

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

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IN THE  
SUPREME COURT OF THE UNITED STATES

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CYNTHIA CLEMONS,  
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. 20-6427

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PETITION FOR WRIT OF CERTIORARI

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## QUESTION PRESENTED

Petitioner Clemons, an advanced nurse practitioner authorized by the Drug Enforcement Administration to prescribe controlled substances under the supervision of a physician who was also authorized, was initially charged with two counts of conspiracy to distribute Schedule II controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, two substantive counts of distribution of controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. Mrs. Clemons was acquitted of all those charges.

Mrs. Clemons was also charged with two counts of violations of 21 U.S.C. § 856(a)(1), in that she did “knowingly and intentionally open, use, and maintain a business . . . for the purpose of illegally distributing and dispensing Schedule II controlled substances outside the scope of professional practice and not for a legitimate medical purpose.” Mrs. Clemons was convicted of both these counts.

The question presented in this case is whether this Court’s recent ruling in *Ruan v. United States*, \_\_ S.Ct. \_\_, 2022 WL 2295024, Case No. 20-1410 (2022), interpreting 21 U.S.C. § 841, also applies to prosecutions in which authorized healthcare providers are charged with maintaining a drug-involved premises under 21 U.S.C. § 856(a)(1) for, in the course of their employment at a licensed pain management clinic, prescribing controlled substances without a legitimate medical purpose and outside the scope of professional practice, and, under *Ruan*, once there is proof that a healthcare provider is authorized by the DEA to prescribe controlled

substances under the Controlled Substances Act, the government is required to prove “that a defendant knew or intended that his or her conduct was unauthorized”, *Id.*, at 15, and that proof is to be evaluated based on a subjective standard and not an objective one.

## **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. Sylvia Hofstetter*  
Sixth Circuit Case No. 20-6245 (decided April 11, 2022)

*United States v. Courtney Newman*  
Sixth Circuit Case No. 20-6428 (decided April 11, 2022)

*United States v. Holli Womack*  
Sixth Circuit Case No. 20-6426 (decided April 11, 2022)

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## **OPINIONS BELOW**

The opinion of the Court of Appeals for the Sixth Circuit affirming Petitioner's convictions was entered on April 11, 2022 and is reported at *United States v. Hofstetter, et al.*, 31 F.4th 396 (6<sup>th</sup> Cir. 2022). A copy of the 6<sup>th</sup> Cir. opinion is attached to this petition as Appendix A. The judgment of the district court is unpublished and attached as Appendix B. The order of the district court denying Cynthia Clemons' Motion for New Trial was filed on September 14, 2020, and is attached as Appendix C. An excerpt from the transcript of the district court's jury instructions is 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 April 11, 2022. This Petition for Writ of Certiorari is filed within ninety days of that date, pursuant to Supreme Court Rule 13.1. The jurisdiction of this Court is invoked 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

21 U.S.C. § 841(a)(1) provides:

(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 intent to manufacture, distribute, or dispense, a controlled substance; or
- (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.

21 CFR § 1306.04(a) provides:

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.

## **STATEMENT OF THE CASE**

Cynthia Clemons received her Associates of Science degree in Nursing from Lincoln Memorial University (LMU) in 1997, her Bachelor of Science degree in Nursing from Lincoln Memorial University (LMU) in 2010, and her Masters degree in Nursing/Family Practitioner from LMU in 2011.

Mrs. Clemons was licensed in Tennessee as a registered nurse and, in 2013, had over fourteen years of clinical experience as an R.N. She was licensed as an Advanced Practice Nurse in 2012 and received her certification as a Family Nurse Practitioner in 2012.

Beginning in April of 2012, Mrs. Clemons worked as a family nurse practitioner for Blount Hospitalists in Maryville, Tennessee. She was issued her DEA number at that time, authorizing her to prescribe controlled substances under the supervision of a licensed physician also authorized to prescribe controlled substances.

Mrs. Clemons began working at East Knoxville Healthcare Services (EKHS) on Lovell Road in Knoxville, Tennessee (the Lovell Road clinic) on November 4, 2013, as an independent contractor nurse practitioner for an hourly wage of \$65.00, roughly the same hourly wage she made when working for Blount Hospitalists. On occasion, she would be called upon to work at an associated clinic in Lenoir City, Tennessee (the Lenoir City clinic). While working at the Lovell Road and Lenoir City clinics, Mrs. Clemons was supervised by a physician authorized to distribute controlled substances.

On March 15, 2015, federal law enforcement agents executed search warrants at the Lovell Road and Lenoir City clinics. Mrs. Clemons was charged in the first superseding indictment in this cause on October 4, 2016. On May 1, 2018, a fourth superseding indictment was filed charging Mrs. Clemons in Counts Two and Four with conspiracy to distribute oxycodone, oxymorphone, and morphine, with enhanced penalty allegations for deaths resulting from the use of controlled substances distributed or dispensed by Mrs. Clemons; in Counts Eleven and Thirteen with opening, using, and maintaining a drug-involved premises in violation of 21 U.S.C. § 856(a)(1); and in Counts Sixteen and Eighteen of distributing a controlled substance outside the usual course of professional practice and not for a legitimate medical purpose in violation of 21 U.S.C. §§ 841(a)(1), 841(b)(l)(C) and 18 U.S.C. § 2.

The trial began on October 21, 2021. On February 13, 2020, the jury returned a verdict finding Mrs. Clemons not guilty of all counts except for Counts Eleven and Thirteen charging using or maintaining a drug-involved premises.

At trial, the government presented a number of former patients of the clinics, some of whom had been treated by Mrs. Clemons.

Each of the patients treated by Mrs. Clemons stated that they told her they had legitimate need for pain medication. Mrs. Clemons gave the patients she treated examinations to determine their range of motion. She examined patients regularly for track marks or other signs of drug abuse. She required patients to come in for pill counts to make sure they were taking the medications as prescribed.

Patients would be discharged by Mrs. Clemons for track marks and dirty drug screens. The monthly drug screens, mandated by Tennessee law, were administered to make sure the patients were not taking drugs they were not supposed to and were taking only the drugs they were prescribed.

The government presented two expert witnesses, one a nurse practitioner and one a medical doctor with no formal training or expertise in pain management. Each of these witnesses reviewed patient files selected by the government from the clinics. Each of these witnesses opined that none of the prescriptions they saw in these selected files were written for a legitimate medical purpose and not in the usual course of professional practice.

The defense presented two expert witnesses, one a nurse practitioner and a medical doctor, each of whom had extensive experience in pain management. Each of

these experts reviewed a random sampling of patient charts from the clinics and each opined that the prescriptions written by Mrs. Clemons and the other co-defendant providers were written for a legitimate medical purpose and in the usual course of professional practice.

At the conclusion of the government's proof, and at the conclusion of all the proof, Mrs. Clemons, along with the other co-defendants orally moved for an F.R.Cr.P 29 motion for judgment of acquittal, a ruling on which the district court reserved until a later date.

During closing argument, the government told the jury that a violation of 21 U.S.C. § 856(a)(1) only had two essential elements:

The good news is, with Counts 11, 12, and 13, it has two elements, those are maintaining a drug premises. First, the defendant knowingly opened or used or maintained a place, where permanently or temporarily. Second, the defendant did so for the purpose of distributing any controlled substance.

What this boils down to is, if you believe these places are pill mills and they're trafficking narcotics, then they are drug premises. And the defendants charged in each of those counts are guilty.

The district court judge, reinforcing the government's argument, instructed the jury that these were the only two essential elements of a violation of 21 U.S.C. 856(a)(1):

In order to prove a defendant guilty of opening, using, or maintaining a drug-involved premises, the government must prove each of the following elements beyond a reasonable doubt as to each of Counts 11, 12, and 13:

First, that the defendant knowingly opened, used, or maintained a place, whether permanently or temporarily;

And second, that the defendant did so for the purpose of distributing any controlled substance.

....

You are instructed that oxycodone, oxymorphone, and morphine are Schedule II controlled substances.

The district court did not instruct the jury in the specific instructions in regard to the § 856 offenses that the controlled substances prescribed by Mrs. Clemons had to have been prescribed without a legitimate medical purpose and outside the usual course of professional practice for Mrs. Clemons to be convicted on those counts.

The district court instructed the jury with regard to the conspiracy counts and the substantive counts related to prescribing controlled substances 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 jury was further instructed that “whether a prescription is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint.”

The district judge’s instructions were in direct contravention of this Court’s recent ruling in *Ruan, supra*.

Mrs. Clemons was acquitted of all counts involving illegal prescribing of controlled substances in which the judge instructed the jury that Mrs. Clemons, to be found guilty, must have prescribed the controlled substances without a legitimate medical purpose and not in the usual course of professional practice. She was convicted of the two counts in which the instructions did not contain that language.

After the jury returned its verdict, Mrs. Clemons renewed her motion for a judgment of acquittal based on errors in the jury instruction for the maintaining a drug related premises count; and also alleging an inconsistent jury verdict - acquitting Mrs. Clemons of conspiracy to distribute controlled substances and actual distribution of controlled substances, while convicting her of maintaining a premises to distribute those same controlled substances. The district court denied the motion. Following the district court's sentencing and final judgment, Mrs. Clemons timely filed an appeal to the United States Court of Appeals for the Sixth Circuit, which had appellate jurisdiction based on 28 U.S.C. § 1291 and Fed.R.App.P. Rules 3 and 4(b).

On April 11, 2022, the Sixth Circuit affirmed Mrs. Clemons' convictions. *United States v. Hofstetter, et al.*, 36 F.4th 396 (6th Cir. 2022) (App. A). As to Mrs. Clemons' challenge to the jury instruction, the Sixth Circuit held that the district court did not err in instructing the jury that they only needed to find that the defendants had 1) opened, used or maintained a place; and 2) that they did so for the purpose of distributing any controlled substance, without any explanation of the specific conduct that made their actions unlawful. *Id.* at 11, ruling that due to the "proximity of the illegality element" and the instructions taken as a whole, particularly relying on the instructions relating to the illegal distribution counts under 21 U.S.C. § 841, that the district court did not plainly err in giving the instruction. *Id.*

The Sixth Circuit's ruling is contrary to *Ruan, supra*, and Mrs. Clemons respectfully files this timely petition for a writ of certiorari.

## REASONS FOR GRANTING THE PETITION

### **A. The standard of proof required by *Ruan* for violations of 21 U.S.C. § 841 should be the same standard of proof required for authorized healthcare professionals charged with violations of 21 U.S.C. § 856(a)(1).**

Mrs. Clemons was convicted of two violations of maintaining a drug-involved premises in violation of 21 U.S.C. § 856(a)(1) based on her prescribing controlled substances while working at pain management clinics, despite the fact that proof was introduced at trial that she was a licensed advanced nurse practitioner authorized by the DEA to prescribe controlled substances under the supervision of a physician who was also authorized.

Both the district court and the 6<sup>th</sup> Circuit recognized that Mrs. Clemons' § 856 convictions rested solely on her writing prescriptions for controlled substances.

Furthermore, the indictment and the jury verdict form underscore the completeness of the jury instruction when taken as a whole because language in both also made clear that the defendants were being charged for and convicted of unlawful opioid distribution.

*Hofstetter, supra*, at 11.

The court's charge also included a "general statement of the law regarding distribution of a controlled substance," which included a section on the "manner and issuance of prescriptions" outlining "how controlled substances must be prescribed under federal law in order for such prescriptions to be legal" and how the jury must determine whether a defendant prescribed controlled substances illegally, that is "without a legitimate medical purpose, and outside the usual course of professional practice.

District Court Order Denying Motion for New Trial, Appendix C, pg. 22.

The district court further instructed the jurors, as part of the "general statement of law regarding the distribution of a controlled substance" that "whether prescription

is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint.” Jury charge, Trial Transcript Vol. XXXIX, pg. 207.

In *Ruan v. United States* \_\_ S.Ct. \_\_\_, 2022 WL 2295024, Case No. 20-1410 (2022), this Court, in interpreting 21 U.S.C. § 841, held that when a physician charged for conduct occurring within the scope of his or her practice introduces evidence that he or she was authorized to prescribe controlled substances, “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.” *Ruan, id.* at 2.

Just as does § 841, § 856 contains a general scienter provision of “knowingly”. And in § 856 prosecutions, just as in § 841 prosecutions, authorization plays a crucial role in separating innocent conduct from wrongful conduct. *Ruan, id.* at 12.

21 U.S.C. § 856(a)(1) makes it a federal crime for anyone to “knowingly open . . . use or maintain any place . . . for the purposes of manufacturing, distributing, or using any controlled substance.” However the statute provides an exception “Except as authorized by this subchapter . . .” This is the same exception contained in § 841 which makes it unlawful for anyone to “manufacture, distribute a controlled substance. . .”. Nurse practitioners, when registered with the DEA, are authorized to prescribe controlled substances when the prescription is issued “for a legitimate medical purpose” in the usual course of professional practice. 21 CFR § 1306.04(a) (2021).

The jury was not instructed by the district court as to this exception contained in § 856.

Mrs. Clemons respectfully submits that the reasoning in *Ruan* applied to § 841 should apply to § 856 given that § 856 also contains the “except as authorized” provision, therefore, in prosecutions under § 856 the government should be required to prove beyond a reasonable doubt that Mrs. Clemons knew she “was acting in an unauthorized manner or intended to do so”, otherwise, physicians and other authorized medical professionals would be held to a different standard of proof in § 856 cases than in cases involving violations of § 841 for essentially the same conduct.

Mrs. Clemons’ defense at trial was that she was registered with the DEA, authorized to write prescriptions for controlled substances, and that the prescriptions she wrote she believed were issued for a legitimate medical purpose in the usual course of her practice, under the supervision of a medical doctor who was also authorized to prescribe controlled substances.

Mrs. Clemons requested a jury instruction that the government would have to prove beyond a reasonable doubt that she had the knowledge and intent to prescribe controlled substances without a legitimate medical purpose and outside the usual course of professional practice.

The district court, in the jury instructions on § 856(a)(1), did not include instructions on the “except as authorized” language in the statute. The district court did not instruct the jury on the *mens rea* of “knowingly” in relation to the authorization exception of § 856. The district court did not instruct the jury that, for Mrs. Clemons to be convicted of a § 856 violation, the government would have to prove beyond a

reasonable doubt that she subjectively knew her prescriptions were not for a legitimate medical purpose and were outside the usual course of professional practice.

The 6<sup>th</sup> Circuit held that the district court judge's instructions on § 856 were not in error, despite the fact that the district court judge's instructions omitted the "except as authorized" language in the § 856 instructions and did not address the *mens rea* required to convict a healthcare professional who is authorized to prescribe controlled substances of a violation of § 856.

The 6<sup>th</sup> Circuit acknowledged that "the Government did not produce any direct evidence that Clemons, Womack, and Newman *knowingly* used the clinics for the purpose of illegal drug activity." (Appendix A, p. 17, emphasis in original).

Mrs. Clemons respectfully submits that the trial court's instructions on the *mens rea* required for § 856 violations and that this *mens rea* was to be judged by an objective standard and not a subjective standard are in contravention of this Court's holding in *Ruan*. This requires application of *Ruan* and reversal of Mrs. Clemons' convictions.

**B. The 6<sup>th</sup> Circuit's decision holding that the jury instruction on 21U.S.C. 856(a)(1) adequately conveyed the illegality of the acts in distributing controlled substances when "taken as a whole" encompasses language that is contrary to this Court's ruling in *Ruan*.**

The 6<sup>th</sup> Circuit held that the district court's jury instructions under 21 U.S.C. § 856(a)(1) adequately conveyed to the jury all of the elements necessary to support a verdict of guilty for Mrs. Clemons when taken as a whole with the other instructions in the case. However, the jury instructions contained the phrase "whether a

prescription is made in the usual course of professional practice is to be determined from an objective and not a subjective viewpoint" which this Court in *Ruan* held to be an incorrect standard of proof. It is true that *Ruan* was addressing a different statute, 21 U.S.C. § 841, however, in authorized healthcare provider-related cases, the proof put on by the government to establish violations of § 856 will be the same sort of proof used to prove violations of § 841. Each statute contains a "knowingly" *mens rea* provision:

And when a statute is not silent as to mens rea but instead "includes a general scienter provision," "the presumption applies with equal or greater force" to the scope of that provision. *Rehaif [v. United States]*, 588 U. S., at \_\_\_ [2019] (slip op., at 3) (emphasis added). We have accordingly held that a word such as "knowingly" modifies not only the words directly following it, but also those other statutory terms that "separate wrongful from innocent acts." *Id.*, at \_\_\_ (slip op., at 6); see, e.g., *ibid.*; *United States v. X-Citement Video, Inc.*, 513 U. S. 64, 72 (1994); *Liparota v. United States*, 471 U. S. 419, 426 (1985).

*Ruan*, at 6

As does 21 U.S.C. § 841, 21 U.S.C. § 856(a)(1) contains an "except as authorized" clause. As noted in *Ruan*,

Nor is the "except as authorized" clause a jurisdictional provision, to which the presumption of scienter would not apply. Cf. *Rehaif*, 588 U. S., at \_\_\_ (slip op., at 4); *United States v. Yermian*, 468 U. S. 63, 68-69 (1984). To the contrary, and as we have explained, a lack of authorization is often the critical thing distinguishing wrongful from proper conduct.

*Id.* at 7,8.

*Ruan* held that, in cases of authorized healthcare professionals prescribing controlled substances, the government must prove that the authorized healthcare professional knowingly and intentionally acted in an unauthorized manner and that the standard for that proof is a subjective one and not an objective one as the jury was instructed here. Physicians and medical professionals authorized to prescribe controlled substances charged with violations of § 856 will be subject to a different standard of proof for the same conduct as in § 841 cases, unable to determine whether their lawful conduct in prescribing medications for their patients will be deemed unlawful for the purpose of operating their business unless this Court rules that the holding in *Ruan* applies to prosecutions under § 856 . This dichotomy is an issue that needs to be addressed under the reasoning of *Ruan*.

**C. 21 U.S.C. §856(a)(1) was not intended to criminalize the conduct that occurred in this case.**

21 U.S.C. §856(a)(1)<sup>1</sup> makes it unlawful for a person to "knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purposes of manufacturing, **distributing**, or using any controlled substance." (Emphasis added). 21 U.S.C. §841(a)(1) makes it a crime to "manufacture, **distribute, or dispense**, or possess with intent to manufacture, **distribute or dispense**, a controlled substance . . ." (Emphasis added.) Clearly Congress did not intend that "dispense" be an unlawful activity under 21 U.S.C. §856(a)(1) or it would have specified so as it did in 21 U.S.C. §841. "[W]here Congress includes particular language in one section of a

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<sup>1</sup>Also referred to as "the crack house statute".

statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."

*Russello v. United States*, 464 U.S. 16, 23 (1983) Congress clearly intended that dispensing and distribution were not interchangeable terms, nor the same activity. In 21 U.S.C. § 802, Congress set forth the definitions it intended to be applied to the subchapter containing both 21 U.S.C. §841 and 21 U.S.C. §856(a)(1). In Paragraph 10 of § 802, the term "dispense" is defined as follows:

The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

In Paragraph 11 of § 802, the term "distribute" is defined as follows:

The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.

Mrs. Clemons respectfully submits that Congress did not intend for dispensing or prescribing by a physician to be unlawful conduct under this statute. If Congress had intended dispensing to be unlawful conduct, they would have said so as they did in 21 U.S.C. § 841. Mrs. Clemons respectfully submits that Congress acted intentionally and with purpose by excluding dispensing as unlawful conduct in §

856(a)(1) and that this Court should find that prosecution of authorized healthcare professionals under this statute and this set of facts is improper.

Finally, because the facts in this Petition are substantially similar for all the petitioners in this case and the related cases of Courtney Newman and Holli Womack, in the interests judicial economy, Mrs. Clemons would adopt by reference the arguments of petitioners Newman and Womack in their petitions for writ of certiorari and respectfully requests this Court allow adoption of such arguments as if fully set forth herein.

## **CONCLUSION**

For the foregoing reasons, Cynthia Clemons respectfully 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 proceedings consistent with this Court's ruling.

Respectfully submitted this the 8<sup>th</sup> day of July, 2022.

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