No. _____

IN THE SUPREME COURT OF THE UNITED STATES

CHYKEETRA MALTBIA,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

Beau B. Brindley
COUNSEL OF RECORD
And Blair T. Westover
For Petitioner Chykeetra Maltbia

Law Offices of Beau B. Brindley
53 W Jackson Blvd. Ste 1410
Chicago IL 60604
(312)765-8878
bbbrindley@gmail.com

QUESTIONS PRESENTED

1. Whether the Circuit Court erred in finding that the defendant had not established prejudice due to an omitted *mens rea* element based on what it believed to be insufficient briefing where prejudice was apparent on the face of the record.

LIST OF PARTIES TO THE PROCEEDINGS

Petitioner, defendant-appellant below, is Chykeetra Maltbia, M.D.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

Eleventh Circuit Court of Appeals:

United States of America v. Chykeetra Maltbia, M.D., No. 21-14446, United States Court of Appeals for the Eleventh Circuit. Judgment entered Feb. 9, 2023. *United States v. Maltbia*, No. 21-14446, 2023 WL 1838783 (11th Cir. Feb. 9, 2023).

United States District Court for the Southern District of Alabama:

United States of America v. Chykeetra Maltbia, M.D., No. 1:19-cr-00209-JB-MU-1. Judgement and conviction entered December 13, 2021.

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OPINIONS AND RULINGS BELOW

United States v. Maltbia, No. 21-14446, 2023 WL 1838783 (11th Cir. Feb. 9, 2023)

JURISDICTION

The court of appeals' judgment was entered on February 9, 2023. Pursuant to Supreme Court Rule 13, a petition for a writ of certiorari is timely if filed within 90 days after entry of the judgment. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

RELEVANT PROVISIONS OF LAW

Federal Rule of Criminal Procedure 52

> "(a) Harmless Error. Any error, defect, irregularity, or variance that does not affect substantial rights must be disregarded.
>
> (b) Plain Error. A plain error that affects substantial rights may be considered even though it was not brought to the court's attention."

21 U.S. Code § 841

> "(a)Unlawful acts: Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—
>
> (1) to manufacture, distribute, or dispense, or possess with the intent to manufacture, distribute, or dispense, a controlled substance."

21 C.F.R. § 1306.05 Manner of issuance of prescriptions.

> "(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.
> . . .

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations."

21 C.F.R. § 1306.04 Purpose of issue of prescription.

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

21 C.F.R. § 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

"(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)

(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

> (iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
> (v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.
> (2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so."

STATEMENT OF THE CASE

Petitioner asks this Court to grant her petition in order to correct a manifest injustice and prevent case law from developing, which will compel a significant increase in the burdening of judicial resources. Petitioner was tried and convicted prior to this Court's decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022). The instructions issued in this case imposed strict liability on the defendant if the charged prescriptions happened to be outside the "usual course of professional practice." The government conceded that they presented no evidence that Petitioner knew the charged prescriptions were issued without a legitimate medical purpose. *Ruan* requires the government to prove intent. *Ruan*, 142 S. Ct. at 2382 ("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.").

The government conceded that it did not do so. On the facts of this case, that concession conclusively establishes prejudice. The omitted *mens rea* element in this

case is different than that at issue in *Greer v. United States*, 141 S. Ct. 2090 (2021). In that case, the fact that the defendant took the acts in question was sufficient to give rise to a reasonable inference that the defendant had the requisite *mens rea*. *Greer*, 141 S. Ct. at 2097 ("In a felon-in-possession case where the defendant was in fact a felon when he possessed firearms, the defendant faces an uphill climb in trying to satisfy the substantial-rights prong of the plain-error test based on an argument that he did not know he was a felon. The reason is simple: If a person is a felon, he ordinarily knows he is a felon.").

One generally knows they are a felon, and the Court emphasized that where the question is up for debate, plain error may be easier for the defendant to establish. *Id.* In contrast, the "regulatory language defining the scope of prescribing authority" is "highly general" and "vague." *Ruan v. United States*, 142 S. Ct. 2370, 2371 (2022); *Gonzales v. Oregon*, 546 U.S. 243, 258, (2006) (describing the relevant administrative guidelines as "ambiguous," written in "generalit[ies], susceptible to more precise definition and open to varying constructions," and "giv[ing] little or no instruction on" major questions).

Here the allegedly criminal "act" Petitioner took was writing prescriptions to patients and dating them on the day that they would be delivered to the patient rather than the date they were signed, in violation of 21 C.F.R. § 1306.05 and local Alabama medical guidelines. The government's expert testified that violating medical guidelines to any degree is outside the usual course of professional practice. The district court found that theory to be the only theory of guilt upon which the

government presented sufficient evidence, and it dismissed charges where the government failed to present facts establishing that theory. Petitioner argued that violating a medical guideline without any evidence of intent, was not sufficient to render a prescription outside the usual course of professional practice. At least according to a plurality of the *Ruan* Court, Petitioner is correct. *Ruan*, 142 S. Ct. at 2389 (J. Alito, concurring) ("Under the correct understanding of that defense, a doctor acts 'in the course of professional practice' in issuing a prescription under the CSA if—but only if—he or she believes in good faith that the prescription is a valid means of pursuing a medical purpose.").

Admittedly, Petitioner's briefing before the circuit court could have done more to articulate an argument for prejudice. However, in this case the government all but conceded that it did not present sufficient evidence to establish the omitted element. An attorney's failure to articulate an argument more precisely or to cite the governing standard does not justify a circuit blinding itself to an obvious miscarriage of justice.

STATEMENT OF FACTS

The charges in this case stem from the prosecution of medical practitioner for issuing prescriptions outside the usual course of professional practice and without a legitimate medical purpose. R. 49. At all times relevant to the indictment, Petitioner was registered with the DEA and licensed to issue prescriptions for schedule II-V controlled substances. Petitioner and her husband, Leroy Dotson, owned and operated, a pain management clinic in Mobile, Alabama. Mr. Dotson had no medical training. Ms. Maltbia was charged with conspiracy as well as sixteen substantive

counts of distribution in violation of 18 U.S.C. § 846 and § 841. R. 49. Mr. Dotson was charged in the conspiracy count and was alleged to have aided and abetted on ten of the substantive counts.

The government's argument in this case was more limited than what one generally sees in a typical pill mill case. The government did not present any evidence that Petitioner knew or believed that the charged prescriptions were being abused or diverted onto the streets. In fact, the government did not even argue that the prescriptions were issued without a legitimate medical purpose.

The district court found, and the government agreed, that the evidence did not establish that Petitioner lacked a legitimate medical purpose for the prescriptions issued. 8/27/2021 Tr. 899 ("And the United States doesn't have a problem with it just going outside the usual course. That was the plan through the bill of particulars. That's how our evidence is shown at trial."); *id.* at 901 ("So his -- the evidence put on by your expert would tend to support the fact that there is not evidence in the case indicating that the prescriptions were not medically necessary."); *id.* ("But there hasn't been testimony about medical necessity in this case . . . It's -- the question is whether it's outside the usual scope of the medical practice."). The government proceeded only on the theory that the prescriptions were issued "outside the usual course" of professional practice. *Id.* at 899.

The government's entire case boiled down to the fact that the charged prescriptions were written by Dr. Maltbia ahead of time and delivered to patients while she was traveling. 8/26/2021 Tr. 800 ("MR. BODNAR: It's that she was -- even

though she was changing the date, she was postdating the prescriptions, as they all saw -- they were printed within minutes on October 11th or June 15th -- sorry. June 12th. They were signed at some point before she left for her trips to Georgia or the Caribbean cruise or I think it was to Jamaica for the Crystal Meyer count. All of those were done before she went on her trip.").

As the governments expert testified, 21 C.F.R. § 1306.12 and parallel state medical guidelines allow licensed practitioners to issue prescriptions for schedule II controlled substances to existing patients without an appointment for up to 90 days. 21 C.F.R. § 1306.12 ("An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met . . . ."); 8/23/2021 Tr. 91-92. However, under DEA and state medical regulations, such prescription must be dated for the day they were issued and include a "do not fill before" note, indicating the date upon which the prescription can be filed by the patient. 21 C.F.R. § 1306.05 ("All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued"); 21 C.F.R. § 1306.12 (requiring the "The individual practitioner [is to] provide[] written instructions on each prescription . . . indicating the earliest date on which a pharmacy may fill each prescription"); 8/23/2021 Tr. 70-71.

That is not what Dr. Maltbia did. Instead, Dr. Maltbia dated the prescription on the day that they were to be delivered to patients. The government's theory was that by violating 21 C.F.R. § 1306.05, Petitioner was definitionally acting outside the usual course of professional practice. 8/26/2021 Tr. 804 ("The appropriate focus is not

on the subjective intent of the doctor -- rests on whether the physician prescribes medicine in accordance with a standard of medical practice generally recognized and accepted in the United States. We think there is evidence that she has not done that by violating the regulations of how to prescribe controlled substances and, therefore, it's enough to go forward on Six through Seventeen.").

At the close of the government's case-in-chief, Petitioner argued that postdating a prescription in violation of § 1306.05 was not sufficient to establish that Petitioner was acting outside the usual course of professional practice. The district court disagreed. However, the district court did dismiss Count Three against both Dr. Maltbia and her codefendant. R. 160. While there was sufficient evidence to allow the jury to conclude that Dr. Maltbia did not see the patient during her appointment, Dr. Maltbia was in the office on the day that the prescription in Count Three was issued. The government did not present evidence that the prescription was written prior to that time. 8/26/2021 Tr. 814-819 ("But … my concern is … there's no evidence that that prescription was written before that date like the logs in the other situations, the other counts indicate."); *id.* at Tr. 815 ("I do recognize Dr. Maltbia was there that day. But I think, based on what has been defined as a usual course of medical practice, it would matter if it was written before that date . . . because of the date that's on that prescription."); *id.* at Tr. 817 ("Where is the evidence that it was signed on the 1st of November? MR. BODNAR: And that is something we cannot tell you, Your Honor. THE COURT: Well, then I think I have to grant the motion as to Count Three.").

The difference between Count Three and the remaining substantive charges was not that the prescription at issue in Count Three served a legitimate medical purpose while the other prescriptions did not. The difference was not that Dr. Maltbia was present for the patient appointment in Count Three but not in the remaining substantive counts. The only difference, and the critical one in the district court's mind, was that Petitioner incorrectly dated the prescription in one case but not the other. Had the prescription been dated correctly, it could have been filled in the exact same manner at the exact same time without running afoul of the law.

At the close of Petitioner's case-in-chief, the district court dismissed the charges against Mr. Dotson and the conspiracy count against Dr. Maltbia. R. 164; 8/26/2021 Tr. 870-878. The district court reasoned that, under an aiding and abetting theory, the government has to prove knowledge of wrongdoing. 8/26/2021 Tr. 872-3. The government did not present sufficient evidence for the jury to infer that Mr. Dotson was aware of the regulations specifically or the impropriety of the charged prescriptions more generally. 8/26/2021 Tr. 875-6. The district court also dismissed Count One against Dr. Maltbia. 8/26/2021 Tr. 878. There was no evidence of any intent to act in an unauthorized manner.

The jury instructions in this case were not consistent with this Court's decision in *Ruan*. Under 21 C.F.R. § 1306.04(a), "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. The Eleventh Circuit interprets this sentence as imposing two different

standards that allow the government to obtain a conviction where either (1) the charged prescriptions were not issued for a legitimate medical purpose, or (2) the manner or method by which the prescriptions were issued is outside the usual course of professional practice. *United States v. Abovyan*, 988 F.3d 1288, 1305 (11th Cir. 2021); *United States v. Joseph*, 709 F.3d 1082, 1094–96 (11th Cir. 2013); *United States v. Tobin*, 676 F.3d 1264, 1282–83 (11th Cir. 2012). Consistent with Eleventh Circuit case law, the jury was instructed that the defendant could be convicted for issuing a prescription outside the usual course of professional practice, even if the prescriptions were serving a legitimate medical purpose. 8/27/2021 Tr. 1012-1014.

At the time of Dr. Maltbia's trial, the Eleventh Circuit imposed strict liability where the government proceeds to trial on the theory that prescriptions were issued outside the usual course of professional practice. The jury was instructed:

> "Whether a prescription was issued in the usual course of professional practice must be evaluated based on an objective standard. Thus, you must not focus on the subjective intent of the prescriber. Rather, your focus must be on whether the controlled substance identified in each count was prescribed by Defendant Chykeetra Maltbia in accordance with an objective standard of medical practice."

8/27/2021 Tr. 1012-1014.

Petitioner's principal argument in closing was that a violation of 21 C.F.R. § 1306.05 was not so significant as to render a prescription outside the usual course of professional practice. 8/27/2021 Tr. at 953-55, 971, 979-81, 989. The jury convicted Petitioner on each of the 13 charges submitted to the jury. R. 169-1.

On appeal, Petitioner argued that the instructions in this case were inconsistent with this Court's holding in *Ruan* for two reasons. First, that the district

court committed plain error by instructing the jury that the defendant could be convicted of violating § 841 in the absence of any evidence that Dr. Maltbia issued the charged prescriptions without a legitimate medical purpose. App. Doc. 31 at 2. Second, that the district court erred in issuing an objective instruction rather than a subjective good faith instruction. App. Doc. 31 at 2.

The Eleventh Circuit found that neither argument was properly preserved at the district court below, and therefore applied a plain error standard of review applied. *United States v. Maltbia*, No. 21-14446, 2023 WL 1838783, at 4 (11th Cir. Feb. 9, 2023).

As the panel below pointed out, Eleventh Circuit case law has long held that proving a prescription lacked a legitimate medical purpose was not necessary for a conviction of a medical practitioner under § 841. Therefore, any error in the instructions is not sufficiently obvious to qualify as "plain" under *United States v. Olano*, 507 U.S. 725, 732 (1993). *Maltbia*, 2023 WL 1838783, at 6.

As to the objective jury instructions, the Eleventh Circuit found that Petitioner could not establish plain error in this case because "she cannot satisfy her burden to prove that there is a reasonable probability that she would have obtained a different result but for the error." *Maltbia*, 2023 WL 1838783, at 5. The Eleventh Circuit emphasized that "the 'burden of showing prejudice to meet the third-prong requirement is anything but easy.'" *Id.* at 6 (quoting *United States v. Rodriguez*, 398 F.3d 1291, 1299 (11th Cir. 2005)). In the absence of an explicit plain error argument,

the Eleventh Circuit declined "to construct a prejudice argument for Maltbia from a blank slate." *Maltbia*, 2023 WL 1838783, at 6.

REASONS FOR GRANTING REVIEW

I. The Eleventh Circuit's Application Of The Plain Error Standard To Foreclose Review In A Case Where The Mens Rea Element Was Omitted From The Instructions And The Defendant's Guilt Turned On The Technical Application Of Regulatory Provisions Resulted In A Miscarriage of Justice That Is Inconsistent With This Court's Plain Error Case Law.

Under Federal Rule of Criminal Procedure 52(b), "[a] plain error that affects substantial rights may be considered" on appeal "even though it was not brought to the court's attention." Fed. R. Crim. Proc. 52(b). An error that was not brought to the attention of the district court may only be corrected where the defendant is able to establish that (1) an error occurred (2) the error was plain and (3) that the error "affect[s] substantial rights." *Olano*, 507 U.S. at 732. In addition, under Rule 52(b), the circuit courts should not correct an error unless it "seriously affect[s] the fairness, integrity or public reputation of judicial proceedings." *United States v. Young*, 470 U.S. 1, 15 (1985) (quoting *United States v. Atkinson*, 297 U.S. 157, 160 (1936)).

The error here was plain. *Ruan* held that the standard for guilt under §841 is subjective, not objective. *Ruan v. United States*, 142 S. Ct. 2370, 2382 (2022). The government must prove that a registered medical practitioner "*knew or intended* that his or her conduct was unauthorized." *Id.* (emphasis added). The instructions in this case stated:

> "Whether a prescription was issued in the usual course of professional practice must be evaluated based on an objective standard. Thus, you must not focus on the subjective intent of the prescriber.

> Rather, your focus must be on whether the controlled substance identified in each count was prescribed by Defendant Chykeetra Maltbia in accordance with an objective standard of medical practice."

219, 8/27/2021 Tr. 1012-1014. Those two statements are diametrically opposed. Nor is this a case where the error could be dismissed as one not "seriously affect[ing] the fairness, integrity or public reputation of judicial proceedings." *Olano*, 507 U.S. at 732 (quoting *Young*, 470 U.S. at 15).

"The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion." *Morissette v. United States*, 342 U.S. 246, 250 (1952). "It 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.* Whether a prescription is authorized is the central question separating innocent, even laudable prescriptions from guilty conduct. *Ruan*, 142 S. Ct. at 2377. For that reason, the government must prove knowledge as to that element. *Id.*

Courts generally recognize that the prejudicial omission of an essential element for conviction requires reversal even under the plain error standard. It is a basic tenet of due process that a criminal defendant's conviction must rest upon a jury's finding beyond a reasonable doubt that he is guilty of each element of the crime charged. *United States v. Gaudin*, 515 U.S. 506, 511 (1995).

The only question in contention is whether Petitioner can establish prejudice. "To satisfy this third condition, the defendant ordinarily must 'show a reasonable probability that, but for the error, the outcome of the proceeding would have been

different.'" *Rosales-Mireles v. United States*, 138 S. Ct. 1897, 1904–05 (2018) (quoting *Molina-Martinez v. United States*, 578 U.S. 189, 194 (2016)) (internal quotation marks omitted). The proceeding at issue in this case is a jury trial. Therefore, the error is prejudicial if it had a "substantial and injurious effect or influence in determining the jury's verdict." *Kotteakos v. United States*, 328 U.S. 750, 776 (1946).

Petitioner concedes that even the omission of an element of the offense is not a structural error, *Neder v. United States*, 527 U.S. 1, 8 (1999), and Petitioner does not ask this Court to revisit that case law. A defendant challenging such an error must establish a reasonable probability that, but for the error, there would have been different outcome at trial. *See United States v. Dominguez Benitez*, 542 U.S. 74, 83 (2004). However, the "reasonable probability" standard does not require a defendant to prove that it is more likely than not that she would be successful at trial. *Id.* at 83 n.9 ("The reasonable-probability standard is not the same as, and should not be confused with, a requirement that a defendant prove by a preponderance of the evidence that but for error things would have been different."). In *Dominguez Benitez*, the Court indicated that the "reasonable probability" standard mirrored the materiality standard under *United States v. Bagley*, 473 U.S. 667, 678 (1985). *Dominguez Benitez*, 542 U.S. at 81-82. Under that standard:

> "The question is not whether the defendant would more likely than not have received a different verdict with the evidence, but whether in its absence he received a fair trial, understood as a trial resulting in a verdict worthy of confidence. A 'reasonable probability' of a different result is accordingly shown when the government's evidentiary suppression 'undermines confidence in the outcome of the trial.'"

Kyles v. Whitley, 514 U.S. 419, 434 (1995) (quoting *Bagley*, 473 U.S., at 678).

Admittedly, previous counsel did not do as much as they could have to highlight the obvious prejudice of the error. However, in this case, a reasonable probability is established on the face of the record and the statement of facts provided on appeal. First, the government conceded that it had no evidence that the defendant intended to act without a legitimate medical purpose. The government *conceded* that it did not prove the intent required by *Ruan*. The government filed a bill of particulars indicating that it did not intend to make that argument. R. 147 at 2 ("[T]he United States will forgo the route of proving lack of medical necessity and will just be presenting evidence and arguments that the prescriptions were illegal because they were issued outside the usual course of professional practice.").

Second, the omitted element in this case went to the heart of Petitioner's guilt or innocence. The allegation was based on a very technical violation of § 1306.05. There was no allegation of wanton misconduct such as issuing prescriptions to known addicts, or to those who did not have a legitimate medical need for the prescriptions. The district court dismissed the charges against Dr. Maltbia's codefendant because of the government's failure to establish knowledge of wrongdoing and dismissed the conspiracy charge against Dr. Maltbia for the same reason .

In *Greer v. United States*, this Court acknowledged that a defendant will face an uphill battle in establishing plain error where the jury instructions erroneously failed to require the government to prove that the defendant had knowledge of their standing as a felon. 141 S. Ct. 2090, 2097 (2021). The Court reasoned that, in most

cases, most people will know that they are a felon. *Id.* ("In a felon-in-possession case where the defendant was in fact a felon when he possessed firearms, the defendant faces an uphill climb in trying to satisfy the substantial-rights prong of the plain-error test based on an argument that he did not know he was a felon. The reason is simple: If a person is a felon, he ordinarily knows he is a felon.").

Whether a prescription is within the usual course of professional practice is not the same kind of element. The standard is highly vague and open to different interpretations both in the medical and legal community. It evolves over time.

The government did not present any evidence that Dr. Maltbia was aware of the rule requiring a prescription be dated on the day it was signed as opposed the day it was handed to a patient, let alone that doing the latter would render the prescription outside the usual course of professional practice or otherwise unauthorized under the CSA. As a point of fact, at least according to the concurrence in *Ruan*, that type of error does not render a prescription unauthorized under the CSA. *Ruan*, 142 S. Ct. at 2389 (Alito, J., concurring) ("Under the correct understanding of that defense, a doctor acts 'in the course of professional practice' in issuing a prescription under the CSA if—but only if—he or she believes in good faith that the prescription is a valid means of pursuing a medical purpose. A doctor who knows that he or she is acting for a purpose foreign to medicine—such as facilitating addiction or recreational drug abuse—is not protected by the CSA's authorization to distribute controlled substances by prescription. Such doctors may be convicted of unlawfully distributing or dispensing a controlled substance under § 841(a)(1).").

Furthermore, Petitioner's second argument, that her conduct was in fact permitted by the CSA, is at least implicitly an argument that the government will not be able to prove that Petitioner knew her conduct was unauthorized under the CSA. If it is even arguable that the prescriptions were authorized, that is reason to believe that the government will not be able to prove that Dr. Maltbia knew that the prescriptions were unauthorized.

The omission of the *mens rea* element in this case may not be structural, but on the facts of this case, the prejudice is self-evident. It is true that prior counsel did not do as much he should have to lead the Court through the prejudice analysis. But that does not change the fact that there was prejudice, and the prejudice was amply apparent on the face of the appeal.

II. The Eleventh Circuit Erred In Holding That Failure To Require The Government To Prove The Defendant Issued The Prescription Without A Legitimate Medical Purpose Was Forfeited.

The issue preservation requirements do "not demand the incantation of particular words; rather, it requires that the lower court be fairly put on notice as to the substance of the issue." *Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469–70 (2000).

In this case, Petitioner argued that the evidence presented by the government was insufficient to convict both after the presentation of the government's case in chief and at the close of the defense evidence. 8/27/2021 Tr. 953-54. The defense further submitted an instruction directing the jury that a violation of § 1306.05 was not sufficient by itself to justify conviction. Appx. F at A32-35. There was argument regarding (and the district court addressed) the question of whether a minor violation

of a DEA regulation was sufficient to establish Petitioner's guilt. To be sure, the appeal argued for a higher standard, more consistent with *Ruan*, than was advocated by the attorneys at the district court level. At the district court level, Petitioner argued that a minor or technical violation was not sufficient to establish Petitioner's guilt. At the appellate court level, Petitioner argued that the reason a minor or technical violation was not sufficient to establish Petitioner's guilt is because the absence of a legitimate medical purpose is a necessary condition for conviction. Though the arguments were not identical, each was sufficient to put the court at each level on notice as to the substance of the issue: Evidence of a technical violation of 21 C.F.R. § 1306.05, without more, is not sufficient to convict a registered prescriber under the CSA.

Furthermore, after *Ruan*, the error is obvious. *Ruan* requires the government to prove a knowing and intentional *mens rea* as to the authorization clause. The authorization clause indicates that a prescription is illegal only when it is not "authorized by this subchapter . . . ." 18 U.S.C. § 841. The language refers to the CSA itself, not any incidental regulation that the Attorney General might issue. Nothing in the CSA grants the attorney general the authority to regulate the manner of medical practice or define the conditions under which a prescription is authorized. *Gonzales v. Oregon*, 546 U.S. 243, 269–70 (2006) ("The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the

statute manifests no intent to regulate the practice of medicine generally."). The government did not identify any language from the *subchapter* that renders any of the charged prescriptions unauthorized.

III. The Correct Application Of Plain Error Doctrine Is An Issue Of Significant Legal Import.

The purpose of the plain error rule is to conserve judicial resources by encouraging objections at the time most likely to result the prompt resolution of error while still allowing corrections of a manifest injustice. *Puckett v. United States*, 556 U.S. 129, 134 (2009) ("This limitation on appellate-court authority serves to induce the timely raising of claims and objections, which gives the district court the opportunity to consider and resolve them. . . . In the case of an actual or invited procedural error, the district court can often correct or avoid the mistake so that it cannot possibly affect the ultimate outcome. And of course the contemporaneous-objection rule prevents a litigant from 'sandbagging' the court--remaining silent about his objection and belatedly raising the error only if the case does not conclude in his favor." (internal quotation marks omitted)). It seems antithetical to the purpose of that rule to sustain convictions based on imprecise appellate court briefing where prejudice and manifest injustice are obvious, and somewhat beyond debate. To do so only encourages habeas petitions based on ineffective assistance of counsel, which wastes judicial resources.

IV. Reversal Is Necessary In This Case To Correct A Significant And Manifest Injustice.

"A rigid and undeviating judicially declared practice under which courts of review would invariably and under all circumstances decline to consider all questions which had not previously been specifically urged would be out of harmony with . . . the rules of fundamental justice." *Hormel v. Helvering*, 312 U.S. 552, 557 (1941).

The reality of the situation is the Dr. Maltbia was convicted and bears the mark of a felony on her record without the jury having been asked to make any finding as to her mental state. Adding insult to injury is the fact that the jury was mis-instructed as to the basic elements the Act required to establish the defendant's guilt. In *Olano*, the Court rejected what it described as a more stringent standard which would have required the defendant to prove a "miscarriage of justice." *United States v. Olano*, 507 U.S. 725, 736 (1993). The Court took it as a given that "[t]he court of appeals should no doubt correct a plain forfeited error that causes the conviction or sentencing of an actually innocent defendant," *Olano*, 507 U.S. at 736.

It serves to reason that, if the defendant can establish that more stringent standard, then they necessarily have also established prejudice under the third prong of *Olano*. What we have here is a defendant who stands convicted of a crime for doing something that is not illegal without any finding that she even intended to do the thing in the first place. She was convicted on a strict liability standard under a law which this Court has since determined requires specific intent.

To be sure, appellate counsel could have and should have done more in its briefing before the circuit court. However, the Eleventh Circuit's overly formulaic application of the prejudice standard required it to ignore not only the nature of the

error, but the manifest inevitability of a substantially different presentation of evidence at retrial and a different result. Under the *Ruan* standard, the government's evidence, as presented, is insufficient as a matter of law because they presented no evidence regarding the defendant's intent and the Court told the jury they did not have to. In a situation like that, a finding of plain error is necessary.

CONCLUSION

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

Respectfully Submitted,

May 9, 2023
DATE

s/ _____

Beau B. Brindley
COUNSEL OF RECORD
For Petitioner Chykeetra Maltbia
Law Offices of Beau B. Brindley
53 W Jackson Blvd. Ste 1410
Chicago IL 60604
(312)765-8878
bbbrindley@gmail.com