

19-7797  
No. \_\_\_\_\_

Supreme Court, U.S.  
FILED

JAN 16 2020

OFFICE OF THE CLERK

\_\_\_\_\_  
IN THE  
SUPREME COURT OF THE UNITED STATES  
\_\_\_\_\_

\_\_\_\_\_  
LONNIE W. HUBBARD

— PETITIONER

(Your Name)

vs.

\_\_\_\_\_  
UNITED STATES OF AMERICA

— RESPONDENT(S)

ON PETITION FOR A WRIT OF CERTIORARI TO

\_\_\_\_\_  
UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

\_\_\_\_\_  
(NAME OF COURT THAT LAST RULED ON MERITS OF YOUR CASE)

PETITION FOR WRIT OF CERTIORARI

\_\_\_\_\_  
LONNIE W. HUBBARD

\_\_\_\_\_  
(Your Name)

\_\_\_\_\_  
FEDERAL CORRECTION INSTITUTION-HAZELTON  
P.O. Box 5000

\_\_\_\_\_  
(Address)

\_\_\_\_\_  
BRUCETON MILLS, WV 26525

\_\_\_\_\_  
(City, State, Zip Code)

\_\_\_\_\_  
NO PHONE

\_\_\_\_\_  
(Phone Number)

ORIGINAL

## QUESTION(S) PRESENTED

### STATEMENT BEFORE QUESTION

After defendant pharmacist Lonnie W. Hubbard was charged in an indictment by the U.S. Attorney's Office for allegedly illegally dispensing controlled substance prescriptions in violation of 21 C.F.R. § 1306.04(a) & 21 U.S.C. § 841(a)(1), defendant pharmacist pled 'not guilty' because he was sure he obtained legitimate medical purposes before every controlled substance prescription was filled. After he lost at trial, he asked the Court of Appeals for the Sixth Circuit, whether there was sufficient evidence to convict him to the Counts in the indictment because the essential element of § 1306.04(a) 'without a legitimate medical purpose' was not satisfied by the government's burden of proof. The Court of Appeals ruled defendant pharmacist's argument frivolous and held "knowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes" and affirmed the District Court's decision.

### QUESTION

WHETHER THE COURT OF APPEALS ERRED BY HOLDING A JURY COULD RATIONALLY CONCLUDE THAT DEFENDANT PHARMACIST ABDICATED HIS DUTY UNDER §§ 1306.04(a) & 841(a)(1), DESPITE PHARMACIST'S ARGUMENT THAT THERE WERE 'LEGITIMATE MEDICAL PURPOSES' FOR THE CONTROLLED SUBSTANCE PRESCRIPTIONS HE FILLED BECAUSE TRIAL WITNESSES TESTIFIED THAT THEY HAD REAL INJURIES AND MEDICAL NEEDS REQUIRING MEDICATION BEFORE PHARMACIST FILLED THEIR PRESCRIPTIONS.

## LIST OF PARTIES

- ☒ All parties appear in the caption of the case on the cover page.
- ☐ All parties **do not** appear in the caption of the case on the cover page. A list of all parties to the proceeding in the court whose judgment is the subject of this petition is as follows:

## TABLE OF CONTENTS

OPINIONS BELOW .....	1
JURISDICTION .....	2
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED .....	3
STATEMENT OF THE CASE .....	4
REASONS FOR GRANTING THE WRIT .....	6
CONCLUSION .....	25

## INDEX TO APPENDICES

APPENDIX A	The opinion of the United States Court of Appeals for the Sixth Circuit.
APPENDIX B	A copy of the order denying the 'Petition for Panel Rehearing'.
APPENDIX C	The opinion of the United States District Court for the Sixth Circuit.
APPENDIX D	The verbatim reading of Federal Statute 21 U.S.C. § 829 because it is too lengthy to cite in 'CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED' page 3.
APPENDIX E	
APPENDIX F	

# TABLE OF AUTHORITIES

CASES	PAGE
<u>Gonzales v. Oregon</u> , 546 U.S. 243, 126 S. Ct. 904 (2006)	12,13,24
<u>United States v. Moore</u> , 423 U.S. 122, 96 S. Ct. 325 (1975)	9,10,12,17,19,23
<u>Yates v. United States</u> , 574 U.S. 528, 135 S. Ct. 1074 (2015)	20
<u>United States v. Armstrong</u> , 550 F.3d 382 (5th Cir. 2008)	14
<u>United States v. Birbragher</u> , 576 Fed. Supp. 2d. 1000 (8th Cir. 2010)	15
<u>United States v. Boettjer</u> , 569 F.2d 1078 (9th Cir. 1978)	18
<u>United States v. Chaney</u> , 921 F.3d 572 (6th Cir. 2019)	15,16,24
<u>United States v. Collier</u> , 478 F.2d 268 (5th Cir. 1973)	14
<u>United States v. Darji</u> , 609 Fed. Appx. 320 (6th Cir. 2015)	14
<u>United States v. Feingold</u> , 454 F.3d 1001 (9th Cir. 2006)	12,17,18
<u>United States v. Fuchs</u> , 467 F.3d 889 (5th Cir. 2006)	11
<u>United States v. Kanner</u> , 603 F.3d 530 (8th Cir. 2010)	13
<u>United States v. Kirk</u> , 584 F.2d 773 (6th Cir. 1978)	10,16
<u>United States v. Kohli</u> , 847 F.3d 483 (7th Cir. 2017)	12
<u>United States v. Lovern</u> , 590 F.3d 1095 (10th Cir. 2009)	13
<u>United States v. Nelson</u> , 383 F.3d 1227 (10th Cir. 2004)	10
<u>United States v. Orta-Rosario</u> , 469 Fed. Appx. 140 (4th Cir. 2012)	14
<u>United States v. Outler</u> , 659 F.2d 1306 (5th Cir. 1981)	10,11
<u>United States v. Rosen</u> , 582 F.2d 1032 (5th Cir. 1978)	11
<u>United States v. Vamos</u> , 797 F.2d 1146 (2nd Cir. 1986)	10
<u>United States v. Volkman</u> , 797 F.3d 377 (6th Cir. 2015)	13,14,24
<u>United States v. Brickhouse</u> , 2016 U.S. Dist. LEXIS 59821 (E.D. Tenn. 2016)	14
<u>United States v. Quinones</u> , 536 Fed. Supp. 2d. 267 (E.D. N.Y. 2008)	14
OTHER	
<a href="http://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm">http://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm</a> (2014)	18

## TABLE OF AUTHORITIES ( cont.)

	PAGE
<a href="https://www.deadiversion.usdoj.gov/pubs/manuals/index.html">https://www.deadiversion.usdoj.gov/pubs/manuals/index.html</a> (2014)	18
<u>Pharmacy Practice and the Law</u> , Richard R. Abood, 7th Ed. 2014	19
CODE OF FEDERAL REGULATIONS	
21 C.F.R. § 1306.04(a)	9,11,12,13,14,15,16,19,20,21,22,23,24
STATUTES	
21 U.S.C. § 801	20
21 U.S.C. § 802	13,21,22
21 U.S.C. § 812(b)	12,21
21 U.S.C. § 829(c)	12,21
21 U.S.C. § 830(b)(3)(A)(ii)	12,21
21 U.S.C. § 841	9,11,12,14,15,16,17,20,22,23,24
FEDERAL RULES	
Rule 29 Motion	23

IN THE  
SUPREME COURT OF THE UNITED STATES

PETITION FOR WRIT OF CERTIORARI

Petitioner respectfully prays that a writ of certiorari issue to review the judgment below.

**OPINIONS BELOW**

☒ For cases from **federal courts**:

The opinion of the United States court of appeals appears at Appendix A to the petition and is

United States v. Hubbard,  
☒ reported at 2019 U.S. App. LEXIS 21311 (6th Cir., 2019) or,  
☐ has been designated for publication but is not yet reported; or,  
☐ is unpublished.

The opinion of the United States district court appears at Appendix C to the petition and is

United States v. Hubbard,  
☒ reported at 2017 U.S. Dist. LEXIS 62982 (6th DIST 2019) or,  
☐ has been designated for publication but is not yet reported; or,  
☐ is unpublished.

☐ For cases from **state courts**:

The opinion of the highest state court to review the merits appears at Appendix \_\_\_\_\_ to the petition and is

☐ reported at \_\_\_\_\_; or,  
☐ has been designated for publication but is not yet reported; or,  
☐ is unpublished.

The opinion of the \_\_\_\_\_ court appears at Appendix \_\_\_\_\_ to the petition and is

☐ reported at \_\_\_\_\_; or,  
☐ has been designated for publication but is not yet reported; or,  
☐ is unpublished.

## JURISDICTION

☒ For cases from **federal courts**:

The date on which the United States Court of Appeals decided my case was July 19, 2019.

☐ No petition for rehearing was timely filed in my case.

☒ A timely petition for rehearing was denied by the United States Court of Appeals on the following date: November 19, 2019, and a copy of the order denying rehearing appears at Appendix B.

☐ An extension of time to file the petition for a writ of certiorari was granted to and including \_\_\_\_\_ (date) on \_\_\_\_\_ (date) in Application No. A.

The jurisdiction of this Court is invoked under 28 U. S. C. § 1254(1).

☐ For cases from **state courts**:

The date on which the highest state court decided my case was \_\_\_\_\_.  
A copy of that decision appears at Appendix \_\_\_\_\_.

☐ A timely petition for rehearing was thereafter denied on the following date: \_\_\_\_\_, and a copy of the order denying rehearing appears at Appendix \_\_\_\_\_.

☐ An extension of time to file the petition for a writ of certiorari was granted to and including \_\_\_\_\_ (date) on \_\_\_\_\_ (date) in Application No. A.

The jurisdiction of this Court is invoked under 28 U. S. C. § 1257(a).



## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

### Federal Statute

21 U.S.C. § 841

§ 841. Prohibited acts A

- (a) Unlawful acts. Except as authorized by this title, 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; or

### Code of Federal Regulation

21 C.F.R. § 1306.04

§ 1306.04 Purpose of issue of prescription.

- (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

### Federal Statute

21 U.S.C. § 829

(See Appendix D for verbatim reading of the statute.)

## STATEMENT OF THE CASE

In 2015, the United States filed a thirty-eight Count indictment against Hubbard, a pharmacist, his pharmacy, Rx Discount of Berea, PLLC, his wife and six others. The indictment alleged that the defendant conspired to distribute oxycodone and pseudoephedrine, distributed oxycodone, pseudoephedrine, and hydrocodone, failed to obtain proper I.D. from persons purchasing pseudoephedrine, maintained a drug premises, and conspired to commit money laundering and other fraudulent financial transactions. Two superseding indictments were subsequently filed bringing the total number of charges to seventy-three. An eight day jury trial was held in February 2017, where Counts 7 & 47 were dismissed on motion by the United States. The jury found Hubbard guilty on the remaining counts and the district court imposed a total term of imprisonment of 360 months, followed by three years supervised release. The district court also ordered criminal forfeiture of real and personal property. Hubbard filed a motion for a new trial, which was overruled.

On direct appeal, Hubbard's counsel filed a motion to withdraw pursuant to Anders v. California, 386 U.S. 738 (1967) notifying the Court of a lack of good-faith issues for appeal. Hubbard responded to counsel's Anders brief with a response-brief. The Court subsequently entered an order granting counsel's motion to withdraw, appointed new counsel under the CJA and allowed the filing of supplemental briefs following appointment of new counsel. Although new counsel was appointed, he filed a motion to withdraw pursuant to Anders, stating he had nothing to add to original counsel's brief. Hubbard filed another response-brief. The Court independently reviewed the record and briefs of counsel and Hubbard and allowed counsel to withdraw because no grounds for appeal could be sustained. Specifically, Hubbard claimed

## STATEMENT OF THE CASE (cont.)

insufficient evidence on the indictment's oxycodone Counts under §§ 1306.04(a) & 841. The Court answered, "[t]his Court long ago held the language in § 841(a)(1) and 21 C.F.R. § 1306.04(a) clearly defines the pharmacist's responsibilities that give rise to conduct that constitutes an unlawful distribution of a prescription drug ... [k]nowingly distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances." The Court found frivolous Hubbard's argument that the controlled substance prescriptions he filled were for legitimate medical purposes finding "[d]espite Hubbard's argument that he filled prescriptions for customers who testified at trial that they had real injuries and medical needs that required prescription medication, a jury could rationally conclude that Hubbard abdicated his duty as a pharmacist to ensure that each of these prescriptions was for a legitimate medical purpose, even in light of the witnesses' alleged injuries or conditions. No arguable issue could be raised on appeal to challenge the sufficiency of the evidence as it related to Counts 49 to 59."

Hubbard filed a timely 'Petition for Panel Rehearing' contesting four aspects of his case. That motion was denied four months later. Hubbard now files this 'Petition for Writ of Certiorari' to the Supreme Court.

## REASONS FOR GRANTING THE PETITION

America's 'Opioid Crisis' has expanded the Department of Justice's prosecution of healthcare practitioners under the criminal statutes of the Controlled Substance Act (CSA), most notably under §§ 1306.04(a) & 841. The Supreme Court in United States v. Moore, 423 U.S. 122 (1975) held a practitioner could be charged and convicted under § 841 when a doctor ceases to be a doctor and becomes a drug pusher. The Court did not fully elaborate on what exact essential elements are required for conviction, but did find practitioners were not exempted from criminal liability because of their status as a registrant.

The Supreme Court not elaborating on what essential elements were required for conviction ended up causing a federal Circuit split as to what essential elements are required to prosecute a practitioner under §§ 1306.04(a) & 841. Today, ten federal Circuits hold a practitioner can be held criminally liable for dispensing controlled substance prescriptions when he dispenses them **either** 'outside the usual course of his professional practice' **or** when he dispenses them 'without a legitimate medical purpose'. Two federal Circuits hold a practitioner can be held criminally liable for dispensing controlled substance prescriptions when he dispenses them 'outside the usual course of his professional practice' **and** when he dispenses them 'without a legitimate medical purpose'. This 'higher showing' for conviction prevents practitioners from being convicted solely on a jury's finding of malpractice, negligence, incompetence, or that he was foolish or reckless. Moreover, several Circuits have ruled the above mentioned phrases can be used interchangeably.

In Gonzales v. Oregon, 546 U.S. 243 (2006), the Supreme Court held that the Attorney General does not have statutory authority to criminalize

## REASONS FOR GRANTING THE PETITION (Cont.)

assisted suicides and that his interpretation was inconsistent with the statute. In the Court's dicta, the Court highlights the statutes which require a 'legitimate medical purpose' in order for a prescription to be valid supporting the notion that this element is required for dispensing controlled substances, and the two phrases of § 1306.04(a) are not interchangeable.

Federal Courts have repeatedly ruled §§ 1306.04(a) & 841(a)(1) are not void for vagueness and clear in their proscriptions to practioners.

The Sixth Circuit's holdings on convicting practioners under §§ 1306.04(a) & 841 seem contrary to its own findings and dicta. In one case the Sixth Circuit holds that 'without a legitimate medical purpose' is a required element to convict a practioner under § 841(a)(1), but in another case, the Sixth Circuit holds that 'knowingly distributing prescriptions outside the course of professional practice [alone] is a sufficient condition to convict a defendant under the criminal statutes'. They both cannot be correct.

The DEA's guidance advises pharmacists literally that § 1306.04(a) requires two elements for the purpose of a prescription: the prescription be issued for a legitimate medical purpose by an individual practioner acting in the usual course of his professional practice. Clearly here also, the two phrases are not interchangeable.

Congress intended the literal reading of the text of the regulation and statutes to include both essential elements 'without a legitimate medical purpose' and 'outside the usual course of professional practice' in order to convict practioners. Congress intended the phrases to have distinct, separate meanings in the regulation and statutes and are not interchangeable.

The Supreme Court should grant this petition and clarify its holdings

## REASONS FOR GRANTING THE PETITION (Cont.)

and dicta in Moore ending the federal Circuit split by ruling unequivocally that Congress intended that § 1306.04(a) requires two essential elements to convict healthcare practitioners under § 841, which is a 'higher showing' for conviction which prevents practitioners from being convicted on a finding of malpractice, negligence, incompetence or otherwise. Furthermore, the Supreme Court should find that the two phrases have distinct, separate meanings in the regulation and statutes and that they may not be used interchangeably, or be used as a single element such as what the Sixth Circuit has held.

**I. FEDERAL CIRCUITS ARE SPLIT IN HOW TO DETERMINE WHETHER A PRACTITIONER VIOLATED THE CRIMINAL STATUTES UNDER THE CSA.**

**A. The Moore Court Allowed Prosecution for Practitioners Under § 841, But Did Not Address the Required Essential Elements for Conviction.**

The Supreme Court in United States v. Moore, 423 U.S. 122, 139-43, 96 S. Ct. 325, 46 L. Ed. 2d. 333 (1975), held that a registered physician could be charged and convicted under § 841 of the CSA for drug trafficking. The precise elements of §§ 1306.04(a) & 841(a)(1) were not specifically addressed in Moore, but the Court held that (1) a physician registered under the Act was not per se exempted from prosecution under § 841 merely because of his status as a registrant, with only the lawful acts of registrants being exempted, and (2) a registered physician could be prosecuted under § 841 when his activities fell outside the usual course of professional practice, and (3) the evidence in the case was sufficient to establish the defendant's conduct exceeded the bounds of professional practice. Thus, a physician remains criminally liable when he ceases to dispense controlled substances as a medical professional, and acts as a "pusher" instead. Moore, 423 U.S. at 138, 143. This hallmark Supreme Court case would be interpreted to allow conviction under § 841 for healthcare practitioners such as doctors, pharmacists, dentists, nurse practitioners, and physician assistants who ceased to be medical professionals and instead became drug pushers. Ten federal Circuits have interpreted §§ 1306.04(a) & 841, Moore to allow conviction of practitioners when they dispense "other than in good faith ... in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." Moore, 423 U.S. at 139. Those ten Circuits are the 1st, 2nd, 3rd, 4th, 5th, 6th, 8th, 10th, 11th and D.C. Circuits. However, two Circuits have held that §§ 1306.04(a) & 841 and the dicta in

Moore, directly and implicitly intended, that a prescription for a controlled substance must be issued for a 'legitimate medical purpose' AND be dispensed in the 'usual course of his professional practice'. Those two Circuits are the 7th & 9th Circuits.

**B. The Phrases 'Without a Legitimate Medical Purpose' and 'Outside the Usual Course of Professional Practice' Have Been Used Interchangeably After Moore, and the Phrases Have No Statutory Definitions.**

The Sixth Circuit, and others, have endorsed a broad approach to determine what conduct falls "outside the accepted bounds of professional practice" so as to constitute a CSA violation utilizing a case-by-case approach. See United States v. Kirk, 584 F.2d 773, 784 (6th Cir. 1978) holding "there is no difference in the meanings of the statutory phrase, 'In the usual course of professional practice' and the regulations' phrase, 'legitimate medical purpose.'" See also, United States v. Outler, 659 F.2d 1306, 1308-09 (5th Cir. 1981) apparently using the phrases "without a legitimate medical reason" and "beyond the course of professional practice" interchangeably by the Court. Moreover, there are no statutory definitions of 'legitimate medical purpose' or 'outside the usual course of professional practice' but caselaw provides that "[t]he term 'professional practice' refers to generally accepted medical practice." United States v. Vamos, 797 F.2d 1146, 1151 (2nd Cir. 1986).

**C. Several Circuits Hold that a Practioner has Unlawfully Dispensed a Controlled Substance if he Dispenses the Substance Either 'Outside the Usual Course of Professional Practice' OR if he Dispenses it 'Without a Legitimate Medical Purpose'.**

In United States v. Nelson, 383 F.3d 1227, 1231-33 (10th Cir. 2004) the Court held that a practioner has unlawfully distributed a controlled substance if she prescribes the substance either 'outside the usual course of medical practice' or 'without a legitimate medical purpose' based on the wordings of



§ 1306.04 and Moore, 423 U.S. at 122, 124 ("Registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice.") The Court also found the converse of § 1306.04(a) true that conversely then, "a practioner would be unauthorized to dispense a controlled substance if he acts without a legitimate medical purpose or outside the usual course of professional practice." Id. at 1233. In United States v. Fuchs, 467 F.3d 889, 899 (5th Cir. 2006), a defendant pharmacist challenged his convictions for dispensing controlled substances not in the usual course of professional practice, in violation of § 841(a)(1), based on the ground that "the government was required to prove not only that he dispensed controlled substances outside the usual course of professional practice but also that he did so without a legitimate medical purpose." Fuchs at 899. Both his indictment and jury instructions did not mention 'legitimate medical purpose', and under plain error review the Court did not find the instruction problematic, recognizing that Circuit's previous caselaw listed as a single element that the dispensing be done "other than for a legitimate medical purpose and in the usual course of his professional practice" (quoting United States v. Rosen, 582 F.2d 1032, 1033 (5th Cir. 1978)). The Fuchs Court further recognized that the phrases 'without a legitimate medical reason' and 'beyond the course of professional practice' can be used interchangeably relying on Outler, holding there is no clearly established law the indictment and jury instructions must reference 'legitimate medical purpose'. Id. at 900-01. This is a 'lower showing' of Circuit interpretation of § 1306.04(a) and Moore to convict a practioner under § 841.

- D. Two Circuits Hold that a Practioner has Unlawfully Distributed a Controlled Substance if he Dispenses the Substance 'Outside the Usual Course of Professional Practice' AND if he Dispenses it 'Without a Legitimate Medical Purpose'.**

The Seventh Circuit holds, "[t]o convict a prescribing physician under § 841(a) of the [CSA], the government must prove that the physician knowingly prescribed a controlled substance outside the usual course of professional practice and [the physician prescribed it] without a legitimate medical purpose.... In other words, the evidence must show that the physician not only intentionally distributed drugs, but that he 'intentionally' act[ed] as a pusher rather than a medical professional." United States v. Kohli, 847 F.3d 483, 489-90 (7th Cir. 2017). "In every case, the critical inquiry is whether the relevant prescriptions were made for a valid medical purpose and within the usual course of professional practice." Id. 491. The Ninth Circuit adds a third essential element; (3) "that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice." United States v. Feingold, 454 F.3d 1001, 1008 (9th Cir. 2006). This is a 'higher showing' of Circuit interpretation of § 1306.04(a) and Moore to convict a practitioner under § 841.

**E. The Dicta in Gonzales by the Supreme Court Suggest 'Medical Use' and 'Medical Purpose' are Essential Elements Enacted by Congress in § 1306.04(a) and the Statutes Required for a Prescription to be Valid.**

In Gonzales v. Oregon, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d. 748 (2006), the Supreme Court held that the Attorney General does not have statutory authority to criminalize assisted suicides and that his interpretation was inconsistent with the statute. In the Court's dicta, the Court noted "[t]he CSA allows prescription of drugs only if they have a 'currently accepted medical use', 21 U.S.C. § 812(b); requires a 'medical purpose' for dispensing the least controlled substance of those schedules, § 829(c); and, in its reporting provision, defines a 'valid prescription' as one 'issued for a legitimate medical purpose', § 830(b)(3)(A)(ii).

Similarly, physicians are considered to be acting as practioners under the statutes if they dispense controlled substances 'in the course of professional practice', § 802(21). The regulation uses the terms 'legitimate medical purpose' and 'course of professional practice'. Gonzales, 546 U.S. at 257. The Court's dicta acknowledged § 1306.04(a)'s requirements that all prescriptions for Schedule II drugs be used "for a legitimate medical purpose by an individual practioner acting in the usual course of his professional practice." Gonzales, 546 U.S. at 256. The Court's dicta fully support the notion that 'legitimate medical purpose' is required for dispensing controlled substance prescriptions, that the phrases 'outside the usual course of professional practice' and 'without a legitimate medical purpose' are not interchangeable concerning, at least, statutory intent and rulemaking authority, and that the phrases have separate, distinct meanings within the regulation and statutes.

**F. Post-Gonzales, the Sixth Circuit joined the Fifth, Tenth & Eighth Circuits Holding that Knowingly Distributing Prescriptions Outside the Course of Professional Practice is a Sufficient Condition to Convict a Defendant Under the Criminal Statutes.**

In United States v. Volkman, 797 F.3d 377, 386 (6th Cir. 2015), Volkman, a medical doctor, challenged the denial of a proposed jury instruction seeking to have the verbatim language of Gonzales included. The Sixth Circuit held Gonzales provided "no guidance" and was "out-of-context" relating to criminal law joining the Tenth Circuit in United States v. Lovern, 590 F.3d 1095 (10th Cir. 2009), leaving the question of what constitutes "the usual course of professional practice for a jury to sort out." The Eighth Circuit adopted and expanded upon the Tenth Circuit in United States v. Kanner, 603 F.3d 530 (8th Cir. 2010), adding that "Gonzales did not supplant the standards for violations of the CSA." Kanner at 535. "Rather, post-Gonzales, knowingly

distributing prescriptions outside the course of professional practice is a sufficient condition to convict a defendant under the criminal statutes relating to controlled substances." (quoting United States v. Armstrong, 550 F.3d 382, 397 (5th Cir. 2008)). Volkman at 386. The Sixth Circuit held Volkman's proposed jury instruction would have narrowed the scope of the jury's inquiry to a question of whether Volkman engaged in 'conventional' drug dealing, inconsistent with the Sixth Circuit's endorsement of the broad approach of finding what conduct falls outside the accepted bounds of professional practice so as to constitute a CSA violation. Id. at 386.

**III THE STATUTE § 841 & THE REGULATION § 1306.04(a) ARE NOT VOID FOR VAGUENESS AS APPLIED TO HEALTHCARE PRACTITIONERS. CONGRESSIONAL INTENT CAN BE INFERRED BY THE REGULATION THAT 'LEGITIMATE MEDICAL PURPOSE' IS A REQUIRED ELEMENT FOR CONVICTION UNDER § 841.**

**A. Federal Courts Have Rejected Void For Vagueness Challenges that §§ 1306.04(a) & 841 are Vague as Applied to Healthcare Practitioners.**

Nearly every Circuit has considered void for vagueness challenges relating to §§ 1306.04(a) & 841. See United States v. Collier, 478 F.2d 268, 270 (5th Cir. 1973)(rejecting "contention ... § 841(a)(1), as applied to physicians, is unconstitutionally vague."), see United States v. Darji, 609 Fed. Appx. 320, 334 (6th Cir. 2015)("this Court has rejected the claim that § 841 and § 1306.04 are void for vagueness."), see United States v. Orta-Rosario, 469 Fed. Appx. 140, 143 (4th Cir. 2012)(rejecting argument of medical doctor that the CSA is impermissibly vague as applied to him because "there is no statutory definition of 'legitimate medical purpose' or 'usual course of professional practice'"), see United States v. Brickhouse, 2016 U.S. Dist. LEXIS 59821, 2016 WL 2654359, at 4 (E.D. Tenn. Mar, 30, 2016) ("The 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."), see United States v. Quinones, 536 Fed. Supp. 2d.

267, 274 (E.D. N.Y. 2008)(rejecting vagueness argument because 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."), and see United States v. Birbragher, 576 F.2d 1000, 1013 (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.") These federal Courts have repeatedly found that practioners CAN be convicted under §§ 1306.04(a) & 841 when they meet certain criteria required for conviction and the Courts have found Congress was clear and unambiguous when it enacted the regulation and statute in the CSA to combat drug abuse in 1971.

**B. The Sixth Circuit's Holdings on Convicting Practioners under §§ 1306.04(a) & 841 Seem Contrary to its Own Findings and Dicta.**

The Sixth Circuit has long held that "In order to obtain a conviction under 21 U.S.C. § 841(a)(1) against a licensed physician ..., the government must show: '(1) That defendant distributed a controlled substance, (2) That he acted intentionally or knowingly; and (3) That defendant prescribed the drug without a legitimate medical purpose AND [he prescribed it] outside the course of professional practice.'" United States v. Chaney, 921 F.3d 572, 589 (6th Cir. 2019) (emphasis added). In Chaney, that Court noted at 591 in its dicta, "as the word purpose implies, [the Court] look[s] at a provider's reason for issuing the prescription when determining whether it was issued for a legitimate medical purpose ... likewise, a doctor who acts in good faith and with all due care but nevertheless issues a prescription to

a patient who was merely faking symptoms is nevertheless acting with a legitimate medical purpose." The Court holds in Chaney that there are three essential elements for conviction under §§ 1306.04 & 841 for a physician with the third element being a two-part requirement that he prescribed a controlled substance 'without a legitimate medical purpose' AND ' he prescribed it 'outside the course of professional practice', which was why the Court was looking at the provider's reason he prescribed the prescription. However, conversely, in this instant case and in Volkman, those Courts held that "knowingly distributing prescriptions outside the course of professional practice [alone] is a sufficient condition to convict a defendant under the criminal statutes related to controlled substances." Volkman at 386. These later holdings by-pass the requirement of finding 'without a legitimate medical purpose' as an element of conviction under §§ 1306.04(a) & 841.

Which holding and dicta are binding? They both cannot be correct. The later holdings are contrary to the first holding and is contrary to the holding of Kirk at 784, that the phrases 'in the usual course of professional practice' and 'legitimate medical purpose' can be used interchangeably because clearly the phrases have different meanings: legitimate medical purpose is the provider's reason he prescribed the prescription, and course of professional practice refers to generally accepted medical practice. The Sixth Circuit, and apparently other Circuits, have not fathomed a scenario where a practitioner dispensed controlled substance prescriptions for a 'legitimate medical purpose' in good faith, but may have dispensed those prescriptions 'outside his usual course of professional practice', which would equate to a civil malpractice or negligent or incompetent or foolish or reckless type of practitioner unfortunately, held criminally liable under a 'lower showing' of most Circuit's caselaw.

**C. The Feingold Court Held that a Jury Instruction is Improper if it Allows a Jury to Convict a Licensed Practioner Under § 841 Solely on a Finding he Committed Negligence, was Incompetent, Foolish or Reckless.**

In United States v. Feingold, 454 F.3d 1001, 1010 (9th Cir. 2006), the Court determined that focusing too heavily on an "outside the scope of professional practice" viewpoint could lead to a mere malpractice standard for conviction and that even intentional malpractice would be inconsistent with Moore's description of a physician violating § 841 as one acting as a drug 'pusher' rather than physician. The Court asserted Moore required that a doctor's actions must completely betray any semblance of 'legitimate medical treatment', and thus criminal liability required a 'higher showing' that "the practioner intentionally has distributed controlled substances for no legitimate medical purpose and [has distributed them] outside the usual course of [his] professional practice." Id. at 1010. The Court openly pondered the question: Can a defendant who intentionally exceeds a generally recognized 'standard of medical practice' still be engaged in the 'usual course of professional practice', such that he be found not guilty under criminal liability? The threats are that practioners could be prosecuted and perhaps convicted as criminals whenever the U.S. Attorneys disapprove of their courses of treatment, or even when they step outside the bounds of convention medical protocols or general medical practice. A violation of the standard of care alone is insufficient to support a criminal conviction of a practioner under § 841. Only after assessing the standards to which medical practioners generally hold themselves, is it possible to evaluate whether a practioner's conduct has deviated so far from "the usual course of [his] professional practice", that his actions become criminal. (quoting Moore, 423 U.S. at 124). Feingold at 1010-11.

Courts must be careful not to allow a jury to conflate the high standard

of criminal liability with a lower standard of civil malpractice or negligence by concentrating on a practitioner's 'usual course of professional practice' alone, permitting a jury to convict a practitioner simply upon a finding that he was negligent, was incompetent, was foolish or reckless. There must be a finding of intent, which requires the jury to find the practitioner intentionally violated the standard of care and a finding the practitioner dispensed prescriptions 'without a legitimate medical purpose', because if not, intentional malpractice or negligence or recklessness would impermissibly meet the standard of criminal liability. The Feingold Court held that an instruction is improper if it allows a jury to convict a licensed practitioner under § 841 solely on a finding that he committed malpractice, negligence, or was incompetent. The Court quoted United States v. Boettjer, 569 F.2d 1078, 1081 (9th Cir. 1978), noting that the standards for liability "itself imports considerations of medical legitimacy and accepted medical standards", and that evidence regarding the applicable standard of care is "not offered to establish malpractice, but rather to support the absence of any legitimate medical purpose in [the practitioner's] prescription of controlled substances." Id. at 1082.

**D. The DEA Publishes a Guide to Help Pharmacists Ensure that the Controlled Substance Prescriptions they Fill are Being Filled for a 'Legitimate Medical Purpose'.**

The DEA, a law enforcement agency and part of the Department of Justice, publishes a guide, titled 'A Pharmacist's Guide to Prescription Fraud', to help pharmacists ensure that controlled substance prescriptions are being issued for a 'legitimate medical purpose'. The guide is found at <http://www.deadiversion.usdoj.gov/pubs/brochures/pharmguide.htm> (2014) and also found in Appendix D of the '2010 Pharmacist's Manual' also published online at <https://www.deadiversion.usdoj.gov/pubs/manuals/index.html> (2014). The DEA advises



pharmacists that § 1306.04(a) requires a prescription to be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. That means that dentists should not write controlled substance prescriptions for chronic back pain because it is outside of the dentist's usual course of professional practice to issue such a prescription where he could not have addressed the patient's true medical need because that is not his specialty. This is a literal advisement based solely on the regulation § 1306.04. This guidance, however, focuses solely on the prescriber's 'usual course of professional practice' and rarely on the pharmacist's 'usual course of professional practice' when filling controlled substance prescriptions presumably because most often as long as a pharmacist dispenses medication within his pharmacy, he is dispensing — within his 'usual course of professional practice'. DEA guidance therefore focuses on the legitimate medical purpose rule, where the objective is to prevent the diversion of medications to the illicit market without impeding the legitimate use of medications. Richard R. Abood, Pharmacy Practice and the Law, 7th Edition 2014, pgs. 238-39, (Jones & Bartlett Learning). DEA guidance is in direct conflict with caselaw in several federal Districts when prosecuting pharmacists where the government can solely look at the pharmacist's usual course of professional practice to determine if the prescriptions dispensed were illegally dispensed under a 'lower showing' for conviction because 'legitimate medical purpose' is not a required finding to convict under their interpretations of § 1306.04(a) and Moore.

It is clear also that the DEA does not interchange the phrases 'legitimate medical purpose' and 'usual course of professional practice' in its admonitions to pharmacists. The DEA is not misinforming or mischaracterizing § 1306.04 to pharmacists, but believes like the Seventh

& Ninth Circuits believes and interprets § 1306.04(a) as a two-part required element for conviction under § 841 for practioners. Those two required elements for conviction are 'without a legitimate medical purpose' AND 'outside the usual course of professional practice'. The DEA's advise is the literal reading of the regulation and related statutes and for pharmacists to exercise their clinical judgment on whether to fill a controlled substance prescription without impeding the legitimate use of medications.

**E. Congressional Intent Can be Inferred by Reading the Regulation and Related Criminal Statutes.**

Congress enacted the CSA in 1971 to combat drug abuse. The inquiry for statutory interpretation must begin with the text of the regulation and related statutes of the CSA, noting, headings although "not commanding", "they supply clues" about Congressional intent. Yates v. United States, 574 U.S. 528, 135 S. Ct. 1074, 1083, 191 L. Ed. 2d. 64 (2015). Under 21 U.S.C. § 801. Congressional findings and declarations: controlled substances, "The Congress makes the following findings and declarations: (1) Many of the drugs included within this title have a useful and **legitimate medical purpose** and are necessary to maintain the health and general welfare of the American people." (emphasis added). Congress realized that illegal import, manufacture, distribution, possession and improper use of controlled substances have a detrimental effect on the American people when used without a legitimate medical purpose. See also Congressional findings in § 801a, pyschotropic substances, where Congress recognized the danger involved in **non-medical** purposes and provided strong legislation to control its legitimate uses. Congress later in the Act, criminalized unauthorized distribution of Scheduled Substances such as in

Schedule II, where it listed drugs generally available only by written prescription. The CSA manifests no intent to regulate the practice of medicine generally, but when Congress meant to do so, it did so by explicit language. 21 C.F.R. § 1306.04(a) explicitly reads that "[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 ...." (emphasis added). Federal Courts have ruled this language is not void for vagueness and unambiguous in its meaning and proclamation. Further, there are two required elements for a prescription to be effective: (1) a legitimate medical purpose, and (2) a practitioner acting in the usual course of his professional practice. These phrases cannot be read as being interchangeable, as certain federal caselaw have held, because that would make the regulation and related statutes redundant. It is clear the phrases have separate, distinct meanings by looking at other federal statutes related to controlled substances. See U.S.C. § 829(c) where "[n]o controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose." See § 812(b) Placement on schedules; findings required, where every scheduled drug II through V "has a currently accepted medical use in treatment in the United States." See § 830(b)(3)(A)(ii) where a "valid prescription means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice." See § 802(21) where the term practitioner is defined "in which he practices ... to dispense ... a controlled substance in the usual course of professional practice or research." See § 802(54) defining "practice of telemedicine", (A)(ii) by a practitioner (I), acting in the usual course of

professional practice, and same in (B)(i). See 802(56) defining "filling new prescriptions for controlled substances in schedule III, IV, or V", (C) "the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription." Clearly, one would not expect Congress to address 'medical use' or 'medical purpose' in so many of the CSA statutes and regulation 1306.04, if it was not meant to be a requirement for conviction of a practitioner under the criminal statutes.

**III. THERE WAS INSUFFICIENT EVIDENCE TO CONVICT DEFENDANT PHARMACIST UNDER § 1306.04(a) & 841 BECAUSE THE GOVERNMENT DID NOT PROVE THERE WERE NO LEGITIMATE MEDICAL PURPOSES FOR THE PRESCRIPTIONS FILLED IN THE INDICTMENT.**

**A. The Indictment and Sixth District Court Jury Instructions Listed Two Essential Elements for Conviction Under §§ 1306.04(a) & 841.**

The Second Superseding Indictment charged defendant pharmacist under §§ 1306.04(a) & 841(a)(1), that he did distribute and dispense, outside the scope of professional practice and not for a legitimate medical purpose, a quantity of pills containing oxycodone in multiple counts. The Sixth District Court's jury instructions also listed these elements for the jury to determine before a conviction could be found. These phrases were not defined in the instructions, nor were these phrases told to be used interchangeably. During an eight day jury trial, defendant pharmacist's whole case revolved around his contention that he dispensed controlled substance prescriptions in the Counts of the indictment for a legitimate medical purpose. Indeed, the government's trial witnesses all testified to having real injuries and medical needs requiring prescription pain medication that were supplied to the pharmacist before he filled the prescriptions. The trial witnesses further testified to supplying pharmacist with real, accurate MRI reports detailing their medical conditions before

the prescriptions were dispensed. This testimony is uncontested by the government. However, the government did put forth lay opinion witness testimony that determined the Counts in the indictment contained several red-flags about the legitimacy of the prescriptions, who argued defendant pharmacist dispensed said prescriptions 'outside the course of professional practice' by ignoring these generalized red-flags or warnings before the controlled substance prescriptions were filled and subsequently diverted. After the close of the government's case-in-chief, pharmacist's defense counsel orally asked for a Rule 29 motion to acquit based on insufficient evidence of the oxycodone Counts in the indictment. The motion was denied. A jury subsequently convicted defendant pharmacist on all Counts and defendant appealed to the Sixth Circuit Court of Appeals.

**B. Defendant Pharmacist's Convictions Under §§ 1306.04(a) & 841(a)(1) Can Not Stand as all the Essential Elements were Not Proven Where he was Convicted Under a 'Lower Showing' of Negligence, Incompetence, Foolishness or Recklessness.**

Defendant pharmacist's convictions under §§ 1306.04(a) cannot stand because both essential elements of § 1306.04(a) were not proven at trial. Defendant pharmacist may not be convicted solely upon a finding that he committed negligence or was incompetent, foolish or reckless by the Court of Appeals for the Sixth Circuit concentrating only on pharmacist's usual course of professional practice, completely ignoring pharmacist's argument that the controlled substance prescriptions he filled had legitimate medical purposes.

The Supreme Court in Moore held that a practitioner can be convicted under § 841 when he acts "other than in good faith ... in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." Moore, 423 U.S. at 139. The Court found he could be prosecuted when a doctor ceased being a

doctor and became a drug 'pusher'. The Supreme Court did not intend to define what every essential element was for conviction under § 841 and did not specifically address § 1306.04(a) or 'legitimate medical purpose'. This case however split the federal Circuits in their interpretation of how to apply § 1306.04 to subsequent practioners prosecuted in their Circuits for illegal dispensing: Whether there were two elements for conviction under § 1306(a) or one, and whether the two phrases could be used interchangeably.

The Supreme Court dicta in Gonzales repeatedly acknowledged 'medical use' and 'medical purpose' in the CSA statutes and regulation supporting the notion these phrases are not interchangeable and that Congress did intend to make 'legitimate medical purpose' a required element for conviction under the CSA statutes and regulation.

Federal Courts have repeatedly ruled §§ 1306.04(a) & 841 are not void for vagueness and have clear meaning that proscribes conduct to practioners.

The Sixth Circuit's holding on convicting practioners under §§ 1306.04(a) & 841 seem contrary to its own findings and dicta. The Court cannot say that 'legitimate medical purpose' is a required element in Chaney, and then say in Volkman, that knowingly distributing prescriptions outside the course of professional practice alone is a sufficient condition for conviction.

The DEA's guidance and admonitions to pharmacists is the literal reading of § 1306.04(a) that two elements are required for the purpose of a prescription: a legitimate medical purpose AND an individual practioner acting in the usual course of his professional practice.

Congressional intent can be inferred that 'legitimate medical purpose' is a requirement of § 1306.04(a) because of the strict reading of the text and headings of the regulation and related CSA statutes. Congress did not intend the two phrases to be used interchangeably because of their distinct and separate uses in the regulation and related statutes.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Respectfully submitted,

x Pamela Hill

Date: January 16<sup>th</sup> 2020