

NO. \_\_\_\_\_

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IN THE  
SUPREME COURT OF THE UNITED STATES

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SYLVIA HOFSTETTER,  
Petitioner,

vs.

UNITED STATES OF AMERICA,  
Respondent.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

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6th Circuit Case No. 20-6245

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PETITION FOR WRIT OF CERTIORARI

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## QUESTION PRESENTED

The questions presented in this case are:

1. On October 17, 2022, this Court vacated the opinion of the Sixth Circuit affirming Petitioner Sylvia Hofstetters convictions and remanded for further proceedings in light of *Ruan v. United States*, 142 S. Ct. 2370, 213 L. Ed. 2d 706 (2022). On remand, the Sixth Circuit agreed with the parties that *Ruan* applies to 21 U.S.C. § 856(a)(1) prosecutions and also agreed that the jury instructions on the *mens rea* element required for a conviction under § 856 of a nurse practitioner authorized to prescribe controlled substances were error in light of *Ruan*. However, in conflict with other circuits' handling of this issue, the Sixth Circuit determined that Ms. Hofstetter could not meet the plain error standard. Is the Sixth Circuit's ruling on the plain error standard contrary to this Court's precedents, including *Ruan* and *Henderson v. United States*, 568 U.S. 266, 133 S. Ct. 1121, 185 L. Ed. 2d 85 (2013)?
2. After determining that the District Court did not “spell out the ‘knowingly’ standard required under *Ruan*, 142 S. Ct. at 2375, for the second element” of § 856, the Sixth Circuit reasoned that by the district court’s insertion of the generic term “illegally” in the instruction, the jury instruction “made clear that the jury had to find that Defendants knowingly opened the clinics for the purpose of illegally distributing Schedule II controlled substances.” Did the Sixth Circuit commit error by substituting the generic term “illegally” for the language mandated in *Ruan*?

## **LIST OF PARTIES**

The caption of this case contains the names of all parties.

## **RELATED CASES**

Pursuant to Supreme Court Rule 14.1(b)(iii), Petitioner submits the following cases which are directly related to this Petition:

*United States v. Cynthia Clemmons 20-6427*  
Sixth Circuit Case No. 20-6427 (decided August 29, 2023)

*United States v. Courtney Newman*  
Sixth Circuit Case No. 20-6428 (decided August 29, 2023)

*United States v. Holli Womack*  
Sixth Circuit Case No. 20-6426 (decided August 29, 2023)

## TABLE OF CONTENTS

QUESTION PRESENTED .....	ii
LIST OF PARTIES.....	iii
RELATED CASES .....	iii
TABLE OF CONTENTS. ....	iv
TABLE OF AUTHORITIES.....	v
OPINIONS BELOW .....	1
STATEMENT OF JURISDICTION.....	1
STATUTORY AND REGULATORY PROVISIONS INVOLVED.....	1
STATEMENT OF THE CASE .....	2
REASONS FOR GRANTING THE PETITION .....	4
1. The Sixth Circuit acknowledged that <i>Ruan</i> applies to 21 U.S.C. § 856 and it was obligated to follow binding Supreme Court precedent in how it applied the law announced in <i>Ruan</i> .....	4
2. A jury instruction which required the jury to use an objective standard to determine whether Ms. Hofstetter could be held responsible for the knowing and intentional distribution of controlled substances outside the usual course of professional practice and without a legitimate medical purpose constitutes plain error requiring reversal of the convictions .....	5
3. The Sixth Circuit's reading of <i>Ruan</i> is in conflict with other circuits.....	9
CONCLUSION .....	13

## INDEX TO APPENDICES

APPENDIX A– Opinion of the 6<sup>th</sup> Cir. 80 F.4th 725 (6<sup>th</sup> Cir. 2023)

APPENDIX B– U.S. Supreme Court Order of Remand 143 S.Ct. 350 (2023)

APPENDIX C– Opinion of the 6<sup>th</sup> Cir. 31 F.4th 396 (6<sup>th</sup> Cir. 2022)

APPENDIX D– Opinion of the District Court September 14, 2020

## TABLE OF AUTHORITIES

### CASES

<i>Francis v. Franklin</i> , 105 S. Ct. 1965, 85 L. Ed. 2d 344 (1985).....	7
<i>Greer v. United States</i> , 141 S. Ct. 2090, 210 L. Ed. 2d 121 (2021) .....	8
<i>Henderson v. United States</i> , 133 S. Ct. 1121, 185 L. Ed. 2d 85 (2013).....	5,7
<i>McDonnell v. United States</i> , 136 S.Ct. 2355, 195 L.Ed.2d 639 (2016).....	12
<i>Rosales-Mireles v. United States</i> , 138 S. Ct. 1897, 201 L. Ed. 2d 376 (2018).....	8,9
<i>Ruan v. United States</i> , 142 S. Ct. 2370, 213 L. Ed. 2d 706 (2022).....	<i>passim</i>
<i>United States v. Anderson</i> , 67 F.4th 755 (6th Cir. 2023).....	9,10
<i>United States v. Hofstetter</i> , 31 F.4th 396 (6th Cir. 2022) .....	3

<i>United States v. Hofstetter</i> , 80 F. 4 <sup>th</sup> 725 (6 <sup>th</sup> Cir. 2023) .....	4
--------------------------------------------------------------------------------------------------	---

<i>United States v. Kahn</i> , 58 F.4th 1308 (10th Cir. 2023) .....	11
---------------------------------------------------------------------	----

<i>United States v. Ruan</i> , 56 F.4th 1291 (11th Cir. 2023) .....	11
---------------------------------------------------------------------	----

<i>United States v. Sakkal</i> , 2023 U.S. App. LEXIS 13489; 2023 WL 3736778 (6th Cir., May 31, 2023) .....	10
-------------------------------------------------------------------------------------------------------------	----

## STATUTES

21 U.S.C. § 841.....	5
----------------------	---

21 U.S.C. § 856. . . . .	4
--------------------------	---

28 U.S.C. § 1254(1) .....	1
---------------------------	---

## RULES

Fed. R. Crim. Procedure Rule 52.....	2
--------------------------------------	---

## OPINIONS BELOW

The opinion of the Court of Appeals for the Sixth Circuit affirming Petitioner's convictions was entered on August 29, 2023, and is reported at *United States v. Hofstetter, et al.*, 80 F.4th 725 (6th Cir. 2023). A copy of the 6th Cir. opinion is attached to this petition as Appendix A. This Court's order remanding this case to the Sixth Circuit for further proceedings is published at 143 S.Ct. 350 and is attached as Appendix B. The Sixth Circuit's original opinion is published at 31 F.4th 396 and is attached as Appendix C. The district court's opinion is unpublished and attached as Appendix D.

## STATEMENT OF JURISDICTION

The opinion of the Court of Appeals for the Sixth Circuit affirming Petitioner's convictions was entered on August 29, 2023. *United States v. Hofstetter*, 80 F. 4th (6th Cir. 2023). Appendix A. This Petition for Writ of Certiorari is filed within ninety days of that date, pursuant to Supreme Court Rule 13.1. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

## STATUTORY AND REGULATORY PROVISIONS INVOLVED

21 U.S.C. § 856(a)(1) provides:

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful to-

(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purposes of manufacturing, distributing, or using any controlled substance

Fed. R. Crim. Procedure Rule 52 provides:

(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.

### **STATEMENT OF THE CASE**

Sylvia Hofstetter came to Tennessee as a business manager to oversee the opening of a pain management clinic “USCC/CHCS” or “Gallagher View” in Knoxville, Tennessee owned by Chris Tipton, Benjamin Rodriguez, Luca Sartini, and Jimmy Palma. Ms. Hofstetter remained in Knoxville, ultimately, opening another clinic “Comprehensive Health Care” or the “Lenoir City clinic”, owned by the same parties, and finally the “Lovell Road Clinic” which she owned with Christopher Tipton. These clinics employed medical directors to oversee nurse practitioners in the treatment of chronic pain including the prescription of opiates.

On March 10, 2015, the Government executed a search warrant at a pain clinic on Lovell Road in Knoxville, Tennessee (“EKHC” or “Lovell Road Clinic”) and an associated clinic located in Lenoir City, Tennessee, Comprehensive Healthcare Systems (“CHCS” or “Lenoir City”) and an indictment was issued for Ms. Hofstetter. On October 16, 2016 a First Superseding Indictment adding others as defendants. A Second Superseding Indictment was issued on July 17, 2017 adding additional defendants and additional counts. The Third Superseding Indictment issued on



January 4, 2018, also added additional defendants and counts. The Fourth Superseding Indictment on May 1, 2018 included additional allegations and is the Indictment upon which the Defendants proceeded to trial.

On October 21, 2019, jury selection began, and the jury was seated on October 22, 2019. The first witness was called on October 28, 2019. On February 13, 2020, after four months of trial, Ms. Hofstetter was convicted on Counts 1-7 and 11-14 and found not guilty on Counts 16 and 18 of the Fourth Superseding Indictment.

Following the verdict, Ms. Hofstetter moved the Court to renew her motion for judgement of acquittal and for a new trial. The district court denied this motion without a hearing on September 14, 2020. *See* Appendix D.

On October 21, 2020, the district court sentenced Ms. Hofstetter to a term a total term of 400 months imprisonment, consisting of 240 months as to Counts 1-5 and 11-13 concurrent, 160 months as to Court 14 to run consecutively, and 120 months on Counts 6 and 7 to be served concurrently to all other counts. Judgment was entered on October 23, 2020. *Id.* A Notice of Appeal was timely filed on October 30, 2020. On April 11, 2022, the Sixth Circuit affirmed Ms. Hofstetter's convictions. *United States v. Hofstetter, et al.*, 36 F.4th 396 (6th Cir. 2022) Appendix C. This Court ordered this case remanded to the 6<sup>th</sup> Circuit for further consideration given the Court's ruling in *Ruan v. United States*, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022). Appendix B. Following supplemental briefing and oral argument, although the Sixth Circuit agreed that *Ruan* applies and the jury was instructed inaccurately,

the jury instructions “taken as a whole” were proper and did not constitute plain error warranting reversal. *U.S. v. Hofstetter et al.* 80 F. 4<sup>th</sup> 725, 730; Appendix A at 6. The Sixth Circuit’s decision on remand was contrary to *Ruan* and this Court should grant Ms. Hofstetter’s petition for certiorari.

## REASONS FOR GRANTING THE PETITION

**The Sixth Circuit acknowledged that *Ruan* applies to 21 U.S.C. § 856 and was obligated to follow binding Supreme Court precedent in how it applied the law announced in *Ruan*.**

On remand from this Court, the Sixth Circuit acknowledged that *Ruan* applies to charges brought under 21 U.S.C. § 856(a)(1). *United States v. Hofstetter*, 80 F.4th 725, 729. (6th Cir. 2023) (“The parties agree that the holding in *Ruan* applies to convictions under §856(a)(1)” ) The Sixth Circuit reasoned that “under *Ruan*, the district court must have instructed the jury that knowledge of illegal distribution is an element of offenses under § 856(a).” However, the Sixth Circuit then conflated the generic term “illegal” with the standard that is required by *Ruan* and other prescribing cases, *i.e.*, the government must prove the defendant subjectively knew or intended that the prescription was unauthorized.

The term “illegal” is generic term and is subject to different interpretations by different people. Twelve jurors could hold twelve different interpretations of “illegal” subjecting a criminal defendant to twelve different interpretations of guilt and convict based on these individual interpretations rather than the standard required by *Ruan*.

Post-*Ruan*, the jury must be instructed that a provider subjectively believed they were prescribing medications in an unauthorized manner. No such instruction was given here and even, taken as a whole, as the Sixth Circuit elected to do, the instruction given did not comport with *Ruan* and thus the jury instruction was erroneous.

This Court should grant certiorari, vacate the decision of the Sixth Circuit, and remand with instruction to follow the decision in *Ruan*.

**A jury instruction which required the jury to use an objective standard to determine whether controlled substances were knowingly and intentionally distributed without authorization constitutes plain error requiring reversal of the convictions.**

The district court instructed the jury that whether prescriptions were intentionally or knowingly written at the clinics at issue were issued illegally was to be determined by an objective standard, not a subjective standard, in contravention of this Court's ruling in *Ruan*, requires vacating her convictions. The Sixth Circuit's determination that the erroneous instructions failed to meet the plain error standard is contrary to this Court's pronouncement in *Henderson v. United States*, 133 S. Ct. 1121, 185 L. Ed. 2d 85 (2013), and must be reversed.

In *Ruan v. United States*, 142 S. Ct. 2370, 213 L. Ed. 2d 706 (2022), this Court, interpreting 21 U.S.C. § 841, determined where illegal prescribing is the basis of criminal charges "the Government must prove beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to

do so." 142 S.Ct., at 2375. In doing so, this Court vitiated lower court rulings which had allowed the Government to prove that the health care professional did not act in "good faith" or in an "objectively reasonable" manner. This Court concluded that "for 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 2382. As discussed previously, the Government and the Sixth Circuit on remand agreed that § 856(a)(1) has the same *mens rea* requirements as § 841 and thus courts are required to follow *Ruan* when instructing a jury as to the elements necessary for an § 856 offense.

In this case, the district court instructed the jury that "[i]f a nurse practitioner prescribes a drug in good faith in the course of medically treating a patient, then the nurse practitioner has prescribed the drug for a legitimate medical purpose in the usual course of accepted medical practice, that is, she has prescribed the drug lawfully." However, the district court further instructed the jury that "whether a practitioner – finally, whether a prescription is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint." While the Sixth Circuit correctly found this instruction to be error under *Ruan*, the court ultimately determined that it was plainly erroneous. In doing so, the court misapplied the plain error standard.

"To establish eligibility for plain-error relief, a defendant must satisfy three threshold requirements. [Citation omitted]. *First*, there must be an error. *Second*, the error must be plain. *Third*, the error must affect 'substantial rights,' which generally means that there must be 'a reasonable probability that, but for the error, the outcome

of the proceeding would have been different." *Greer v. United States*, 141 S. Ct. 2090, 2096, 210 L. Ed. 2d 121 (2021).

*Henderson* made clear that the "time of error" rule does not apply to a plain error review – that the error is in fact an error at the time of appellate review satisfies the standard, even when the district court was not "in error" at the time of trial. *Henderson v. United States*, 568 U.S. 266, 275, 133 S. Ct. 1121, 1128, 185 L. Ed. 2d 85 (2013). "Plain error review is not a grading system for trial judges. It has broader purposes, including in part allowing courts of appeals better to identify those instances in which the application of a new rule of law to cases on appeal will meet the demands of fairness and judicial integrity." 568 U.S. at 277.

At issue is the Sixth Circuit's interpretation of the third requirement. The Sixth Circuit determined that the district court's "overview of the charges" at the beginning of the jury instructions, which allegedly gave a conflicting answer as to whether the jury should use an objective or subjective standard, was adequate to show that, absent the error, the jury would have come to the same conclusion. This reliance on the overview of the charges is erroneous for two reasons. First, the district court informed the jury, as to the overview, that the "brunt" of the instructions were the elements, and that, as to those instructions, they would be placed on the screens as the court read them. Further, the district court's summary was not a recitation of the elements of the offenses.

It was plain error for the district court not to give an instruction which did not meet the *Ruan* standard. The Sixth Circuit further compounded that error by finding

that the undefined term "illegally" was an adequate replacement for the *Ruan* language.

Likewise, the Sixth Circuit's admission that the instructions were contradictory in places makes clear that the error could not, in fact, be harmless. This Court has held that "[L]anguage that merely contradicts and does not explain a constitutionally infirm instruction will not suffice to absolve the infirmity. A reviewing court has no way of knowing which of the two irreconcilable instructions the jurors applied in reaching their verdict." *Francis v. Franklin*, 471 U.S. 307, 322, 105 S. Ct. 1965, 1975, 85 L. Ed. 2d 344 (1985). Thus, that the instructions contradicted each other as to this critical issue – the only real contested issue in the trial, establishes a finding of plain error.

The Sixth Circuit determined that reference to an "objective viewpoint" was not error because "[w]hether a prescription was unauthorized is an objective question because 'the regulation defining the scope of a doctor's prescribing authority does so by reference to objective criteria[.]' *Ruan*, 142 S. Ct. at 2382. In contrast, as *Ruan* makes clear, the subjective question is whether Defendants knowingly or with intent issued unauthorized prescriptions."

Although the regulation itself is an objective standard, the Government's burden is clear: "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* , at 2382. The Sixth Circuit's decision ultimately reflects a misunderstanding of the plain error standard. As this Court held in *Rosales-Mireles v. United States*, 138 S. Ct. 1897, 201 L. Ed. 2d 376 (2018), even unintended or inadvertent errors can rise to the level of

plain error. This Court, in rejecting the Fifth Circuit's "shock the conscience" standard of plain error review, found that "[b]y focusing instead on principles of fairness, integrity, and public reputation, the Court recognize[s] a broader category of errors that warrant correction on plain-error review." 138 S.Ct. at 1906. Moreover, "[t]he risk of unnecessary deprivation of liberty particularly undermines the fairness, integrity, or public reputation of judicial proceedings . . ." *Id.*, at 1908.

The Sixth Circuit's plain error analysis wholly ignores this plain error standard, and instead replaces it with a new one: if in the context of a jury instruction error, the jury was given both incorrect and partially correct instructions, it should be assumed that the jury followed the partially correct ones, and therefore, no plain error exists. This Court's precedents in *Rosales-Mireles* and elsewhere require otherwise.

Finally, the Sixth Circuit's analysis does not show what evidence would have supported a jury finding on subjective intent. The only evidence presented by the Government was expert opinion whether prescribing met an objective standard within the healthcare professional community. The Government provided no evidence as to Ms. Hofstetter's actual knowledge of prescribing practices or criminal intent as to the prescribing practices at these clinics and therefore failed to meet the standard required by *Ruan*.

**The Sixth Circuit's reading of *Ruan* is in conflict with other circuits.**

The Sixth Circuit has attempted to interpret *Ruan* too narrowly. In addition to the instant cases, in *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023) the Sixth Circuit held that the jury instructions in that case "substantially covered" the *mens rea*

requirement as set forth in *Ruan*, even though it used language that had been specifically rejected in *Ruan*.<sup>1</sup> In *United States v. Sakkal*, 2023 U.S. App. LEXIS 13489; 2023 Fed. App. 0242N; 2023 WL 3736778 (6th Cir., May 31, 2023), the Sixth Circuit again found that the inclusion of language that had been rejected in *Ruan* was sufficient because, although Dr. Sakkal had requested a subjective good faith instruction, he had failed to object to the language in the final instruction.

Ms. Hofstetter argued that the jury instructions related to distributing a controlled substance and conspiracy to distribute a controlled substance and specifically the deliberate indifference instruction did not comport with *Ruan*. The Sixth Circuit reasoned that the jury was sufficiently instructed as a whole and that the deliberate indifference instruction was sufficient because it was substantially similar to the jury instruction approved in the intervening decision in *Anderson*. Again, the Sixth Circuit too narrowly interpreted *Ruan*. Where all of Ms. Hofstetter's conviction hinge on proper instruction for illegally distributing a controlled substance erroneous instruction failing to meet the *Ruan* standard impacted each of her convictions.

The Sixth Circuit's narrow and erroneous interpretation of *Ruan* is contrary to other circuits that have decided this very issue, creating a conflict among the circuits

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<sup>1</sup> But cf. *United States v. Hofstetter*, 80 F.4th 725, 732 (6th Cir. 2023) Cole, CJ concurrence (“...I write separately to highlight how *Anderson* conflicts with *Ruan*... Judge White penned a forceful dissent explaining why the instruction does not meet the Court’s mens rea standard for unauthorized prescription distribution...I agree with her dissent...”)



which must be resolved by this Court.

The Tenth Circuit's decision in *United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023) is directly on point. There, the defendant received certiorari relief based upon *Ruan*. Upon remand to the Tenth Circuit, the Government argued that the error in the instructions was harmless. The Tenth Circuit disagreed. The court noted that the defendant did not contest he distributed the substances in his role as a physician, nor did he contest that some of his patients abused the drugs. The only issue at trial was his intent. The Government cited voluminous evidence in the record to support their argument that, under a subjective standard, there was "overwhelming" evidence to convict under the new *Ruan* standard. The Tenth Circuit disagreed with this analysis, finding "[w]here an element of an offense is contested at trial, as it was here, the Constitution requires that the issue be put before a jury— not an appellate court. . . . In this case, Dr. Kahn's intent was in dispute throughout his trial and was the centerpiece of his defense. A jury, properly instructed, must address whether the government carried its burden to establish Dr. Kahn's intent beyond a reasonable doubt." *Id.*, at 1319.

A similar result was reached in *Ruan*. *United States v. Ruan*, 56 F.4th 1291 (11th Cir. 2023). After remand from this Court, the Eleventh Circuit determined that, even though a "good faith" instruction was given to the jury, vacation of the 21 U.S.C. § 841 convictions was necessary. "[T]he district court did not adequately instruct the jury that the defendants must have 'knowingly or intentionally' prescribed outside the usual course of their professional practices. At a minimum, as discussed above, without

the limiting qualification that only subjective good faith was sufficient for conviction, the jury was authorized to convict under the sort of objective good faith or honest effort standard rejected by the Supreme Court." *Id.*, at 1298. As such, "a properly instructed jury may not have convicted the defendants had it known that Dr. Ruan's and Dr. Couch's subjective beliefs that they were acting properly was a defense to these charges. Similar to *McDonnell* [*v. United States*, 579 U.S. 550, 136 S.Ct. 2355, 195 L.Ed.2d 639 (2016)], under the erroneous instruction in this case the jury was authorized to convict the defendants for conduct that was lawful. Thus, we cannot conclude that these errors were harmless." *Id.*, at 1298.

The Sixth Circuit's treatment of *Ruan* is fundamentally different from that of the Tenth and Eleventh Circuits. This creates a conflict among the circuits which must be addressed by this Court. *Ruan* requires the jury to determine subjective intent – a finding the jury never made in this case. The Sixth Circuit's finding that this did not constitute plain error is a misinterpretation of not only *Ruan*, but this Court's plain errors precedents. This Court should grant certiorari review, and remand for a new trial.

The issues related to erroneous jury instruction pursuant to this Court's decision in *Ruan* are substantially the same for all four appellants in this case and the briefs thereof have been utilized in preparation of Ms. Hofstetter's Petition. Accordingly, to the extent not already included herein, Ms. Hofstetter specifically adopts and incorporates by reference the Petitions for Writ of Certiorari filed by Co-Defendants Cynthia Clemons, Courtney Newman, and Holli Womack.

## CONCLUSION

For the foregoing reasons, Sylvia Hofstetter requests this Court grant her Petition for a Writ of Certiorari, vacate the decision of the United States Court of Appeals for the Sixth Circuit, and remand for a new trial.

Respectfully submitted this the 26<sup>th</sup> day of November 2023.



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