular medication is irrelevant to that analysis.

In its motion *in limine*, the Government argued that per the standards set forth in *Singh* and *Tran Trong Cuong,* it need not prove lack of "legitimate medical purpose." It tied its argument to the holdings in both cases that the Government is not required to prove that the physician acted with improper purpose: "In sum, although the testimony does not adduce compelling evidence that [the defendant]

prescribed with malicious motive or desire to make a profit, those motivations, though common in 841(a)(1) prosecutions are not required to convict." U.S.'s Motion *in Limine* at 3, *United States v. Naum,* No. 18-cr-00001 (N.D. W.Va. filed Apr. 15, 2019), ECF No. 273. While Fourth Circuit caselaw does suggest that the Government is not required to prove motive or improper purpose in an §841(a)(1) prosecution, that court has never held that the medical purpose for the prescription is irrelevant, and the burden of proof can be satisfied by showing that a prescription was either for other than a legitimate medical purpose or outside the bounds of professional practice. *United States v. Hitzig,* 63 Fed. Appx. 83 (4th Cir. 2003).

The language the Government cited in its motion *in limine* did not authorize it to sever the standard and pick whichever one it wished to prove:

> Our precedent makes it clear that the standard for criminal liability is that the physician's conduct in dispensing a controlled substance "falls outside the boundaries of the physicians professional practice." While the government may meet its burden of proving guilt by showing that a physician dispensed a controlled substance for an illegitimate purpose, the government is not required to make such a showing.

*Id.* at 86.

In affirming the trial court's decision, the Fourth Circuit, for the first time and in an unpublished opinion, stated: "the Government is not required to prove both prongs (*i.e.,* no legitimate purpose and beyond professional bounds), and therefore, there was no error in permitting the Government to proceed only on the theory that Naum's actions were beyond the bounds of professional medical practice. *See Singh,* 54 F.3d at 1188." Unpublished Per Curiam Opinion at 9, *United States v. Naum,* No. 20-4133 (4th Cir. filed October 13, 2020), ECF No. 31. The Fourth Circuit did not

explain how, under *Moore* and *Gonzales*, it is possible for a physician's prescription to be issued for a legitimate medical purpose but outside the bounds of medical practice.

The problem in the instant case lies with the Fourth Circuit's formulation of the third element. The first portion of this element draws directly from the language of 21 C.F.R. §1306.04(a) and is not problematic. The second portion ("or [the defendant's actions] were beyond the bounds of medical practice"), however, takes the second element required by the regulation, separates it from the first, and permits a jury to convict based upon a finding of that element alone.

Other courts formulate the requirements in harmony with 21 C.F.R. §1306.04(a), imposing a conjunctive duty on the prosecution, and hold that the Government must establish that each prescription was dispensed without a legitimate medical purpose and outside the usual course of medical practice. *See, e.g., United States v. Rosenberg*, 585 F.3d 355, 357 (7th Cir. 2009) ("In order for a prescription to be unlawful it must not have a legitimate medical purpose and must be dispensed outside the usual course of medical practice;" *United States v. Chube,* 538 F.3d 693, 701 (7th Cir. 2008) (same); *United States v. Feingold,* 454 F.3d 1001, 1008 (9th Cir. 2006) ("[T]o convict a practitioner under 841(a), the government must prove ... that the distribution of those controlled substances was outside the usual course of professional practice and without a legitimate medical purpose"); *United States v. Johnson,* 71 F.3d 539, 542 (6th Cir. 1995) ("In order to obtain a conviction under 21 U.S.C. 841(a)(1) against a licensed physician ... the government must show:

... [t]hat defendant prescribed the drug without a legitimate medical purpose and outside the course of professional practice"). The Eleventh Circuit uses a formulation of the Government's burden that eliminates the problem entirely by closely tracking the language of the regulation and not including additional verbiage. *See United States v. Ignasiak,* 667 F.3d 1217, 1228 (11th Cir. 2012).

The error in this case was compounded by the District Court's preventing Defendant from introducing evidence that patients were seeking treatment for legitimate purposes: treatment for their addiction. As such, the court prevented Defendant from presenting evidence that the prescriptions were for a "legitimate medical purpose," relying on the Fourth Circuit Court's precedent in *Singh* and *Tran Trong Cuong.* In upholding the trial court's determination, the panel ruled: "[t]he Government is not required to prove both prongs (i.e., no legitimate purpose and beyond professional bounds), and therefore, there was no error in permitting the Government to proceed only on the theory that Naum's actions were beyond the bounds of professional medical practice." Unpublished Per Curiam Opinion at 9, *United States v. Naum,* No. 20-4133 (4th Cir. filed October 13, 2020), ECF No. 31. The error with this decision is that it ignores Supreme Court precedent stating that the standard is not conjunctive or disjunctive, but is one single standard that cannot be split into two meanings.

The *Moore* Court clearly articulated that the meaning behind "bounds of professional practice" is merely another way of stating "for a legitimate medical purpose in the course of professional practice":

> The evidence presented at trial was sufficient for the jury to find that respondent's conduct exceeded the bounds of "professional practice." As detailed above, he gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher" — not as a physician.

*Id.* (emphasis added).

It was critical that Moore "acted as a large-scale 'pusher' — not as a physician." *Id.* Thus, when a physician ceases acting as a physician (*i.e.*, acts "outside the bounds of medical practice"), he engages in an unlawful drug transaction akin to a "pusher" and no different than a corner drug dealer. The only other opportunity this Court has had to evaluate the standard under 21 U.S.C. §841(a) was in *Gonzales*, where it repeated *Moore*: "it comes as little surprise, then, that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician." *Id.* The Court's message is clear: the Federal Government does not have authority to regulate the way in which a physician practices medicine, only whether the physician is seeking to practice medicine or engage in drug dealer:

> 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. The silence is understandable given the structure and limitations of federalism, which allow the States "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons."

*Id.* at 270.

*Moore* and *Gonzales* emphasize that Defendant can only be convicted if he stepped away from the practice of medicine and began trafficking in narcotics. It is not sufficient to show that he failed to adhere to a specific standard of practice. Thus, it is supremely relevant whether the practice's patients endeavored to seek medical treatment or engage in an unlawful transaction for buprenorphine. *Moore* requires the Government to prove not that the physician violated some sort of practice standard, as the Fourth Circuit has held, but that he/she abandoned the practice of medicine by prescribing medication that lacked a legitimate medical purpose.

Here, the Fourth Circuit's conclusion that the standard "not for a legitimate medical purpose in the course of professional medical practice or beyond the bounds of medical practice" can be split. That a defendant can be precluded from introducing evidence of the medical purpose of his prescription contradicts *Moore* and cannot stand. The standard is one single standard, and to meet its burden the Government must prove that the physician acted outside the usual course of professional practice *and* not for a legitimate medical purpose. *Feingold*; *Chube; United States v. Kholi,* 847 F.3d 483, 491 (7th Cir. 2017); *United States v. Bartee,* 479 F.3d 484, 488 (10th Cir. 1973).

Despite this Court's clear holding in *Gonzales,* that the CSA cannot be used as a tool to regulate the practice of medicine and only criminalizes conduct of those who exceed the bounds of practice, there is a split of authority as to the proper elements under 21 U.S.C. §841(a) that this Court must resolve.

### d. Various Circuits have interpreted the vague language of 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04 to permit physicians to be prosecuted for professional disagreements, which has a dangerous impact on medical advancement

Despite nearly 100 years of controlled substance jurisprudence, courts are still split and often confused about the standard of evidence required to convict a practitioner[1] of prescribing controlled substance unlawfully. Since this Court's decision in *Moore*, finding that a doctor can be convicted as a drug trafficker under §841(a)(1) for unlawfully prescribing controlled substances, federal circuits have shifted to interpret §841(a)(1) as not prohibiting the non-medical prescribing of drugs, but rather a deviation from a medical standard. Such a shift presents a danger to the medical community as a whole, which must now ensure that its conduct adheres to unclear, wildly shifting professional norms in the emerging pain management field. Despite this Court's seemingly clear direction as to the limits of federal power when prosecuting physicians for prescribing decisions, many courts have begun to apply a "national standard of care" analysis to physician prescribing cases.

It is necessary for this Court to weigh in and reaffirm *Gonzales* and *Moore* to prevent an abuse of federal power in regulating the practice of medicine. The Circuit

[1] The term "practitioner" is used to describe any health professional with prescriptive authority as defined by 21 C.F.R. §1301.01. This includes physicians, nurse practitioners, physician assistants, veterinarians, dentists, and any other health professional or entity granted the ability to issue a prescription for controlled substances. A split in the Circuits has far-reaching implications for the practice of various healthcare professions.

shift in interpreting *Moore,* 21 U.S.C. §841(a)(1), and 21 C.F.R. §1306.04 expands prosecutions under *Moore* in a way this Court specifically rejected in *Gonzales*, which explicitly holds that the CSA's powers cannot be used to regulate the practice of medicine. *Gonzales.*

Prophetically, Justice Stewart in *Moore* was concerned that an expansion of the limits of federal power to regulate the practice of medicine would prevent progress in the medical field:

> And is it not true that historically most, if not all of the great breakthroughs and advances in medical science are made by people who did not follow the conventional way of doing things. They followed a new way, their way, and most of the conventional physicians of their day would have disagreed with them because this is not the way it has always been done. ... [I]t bothers me that this kind of evidence ... is the basis for criminal liability. This man was a physician, he was not a fraud.

*United States v. Moore,* Oyez, https://www.oyez.org/cases/1975/74-759 (last visited Jan. 27, 2021).

In the instant case, the Fourth Circuit held that a physician can be convicted for prescribing "outside the bounds of professional practice" even if the medication prescribed is for a legitimate medical purpose. *Naum* at 11. The Fourth Circuit was silent on its "beyond the bounds of professional practice" interpretation and whether such a phrase does not include an inquiry into the medical purpose of the medication. Yet, in its opinion, the Fourth Circuit faulted Defendant for failing to adhere to West Virginia Board of Medicine requirements as evidence of practice outside the bounds of professional practice. By eliminating the inquiry into the medical purpose of a medication and permitting a jury to convict based on violations of medical board

rules, the Fourth Circuit appears to interpret the phrase "beyond the bounds of professional practice" as requiring a physician to adhere to a standard of practice generally accepted in the community.

Prior to *Naum,* the Fourth Circuit struck a much different tone than its previous opinions in *United States v. Alerre* and *Tran Trong Cuong. United States v. Alerre,* 430 F.3d 681 (4th Cir. 2005); *Tran Trong Cuong,* 18 F.3d at 1133. In both cases, the Fourth Circuit held that a physician is acting "outside the bounds of professional medical practice when the authority to prescribe is being used not for the treatment of a patient but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose *i.e.* the personal profit of a physician." Although the Fourth Circuit's prior interpretation of the phrase "beyond the bounds of medical practice" included an analysis of the medical purpose of the drug, the Fourth Circuit's opinion in *Naum* was not published and did not seek to overturn prior ruling. En banc hearing to resolve this conflict was denied. *United States v. Naum*, No. 20-4133, 2020 U.S. App. LEXIS 37150, at *1 (4th Cir. Nov. 24, 2020).

The Fifth Circuit also holds that a physician may be convicted for violations of professional standards. In *United States v. Armstrong,* the court upheld a jury instruction providing:

> 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 or her in good faith, medically treating a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.

*United States v. Armstrong,* 550 F.3d 382 (5th Cir. 2008).

In essence, the Fifth Circuit held that a provider who deviates from the standard of care is in violation of §841. *Id.*

Similarly, the Eleventh Circuit upheld a jury instruction in *United States v. Enmon*, permitting the jury to find the defendant guilty of an §841 violation if his conduct did not comport with "generally recognized" standards of medical practice. *United States v. Enmon,* 686 Fed. Appx. 796 (11th Cir. 2017), cert denied, 2017 U.S. LEXIS 5460 (U.S., Oct. 2, 2017). The instruction specifically stated, "[w]hether the Defendant acted outside the usual course of professional practice is to be judged objectively by reference to the standards of medical practice generally recognized and accepted in the United States." *Id.* Therefore, "whether the Defendant had a good faith belief that he dispensed a controlled substance in the usual course of his professional practice is irrelevant." *Id.* at 774. In *Enmon*, the Eleventh Circuit went one step further and declared "good faith" medical practice that does not conform to generally accepted standards of practice as unlawful.

In the Second Circuit, the mistaken but well-intentioned physician can be convicted for a simple departure from the standard of care. *United States v. Vamos*, 797 F.3d 1146 (2nd Cir. 1986). In *Vamos,* the Second Circuit reasoned that medical practitioners have limited authority to engage in the distribution of a controlled substance and practitioners can be stripped of that protection when they act in a manner not generally accepted in the medical community. *Id.* The Second Circuit acknowledged that this position subjects physicians to prosecution for malpractice

but dismissed this argument on the basis that a jury must still find proof beyond a reasonable doubt that the physician acted outside the scope of medical practice.

In the Sixth Circuit, mere violations of professional standards are not enough to convict. In *United States v. Volkman,* a physician charged with drug trafficking under §841(a)(1) received a jury instruction: "carelessness or negligence or foolishness on Dr. Volkman's part are not the same as knowledge and are not enough to find him guilty on any of these counts." *United States v. Volkman,* 736 F.3d 1013, 1020 (6th Cir. 2013). The same physician prosecuted in the Fourth, Fifth and Eleventh circuits would not receive such an instruction and can be prosecuted for professional negligence.

The Seventh Circuit aligns with the Sixth Circuit in that the Government must prove "something more than conduct below the usual standard of care to show an absence of a valid medical purpose." *United States v. Chube,* 538 F.3d 693, 698 (7th Cir. 2008). In *Chube*, defendant sought to exclude all expert testimony that suggested a violation of the standard of care applicable to civil medical malpractice cases. *Id.* at 697. He argued that such testimony admitted during trial confused the jury and reduced the Government's burden from criminal intent to mere negligence. *Id.* The Seventh Circuit found it sufficient that the difference between civil and criminal standards was adequately spelled out in instructions, opening, cross-examination, and closing.

The Ninth Circuit in *Feingold* also tracks this Court's language in *Moore* by holding that a physician should not be subject to prosecution for mere deviations of

the standard of care, even if done intentionally, because it would permit the Attorney General to prosecute any physician who steps outside the bounds of conventional medical protocols in order to provide some sort of special treatment for uniquely needy patients. *Feingold.* In explicitly disavowing the disjunctive view favored by the Fourth Circuit in the instant case, the Ninth Circuit stated:

> An instruction is improper if it allows a jury to convict a licensed practitioner under §841(a)(1) solely on a finding that he has committed malpractice, intentional or otherwise. Rather, the district court must ensure that the benchmark for criminal liability is the higher showing that the practitioner intentionally has distributed controlled substances for no legitimate medical purpose and outside the usual course of professional practice.

*Id.* at 1010.

The Eighth Circuit takes a refreshing approach to both the applicability of the "standard of care" and the debate over the disjunctive or conjunctive interpretation of §841(a). In *United States v. Smith,* the defendant challenged the use of the malpractice standard in the trial court but was ultimately convicted. *United States v. Smith,* 573 F.3d 639, 649 (8th Cir. 2009). In answering the defendant's concerns pertaining to the introduction of evidence related to the standard of care, the court emphasized that the jury instructions required finding that defendant failed to adhere to prevailing medical standards and a lack of a legitimate medical purpose for the medication before it could convict. *Id.*

The DEA in its own administrative tribunal has another interpretation of 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04. The DEA administrator decided *In Re Wesley Pope*, determining that the phrases "legitimate medical purpose" and "usual

course of professional practice" are the same and thus interchangeable. *In Re Wesley Pope, M.D.,* 82 Fed. Reg. 14944, 14967 n.38 14976 (Drug Enf't Admin. Mar. 23, 2017). In *Pope,* the Government issued notice to Pope that his DEA registration should be revoked exclusively on the theory that he issued prescriptions "outside the usual course of professional practice," which the DEA found sufficient notice because there is no difference between the two phrases. *Id.* Chief DEA Administrative Law Judge John J. Mulrooney, in a recent law review article, expressed disagreement with the DEA Administrator's interpretation of "legitimate medical purpose" and "usual course of professional practice" as identical. John J. Mulrooney II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters,* 101 Marq. L. Rev. 333, 425-426 (2017). Judge Mulrooney cited language in *United States v. Nelson,* the case the administrator relied on in *Pope*:

> Similarly it is difficult to imagine circumstances in which a practitioner could have prescribed controlled substances with a legitimate medical purpose and yet be outside the usual course of medical practice. When asked at oral argument if the two phrases were not merely two ways of saying the same thing, appellant's counsel was unable to explain satisfactorily how or whether it might make a difference if the jury had been instructed in the conjunctive as he had requested. Nevertheless, recognizing the limits of our imagination, we are hesitant to say that it never could make a difference, and we proceed to consider Nelson's argument.

*United States v. Nelson,* 383 F.3d, 1227, 1231 (10th Cir. 2004).

Despite differing interpretations among circuits, Courts have stood firm on vagueness challenges to the definitions in 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04: *United States v. Collier,* 478 F.2d 268, 270 (5th Cir. 1973) (rejecting

"contention ... that §841(a)(1), as applied to physicians, is unconstitutionally vague"); *United States v. Darji,* 609 F. App'x 320, 334 (6th Cir. 2015) ("this Court has rejected the claim that §841 and §1306.04(a) are void for vagueness"); *United States v. Orta-Rosario,* 469 F. App'x 140, 143 (4th Cir. 2012), cert. denied, 568 U.S. 902; 133 S. Ct. 311; 184 L. Ed. 2d 185 (2012) (rejecting medical doctor's argument that the CSA is impermissibly vague as applied to him because "there is no statutory definition of 'legitimate medical purpose' or 'usual professional practice'"); *United States v. Brickhouse,* No. 3:14-CR-124, 2016 U.S. Dist. LEXIS 59821, 2016 WL 2654359, at *4 (E.D. Tenn. Mar. 30, 2016) ("[t]he Court disagrees that §841(a)(1) and the regulation at §1306.04 leave medical practitioners rudderless and adrift in the murky waters of criminal liability"); *United States v. Quinones,* 536 F. Supp. 2d 267, 274 (E.D.N.Y. 2008) (rejecting vagueness argument because the phrase "within the usual scope of professional practice" has an "objective meaning that prevents arbitrary prosecution and conviction: neither the government nor the jury is free to impose its own subjective views about what is and is not appropriate; rather, the government is obliged to prove, and the jury constrained to determine, what the medical profession would generally do in the circumstances"); *United States v. Birbragher,* 576 F. Supp. 2d 1000, 1013 (N.D. Iowa 2008), aff'd, 603 F.3d 478 (8th Cir. 2010) ("courts have held the language 'legitimate medical purpose' and 'usual course of his professional practice' is not unconstitutionally vague as applied to physicians"); *United States v. Prejean,* 429 F. Supp. 2d 782, 805 (E.D. La. 2006) (rejecting argument that this framework is vague because "the medical community has not established clear,

nationwide standards for what is considered 'legitimate medical purpose' in the field of pain management").

This Court is presented with a trend of jurisprudence drifting far from its 40-year precedent, a vast circuit split, and the agency charged with enforcing the CSA being at odds with its Chief Administrative Law Judge in interpreting the applicable standard for physician conduct. It is time for this Court to weigh in and re-affirm its holding in *Moore* so that the medical community can have a clear definition of the conduct required to conform to 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04.

**e. There is no generally accepted standard for prescribing controlled substances in the U.S.**

The crucial issue for physicians in the Second, Fourth, Fifth, and Eleventh circuits who are subjected to an objective standard of care analysis for criminal liability is that the pain management and addiction medicine fields are rapidly evolving and standards are constantly shifting. In 1986, opioid maintenance therapy using high doses of powerful narcotics was considered to be a "safe, salutary, and more humane alternative to the options of surgery or not treatment in those patients with intractable non-malignant pain and no history of drug abuse." R.K. Portenoy & K.M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25(2) PAIN, 171-86 (May 1986). In the 1990s, chronic pain management was a significant healthcare policy concern, and practitioners were advised by the Joint Commission, an accrediting body, to treat pain as a fifth vital sign. Andrew Rosenblum et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current*

*Status, and Future Directions,* 16(5) EXP. CLIN. PSYCHOPHARMACOL, 405 (2018). Since the "pain as the fifth vital sign" movement, physician opioid prescribing surged, becoming one of the current opioid epidemic's causes. *Id.* This was principally because Centers for Medicare and Medicaid Services (CMS) tied post-hospitalization patient survey questions about the effectiveness of a patient's pain management to physician reimbursement and performance rankings. Only recently has the tide turned. A proposed rule to remove the policy was only introduced in 2016. 81 Fed. Reg. 45603. This reversal was done contemporaneously with a sweeping drug policy change and the implementation of the Centers for Disease Control (CDC) Guidelines for Prescribing Opioids for Chronic Pain. Centers for Disease Control and Prevention, *CDC Guidelines for Prescribing Opioids for Chronic Pain,* (last updated Aug. 29, 2017), https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

When the Government "woke up" in 2016, it steered too hard in the other direction by implementing a substantial number of policy changes, including the CDC guidelines: while only intended as a "guideline," they read as a standard of care, and State Medical Boards began adopting them into their administrative code. Doug Campos-Outcalt, M.D., M.P.A., *Opioids for Chronic Pain: The CDC's 12 Recommendations,* 65(12) J. FAM. PRACT. 906-909 (Dec. 2016) ("given the prominence of the CDC, this clinical guideline will likely be considered standard of care for family physicians"). In 2019, Medicare adopted a rule, coming directly from the CDC guidelines, to deny coverage, in certain circumstances, for opioid prescriptions issued for more than seven days and over a 50 morphine milligram

equivalent dose. CMS, *Advance Notice of Methodological Changes for Calendar Year (CV) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter,* (Feb. 1, 2018). Within one year of the guidelines' creation, nine states added statutes and administrative rules adopted from those guidelines. Andy Baker-White, *A Look at State Legislation Limiting Opioid Prescriptions,* ASTHO (Feb. 23, 2017), http://www.astho.org/StatePublicHealth/A-Look-at-State-Legislation-Limiting-Opioid-Prescriptions/2-23-17/.

The CDC guidelines have been introduced as evidence in many opioid prosecutions over the last four years. *See United States v. Lague,* 971 F.3d 1032, 1041 (9th Cir. 2020) (provider convicted of prescribing pain medication multiple times over the "CDC limit for exercised induced shoulder pain"); *United States v. Newman,* No. 3:19-CR-59-TAV-DCP, 2020 U.S. Dist. LEXIS 221891, at *37 (E.D. Tenn. Sep. 8, 2020) (CDC guidelines related to opioid thresholds included in search warrant affidavit to secure a search).

Just as the Circuits shifted to anchor violations of 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04 to a violation of the objective "standard of care," that "standard of care" became heightened, more complex, and difficult to follow. Four years after the sweeping policy change brought about by the CDC guidelines, in 2020 the American Medical Association publicly criticized the guidelines and called for widespread changes. It released a paper urging the CDC to make significant revisions to its 2016 Guidelines for Prescribing Opioids for Chronic Pain, which have been touted as a medical standard by federal prosecutors, to protect patients with pain from the

ongoing unintended consequences and misapplication of the guidance. American Medical Association, *AMA Urges CDC to Revise Opioid Prescribing Guidelines,* June 18, 2020, https://www.ama-assn.org/press-center/press-releases/ama-urges-cdc-revise-opioid-prescribing-guideline, accessed Jan. 19, 2021.

Since 1985, physicians have been subject to shifting and evolving standards. Questions of professional disagreement cannot be the basis for prosecution because the risks of medical progress and proper pain management become too great, which will lead to a suffering patient population. This is precisely why this Court in *Gonzales* refused to engage in medical questions and determined this is better left to the state and its police powers.

Justice Stewart's foretelling in *Moore*, that we are embarking on dubious grounds when we begin prosecuting physicians for professional disagreements, has rung true. Misinterpretation of the phrases "legitimate medical purpose," "course of professional practice," and "bounds of professional practice" have led criminal courts to embark on an exploration of civil malpractice issues when determining whether a physician should spend years, if not decades, in jail. Lack of consensus about the criminal standard to be applied has somehow survived vagueness challenges notwithstanding the fact that courts cannot agree over whether the standard is objective or subjective, disjunctive or conjunctive, and even whether "legitimate medical purpose" and "usual course of professional practice" mean the same thing. Meanwhile, the practice of medicine hangs in the balance: pain management, addiction medicine, and family practice physicians alike remain fearful of

prescribing, until some definitive standard is set forth so that this "risk adverse" population can know the limits of their liability.

## CONCLUSION

For the forgoing reasons, the petition for a write of certiorari should be granted.

Respectfully Submitted,
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