

No. _____

IN THE SUPREME COURT OF THE UNITED STATES

ETHEL OYEKUNLE-BUBU,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United
States Court of Appeals for the Tenth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

1. Whether Fifth Circuit’s gas failed to follow this Court’s decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022) by holding that a registered medical practitioner or pharmacist charged under 21 U.S.C. §841 “can be convicted either for knowing prescriptions were issued for an illegitimate purpose or knowing they were dispensed outside the usual course of professional practice” and created a Circuit Split in so interpreting *Ruan*.

LIST OF PARTIES TO THE PROCEEDINGS

Petitioner, defendant-appellant below, is Ethel Oyekunle-Bubu.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

Fifth Circuit Court of Appeals:

United States v. Capistrano, Case No. 20-10620, United States Court of Appeals for the Fifth Circuit. Judgment entered July 25, 2023. *United States v. Capistrano*, 74 F.4th 756, 765 (5th Cir.), *cert. denied*, 144 S. Ct. 516, 217 L. Ed. 2d 271 (2023), *reh'g denied*, No. 23-5975, 2024 WL 675329 (U.S. Feb. 20, 2024), *and cert. denied sub nom. Thomas v. United States*, 144 S. Ct. 517, 217 L. Ed. 2d 271 (2023).

United States District Court for the District of Kansas:

United States v. Oyekunle-Bubu, No. 4:20-CR-290-4. Judgement and conviction entered June 18, 2021.

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United States v. Capistrano, 74 F.4th 756, 765 (5th Cir.)

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2023. Petitioner's petition for rehearing *en banc* was denied on November 27, 2023. On January 31, 2024 this Court granted petitioner's motion for an extension of time to file the instant petition for writ of certiorari to March 26, 2024. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

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 C.F.R § 1306.04(a) provides the requirements for prescriptions by a physician to be “effective”:

“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

The panel’s decision conflicts with *Ruan v. United States*, 142 S. Ct. 2370 (2022) by holding that a registered medical practitioner or pharmacist charged under 21 U.S.C. §841 “can be convicted either for knowing prescriptions were issued for an illegitimate purpose or knowing they were dispensed outside the usual course of professional practice.” *Ruan* directly held that these were not sufficient bases for conviction, which “requires proving that a defendant knew or intended that his or her conduct was unauthorized.” By affirming Petitioner’s conviction, the Fifth Circuit’s interpretation of this Court’s holding in *Ruan* creates a circuit split with at least the Tenth Circuit, which has properly interpreted *Ruan* as requiring that, in order to convict a registered practitioner under §841, the government must prove that the defendant not only issued (or filled) an unauthorized prescription, but that the “defendant knew or intended that his or her conduct was unauthorized.” *United States v. Kahn*, 58 F.4th 1308, 1314 (10th Cir.2023).

Historically, the usual course of professional practice was dependent upon a medical practitioner’s subjective purpose in issuing a prescription. When unmoored from any question of “medical purpose,” the phrase, “usual course of professional practice” becomes unconstitutionally vague. The issue is one of significant national importance to both medical practitioners and patients. Threatening physicians with the potential of decades long incarceration for violations of medical norms stifles the development of medicine. The indeterminacy of the standard has led to a chilling effect on the practice of medicine because

practitioners are unable to predict what procedures or policies a prosecutor will deem to be outside the usual course of professional practice.

This case provides the Court with an opportunity to resolve a significant circuit split that continues to develop and deepen following *Ruan*. Courts continue to struggle with how to apply the rules announced in *Ruan*, and district courts in different parts of the country are now being provided different interpretations by different Circuit Courts of Appeal. Guidance from this Court is thus necessary to resolve this issue and provide definitive guidance on how to apply *Ruan* to ensure uniformity and equal justice.

FACTUAL BACKGROUND

Ethel Oyekunle-Bubu was indicted for three counts of conspiracy to dispense and distribute prescription narcotics under 21 U.S.C. §§841 and 846. (ROA.131-33), and two counts of possession with intent to distribute and dispense hydrocodone and carisoprodol, respectively. (ROA.134-35) Oyekunle-Bubu was convicted following a jury trial and sentenced to 240 months' incarceration. (ROA.4622)

Oyekunle-Bubu appealed her sentence and her conviction, including among other grounds her objection to the district court's elements instructions. The Fifth Circuit panel Affirmed, and was unanimous with respect to the jury instructions issue.

As recited in the Fifth Circuit opinion, Dr. Caesar Capistrano and two pharmacists, Wilkinson Thomas and Ethel Oyekunle-Bubu were charged for roles in a "pill-mill" operation. The Government's theory was that Capistrano prescribed controlled substances and Bubu and Thomas filled those prescriptions and others, for which there was no legitimate medical purpose. The conspiracy involved recruiters coordinating with pill mills and complicit pharmacies to fill unlawful prescriptions for street-level distribution. Defendants invoked § 841(a) of the

Controlled Substances Act, which exempts doctors and pharmacists from criminal liability for distributing “authorized” controlled substances. By regulation, prescriptions are “authorized” if they are (1) “issued for a legitimate medical purpose” and (2) “by an individual practitioner acting in the usual course of his professional practice.”

The trial court charged the jury that it was a crime “to knowingly or intentionally distribute or possess with intent to distribute a controlled substance outside the scope of professional practice or not for a legitimate medical purpose.” (Cert.Appx. A55). The law, it said, exempts medical professionals from this prohibition “but only to the extent that they distribute or dispense a controlled substance pursuant to a valid prescription, for a legitimate medical purpose and within the usual course of professional practice.” (Cert.Appx. A62). The “usual course of professional practice,” it said, is measured by an objective rather than a subjective standard. (Cert.Appx. A63). And speaking specifically of the exemption for pharmacists, the charge said:

Licensed pharmacists can fill prescriptions subject to the same duty that the practitioner or doctor has when he or she issues the controlled substances prescription. The prescription must be issued **by a registered doctor** for a legitimate medical purpose in the usual course of **his or her** professional practice.

(Cert.Appx. A62-63) (emphasis added). The charge thus effectively told the jury that it should convict upon proof of either an illegitimate purpose or conduct falling below an objective standard of professional care. (Cert.Appx. A63). Further, it effectively told the jury that a pharmacist could be criminally liable for unwittingly filling a prescription that a doctor issued for illegitimate purposes, or outside their standards of practice. (Cert.Appx. A32-63)

While Oyekunle-Bubu’s appeal was pending, this Court decided *Ruan v. United States*, 142 S. Ct. 2370 (2022), which held that, “for purposes of a criminal conviction under § 841,” the government’s burden is “proving that a defendant [medical practitioner] knew or intended that

his or her conduct *was unauthorized*.” 142 S. Ct. at 2382 (emphasis added). As have other Circuits to consider the issue, the Fifth Circuit has explicitly applied *Ruan* to pharmacist violations of § 841. *United States v. Ferris*, 52 F.4th 235, 242–43 (5th Cir. 2022).

However, the Fifth Circuit construed *Ruan* differently from the plain meaning of the words of the opinion. According to the opinion:

Ruan held that “§ 841’s ‘knowingly or intentionally’ *mens rea* applies to the ‘except as authorized’ clause.” 142 S. Ct. at 2376. The decision does not require that both prongs of authorization be lacking, which Bubu appears to recognize in her reply. Accordingly, a defendant can be convicted either for knowing prescriptions were issued for an illegitimate purpose or knowing they were dispensed outside the usual course of professional practice. We view *Ruan* as ridding the Government of the option—previously accepted under *Armstrong*—that a defendant can be convicted without knowledge for distributing prescriptions outside the objectively usual course of professional practice. 550 F.3d at 397.

(Cert.Appx. A12-13 n.51). (emphasis added).

The Fifth Circuit ultimately found that the district court’s jury instruction violated *Ruan* by omitting the required *mens rea element*, which it viewed as knowingly filling prescriptions without a legitimate medical purpose or outside the usual course of professional practice. However, the Court found that the error did not merit reversal under plain error review because the error did not affect Oyekunle-Bubu’s substantial rights as the trial evidence was sufficient to establish the *mens rea* element the Fifth Circuit (erroneously) believed to apply.

REASONS FOR GRANTING REVIEW

A. The Fifth Circuit is on the wrong side of a post-*Ruan* circuit split

The Fifth Circuit’s denial of Oyekunle-Bubu’s appeal was in error because it rested on a facially incorrect interpretation of *Ruan* and the *mens rea* standard it requires in §841 prosecutions against registered medical practitioners, including pharmacists. The Fifth Circuit

specifically stated that *Ruan* permitted conviction of a defendant “*either* for knowing prescriptions were issued for an illegitimate purpose *or* knowing they were dispensed outside the usual course of professional practice.” (Cert.Appx. A13 n.51) (emphasis in original).

This is precisely what *Ruan* found to be insufficient to establish guilt. Under *Ruan*, the government must prove both that (1) the charged prescriptions were in fact “unauthorized” as that term is used in §841 and (2) the defendant knew the charged prescriptions were unauthorized. *Ruan*, 142 S. Ct. at 2382 (“[F]or purposes of a criminal conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.”); *id.* at 2375 (“We hold that the statute’s ‘knowingly or intentionally’ *mens rea* applies to authorization.”). As noted by the Fifth Circuit Opinion, “By regulation, prescriptions are “authorized” if they are (1) “issued for a legitimate medical purpose” and (2) “by an individual practitioner acting in the usual course of his professional practice.” (Cert.Appx. A3) (quoting 21 C.F.R. §1306.04(a)).¹ Even if this is the proper standard for defining what is or is not authorized, it does not follow that knowingly failing to meet that standard is sufficient to establish guilt under *Ruan*.

¹ 21 U.S.C. § 841(a) criminalizes distribution of controlled substances “[e]xcept as authorized *by this subchapter*,” and does not reference or incorporate any federal regulations. C.F.R. §1306.04(a) defines what makes a prescription “effective,” and does not purport to determine or define “authorization.” The Fifth Circuit permitting a federal agency regulation to define what qualifies as an “authorized” prescription under §841 without any indication that Congress intended the regulation to be controlling when enacting the Controlled Substances Act is inconsistent with its rulings in other analogous contexts. See *Cargill v. Garland*, 57 F.4th 447, 467 (5th Cir.2023)(Agency interpretations of criminal statutes warrant no deference “where, as here, the Government seeks to define the scope of activities that subject the public to criminal penalties.”); *United States v. Garcia*, 707 F. App’x 231, 234 (5th Cir. 2017) (unpublished).

The government must prove that the defendant filled prescriptions that were in fact unauthorized, which is an objective standard. That is the *actus reus* in this case and it may be proved with reference to objective standards and norms in the medical community under *Ruan*. However, that is not the end of the inquiry. The government must then prove that the defendant subjectively believed that her conduct was unauthorized. *Ruan*, 142 S. Ct. at 2382 (“But the Government must still carry this burden. And for purposes of a criminal conviction under § 841, this requires proving that a defendant knew or intended that his or her conduct was unauthorized.”). *Ruan* applied §84’s *mens rea* to the “statutory requirement” of authorization, citing “the vague, highly general language of the regulation” as a reason for “applying normal scienter principles to the ‘except as authorized’ clause.” *Ruan*, 142 S. Ct. at 2380; *Kahn II*, 58 F.4th at 1316. This makes sense, given “that a fair warning should be given to the world in language that the common world will understand of what the law intends to do if a certain line is passed.” *Dubin v. United States*, 143 S. Ct. 1557, 1572 (2023) (quotation marks and brackets omitted). “After all, crimes are supposed to be defined by the legislature, not by clever prosecutors riffing on equivocal language.” *Id.* (quotation marks and brackets omitted).

The Fifth Circuit’s opinion commits a fundamental error of parsing basic logical arguments. Under *Ruan*, the government must prove knowledge of [lack of authorization], not knowledge of [the things that would make the prescription unauthorized under the Regulation]. As it applies to registered prescribers, § 841 is now in substance a specific intent or willfulness crime that requires actual knowledge of lack of authorization, as the Tenth Circuit has clearly and unequivocally indicated in *United States v. Kahn*, 58 F.4th 1308, 1314 (10th Cir.2023) (“*Kahn IP*”), which was the companion case to *Ruan* before this Court and was on direct remand

to the Tenth Circuit following the Court’s issuance of the *Ruan* opinion. Under *Ruan*, the government must prove that the defendant not only issued an unauthorized prescription, but that the “defendant knew or intended that his or her conduct was unauthorized.” *Id.* (quoting *Ruan*, 142 S. Ct. at 2381–82).

Following *Ruan*, it is not enough for the government to prove that the defendant knowingly acted outside the usual course of professional practice or even that he knowingly acted without a legitimate medical purpose. That language comes from CFR §1306.04(a), not the CSA. This “regulatory language” is “ambiguous, written in generalit[ies]” and “susceptible to more precise definition and open to varying constructions” and does not serve “as distinct bases to support a conviction, but as ‘reference to objective criteria’ that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner.” *Kahn*, 58 F.4th at 1316; *Ruan*, 142 S. Ct. at 2377.

Ruan resolved the *mens rea* issue, not with reference to the language of the CFR, but in reference to the language of the statute itself. *Ruan*, 142 S. Ct. at 2375. Under *Ruan*, “authorization” is the element that separates innocent from guilty conduct. Therefore, it is to the statutory term, “authorization,” that the *mens rea* must attach. *Id.* at 2377.

In reaching this result, the Court explicitly drew a parallel between the *mens rea* standard applicable in *Liparota v. United States*, 471 U.S. 419 (1985). and the *mens rea* standard applicable to medical practitioners charged under §841:

“In *Liparota*, we interpreted a statute penalizing anyone who ‘knowingly uses [food stamps] in any manner not authorized by’ statute.... We held that ‘knowingly’ modified both the ‘use’ of food stamps element and the element that the use be ‘not authorized.’ ... We applied ‘knowingly’ to the authorization language even though Congress had not ‘explicitly and unambiguously’ indicated that it should so apply.”

Ruan, 142 S. Ct. at 2378. *Liparota* involved the standard necessary to convict a defendant under 7 USC §2024(b)(1) for “unauthorized” use of food stamps. 471 U.S. at 430. The Supreme Court held that to obtain a conviction under §2024(b)(1) the government must prove “that petitioner knew that his conduct was unauthorized or illegal.” *Id.* at 434. The defendant in *Liparota* did purchase food stamps at below the market rate from an undercover government agent. *Id.* at 421–22. Furthermore, the defendant *knew* he was purchasing food stamps below the market rate. *Id.* The Court found that this was not enough to establish guilt. “The Supreme Court held that knowingly engaging in conduct that is, in fact, unauthorized is not sufficient, even if one is aware of all the factors that render it unauthorized.” *Kahn II*, 58 F.4th at 1315 n.3. Instead, the government must also prove that the defendant actually knew his conduct to be legally unauthorized. *Id.* *Ruan* applied the same standard articulated in *Liparota* to medical practitioners charged under §841. *Kahn II*, 58 F.4th at 1315.

In *Kahn II*, the Tenth Circuit found that the instructions given in that case were erroneous because they systematically articulated the incorrect standard:

Ruan treats the two criteria in § 1306.04(a) not as distinct bases to support a conviction, but as ‘reference to objective criteria’ that may serve as circumstantial evidence of a defendant's subjective intent to act in an unauthorized manner.

Id. The Tenth Circuit found that every instruction which referenced the language from CFR §1306.04(a) was erroneous. *Kahn II*, 58 F.4th at 1315-16.

The Tenth Circuit was clear that instructions attaching subjective scienter only to the language of CFR §1306.04(a) are insufficient under *Ruan*:

[T]he jury instructions were erroneous because they allowed the jury to convict Dr. Kahn after concluding either that Dr. Kahn subjectively knew a prescription was issued not for a legitimate medical purpose, or that he knowingly issued a prescription that was objectively not in the usual course of professional practice. *Both approaches run counter to Ruan.*

Id. at 1316 (emphasis added). According to *Kahn II*, even issuing or filling a prescription that one *knows* does not serve a legitimate medical purpose, or, in other words, a purpose that most doctors would deem legitimate, is not sufficient. Similarly, filling a prescription that a pharmacist *knows* is outside the usual course of practice is not sufficient to support a conviction. *Ruan* requires proof of actual knowledge that the prescription *is unauthorized*.

Knowingly acting in a manner that happens to be unauthorized is different from knowing that a prescription *is* unauthorized. The former imposes a standard that allows for conviction when a defendant is aware of all the factors that render a prescription unauthorized, even if he is not actually aware that he is legally unauthorized to write it, but the latter is plainly what was intended by this Court in *Ruan*. *Kahn II*, 58 F.4th at 1315 n.3. The Fifth Circuit has expressed the belief that this Court meant only the former, directly contradicting the Tenth Circuit’s interpretation of *Ruan* (and the plain meaning of the text of that opinion).

More fundamentally, even where an instruction articulates the correct elements, it is error for the trial court to define those elements in such a way as to reduce the government’s burden of proof or allow for conviction based on innocent conduct. *Cheek v. United States*, 498 U.S. 192, 197 (1991); *McDonnell v. United States*, 579 U.S. 550, 579 (2016). Nowhere did the instructions in this case require the government to prove anything remotely resembling that Oyekunle-Bubu knew the charged prescriptions were not authorized. The Fifth Circuit failed to recognize that this is an actual requirement under the current state of the law. Instead, the Fifth Circuit endorsed the view that, contrary to the plain text of *Ruan*, a “defendant can be convicted either for knowing prescriptions were issued for an illegitimate purpose or knowing they were dispensed outside the usual course of professional practice.” This Court expressly disavowed this position. “But the Government must still carry this burden. And for purposes of a criminal conviction

under § 841, this requires proving that a defendant knew or intended that his or her conduct *was unauthorized*.” *Ruan*, 142 S. Ct. at 2382 (emphasis added). Knowledge of lack of authorization is unnecessary under the Fifth Circuit’s view that a defendant is guilty if she knowingly filled a prescription that is merely outside of professional norms. Norms are not criminal statutes, and even if they were, knowingly violating those norms would not be a sufficient basis to convict under *Ruan* unless the government proves beyond a reasonable doubt that the defendant subjectively believed that violating the norms made the prescriptions unauthorized. Under *Ruan*, the defendant’s subjective beliefs about authorization are absolutely decisive. The panel’s finding is inconsistent with this reality.

The Fifth Circuit’s view of the scienter requirement for these offenses is no different from the elements instructions that were actually given in *Kahn*, which were ultimately found in error by both this Court and the Tenth Circuit. There, the jury was instructed that the government must prove:

Defendant Shakeel Kahn knowingly or intentionally distributed or dispensed the controlled substance outside the usual course of professional practice or without a legitimate medical purpose.

United States v. Kahn, 2:17 CR 29, (D. Ct. WY), Dkt.741.

The *Kahn* instructions defined medical purpose as subjective. *Kahn II*, 58 F.4th at 1316. In addition, the *Kahn* jury was instructed that under the “usual course” prong, “it could only convict Kahn if it found beyond a reasonable doubt that [he] failed to even attempt or make some honest effort to apply the appropriate standard of care.” *United States v. Khan*, 989 F.3d 806, 826 (10th Cir.2021) (“Kahn I”). The Tenth Circuit concluded that “[b]oth approaches run counter to *Ruan*.” *Kahn II*, 58 F.4th at 1316 (emphasis added); *id.* at 1320 (“It is not enough that the jury found that Dr. Kahn failed to attempt or make some honest effort to apply the appropriate

standard of care, nor is it enough that the jury accepted that Dr. Kahn subjectively knew a prescription was issued not for a legitimate medical purpose, and/or issued a prescription that was objectively not in the usual course of professional practice.”). Under *Ruan*, even proof that a doctor subjectively knew that a prescription was not issued for a legitimate medical purpose (which was not required here) is not sufficient to establish guilt. *Id.* The Fifth Circuit’s construction of the *Ruan* standard would render it a nullity. It also conflicts directly with the Tenth Circuit’s analysis and creates an untenable circuit split.

The results of the circuit split are already apparent. The Wyoming District Court’s jury instructions at retrial in *United States v. Kahn*, 17-CR-0029, evidence the same interpretation of *Kahn II* and *Ruan* that Petitioner has proposed: The government is required to prove knowledge or intent as it pertains to legal authorization, not merely the facts or circumstances rendering a prescription unauthorized. *See* 17-CR-0029 Dkt. 1310 at 43 (“A registered practitioner only violates 21 U.S.C. § 841(a)(1) if he or she knowingly or intentionally issues an unauthorized prescription (that is, a prescription not issued for a medical purpose in the course of professional practice) **and**, at the time, knew the prescription was unauthorized or intended it to be unauthorized.”) (emphasis in original).

The district court in that case not only addressed the *mens rea* required after *Ruan* and *Kahn II*, but also declined to define authorization in terms of the regulation. Taking note of the criticism of the regulatory language from both the Supreme Court and the Tenth Circuit as vague, highly general, and giving little or no instructions on major questions, Judge Johnson defined authorization using the statutory language as informed by the original understanding thereof. This definition closely aligned with Justice Alito’s concurrence in *Ruan*, instructing the jury that a registered practitioner is authorized to issue prescriptions for controlled substances in the course

of professional practice, i.e. the practice of medicine, which requires that the practitioner act for a medical purpose. 17-CR-0029 Dkt. 1310 at 25.

The Kansas District Court in *United States v. Henson*, 16-CR-10018, which was also on remand for retrial following a conviction vacated by the Tenth Circuit after a grant of *cert* by this Court post-*Ruan*, indicated its intention to follow the Wyoming District Court's *Kahn* instructions regarding authorization before the case was resolved. The transcript of the pretrial conference in *Henson* shows that Judge Broomes's interpretation of the CSA, *Ruan*, and *Kahn II* aligns with that of Petitioner. (KSD 6:16-cr-10018 Dkt. 680).

Judge Broomes indicated that he intended to closely adhere to Judge Johnson's *Kahn* retrial instructions, "not using the regulatory definition" of authorization. (*Id.* at 36). Acknowledging the merit of the defendant's challenge to the Attorney General's authority to define authorization, Judge Broomes noted that cases assuming the propriety of 21 C.F.R. § 1306.04 were predicated on the observation that the regulatory definition was not challenged, but alluded to statutory definitions of authorization. (*Id.* at 36-38). Moreover, he found that harsh criticism of the regulatory language from both the Supreme Court and Tenth Circuit counseled in favor of adherence to the statutory language in defining authorization. (*Id.* at 37).

Discussing *Moore*, *Ruan*, and *Kahn II*, Judge Broomes noted that the government is required to prove both that a prescription was objectively authorized, and that the defendant subjectively knew that a description was unauthorized, as set forth in Judge Johnson's instructions. (*Id.* at 42-44). After describing the circumstantial evidence that may serve as indicia of knowledge under *Ruan*, Judge Broomes explained that defining authorization with the qualifiers "legitimate" medical purpose and "usual" course of professional practice would be inconsistent with the latitude necessary in the practice of medicine. (*Id.* at 43-50). Discussing

preliminary instructions, Judge Broomes again rejected the government’s argument for defining authorization using the regulatory language, explaining that requiring that the defendant believe in the medical legitimacy of a prescription allows for the circumstantial proof contemplated by *Ruan*. (*Id.* at 79-80).

Judge Broomes’s discussion of the anticipated instructions in *Henson* further exemplifies acceptance in the Tenth Circuit of the interpretation of the CSA under *Ruan* and *Kahn II* proposed by Petitioner. The Fifth Circuit’s interpretation remains in stark contrast.

For example, in *United States v. Lamartiniere*, (LAMD 3:18-cr-00087), the district court instructed the jury that “In other words, knowingly issuing a prescription outside the course of professional practice is a sufficient condition to convict a medical practitioner of unlawful dispensation of a controlled substance. Likewise, knowingly issuing a prescription without a legitimate medical purpose is a sufficient condition to convict a medical practitioner of unlawful dispensation of a controlled substance.” (LAMD 3:18-cr-00087 Dkt. 240 at 3). The *Lamartiniere* conviction is presently on appeal before the Fifth Circuit (23-30191) and scheduled for oral argument on April 5, 2024.

Conversely, the Fourth Circuit recently reversed the conviction of a medical doctor under § 841 after agreeing that the pre-*Ruan* jury instructions in his case “(1) failed to state that [the defendant] could only be convicted if he knew that his conduct was unauthorized and (2) created a strict liability offense by phrasing the mens rea requirements in the disjunctive.” *United States v. Smithers*, 92 F.4th 237, 248 (4th Cir. 2024). The Fourth Circuit, at least, appears to agree with the Tenth Circuit’s interpretation of *Ruan* and reject the Fifth’s.

Meanwhile, Appellants in *United States v. Hofschulz* (Seventh Circuit 21-3403 and 21-3404) raised identical arguments about the pre-*Ruan* jury instructions. The Seventh Circuit heard oral

argument on September 8, 2023, and has yet to issue an opinion. This lengthy deliberation evinces that at least one Circuit is unsure how to rule against the backdrop of a lack of uniformity in Circuit court opinions following *Ruan*. Additional guidance is evidently required. *Certiorari* is necessary to both resolve this split and ensure that the Fifth Circuit’s decisions actually comply with controlling Supreme Court law.

B. The error here cannot be harmless

The Fifth Circuit’s ultimate conclusion that the jury instructions actually given in the trial were error but did not impact Oyekunle-Bubu’s substantial rights under plain error review is untenable because the Opinion failed to recognize the magnitude of the error that actually transpired.

The jury instructions did not require the government to prove that the defendant knew that the charged prescriptions were outside the scope of her authorization under the CSA. That is the *mens rea* that is required by *Ruan*. The original *Kahn* instructions, substantially identical to the formulation endorsed by the Fifth Circuit here, “effectively lowered the government’s burden to showing only that Dr. Kahn’s behavior was objectively unauthorized—not that Dr. Kahn *intended to act without authorization.*” *Kahn II*, 58 F.4th at 1317 (emphasis added). “The question to be posed to a jury is whether a physician was subjectively intending to act in a way that he believed was unauthorized—not whether he was attempting to act in a way that a ‘reasonable physician should believe’ was authorized or unauthorized.” *Id.* at 1318 (emphasis added).

Even under a plain error standard, the erroneous instruction require reversal. “To establish eligibility for plain-error relief, a defendant must show (i) that there was an error, (ii) that the error was plain, and (iii) that the error affects ‘substantial rights.’” *Greer v. United*

States, 141 S. Ct. 2090, 2095 (2021). The third category is established where a defendant “show[s] a reasonable probability that, but for the error, the outcome of the proceeding would have been different.” *Molina-Martinez v. United States*, 578 U.S. 189, 194 (2016).

The Fifth Circuit found that the erroneous instructions were in error and that the error was plain, but found that it did not affect Oyekunkle-Bubu’s substantial rights because there was no prejudice where the trial evidence was sufficient to establish that she filled the prescriptions knowingly without a legitimate medical purpose or knowingly outside the usual course of professional practice. But this analysis was premised on an incorrect standard. The erroneous instruction affected Oyekunkle-Bubu’s substantial rights because it permitted the jury to convict without ever finding—or even being aware that it was required to find—that Oyekunkle-Bubu believed she was legally unauthorized to fill the charged prescriptions under §841. “[A] defendant is ‘indisputably entitled’ to ‘a jury determination that he is guilty of every element of the crime with which he is charged, beyond a reasonable doubt.’” *United States v. Stanford*, 823 F.3d 814, 834 (5th Cir. 2016) (quoting *Apprendi v. New Jersey*, 530 U.S. 466, 477 (2000)) (brackets omitted); cf. *In re Winship*, 397 U.S. 358, 364 (1970) (“[T]he Due Process Clause protects the accused against conviction except upon proof beyond a reasonable doubt of every fact necessary to constitute the crime with which he is charged.”). The jury in this case was not required to make any finding regarding whether Oyekunkle-Bubu subjectively understood that her conduct was unauthorized.

The erroneous jury instructions seriously affected the fairness, integrity, and public reputation of judicial proceedings. As the Court emphasized in *Ruan*, “consciousness of wrongdoing is a principle as universal and persistent in mature systems of criminal 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.” *Ruan*, 142 S. Ct. at 2376-77. In prosecutions of medical professionals under § 841, “authorization plays a crucial role in separating innocent conduct—and, in the case of doctors, socially beneficial conduct—from wrongful conduct.” *Id.* at 2377. Indeed, the very reason that the Court applied § 841’s mens rea to authorization is that such a reading of the statute was necessary to separate wrongful conduct from otherwise innocent conduct. *Id.* Relieving the government of its burden to prove this critical and necessary element contravenes these fundamental principles of criminal law and thus casts serious doubt on the fairness, integrity, and public reputation of Oyekunle-Bubu’s trial.

In finding a lack of prejudice effecting Oyekunle-Bubu’s substantial rights, the Fifth Circuit cited *Neder v. United States*, 527 U.S. 1, 12 (1999) for the proposition that “an instruction that omits an element of the offense does not necessarily render a criminal trial fundamentally unfair or an unreliable vehicle for determining guilt or innocence.” However, the fact that the omitted element was uncontested was foundational to the *Neder* decision:

In this situation, where a reviewing court concludes beyond a reasonable doubt that the omitted element was uncontested and supported by overwhelming evidence, such that the jury verdict would have been the same absent the error, the erroneous instruction is properly found to be harmless.

Id. at 17. But *Neder* explicitly states that a reviewing court “should not find the error harmless,” “where the defendant contested the omitted element and raised evidence sufficient to support a contrary finding.” *Id.* at 19.

Here, as noted by the Fifth Circuit’s decision, “the record shows that Bubu’s counsel spent substantial time arguing that Bubu did not knowingly commit a crime.” (Cert.Appx. A14). Hence, the element was contested at trial. Unfortunately, under the erroneous jury instructions, the jury was told that Oyekunle-Bubu’s subjective beliefs about whether her conduct was legally authorized did not matter. Under *Ruan*, those beliefs not only matter, they are completely

dispositive. The erroneous jury instructions deprived Oyekunle-Bubu of a fair trial and allowed her to be convicted without the jury ever making a finding that she had the requisite *mens rea*, even while she argued that she did not possess the *mens rea* that the Court has now recognized is needed for conviction. Hence, the erroneous jury instructions warrant reversal even under a plain-error analysis, and the Fifth Circuit's decision must be revisited and corrected by the Court to ensure that fundamental rights are uniformly protected nationwide in accordance with its binding precedent.

Conclusion

Because the panel's decision conflicts with controlling Supreme Court law and creates a circuit split, Petitioner respectfully prays that the Court will grant her Petition for Certiorari.

Respectfully Submitted,

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