No. 21-762

ORIGINAL

IN THE

SUPREME COURT OF THE UNITED STATES

Lena Lashen — 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 Second Circuit
(NAME OF COURT THAT LAST RULED ON MERITS OF YOUR CASE)

PETITION FOR WRIT OF CERTIORARI

Lena Lashen
(Your Name)

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QUESTIONS PRESENTED

1. Where the government prosecutes a licensed pharmacist under "Misbranding", 18 usc§ 371, 21 USC§§ 331(a) and 333(a)(2), for dispensing "invalid" prescription issued by licensed medical practitioners, is the government required to prove that the pharmacist knew the prescription written by licensed medical practitioners to be "invalid" and "outside the scope of the medical practitioners scope of professional practice? See 20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED

2. Does a "good faith" defense in the context of a licensed pharmacist prosecuted under "Misbranding", 18 usc§ 371, 21 USC§§ 331(a) and 333(a)(2), protect pharmacists who have an honest but mistaken belief that they have dispensed the charged prescription in "the usual course of medical practitioners' professional practice;" and, if so, must that belief be objectively reasonable? See 20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED

3. Was the Plaintiff's constitutional right denied due to prosecutors' suppression of exculpatory video recordings evidence in the government's possession, in violation of *Brady v. Maryland?*

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:

RELATED CASES

TABLE OF AUTHORITIES

Cases

United States v. Gross, 961 F.2d 1097 (3rd Cir. 1992)

United States v. Hayes, 794 F.2d 1348 (9th Cir. 1986)

United States v. Hurwitz, 459 F.3d 463 (4th Cir. 2006)

United States v. Jones, 825 F. App'x 335 (6th Cir. 2020)

United States v. Joseph, 709 F.3d 1082 (11th Cir. 2013)

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

United States v. Katz, 445 F.3d 1023 (8th Cir. 2006)

United States v. King, 898 F.3d 797 (8th Cir. 2018)

United States v. Kirk, 584 F.2d 773 (6th Cir. 1978)

United States v. Kohli, 847 F.3d 483 (7th Cir. 2017)

United States v. Lawson, 682 F.2d 480 (4th Cir. 1982)

United States v. Lee, 966 F.3d 310 (5th Cir.)

United States v. Li, 819 F. App'x 111 (3d Cir. 2020)

United States v. Limberopoulos, 26 F.3d 245 (1st Cir. 1994)

United States v. Lovern, 590 F.3d 1095 (10th Cir. 2009)

United States v. McElroy, 910 F.2d 1016 (2d Cir. 1990)

United States v. McIver, 470 F.3d 550 (4th Cir. 2006)

United States v. Merrill, 513 F.3d 1293 (11th Cir. 2008)

United States v. Moore, 423 U.S. 122 (1975)

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

United States v. Nivica, 887 F.2d 1110 (1st Cir. 1989)

United States v. Norris, 780 F.2d 1207 (5th Cir. 1986)

United States v. Plesons, 560 F.2d 890 (8th Cir. 1977)

United States v. Purpera, 844 F. App'x 614 (4th Cir. 2021)

United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975)

United States v. Ruan, 966 F.3d 1101 (11th Cir. 2020)

United States v. Sabean, 885 F.3d 27 (1st Cir. 2018)

United States v. Singh, 54 F.3d 1182 (4th Cir.1995)

United States v. Smith, 573 F.3d 639 (8th Cir. 2009)

United States v. Stump, 735 F.2d 273 (7th Cir. 1984)

United States v. Tobin, 676 F.3d 1264 (11th Cir. 2012)

United States v. Tran Trong Cuong, 18 F.3d 1132 (4th Cir. 1994)

United States v. U.S. Gypsum Co., 438 U.S. 422 (1978)

United States v. Vamos, 797 F.2d 1146 (2d Cir. 1986)

United States v. Voorhies, 663 F.2d 30 (6th Cir. 1981)

United States v. Wexler, 522 F.3d 194 (2d Cir. 2008)

Statutes

21 U.S.C. SS 331(a) and 333(a)(2)

21 U.S.C. § 821

21 U.S.C. §841

Treatises

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

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

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

Deborah Hellman, Prosecuting Doctors For Trusting Patients, 16 G EO . M ASON L. R EV . 701 (2009)

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

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

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

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

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

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

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

O'Donnell & Alltucker, Pain patients left in anguish by doctors 'terrified' of opioid addiction, despite CDC change, USA T ODAY (June 24, 2019)

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

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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

[ ] reported at _____; 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 _____ to the petition and is

[ ] reported at _____; 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 August 11, 2020.

[ ] 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: October 29, 2020, 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 November 12, 2021 (date) on September 14 2021 (date) in Application No. USCA2 No. 20-221

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

The Fifth Amendment to the United States Constitution prohibits any person from being deprived of his or her liberty without due process of law:

> "No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

18 U.S.C.A § 841 (a)(1) states:

> "Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally -to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance"

21 U.S.C. SS 331(a) and 333(a)(2):

Introducing misbranded drugs into interstate commerce

21 C.F.R § 1306.04(a) provides the requirements for lawful prescription by a physician:

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

STATEMENT OF THE CASE

I. This case presents a clear and unambiguous vehicle for the Court to address increasingly divergent inter and intra-circuit splits pertaining to the mens rea the government must establish to secure the conviction of a licensed pharmacist under Misbranding. **Here, the pharmacist dispensed "regular" "non-controlled" prescriptions written by licensed medical practitioners the Government claimed to be "invalid".**

"Currently, there are at least three different mens rea requirements recognized by the Courts of Appeal. Three circuits unequivocally impose strict liability on practitioners who prescribe outside the usual course of professional practice; two (arguably three) impose a knowing or intentional scienter; and the remainder

impose varying degrees of negligence. Confusion on this point has led to a number of inter- and intra-circuit splits regarding what constitutes a "good faith" defense for doctors charged under §841. A valid defense in one circuit amounts to an admission of guilt in another.

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

The Eleventh, Tenth, and Fifth Circuits hold that, while the government must prove that a defendant knew she was issuing a prescription for no legitimate medical purpose, a doctor charged under the "usual course" prong is strictly liable for any prescriptions she writes that are, in fact, outside the scope of professional practice regardless of whether she knew that they were outside said scope. United States v. Tobin, 676 F.3d 1264, 1283 (11th Cir. 2012); United States v. Norris, 780 F.2d 1207, 1209 (5th Cir. 1986).

The First, Second, Third, Fourth, Sixth, Seventh, Eighth, and Ninth Circuits have each issued decisions explicitly or implicitly requiring the government to prove that the defendant knowingly or intentionally acted outside the scope of professional practice. United States v. Sabean, 885 F.3d 27, 45 (1st Cir. 2018); United States v. Wexler, 522 F.3d 194, 206 (2d Cir. 2008); United States v. Li, 819 F. App'x 111, 118 (3d Cir. 2020) (unpublished); United States v. Hurwitz, 459 F.3d 463, 478, 480 (4th Cir. 2006); United States v. Jones, 825 F. App'x 335, 339 (6th Cir. 2020); United States v. Kohli, 847 F.3d 483, 490 (7th Cir. 2017); United States v. Smith, 573 F.3d 639, 649–50 n.4 (8th Cir. 2009); United States v. Feingold, 454 F.3d 1001, 1008 (9th Cir. 2006).

Despite the majority of circuits' consensus that a doctor must intentionally or knowingly issue a prescription outside the scope of professional practice, jury instructions in the Second, Fourth, Sixth, and Eighth Circuits define good faith "objectively." In those circuits, a defendant acts in good faith only when she acts

within what she reasonably should have believed or "reasonably believed" to be the usual course of professional practice. United States v. Vamos, 797 F.2d 1146, 1152 (2d Cir. 1986); Hurwitz, 459 F.3d at 478 (4th); United States v. Godofsky, 943 F.3d 1011, 1026 (6th Cir. 2019); United States v. King, 898 F.3d 797, 807–08 (8th Cir. 2018). The effect of these instructions is to allow a jury to convict based on a mens rea of negligence rather than knowledge or intent. In those circuits, a defendant who holds a sincere belief about what prescription practices are permissible and writes prescriptions based on that belief can still be convicted under the CSA.

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

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

This Court last considered any case involving the prosecution of a medical practitioner under §841 in 1975. United States v. Moore, 423 U.S. 122 (1975). The increase of prosecutions against medical practitioners under the CSA over the last decade has not worked to clarify circuit court law but instead has birthed an exponential increase in inter- and intra- circuit inconsistency. This case presents a clear opportunity to resolve these inconsistencies precisely because the holding of the Tenth Circuit unambiguously imposes strict liability on doctors acting outside the scope of professional practice. United States v. Kahn, 989 F.3d 806, 825 (10th Cir. 2021) (We hold that §841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant ... issued a prescription that was objectively not in the usual course of professional practice.").

Statutory Framework

The Controlled Substances Act makes it unlawful for any person "knowingly or intentionally to distribute or dispense a controlled substance." 21 U.S.C. §841(a). Medical practitioners are exempt from this prohibition. See 21 U.S.C. §§ 821–23. In Moore, this Court recognized that a doctor's scope of authority as

defined in the CSA is somewhat circular. 423 U.S. at 124. ("Section 822(b) defines the scope of authorization under the Act in circular terms. 'Persons registered . . . under this subchapter . . . are authorized (to dispense controlled substances) . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.") Id. The defendant in Moore challenged his conviction arguing that he could not be prosecuted under §841 because he was duly licensed and registered under the CSA. Id. This Court reasoned that the CSA could not have intended to exempt all practitioners from liability under §841. Id. Thus, the Court found that a physician remains criminally liable when he ceases to distribute or dispense controlled substances as a medical professional and acts instead as a "pusher." Id. at 138.

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

> "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."" 21-5261 KAHN, SHAKEEL V. UNITED STATES, CERTIORARI GRANTED

In the Plaintiff's case, the **Government never proved that the Plaintiff knew the prescriptions she dispensed were "invalid".**

II. The District Court denied the Plaintiff's 3/19/2020 motion for a certificate of appealability based on newly-discovered-evidence motion for a new trial, challenging the denial of a newly-discovered-evidence motion for a new trial after the May 15, 2015 verdict, as untimely in that "any motion for a new trial grounded on newly discovered evidence must be file within 3 years after the verdict or finding of guilty." **However**, the **suppressed exculpatory video recordings**, a **Brady violation**, were **NOT turned over to the Plaintiff** until July 24, 2018, which was **more than 3 years after the Plaintiff's verdict**. Therefore, it was **IMPOSSIBLE for "such motions be made within three years after verdict"**.

It must be stressed that the prosecutors referenced these video recordings as if they were in evidence at trial, while knowing the video evidence was exculpatory. Their suppression of it, and their tampering with the evidence, also show that they knowingly presented false evidence to the jury.

Judge Buchwald denied the Plaintiff's request for a new trial based on newly discovered evidence as

"untimely". She chose to ignore the Supreme Court's recent ruling of Arsean Lamone HICKS v. Director, DEPARTMENT OF CORRECTIONS. Record No. 131945. Decided: 7 February 26, 2015 in that **"the statute of limitations for habeas claims must be tolled while such evidence is suppressed." The Appellate Court should grant the Plaintiff a new trial based on** the Supreme Court's recent ruling of Arsean Lamone HICKS v. Director, DEPARTMENT OF CORRECTIONS. Record No. 131945. Decided: February 26, 2015, and based on the fact the newly discovered evidence were not turned over to the Plaintiff until July 24, 2018, more than 3 years **after** the Plaintiff's verdict; thus the Plaintiff is not capable nor able to file within the 3 years statute of limitation. Therefore, the **Plaintiff is seeking to toll the statute**.

A. The exculpatory video recordings evidence, which were previously suppressed by the prosecution, AUSA DANIEL RICHENTHAL, show:

(1) The Plaintiff was not present at the alleged crime scene on the dates (6/1/2012,6/12/2012, 7/16/2012, 7/17/2012, 8/13/2012, 8/16/2012, 8/27/2012, and 10/2/2012 the alleged crimes were supposedly committed, and

(2) The Plaintiff was working in a different pharmacy and not engaged in any of the alleged acts the prosecution describes, such as remotely monitoring or supervising, nor directing employees in other locations to commit the alleged crime.

(3) The Plaintiff was working at a different pharmacy on October 2, 2012 when opioids was dispensed to "unkempt" individuals,

(4) The Plaintiff never dispensed the drug "butalbital" as indicted, charged, and convicted of, and proof of same was withheld from the jury.

Most importantly, the Plaintiff's lack of presence is also shown on the work schedule and EZY passes. The governing pharmacy law (PA 27.12(b)(2) and the criminal statute 21 U.S.C. Sec. 321 (g)(1), 352(a), 352(c), 353(b)(1), 353(b)(4)(A), 21 U.S.C. Sec. 331(a) and 333 (a)(2) REQUIRE the accused to be present at the pharmacy at the time the specific prescriptions in question were filled and/or "shipped". Also, the governing pharmacy law protects a pharmacist from being held liable for another's actions. Numerous pharmaceutical law and protocol support the Plaintiff's testimony while impeaching the testimony of Prosecution witnesses and one of the main contentions of the prosecution's case. The lack of ability to present that critical video evidence,

while the government asserted the knowledge of it's existence further undermined the truth and advanced the perjured testimony. See Demarco v United States 928 F.2d 1074 (11th cir. 1991). The failure for the prosecution to correct perjured testimony is ground for the reversal of conviction.

The Government also has a copy of the work schedule from the Hellertown Pharmacy (HP) and Palmer Pharmacy & Much More (PP) showing Plaintiff was not at work during the dates and times of the shipments referenced.

The Prosecution and their witnesses also claim the Plaintiff was in New Jersey: remotely monitoring, supervising, and directing employees in the PA stores to commit the crimes. The Prosecutors specifically stated that the video evidence showed the Plaintiff remotely monitoring and remotely directing workers in Pennsylvania pharmacies to commit the alleged acts. But the Prosecution never presented that video evidence. They instead suppressed it and the Judge withheld it. Unsurprisingly, the **video shows the Plaintiff busily working in a New Jersey Pharmacy on all of the dates in question, not remotely monitoring or supervising employees in the other stores, as the prosecution claimed.** The prosecution and its witnesses claimed the Plaintiff did not count pills, reused medications, improperly labeled and stored medications. However, the **admittance of vastly superior video evidence will show that the Plaintiff follows rules and regulations of pharmacy law, properly handling pills and prescriptions, labeling and storing and destroying medications properly, and dispensing medications with valid prescriptions which were verified by doctors, all contradicting the prosecutors' witnesses sworn testimony**. The video recordings will further prove **the drug "butalbital" NEVER existed in the pharmacies**.

The United States Supreme Court stressed that a defendant's due process rights are violated both when a prosecutor knowingly presents false testimony and when he knowingly fails to correct such perjury. The Court also held that the same rule applies even when the false testimony concerns only the witness's credibility, since "a lie is a lie, no matter what its subject." Napue v. Illinois, 360 U.S. 264 (1959). Bivens v. Six Unknown Fed. Narcotics Agents, 403 U.S. 388 (1971)

FACTS

On September 2, 2016, the Second Court wrongfully affirmed the petitioner's conviction of May 15, 2015 in violation of 18 U.S.C. 371 (Count I); introducing misbranded drugs into interstate commerce in

violation of 21 U.S.C. 331(a) and 333(a)(2) (Count II); conspiracy to commit mail and wire fraud in violation of 18 U.S.C. 1349 (Count III); and mail and wire fraud in violation of 18 U.S.C. 1341 and 1343 (Counts IV and V). She was sentenced to 36 months' imprisonment, for:

a. dispensing "butalbital" (See Exh D) which NEVER existed in the pharmacies,

b. the dispensing of tramadol which was **NOT a controlled substances at the time of dispensing**, but became a federally controlled substance **nineteen months after the Petitioner's indictment/arrest**, but the only misbranding alleged about Tramadol is only applicable to controlled substances (Valid Prescription standard),

c. the dispensing of "highly addictive pain meds" which is a term that does not exist in law nor in the health care industries and used only to deceive the jury by creating standards that do not exist under the law, which both the District and Appellate Court failed to mention ONE name of the "highly addictive pain meds" that was dispensed, because there were NONE.

The principal argument was that Lasher dispensed **"regular" "non-controlled" prescriptions written by licensed medical practitioners the Government deemed to be "invalid".** The government further lied to the jury that the "regular" "non-controlled" prescriptions Lasher dispensed were "highly addictive pain meds" and they presented testimony known to be false multiple times during the trial. In fact, the prosecution placed regular prescription drugs, drugs that are not controlled substances and have no known potential for abuse, into a "made-up" category that NO drug has ever been placed in, a category they called "highly addictive pain meds" sometimes calling it "addictive pain meds", without any facts to back up the invention of this phrase nor any references to scientific, medical, pharmaceutical or pharmacological literature (T.1768). This was done to prejudice and profile the Plaintiff; in fact, NONE of the drugs the Plaintiff dispensed via the "fulfillment" pharmacy were classified as "pain meds"(T.1768), or a controlled substance at the time of dispensing.

Multiple DEA agents testified to receiving the drug "butalbital" even though the drug they were prescribed and received was Fioricet. Early in the pre-trial phase it was established that the pharmacies never stocked nor dispensed butalbital. It is a very uncommon drug, its use is primarily if not exclusively in manufacturing. The drug dispensed was Fioricet. **To call the drug by a different name is a lie, misrepresenting the material fact of the matter. It also defies the definitions within the law for both Drug and Fixed-Combination Drug.** These **agents committed perjury**; the Jury were deceived as to the drug

prescribed. If a juror ever had to see a doctor over tension headaches, or had a loved one who did, they would very likely know that **Fioricet is not a controlled substance** and there is a chance they would have seen through the deceptions that were presented to them about the drug.

A jury convicted Lasher on five counts and she was sentenced to three years in prison

"The original good faith instruction proposed by Kahn read:

"The good faith of a defendant, whether or not objectively reasonable, is a complete defense to the crimes charged, because good faith on the part of a defendant is inconsistent with specific intent, which is an essential part of the charges. A defendant who acts upon an opinion honestly held by him or her at the time of the alleged acts, or pursuant to a belief honestly entertained by him or her at the time of the alleged acts, cannot be found guilty even though his or her opinion is erroneous or his or her belief is mistaken or wrong.

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

While the term "good faith" has no precise definition, it means, among other things, a belief or opinion honestly held, an absence of malice or ill will, and an intention to avoid taking unfair advantage of another." **20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

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

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

In determining whether or not the government has proven that a defendant acted intentionally, you the jury should consider all of the evidence in the case bearing on that defendant's state of mind." R. 694 at 10-11."

The instruction issued by the Petitioner's district court read:

" The defendant has advanced the defense of good faith. Good faith means a state of mind consisting of honesty in belief or purpose and the absence of intent to defraud or mislead." T. 1924 At 14-17"

"Petitioner argued that the government must prove both that the instant prescriptions were written outside "usual course of the medical practitioner's profession" and without a "legitimate medical purpose." R.729 at 8-9; 5/21/19 Tr. 7." **20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

The Petitioner, a licensed pharmacist, is not responsible for a doctor's actions or state of mind and the Government can not make up a standard out of thin air accusing the Petitioner of dispensing "invalid" prescriptions prescribed by licensed medical practitioners; the Government did not prove that the Plaintiff knew the prescriptions written by licensed medical practitioners which the Plaintiff dispensed were "invalid".

A. The Court of Appeals' Decision

Petitioner appealed to the Second Circuit, arguing that:

1. The Petitioner abided by all pharmacy law in dispensing these prescriptions and there was no reason to suspect that these prescriptions were not valid; to date, the Government **never proved that the Plaintiff knew the prescriptions she dispensed were "invalid".**

2. **The statute of limitations for habeas claims must be tolled while exculpatory evidence is suppressed.**

The Second Circuit affirmed. Lena Lasher v. United States, 20-221 (2nd Cir. 2019).

On August 11, 2020 United States Court of Appeals for the Second Circuit **GRANTED** the Plaintiff leave to file an oversize motion for a certificate of appealability; however, they:

1. Then Denied her Document for panel RECONSIDERATION and a motion for RECONSIDERATION ENBANC for a certificate of appealability on October 29, 2020 (See Appendix B)

2. Dismissed Lasher's appeal stating they "lacked jurisdiction to hear Lasher's appeal because a district court's order denying a certificate of appealability is not an appealable final order". However, the Second Circuit Court was incorrect.

"Kahn's assertion that "good faith is a defense because it negates the mens rea element of the offense" is without merit. ... Unlike other criminal offenses, good faith does not go to mens rea for §841 offenses involving practitioners. Rather, as numerous other circuits have recognized, good faith defines the scope of professional 11

practice, and thus the effectiveness of the prescription exception and the lawfulness of the actus reus." Id. at 826. The Tenth Circuit, thus, asserted that a doctor's actual intentions or beliefs are irrelevant. According to the Tenth Circuit's decision, a doctor who unintentionally writes a prescription negligently is guilty of a crime under the CSA. The Tenth Circuit has imposed strict liability on doctors who act outside the usual course of professional practice even if they do so unintentionally." **See 20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

In this Petitioner's case, "good faith is a defense because it negate the mens rea element of the offense" in that a pharmacist cannot read the mind of the licensed medical practitioners in regard to his doctor patient relationship; the law simple does not require this, because the law expects doctors to adhere to their own professional standards. Pharmacists dispense prescriptions. Here, no specific prescription was cited to be misbranded by any one. No evidence of such was provided by anyone. Instead, the Government's allegation was intentionally vague so as to deceive the jury. Further, the indictment intentionally conflates an allegation that the Plaintiff did this or that she directed "others" to commit these alleged crimes, but does not name anyone else. Again, no evidence was ever presented to support these allegations other than testimony that can shown to be false. There is nothing of intent in the indictment, there is nothing specific in the indictment.

The Defendants also should know that the bonafide relationship standard for normal **NON – controlled prescriptions** do not require a pharmacist to assess a doctor-patient relationship. In fact, there is no formal assessment for a pharmacist to determine whether there is a bonafide relationship between a doctor and his patient, that relationship is between them; there is no established criteria under federal law for a pharmacist to know if the doctor consulted their patients. The signatures on the prescriptions are the doctor's promise to the rest of the health care community and the patients, that the prescriptions are valid and that their job was done properly. A relationship could in fact exist and be denied at trial, as the doctors testifying at the criminal trial against the Plaintiff were only testifying to avoid their own jail time for other crimes. On top of this, the Plaintiff, before filling these fulfillment pharmacy prescriptions, actually required doctors to fill out and submit forms stating that they did phone consult directly with the patients. Evidence of this requirement that went above and beyond the requirements under the law was withheld by the District Court because it was physical evidence that would directly contradict testimony of one of the prosecution's witnesses.

None of this changes the fact that the Prosecution's and the district court's applying of the face-to-face requirement to non-Controlled Substances is a deception, deceiving the jury that the Controlled Substances Act's requirements for valid prescriptions was meant to be applied to NON – Controlled Substances.

Plaintiff now moves for a certificate of appealability to appeal the District Court's unconstitutional denial of her habeas corpus by submitting this writ of certiorari, to affirm her actual innocence.

REASONS FOR GRANTING REVIEW

I. REVIEW IS NECESSARY TO RESOLVE A NUMBER O F CIRCUIT SPLITS CENTERING AROUND THE CENTRAL QUESTION O F WHAT LEVEL OF INTENT IS NECESSARY FOR CONVICTION OF A LICENSED PHARMACIST UNDER MISBRANDING – DISPENSING "regular" "non-controlled" prescriptions written by licensed medical practitioners the Government claimed to be "invalid". "The Tenth Circuit, in the case at bar, as well as the Eleventh and Fifth Circuits, have explicitly held that a defendant is strictly liable for acting outside the scope of professional practice. Tobin, 676 F.3d at 1283; Norris, 780 F.2d at 1209. In those circuits, a doctor acting outside the scope of professional practice is culpable under §841 even if she intended to comply with what she believed to be the usual course of professional practice and the charged prescriptions were actually serving a legitimate medical purpose. Having a mistaken view about what the standards of medical practices are or what most doctors actually do (depending upon one's interpretation of "usual course of professional practice") is not a defense.

The Ninth and Seventh Circuits are the most explicit in holding that the government must prove that a medical practitioner intentionally acted outside the usual scope of professional practice and/or issued a prescription knowing it served no legitimate medical purpose. Kohli, 847 F.3d at 490 ("In other words, the evidence must show that the physician not only intentionally distributed drugs, but that he intentionally 'act[ed] as a pusher rather than a medical professional.'"); Feingold, 454 F.3d at 1008 ("[T]he government must prove ... that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional."); United States v. Garrison, 888 F.3d 1057, 1064 (9th Cir. 2018).

Other Courts of appeal have issued decisions that either implicitly or explicitly required a finding of knowledge. See Hurwitz, 459 F.3d 463 (4th) ("attorney's statement [admitting that his client acted outside the scope of professional practice] therefore cannot be viewed as a clear and unambiguous admission that [the defendant] knowingly acted outside the bounds of accepted medical practice."); Jones, 825 F. App'x at 339 (6th) ("To have convicted [the defendant] under §841(a)(1), the jury must have found that Jones filled prescriptions for Schedule II substances knowing that the prescriptions were outside the scope of professional practice and that they were not for a legitimate medical purpose.") (unpublished); Sabean, 885 F.3d at 45 (1st) ("It stressed that the government had to prove, at a minimum, that the defendant "was aware to a high probability the prescription was not given for a legitimate medical purpose in the usual course of professional practice" and that the defendant "consciously and deliberately avoided learning that fact."); Li, 819 F. App'x at 118 (3rd) ("It is settled law that 'a district court does not abuse its discretion in denying a good faith instruction where the instructions given already contain a specific statement of the government's burden to prove the elements of a 'knowledge' crime.' Here the District Court instructed the jury on the requirements to prove knowledge. Thus, it acted within its discretion.") (unpublished); Wexler, 522 F.3d at 206 (2nd) (mistake "however gross" insufficient); Smith, 573 F.3d at 649–50 n.4 (8th) (instruction conflating civil standard of care with usual course of professional practice was cured, in part, by good faith instruction which noted that "unreasonable belief sincerely held is good faith.").

Even among those circuits requiring that a doctor knowingly act outside the scope of professional practice, a split has developed as to what constitutes "good faith." See Deborah Hellman, Prosecuting Doctors For Trusting Patients, 16 G EO . M ASON L. R EV . 701, 715 (2009). The consensus view in the circuits is that medical practitioners charged with violating §841 are entitled to some form of good faith instruction. However, the good faith instructions approved of by the courts of appeals are often inconsistent with the circuit's proffered view on the level of intent required to prove a practitioner's guilt.

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

The Seventh, and Ninth, and First Circuits allow for instructions that define good faith

"subjectively." That is, instructions that ask the jury to consider the defendant's "honest efforts" without requiring that a defendant's belief regarding the usual course of professional practice be "reasonable."

> "[T]he Defendant may not be convicted if he dispenses or causes to be dispensed controlled substances in good faith to patients in the usual course of professional medical practice. Only the lawful acts of a physician, however, are exempted from prosecution under the law. The Defendant may not be convicted if he merely made an honest effort to treat his patients in compliance with an accepted standard of medical practice.... Good faith in this context means good intentions and the honest exercise of good professional judgment as to the patient's medical needs."

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

> "[G]ood faith means an honest effort to prescribe for a patient's condition in accordance with the standard of medical practice generally recognized and accepted in the country. Mistakes, of course, are not a breach of good faith.... You need not agree with or believe in a standard practice of the profession, but must only be concerned with a good faith attempt to act according to them. Good faith is not merely a doctor's sincere intention towards the people who come to see him, but, rather, it involves his sincerity in attempting to conduct himself in accordance with a standard of medical practice generally recognized and accepted in the country."

Hayes, 794 F.2d at 1351 (9th). In both the Seventh and Ninth Circuits, what actually constitutes the usual course of professional practice is an objective question. The subjective aspect requires that the doctor know he is acting outside the scope of what is objectively accepted medical practice. Id.

On the other side of the spectrum, the Eleventh Circuit's good faith instruction is consistent with its view that a doctor is strictly liable and takes all consideration of a doctor's mental state out of consideration. The Eleventh Circuit instruction defines good faith as a doctor actually acting in accordance with a standard of medical practice generally recognized in the United States. Ruan, 966 F.3d at 1167 ("A controlled substance is prescribed by a physician in the usual course of professional practice and, therefore, lawfully if the substance is prescribed by him in good faith as part of his medical treatment of a patient in accordance with the standard of medical practice generally recognized and accepted in the United States.").

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

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

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

In *King*, 898 F.3d at 808, the Eighth Circuit upheld the district court's refusal to issue the defendant's proffered good faith instructions, finding (1) that the defendant's good faith instruction was erroneous because it was not "objective" and (2) that the district court properly required the jury to find knowledge. But see Smith, 573 F.3d at 649–50 (noting that instruction conflating civil standard of care with usual course of professional practice was cured, in part, by good faith instruction which noted that "unreasonable belief sincerely held is good faith."). A good faith instruction that is purely objective is inconsistent with a requirement that the jury find subjective knowledge or intent.

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

In each of these circuits, it is sufficient for the government to prove that the doctor acted unreasonably, even if honestly, and still obtain a conviction. As a practical effect, therefore, there are at least three different versions of the scienter requirements that the government must prove to convict a licensed practitioner under §841. Three circuits impose strict liability (Fifth, Eleventh, and Tenth), two require actual intent or knowledge (Seventh and Ninth), and the remainder of circuits require some degree of negligence." **20-1410**

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> "Clarification from this Court as to the elements the government must prove to secure the conviction of a medical practitioner under §841 would also provide much needed guidance on other inconsistencies among the circuits. For example, even in circuits where knowledge is not a requirement, the issuance of a willful blindness instruction is commonplace. See, e.g., United States v. Lee, 966 F.3d 310, 323 (5th Cir.) ("The instruction "should rarely be given," ... but what seems rare is a health care prosecution without the instruction."); Sabean, 885 F.3d at 45; United States v. Leonard, 738 F. App'x 7, 11 (2d Cir. 2018); Hurwitz, 459 F.3d at 481; United States v. Katz, 445 F.3d 1023, 1031 (8th Cir. 2006). The only logical reason to issue the willful blindness instruction is if knowledge is an element of the offense. If a defendant's knowledge of acting outside the scope of professional practice is not an element of the offense, it seems incongruous to issue a willful blindness instruction. Furthermore, even in those circuits where medical practitioners are subject to a negligence or strict liability standard, the conviction of other medical practitioners (such as nurses or technicians) for dispensing medication outside the scope of professional practice under the same statute requires proof of actual knowledge. See, e.g., United States v. Lovern, 590 F.3d 1095, 1105 (10th Cir. 2009) (finding insufficient evidence that technician knew prescriptions were outside the scope of professional practice); United States v. Lawson, 682 F.2d 480, 482 (4th Cir. 1982) ("[t]he question, then, in any case where a pharmacist is charged with illegal distribution of controlled substances, is whether he knew that the purported prescription was not issued for a legitimate medical purpose or in the usual course of medical practice.17

But see Sabean at 45 (allowing good faith instruction as to nurse practitioner that referenced the nurse's "reasonable belief")." **20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

The difference is not insignificant. What are very plausible and sometimes successful defenses in one circuit are admissions of guilt in others. Cf. Hurwitz, 459 F.3d at 480 (reversing despite counsel's admission that his client was acting outside the scope of professional practice because said admission did not necessarily concede that defendant knew he was acting outside the usual scope of professional practice) with Kahn, 989 F.3d at 825 ("We hold that §841(a)(1) and § 1306.04(a) require the government to prove that a practitioner-defendant ... issued a prescription that was objectively not in the usual course of professional practice.").

Section 841 is not a minor or technical criminal statute. It imposes significant penalties on those convicted. It is difficult to find a similar statute with such wide-ranging disagreement as to the basic mens rea elements of the offense." **20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

In the petitioner's case, mens rea requires the Petitioner to know that the licensed medical prescribers were acting outside the scope of professional practice. The Petitioner believes all the prescriptions she dispensed, written and signed by the licensed medical prescribers, were within the licensed medical prescribers' scope of professional practice in which the prescriptions were prescribed properly for the correct medical condition, and were with correct strength, dosage, and instruction as documented in, including but not limited to, the "Drug Facts and Comparisons", "Lexicomp", and "Physicians Desk Reference". The trial judge withheld evidence that further proved I was acting in good faith. In fact, the government is not citing a legal standard but is making up one in regard to misbranding as they did with the definition of "drug". Further, **the doctor's signature on the prescription is their own legal OATH that the prescription is legitimate.**

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

"As the Tenth Circuit recognized, the "objective" good faith instruction is not a "good faith" instruction as commonly understood. Generally, good faith is not a "defense" as such. Rather, it is an articulation of a defendant's theory of the case. Good faith is inconsistent with conviction precisely because a person acting in good faith does not have the required mens rea. Daniel S. Jonas, The Circuit Split Over Instructing The Jury

Specifically On The Good Faith Defense: A Consequence of Superlegislation By Courts Or The Standards Of Appellate Review, 46 S YRACUSE L. R EV . 61, (1995) (collecting appellate cases indicating that a good faith instruction need not be issued if the jury is adequately instructed on the intent element of the offense); Adam H. Kurland, Prosecuting Ol' Man River: The Fifth Amendment, the Good Faith Defense, and the Non-Testifying Defendant, 51 U. Pitt L. Rev. 841, 856 (1990). Therefore, good faith instructions are tailored to the mens rea of the offense. The understanding that good faith is a negation of a knowing or intentional mens rea is so ingrained that a plurality of appellate courts will not reverse a conviction for failure to give a good faith instruction if the jury instructions otherwise properly defined the knowledge and intent elements of the offense. United States v. Nivica, 887 F.2d 1110, 1125 (1st Cir. 1989); United States v. McElroy, 910 F.2d 1016, 1026 (2d Cir. 1990); United States v. Gross, 961 F.2d 1097, 1103 (3rd Cir. 1992), United States v. Dorotich, 900 F.2d 192, 193-94 (9th Cir. 1990); United States v. Gambler, 662 F.2d 834, 837 (D.C. Cir. 1981).

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

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

An objective "Good Faith" instruction is inconsistent with this Court's decision in Moore and this court's pre-CSA case law. Prior to the enactment of the CSA, the distribution of narcotics was governed by the Harrison Act, 38 Stat. 785. Under the Harrison Act, distribution of controlled substances by registered medical professionals was permitted "in the course of his professional practice only." Linder v. United States, 268 U.S. 5, 13 (1925). In Moore, this Court considered the question of whether a registered medical practitioner was "exempted from prosecution under s 841 by virtue of his status as a registrant" under the CSA. 423 U.S. at 124. 27The Court found that, were the CSA construed to authorize all prescriptions "thereby exempting them from other constraints, it would constitute a sharp departure from other laws." Id. 132-33 ("It is unlikely that Congress would seek, in this oblique way, to carve out a major new exemption, not found in the Harrison Act..."). However, the standard as articulated in Moore did not allow for a conviction simply because the doctor happened to step outside of the usual course of professional practice. The jury in Moore was instructed that the defendant "could not be convicted if he merely made 'an honest effort' to prescribe for detoxification in compliance with an accepted standard of medical practice." Id. at 143 n. 20. The defendant testified that he knew he was acting outside the scope of accepted medical standards. Id. at 144. Nothing in Moore suggested that a medical professional could be convicted as a drug dealer if he held mistaken beliefs about the practices that most medical professionals employ.

The fact that doctors charged under the Harrison Act were entitled to a good faith defense was well established in the Court's Harrison Act Cases. In Linder, the Court reversed because the indictment failed to articulate facts that the defendant doctor had any "conscious design to violate the law." 268 U.S at 17. In Boyd the "disputed question was whether the defendant issued the prescriptions in good faith." Boyd v. United States, 271 U.S. 104, 105 (1926). The instruction in Boyd read in part: "whether or not the defendant in prescribing morphine to his patients was honestly seeking to cure them of the morphine habit, while applying his curative remedies, it is not necessary for the jury to believe that defendant's treatment would cure the morphine habit, but it is sufficient if defendant honestly believed his remedy was a cure for this disease." Id. At 107– 08. Hence, the need to prove more than a practitioner's failure to comply with objective standards in the medical field finds its origin in this Court's pre-CSA case law and in Moore. Moore, Linder, and Boyd all required knowledge and provided subjective standards for judging good faith. The Tenth Circuit's opinion in Kahn is, consequently, 20

inconsistent with this Court's precedent." **20-1410 RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

In the Petitioner's case, the government did not prove that the Petitioner knew the prescriptions written by licensed medical practitioners were outside the scope of the licensed medical providers' professional practice and there's still no reason to believe these prescriptions were not valid. Therefore, Mens Rea of knowledge was not proven in the Petitioner's case because it does not exist.

III. REQUIRING THAT THE GOVERNMENT PROVE THAT A PHARMACIST *KNOW* A GIVEN PRESCRIPTION IS OUTSIDE THE SCOPE OF PROFESSIONAL PRACTICE IS NECESSARY TO SAVE MISBRANDING FROM BEING VOID FOR VAGUENESS AS APPLIED TO PHARMACISTS.

""[T]he Government violates [the due process] guarantee by taking away someone's life, liberty, or property under a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes, or so standardless that it invites arbitrary enforcement." Johnson v. United States, 135 S.Ct. 2551, 2556 (2015). "As generally stated, the void-for-vagueness doctrine requires that a penal statute define the criminal offense with sufficient definiteness that ordinary people can understand what conduct is prohibited, and in a manner that does not encourage arbitrary and discriminatory enforcement." Kolender v. Lawson, 461 U.S. 352, 357(1983). The "doctrine guards against arbitrary or discriminatory law enforcement by insisting that a statute provide standards to govern the actions of police officers, prosecutors, juries, and judges." Sessions v. Dimaya, 138 S. Ct. 1204, 1212 (2018); United States v. U.S. Gypsum Co., 438 U.S. 422, 442 (1978) ("criminal sanctions would be used, not to punish conscious and calculated wrongdoing at odds with statutory proscriptions, but instead simply to regulate business practices regardless of the intent with which they were undertaken.").

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

Additionally, the Courts of Appeal appear to agree that acting outside the "usual course of professional practice" requires something more than failure to abide by the civil duty of care. Sabean, 885 F.3d 27 (1st);

Wexler, 522 F.3d at 206 (2nd); Feingold, 454 F.3d at 1007(9th); United States v. Tran Trong Cuong, 18 F.3d 1132, 1137 (4th Cir. 1994); United States v. Stump, 735 F.2d 273, 276 (7th Cir. 1984). On the other hand, whether a given prescription falls within the usual course of professional practice is dependent upon "whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States." United States v. Merrill, 513 F.3d 1293, 1306 (11th Cir. 2008). See also, Feingold, 454 F.3d at 1011 n. 3 ("The term 'professional practice' implies at least that there exists a reputable group of people in the medical profession who agree that a given approach to prescribing controlled substances is consistent with legitimate medical treatment."); Norris, 780 F.2d at 1209 (5th); Hurwitz, 459 F.3d at 480 (4th); Vamos, 797 F.2d at 1153 (2nd); Smith, 573 F.3d at 647–48 (8th). While the courts of appeal are emphatic that the "duty of care" and "practice generally recognized and accepted in the United States" are not the same thing, none provide a meaningful method of distinguishing between the two. There is general agreement that a "mistake however, gross" is not sufficient to constitute a breach of generally accepted medical practice. Wexler, 522 F.3d at 206. That statement is facially inconsistent with allowing the conviction of doctors who make unreasonable but honest mistakes.

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

The "usual course of professional practice" suffers from two different forms of indeterminacy. It is indeterminate as to how it should be measured because there is no clear way to determine the standard by

which "usual course of professional practice" is to be determined. It is also indeterminate as to degree, because it is not clear how "usual" or by what percentage of physicians a practice must be generally accepted before deviation becomes criminal. See Johnson, 135 S. Ct. at 2558 ("By combining indeterminacy about how to measure the risk posed by a crime with indeterminacy about how much risk it takes for the crime to qualify as a violent felony, the residual clause produces more unpredictability and arbitrariness than the Due Process Clause tolerates.").

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

This Court has "repeatedly held that 'mere omission from a criminal enactment of any mention of criminal intent should not be read as dispensing with it." Elonis v. United States, 135 S. Ct. 2001, 2008 (2015). Where an intent element is missing from some aspect of an offense, the Court will read the statute "to include broadly applicable scienter requirements." Id. "[W]rongdoing must be conscious to be criminal.' ... [T]his principle is 'as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.'" Id.

"[A] defendant generally must 'know the facts that make his conduct fit the definition of the offense,'" Id. at 2009. See Posters 'N' Things, Ltd. v. United States, 511 U.S. 513 (1994) (Finding the government must also prove that the defendant "knew that the items at issue [were] likely to be used with illegal drugs."); Rehaif v. United States, 139 S. Ct. 2191, 2197 (2019) ("Without knowledge of that status, the defendant may well lack the intent needed to make his behavior wrongful. His behavior may instead be an innocent mistake to which criminal sanctions normally do not attach.")

The fact that makes a medical practitioner's conduct unlawful is not simply distributing a controlled substance, but rather distributing a controlled substance outside the scope of professional practice. The Court includes a "broadly applicable scienter requirement[]" even where the fact that renders a defendant's conduct illegal is derived from a CFR. See Liparota v. United States, 471 U.S. 419, 425 (1985) (interpreting a statute criminalizing "knowingly possess" or "use" food stamps in an unauthorized manner as requiring knowledge that the use is unauthorized.). Issuing prescriptions outside the scope of professional practice "is the 'crucial

element' separating innocent from wrongful conduct." Rehaif, 139 S. Ct. at 2197." **RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

Requiring that the government prove a defendant pharmacist knew she was dispensing licensed medical providers' prescriptions "outside the scope of professional practice could save the statute from fatal vagueness problems and eliminate the circuit splits and uncertainties noted above. ""This Court has long recognized that the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of mens rea." Colautti v. Franklin, 439 U.S. 379, 395 (1979).

The CDC and FDA guidelines on treating chronic pain are explicitly not mandatory. Removing any requirement that the government prove that a medical professional is knowingly acting outside the scope of professional practice subjects a wide range of well-intentioned medical practitioners, who issue prescriptions that in fact serve a legitimate medical purpose, to the threat of incredible penalties. This Court does not "construe a criminal statute on the basis that the government will use it reasonably." McDonnell v. United States, 136 S. Ct. 2355, 2372-73 (2016). "[A]a statute ... that can linguistically be interpreted to be either a meat axe or a scalpel should reasonably be taken to be the latter." Id." **RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

In the Petitioner's case, the pharmacist uses her professional judgment each and every time she dispenses a prescription. Prior to the instant charges, which is during the time period covered in the indictment, the Pennsylvania Board of Pharmacy inspected the pharmacies where Lasher was employed at, they inspected the same prescriptions that the Government alleged as invalid (2012) **BUT** the Pennsylvania Board of Pharmacy found nothing wrong with these prescriptions because there was and remains nothing wrong with these prescriptions. Removing any requirement that the government prove that a medical professional is knowingly acting outside the scope of professional practice subjects those same medical professionals to unlawful and capricious prosecution.

IV. THE PRESENT ISSUE IS OF SIGNIFICANT NATIONAL IMPORTANCE .

The absence of any clear mechanism for determining whether a given prescription falls inside or outside of generally recognized medical practice has led to a fear of prosecution and an increasing number of doctors **AND PHARMACISTS** withholding medication from patients suffering from chronic pain or even acute

illness. Kelly K. Dineen, Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems, 40 Law & Psychol. Rev. 1, 51 33(2016); Amy J. Dilcher, Damned If They Do, Damned If They Don't: The Need for a Comprehensive Public Policy to Address the Inadequate Management of Pain, 13 ANNALSHEALTH L. 81, 85 (2004). MM. Reidenberg & O. Willis, Prosecution of Physicians for Prescribing Opioids to Patients, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 903 (2007) (fear of prosecution resulting in reduced opioid prescriptions).

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

Press reports in recent years document numerable instances, if anecdotal, of patients in desperate need of legitimate pain medication who are unable to find a doctor willing to prescribe to them or who are abruptly cut off from needed medication. McCoy & Mount, Unintended Consequences: Inside the fallout of America's crackdown on opioids, THE WASHINGTON POST (May 31, 2018), https://www.washingtonpost.com/graphics/2018/local/impact-of-americas-opioid-crackdown/; Rider, Travis, What Chronic-Pain Patients Are Deeply Afraid Of, THE N EW YORK TIMES (Oct. 31, 2019), https://www.nytimes.com/2019/10/31/opinion/opioid-crisis-addiction.html: Goodnough & Hoffman, Good

News: Opioid Prescribing Fell. The Bad? Pain Patients Suffer, Doctors Say, THE NEW YORK TIMES (March 6, 2019), https://www.nytimes.com/2019/03/06/health/opioids-pain-cdc-guidelines.html?smid=nytcore-ios-share; O'Donnell & Alltucker, Pain patients left in anguish by doctors 'terrified' of opioid addiction, despite CDC change, USA T ODAY (June 24, 2019), https://www.usatoday.com/story/news/health/2019/06/24/pain-patients-left-anguish-doctors-who-fear-opioid-addiction/1379636001/; Fuqua, Anne, The other opioid crisis: pain patients who can't access the medicine we need, T HE W ASHINGTON P OST (March 9, 2018), https://www.washingtonpost.com/outlook/the-other-opioid-crisis-pain-patients-who-cant-access-the-medicine-they-need/2018/03/09/5ad83b24-2301-11e8-badd-7c9f29a55815_story.html." **RUAN, XIULU V. UNITED STATES, CERTIORARI GRANTED**

In the Petitioner's case, the Second Circuit has effectively allowed pharmacists to be convicted of a criminal offense for dispensing prescriptions that (1) a pharmacist may honestly believe are helping a patient and (2) are actually helping the patient. Therefore, requiring the government to prove both that a practitioner intentionally issued a prescription not for a legitimate medical purpose and outside the usual course of medical practice would help to prevent that result.

V. Not only that the decision of the Appellate Court is erroneous, but the national importance of having the Supreme Court decide the issue to resolve the existence of multiple conflicts between the decision of which review is sought and a decision of the second appellate court on the same issue.

In this case, the decision of the court that decided the Petitioner's case is in conflict with the decisions of the Supreme Court, Arsean Lamone HICKS v. Director, DEPARTMENT OF CORRECTIONS. Record No. 131945. Decided: February 26, 2015

The Appellate Court denied the Plaintiff's October 8, 2018 motion for a certificate of appealability based on newly-discovered-evidence motion for a new trial, challenging the denial of a newly-discovered-evidence motion for a new trial **after** the May 15, 2015 verdict. **However**, the suppressed exculpatory video recordings were **NOT turned over to the Plaintiff** until July 24, 2018, which was **more than 3 years after the Plaintiff's verdict**. Therefore, it is IMPOSSIBLE for "such motions be made within three years after verdict". 26

It must be stressed that the prosecutors referenced these video recordings as if they were in evidence at trial, while knowing the video evidence was exculpatory. Their suppression of it, and their tampering with the evidence, also show that they knowingly presented false evidence to the jury.

Judge Buchwald denied the Plaintiff's request for a new trial based on newly discovered evidence as "untimely". She chose to ignore the Supreme Court's recent ruling of Arsean Lamone HICKS v. Director, DEPARTMENT OF CORRECTIONS. Record No. 131945. Decided: February 26, 2015 in that **"the statute of limitations for habeas claims must be tolled while such evidence is suppressed." The Appellate Court should grant the Plaintiff a new trial based on** the Supreme Court's recent ruling of Arsean Lamone HICKS v. Director, DEPARTMENT OF CORRECTIONS. Record No. 131945. Decided: February 26, 2015, and based on the fact the newly discovered evidence were not turned over to the Plaintiff until July 24, 2018, **more than 3 years after the Plaintiff's verdict**; thus the Plaintiff is not capable nor able to file within the 3 years statute of limitation. Therefore, the **Plaintiff is seeking to toll the statute**.

The exculpatory video recordings are superior to testimony about the Plaintiff's actions and superior to the Prosecutions own references to these video recordings that they suppressed from evidence while simultaneously referred to them at trial. The matter at hand is the actions taken by the Plaintiff on all the dates the alleged crimes took place and on other dates the Plaintiff was working. The **video evidence is superior so thoroughly and completely that no jury could convict the Plaintiff** because it shows exactly what the Plaintiff was doing both on dates where she is accused of committing crimes and her conduct at work in general, whereas the testimony about her actions and how she conducted herself in her profession are subject to individual biases. In this case the video evidence shows none of what Prosecutors or its witnesses claim on the dates cited in the indictment. It directly refutes testimony and the prosecutors description of the video evidence spoken to, but not shown to, the jury. The **video recordings show she was not present on the alleged days of the criminal activity** (6/1/2012, 6/12/2012, 7/16/2012, 7/17/2012, 8/13/2012, 8/16/2012, 8/27/2012, and 10/2/2012 (See Exh O), and the lack of her presence on October 2, 2012 when opiods was dispensed to allegedly "unkempt" individuals. The factors present in Plaintiff's case requires the accused to be present at the pharmacy at the time the drug was shipped on the dates referenced. The Government has a copy of the work schedule from the Hellertown Pharmacy (HP) and Palmer Pharmacy & Much More (PP) showing the Plaintiff was not at work 27

during the dates and times of the shipments referenced. First, the governing law (PA 27.12(b)(2) and the criminal statute 21 U.S.C. Sec. 321 (g)(1), 352(a), 352(c), 353(b)(1), 353(b)(4)(A), 21 U.S.C. Sec. 331(a) and 333 (a)(2) REQUIRE the accused to be present at the pharmacy at the time the specific prescriptions in question were filled. Also, the governing pharmacy law protects a pharmacist from being held liable for another's actions. Numerous pharmaceutical law and protocol support the Plaintiff's testimony while impeaching the testimony of Prosecution witnesses and one of the main contentions of the prosecution's case. The lack of ability to present that critical video evidence, while the government asserted the knowledge of it's existence further undermined the truth and advanced the perjured testimony. See Demarco v United States 928 F.2d 1074 (11th cir. 1991). The failure for the prosecution to correct perjured testimony is ground for the reversal of conviction.

In its February 2015 opinion, the court held that inmates like Hicks must be able to raise their claims. Senior Supreme Court Justice Elizabeth B. Lacy, writing for the court, said that that the statute of limitations for habeas claims must be tolled while such evidence is suppressed. To "toll" suspends existing statutes of limitation. The court agreed with the clinic's argument that tolling is required by a Virginia law that creates a remedy against obstructions that prevent legal actions from being filed.

Therefore, the **Plaintiff is seeking to toll the statute**.

CONCLUSION

The Plaintiff, Lena Lasher, sincerely believes that she can justifiably rely on the US Supreme Court case Haines v. Kerner 404 U.S. 519 (1972), which clearly states that "all Pro-Se litigants must be afforded the opportunity to present their evidence and that the Court should look to the substance of the" appeal "rather than the form."

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

Respectfully Submitted, November 12, 2021

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