No. 23-_____

In the Supreme Court of the United States

DR. ROGER DALE ANDERSON,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In *Ruan v. United States*, 142 S. Ct. 2370 (2022), this Court held that a physician may be convicted under 21 U.S.C. § 841(a)(1), of the Controlled Substances Act ("CSA"), only if the government proves that the physician "knew or intended that his or her conduct was unauthorized." *Id.* at 2382. Following remand, *United States v. Xiulu Ruan*, 56 F.4th 1291, 1300-02 (11th Cir. 2023) was decided before Petitioner's appeal, where the Sixth Circuit held that the jury instructions were sufficient despite lack of reference to the CSA's "authorization" requirement. *See*, Petitioner's Appendix ("App.") at 1a-34a. The Sixth Circuit's opinion is in conflict with this Court's opinion in *Ruan*, as well as the Tenth Circuit's opinion in *United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023). A spit between circuits has formed which will continue to grow.

The question presented, on which the circuits are divided, is whether a CSA jury instruction may omit the statute's "except as authorized" requirement contrary to the express wording of the CSA, 21 U.S.C. § 801 et seq., reinforced by *Ruan*.

LIST OF PROCEEDINGS

United States v. Anderson, No. 2:19-cr-00067-ALM-1,
United States Southern District of Ohio

Verdict: March 5, 2023

Judgment: January 14, 2021.

United States v. Anderson, No. 21-3073,
United States Court of Appeals for the Sixth Circuit.

Judgment entered on April 17, 2023.

Rehearing denied: June 6, 2023.

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Sixth Circuit is reported at 67 F.4th 755. *See*, Petitioner's Appendix ("App."), App.1a. The order of the Sixth Circuit denying rehearing is not reported. App.62a.

JURISDICTION

The Sixth Circuit's judgment was entered on April 17, 2023. App.1a. The court denied rehearing on June 6, 2023. App.62a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

21 U.S.C. § 841(a)(1), CSA 841(a)(1)
Unlawful acts A

> 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[.]

21 U.S.C. § 846
Attempt and conspiracy

> Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

21 C.F.R. § 1306.04(a)
Purpose of issue of prescription

> 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.

STATEMENT OF THE CASE

Petitioner filed his opening brief before the Sixth Circuit on November 8, 2021. The government then filed their responsive brief on February 9, 2022, before Petitioner filed his reply brief on March 2, 2022. Because Petitioner challenged the 21 U.S.C. § 841 jury instructions given at his trial, the Sixth Circuit suspended review of the briefings pending the Supreme Court's decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022). *See*, Doc. 40.

After *Ruan* was decided, the Sixth Circuit affirmed Petitioner's unlawful prescribing convictions under § 841, finding that, taken as a whole, the jury instructions given at his trial "substantially covered" the *mens rea* requirement set forth by this Court in *Ruan*. *See*, App.12a-18a. Yet, those jury instructions replaced

the CSA's "without authorization" requirement with the "ambiguous," *Ruan*, 142 S. Ct. at 2377, language of 21 C.F.R. § 1306.04(a), *see*, App.12a-13a. The Sixth Circuit's decision stands in direct conflict with the Tenth Circuit's opinion following remand in *United States v. Kahn*, 58 F.4th 1308 (10th Cir. 2023). There, the Tenth Circuit held that all of Dr. Shakeel Khan's convictions flowing from § 841 must be vacated because the jury instructions at his trial replaced the statutory requirement of, "except as authorized," with the "ambiguous" language from § 1306.04(a), "outside the usual course of professional practice and without a legitimate medical purpose." *Id.* at 1316-17, 1321-22.

This split in § 841 instructions extends further. The Eleventh and Fifth Circuit have also affirmed § 841 convictions where the trial court failed to instruct the jury that the prescription must be unauthorized. *Ruan*, 56 F.4th at 1300-02; *United States v. Germeil*, 2023 WL 1991723, at *8-10 (11th Cir. Feb. 14, 2023); *United States v. Heaton*, 59 F.4th 1226, 1241 (11th Cir. 2023); *United States v. Maltbia*, 2023 WL 1838783, at *5 (11th Cir. Feb. 9, 2023), *cert. petition filed*, No. 22-7531 (U.S. May 11, 2023); *United States v. Mencia*, 2022 WL 17336503, at *14 (11th Cir. Nov. 30, 2022); *United States v. Ajayi*, 64 F.4th 243, 247-48 (5th Cir. 2023).

Although over one year has passed since *Ruan* was decided, the lower federal courts continue to uphold instructions that substitute the language of 21 C.F.R. § 1306.04(a) for the "except as authorized" language required by this Court. Pet. 16.[1] The problem with this approach is that the regulation, 21 C.F.R. § 1306.04, is the interpretation of the phrase "usual course of professional practice," without reference to the requirement that a physician "knowingly" issued an unauthorized prescription creates a crime Congress did not intend. Absent the "authorization requirement," a physician will face conviction for simply engaging in conduct that differs from what other physicians might regard as "legitimate". Resolving this circuit split is of extreme import to both doctors and patients. Physicians are a notoriously risk adverse group. The current split in circuits ensures that physicians operate within a sphere of uncertainty every time they pick up their prescription pad. This uncertainty translates into overly conservative treatment and the result is suffering, pain, and even suicide. This is especially true in the Sixth Circuit, where unlike in *Ruan*, 56 F.4th at 1298, physician convictions under § 841 are sustained in the absence of the required *mens rea*, *Ruan*, 142 S. Ct. at 2382, by reference to deliberate ignorance jury instructions—an instruction intended to reduce the government's burden to prove that a defendant acted knowingly. *United States v. Anderson*, 67 F.4th 755, 764-66 (6th Cir. 2023).

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[1] This petition uses "Pet." to refer to the petition for a writ of certiorari in *Ruan v. United States*, No. 22-1175.

The petition for a writ of certiorari should be granted, and this Court must act to provide clear direction to physicians and pain management patients.

A. Statutory and Regulatory Framework

The CSA makes it unlawful for "any person knowingly or intentionally . . . to manufacture, distribute, or dispense" a controlled substance," "[e]xcept as authorized by this subchapter." 21 U.S.C. § 841(a)(1). "[T]his subchapter" authorizes persons who have registered with the Attorney General to dispense controlled substances "to the extent authorized by their registration." *Id.* § 822(b). The CSA also directs the Attorney General to accept the registration of a medical doctor or other practitioner if he is "authorized to dispense . . . controlled substances under the laws of the State in which he practices." *Id.* § 823(g)(1). The regulation, 21 C.F.R. § 1306.04(a) provides, in pertinent part:

> 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.

B. Factual Background

Petitioner, Dr. Roger Dale Anderson, practiced as a licensed physician in Marietta, Ohio, where he specialized in infectious diseases and internal medicine. *Anderson*, 67 F.4th at 759. Dr. Anderson would divide his time between Marietta Memorial Hospital, where he treated both inpatients and outpatients, and Marietta Medical, an independent practice he founded focusing on infectious diseases. *Id.* While treating patients at both sites, Dr. Anderson would prescribe

controlled substances under his registration with the Drug Enforcement Administration (DEA). *Id.*

The DEA received a tip from a local pharmacist in early 2015, claiming that Dr. Anderson was treating patients who had been discharged by other physicians for non-compliance, prompting the DEA to launch an investigation into his practice. *Id.* Then, in February 2016, the DEA executed a search warrant and seized various documents from Marietta Medical, including medical files, prescriptions, and appointment and payment records. *Id.* Dr. Anderson was eventually indicted by a federal grand jury in March 2019, charging him with fourteen counts: one count of conspiracy to distribute controlled substances, 21 U.S.C. § 846; nine counts of unlawful distribution of controlled substances, 21 U.S.C. § 841(a)(1); one count of conspiracy to commit healthcare fraud, 18 U.S.C. § 1349; and three counts of healthcare fraud, 18 U.S.C. § 1347. *Id.* The Government voluntarily dismissed one count of the § 841 charges, as well as the conspiracy to commit health care fraud count and two of the substantive health care fraud counts. *Id.* at 768, 770.

The Government's case was centered on the CSA charges against Dr. Anderson, and the non-CSA charge relied on the underlying facts of the CSA charges. *See*, Doc. 1 ¶¶ 48-59 (conspiracy to dispense and distribute controlled substances), ¶ 60 (illegal dispensing of controlled substances), ¶¶ 68-73 (health care fraud). The government therefore argued to the jury that all its indicted charges were supported because Dr. Anderson prescribed outside the usual course of professional practice and not for a legitimate medical purpose. *See*, *e.g.*, Tr. 57, PgID #: 398; 82, PgID #: 1128; 89, PgID #: 2398 ("Roger Anderson acted outside the

course of professional practice, and his prescriptions were without a legitimate medical purpose. That's the core of the case"); 89, PgID #: 2402; 89, PgID #: 2403; 89, PgID #: 2416-17. Incredibly, the words "without authorization," or even just "authorization," were entirely omitted from the government's summation.

The district court also instructed the jury based on 21 C.F.R. § 1306.04(a), telling the jury, with respect to both Section 841(a)(1) and Section 846, that it was unlawful for Dr. Anderson to prescribe "outside the usual course of professional medical practice" or without a "legitimate medical purpose." *See*, Tr. 89, PgID #: 2470-78 (the only instance of "authorized" being: "Federal law authorizes registered medical practitioners to dispense a controlled substance by issuing a lawful prescription"). But the district court denied Dr. Anderson's requested good faith instruction, which he argued was necessary to protect him from being convicted for mere medical malpractice, the standard for negligence used in civil trials; instead, opting to provide a deliberate ignorance instruction to the jury. The instructions therefore read:

> First, the defendant knowingly or intentionally dispensed or distributed a Schedule II controlled substance, including fentanyl, Adderall, oxycodone and hydrocodone; and,
>
> Second, that the defendant, Dr. Anderson, prescribed the drug without a legitimate medical purpose and outside the course of professional practice.

Tr. 89, PgID #: 2474.

Although knowledge of the defendant cannot be established merely by demonstrating he was careless,

knowledge may be inferred if the defendant deliberately blinded himself to the existence of a fact. No one can avoid responsibility for a crime by deliberately ignoring the obvious. If you are convinced that the defendant deliberately ignored a high probability that the controlled substance was distributed or dispensed without a legitimate medical purpose in the usual course of professional practice, then you may find that the defendant knew that this was the case. But you must be convinced beyond a reasonable doubt that the defendant was aware of a high probability that the controlled substances were distributed or dispensed other than for a legitimate medical purpose while acting in the usual course of professional practice, and that the defendant deliberately closed his eyes to what was obvious. Carelessness, or negligence, or foolishness on his part are not the same as knowledge and are not enough to find him guilty on this count. Tr. 89, PgID #: 2476-77.

Dr. Anderson was convicted on all ten counts, and sentenced to 96 months of imprisonment, to run concurrently on each of the counts. *See*, Doc. 68.

C. Appellate Proceedings

Petitioner appealed, raising, among other issues, whether the trial court erred in denying a defense requested instruction on "good faith". *Anderson*, 67 F.4th at 764-66. At the time briefing was completed, the binding precedent in the Circuit was *Godofsky*, which held that the subjective good faith of the defendant was irrelevant to the "except as authorized" clause for physicians tried under 841(a). *United States v. Godofsky*, 943 F.3d 1011 (6th Cir. 2019).

However, after briefing in the case was completed, this Court decided *Ruan v. United States*, 142 S. Ct. 2370 (2022), holding that the *mens rea* standard of "knowingly or intentionally" applies to the entirety of 841(a) – including the "except as authorized" clause. 142 S. Ct. at 2375. In its order, Sixth Circuit recognized this change in the law but declined to follow it. Opinion and Order, App.14a. At the time of the opinion, only one Circuit, the Eleventh, addressed whether a good faith instruction can comport with *Ruan*. *United States v. Ruan*, 56 F4th 1291 (11th Cir. 2023).

The Eleventh Circuit remanded *Ruan* back to the district court concluding that the totality of the jury instructions failed to "convey that a subjective analysis was required for the 'except as authorized' clause of 841. *Id*. From there, the Sixth Circuit determined that a "properly qualified subjective good faith instruction performs the same function as the "knowledge or intent" requirement identified by the Supreme Court". Opinion and Order at 11. Of course, such an assumption was never made by this court in *Ruan* or any other case.

The Sixth Circuit ultimately held that the "instruction given to the jury substantially covers the holding of *Ruan*, by referring continuously to the "knowledge of the defendant", his "deliberate ignorance," and if he "knew" that the prescriptions were dispensed illegitimately. Opinion and Order, App.12a-18a. In affirming the instruction, the Sixth Circuit incorporated the "deliberate ignorance" instruction, a wholly separate and distinct instruction, into the elements of the § 841 offense. *Id*.

Judge Helene N. White dissented from the Court's analysis of the requested instruction and the elements

of the offense. Opinion and Order. App.30a. Judge White determined that the second element's instruction identified no *mens rea* requirement. Judge White correctly pointed out that this Court's opinion in *Ruan* "teaches that the second element too must be performed knowingly and intentionally". 142 S. Ct. at 2375. Further, Judge White was unconvinced that the "deliberate ignorance" instruction could save a faulty instruction that is inconsistent with this Court's precedent. Opinion and Order, App.30a.

"Yet, the second element does not depend on perceiving or ignoring probabilities. [Petitioner] either understood and intended to prescri[be] controlled substances without a legitimate medical purpose in the usual course of professional practice, or he did not. That is, the instruction does not further clarify that both elements require the "knowledge or intent" *mens rea*. Telling the jury that carelessness, negligence, or foolishness is insufficient is not tantamount to instructing what mental state is required." App.31a-32a..

The dissent then went one step further and stated that the "good faith" instruction proposed by Dr. Anderson comports with *Ruan* and is near identical to the instruction given in *United States v. Godofsky,* 943 F.3d 1011, 1019 (6th Cir. 2019). Opinion and Order p. 22.

Finally, Judge White was unconvinced that Petitioner conceded the improper 841(a) instruction given that he objected to the Court's instruction and filed briefing on appeal prior to this Court's decision in *Ruan*. Opinion and Order, App.34a fn.1.

REASONS FOR GRANTING THE PETITION

The *Ruan* decision is a narrow but important decision that emphasizes the role of scienter in separating innocent from criminal conduct.[2] This Court's decision corrected years of conflicting and eroding standards for what the government must prove to secure a conviction in 841(a)(1) prosecutions against doctors or other prescribing practitioners.[3]

In the wake of *Ruan*, a physician should not be convicted for innovative, mistaken, negligent, or less-than-careful prescribing. By affirming a conviction where a jury was not instructed on the proper *mens rea* under the CSA, which requires a controlled substance prescription to be issued "without authorization," the 6th Circuit has eviscerated the meaning and intent of this important decision.

It has further widened the divide between circuits. The impact of the 6th Circuit's decision leaves a chilling impact on the practice of medicine and has impacted the treatment of legitimate pain as a risk adverse population of physicians have elected to cease prescribing necessary medications for fear of criminal conviction.

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[2] *Ruan v. United States*: *"Bad Doctors," Bad Law, and the Promise of Decriminalizing Medical Care*, 2022 CATO SUP. CT. REV. 271.

[3] *Id.*

I. THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER CIRCUITS AND IS DIFFICULT TO RECONCILE WITH DECISIONS OF THIS COURT

A. The Courts of Appeals Are Deeply Divided on the Meaning of the Phrase "Legitimate Medical Purpose in the Usual Course of Professional Practice"

Following the *Ruan* decision, the deep divide in lower courts has not resolved, rather division has widened. As of the filing date of this brief, the Second Circuit, Third Circuit, and the Seventh Circuit have not addressed *Ruan*'s impact, with the remaining Circuits coming to drastically different conclusions. Some have elected to sustain instructions that substantiate the language of 21 C.F.R. § 1306.04(a) for the "except as authorized" language required by this Court's decision. *See*, 142. S. Ct. at 2375. This permits a regulatory agency to create a criminal offense that Congress itself did not envision.[4] Others have vacated convictions and strictly followed this Court's decision.

The Eleventh Circuit was the first to act post-*Ruan* on remand. *Ruan*, 56 F.4th at 1298. In vacating some of *Ruan*'s convictions, the court observed that, absent a specific subjective intent component, reference to "objective good faith" connotes both objective and subjective good faith, and an instruction lacking a subjective good faith distinction is reversible error. *Id*. at 1297. Interestingly, however, the Eleventh Circuit did not reverse *Ruan*'s conspiracy conviction under 21 U.S.C. § 846. *Id*. at 1299. The Eleventh

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[4] Pet. No. 22-1175.

Circuit reasoned that even if the definition of unlawful distribution was in error it "would have no effect on the jury's analysis for the conspiracy counts". *Id.* at 1299. Despite a lack of any language in the 846 instruction, the Eleventh Circuit determined that the jury was "already required" to find that the defendant acted with subjective knowledge. *Id.* The jury was instructed that the government must prove:

> (1) There was an agreement between two or more people to commit a crime;
>
> (2) The defendant knew about the agreement; and
>
> (3) The defendant voluntarily joined the agreement.

Id.

Predicated on a faulty 841(a) instruction, and with no reference to the subjective knowledge of the defendant, the Eleventh Circuit still determined that Defendant's conspiracy conviction must be affirmed.

Later Eleventh Circuit opinions doubled down on this approach. *United States v. Germeil*, 2023 WL 1991723, at *8-10 (11th Cir. Feb. 14, 2023); *United States v. Heaton*, 59 F.4th 1226, 1241 (11th Cir. 2023); *United States v. Maltbia*, 2023 WL 1838783, at *5 (11th Cir. Feb. 9, 2023), *cert. petition filed*, No. 22-7531 (U.S. May 11, 2023); *United States v. Mencia*, 2022 WL 17336503, at *14 (11th Cir. Nov. 30, 2022).

Following the Eleventh Circuit's decision in *Ruan*, the Sixth Circuit came to an even harsher conclusion, incorporating a deliberate ignorance instruction to save a faulty 841(a) instruction. *See*, *Anderson,* 67 F.4th at 764-66. The Sixth Circuit later doubled down

on its holding in *Andersen*, deciding *United States v. Sakkai*, 2023 U.S. App. LEXIS 13489 (6th Cir. 2023), and again upheld a jury instruction that only applied the applicable *mens rea* to the distribution and not the lack of authorization. *Id.* at 17. *Sakkai* was given the same "deliberate ignorance" instruction as in *Anderson* which omitted the "authorization" requirement inconsistent with this Court's holding in *Ruan*.

The Fifth Circuit quickly followed suit. In *United States v. Ajayi*, 64 F.4th 243 (5th Cir. 2023), the Fifth Circuit affirmed conviction of a pharmacist where the jury charge read: "to possess with intent to deliver or transfer possession of a controlled substance to another person, with or without any financial interest in the transaction, and outside the scope of professional practice or not for a legitimate medical purpose". *Id.* at 247. This instruction would permit conviction where the pharmacist intended to deliver but where the delivery was also not for a legitimate medical purpose. The district court did not apply the *mens rea* to the second prong as *Ruan* requires.

Later the Fifth Circuit went further and determined that even where a district court blatantly stated the wrong *mens rea* element, relief was not appropriate. The Fifth Circuit in *United States v. Capistrano*, 2023 U.S. App. LEXIS 19003 (5th Cir. 2023), under plain error review, determined that the district court's instructions incorrectly stated the law by omitting the *mens rea* element. *Id.* at 13. Moreover, the trial court misread the instruction holding the defendant to an objective standard and not a subjective standard. *See*, *Id.* The Fifth Circuit did not reverse, holding "an instruction that omits an element of the offense does not necessarily render a criminal trial

fundamentally unfair or an unreliable vehicle for determining guilt or innocence". *Id*.

The Ninth and Tenth Circuits have chosen to follow this Court's decision in *Ruan*. In *United States v. Kabov*, 2023 U.S. App. LEXIS 18214 (9th Cir. 2023), the Ninth Circuit vacated the defendant's convictions for importation of controlled substances and remanded to apply *Rehaif* and *Ruan* in the first instance. *Id*. at 16. In *United States v. Henson*, 2023 U.S. App. LEXIS 5075 (10th Cir. 2023), after this Court vacated the judgment, the Tenth Circuit remanded the case with instructions to vacate all of Dr. Hensen's controlled substance convictions. *Id*. at 3-4.

In *United States v. Kahn*, 58 F.4th 1308 (2023), the Tenth Circuit, strictly following this Court's decision in *Ruan*, vacated Dr. Kahn's controlled substance convictions and remanded for a new trial. The district court in Kahn instructed the jury: "Defendant Kahn knowingly or intentionally distributed or dispensed the controlled substance outside the usual course of professional medical practice or without a legitimate medical purpose". Kahn also received a subjective good faith instruction. *Id*. at 1313.

"The good faith defense requires the jury to determine whether Defendant Shakeel Kahn acted in an honest effort to prescribe for patients' medical conditions in accordance with generally recognized and accepted standards of practice." *Id*.

The Tenth Circuit went even further and determined that Kahn's convictions for violations of 21 U.S.C. § 843(b), 18 U.S.C. § 926(c)(1), 21 U.S.C. §§ 848 (a)9,(b), and (c) and 18 U.S.C. § 1957 were predicated, at least in part, on one or more of the erroneous

instructions. The Court vacated all of Dr. Kahn's convictions. *Id*. 1321.

The split amongst the circuits has continued to gain increasing attention. As one district court recently declared, "[i]t is far above this Court's pay grade to resolve a Circuit split-if, indeed, there is one." *United States v. Lamartiniere*, 2023 WL 2645343, at 2 (M.D. La. Mar. 27, 2023). The division will widen drastically when the Second Circuit, Third Circuit, Fourth Circuit, and Seventh Circuit choose their side.

The implications for controlled substance prescribers, pharmacists, and pain patients are drastic. Without a clear *mens rea* standard, and without clear resolution of the circuit conflict, physicians not knowing the limits of their liability will adopt ever more conservative approaches to treatment and may avoid prescribing altogether.

B. The Court of Appeals Decision Is Difficult to Square with This Court's Case Law

The Sixth Circuit's decision in the instant case is not only difficult to square with this Court's case law, its utterly impossible. Here the district court instructed that the elements were: "First, the defendant knowingly or intentionally dispensed or distributed a Schedule II controlled substance . . . ; and, Second, that the defendant, Dr. Anderson prescribed the drug without a legitimate medical purpose and outside the course of professional practice." *Anderson*, 67 F.4th at 766. The court further told the jury that it could convict if the defendant "deliberately ignored a high probability that the controlled substance was distributed or dispensed without a legitimate medical purpose in the usual course of professional practice"

or "was aware of a high probability that the controlled substances were distributed or dispensed other than for a legitimate medical purpose while acting in the usual course of professional practice." *Id.* These instructions replaced the authorization requirement with the language of 21 C.F.R. § 1306.04(a) and still the Sixth Circuit held that they comport with *Ruan*. *Id.* One member of the panel dissented, determining that "the second element's instruction identified no mens rea requirement," and that it did not "comport with *Ruan*". *Id.* at 12-13 (White, J. concurring in part and dissenting in part).

In *Ruan*, the Court confirmed that the CSA makes it unlawful to distribute or dispense controlled substances "[e]xcept as authorized by this subchapter," 21 U.S.C. § 841(a)(1), and "this subchapter" authorizes persons registered by the Attorney General, like physicians, to distribute or dispense controlled substances "to the extent authorized by their registration," 21 U.S.C. § 822(b). *See*, 142 S. Ct. at 2376-78. The statute does not say that it is unlawful to prescribe "outside the course of professional practice" or not for a "legitimate medical purpose." 21 U.S.C. § 841(a)(1). But this did not stop the Sixth Circuit, it simply bypassed the "except as authorized" requirement in the CSA, substituting the language of 21 C.F.R. § 1306.04(a) for the text of the CSA. *See*, *Anderson*, 67 F.4th at 764-66. This substitution is unconstitutional because the Attorney General's rulemaking authority under the CSA, *see*, 21 U.S.C. §§ 821, 871(b), does not give him the power revise criminal laws that were enacted by Congress—and, if the Attorney General had this type of authority, then it would be an unconstitutional delegation of Congress' power to enact

laws. *See*, *Gundy v. United States*, 139 S. Ct. 2116, 2144-45 (2019) (Gorsuch, J., dissenting, joined by Roberts, C.J., and Thomas, J.) ("To allow the nation's chief law enforcement officer to write the criminal laws he is charged with enforcing—to unit[e] the legislative and executive powers . . . in the same person—would be to mark the end of any meaningful enforcement of our separation of powers and invite the tyranny of the majority that follows when lawmaking and law enforcement responsibilities are united in the same hands."); *Whitman v. United States*, 135 S. Ct. 352, 354 (2014) (Scalia, J., respecting denial of certiorari) ("[T]he rule of lenity . . . vindicates the principle that only the legislature may define crimes and fix punishments. Congress cannot, through ambiguity, effectively leave that function to the courts—much less to the administrative bureaucracy."); *Loving v. United States*, 517 U.S. 748, 768 (1996) ("We have upheld delegations whereby the Executive or an independent agency defines by regulation what conduct will be criminal, so long as Congress makes violation of regulations a criminal offense . . . (emphasis added)).

Courts should also not defer to an agency's interpretation of what statutes mean; instead, a court should hew closely to the text of a statute. *See*, *e.g.*, *Buffington v. McDonough*, 143 S. Ct. 14, 22 (2022) (Gorsuch, J., dissenting) ("We should acknowledge forthrightly that *Chevron* did not undo, and could not have undone, the judicial duty to provide an independent judgment of the law's meaning in the cases that come before the Nation's courts. Someday soon I hope we might."); *Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 142 S. Ct. 2354, 2368-69

(2022) (Kavanaugh, J., dissenting) ("[T]his case is resolved by the most fundamental principle of statutory interpretation: Read the statute."); *Michigan v. EPA*, 576 U.S. 743, 761 (2015) (Thomas, J., concurring) ("*Chevron* deference precludes judges from exercising [their independent] judgment, forcing them to abandon what they believe is the best reading of an ambiguous statute in favor of an agency's construction. It thus wrests from Courts the ultimate interpretative authority to say what the law is and hands it over to the Executive."); *see*, *United States v. Apel*, 571 U.S. 359, 369 (2014) (addressing United States Attorneys' Manual and opinions of the Air Force Judge Advocate General, and stating, "we have never held that the Government's reading of a criminal statute is entitled to any deference"); *see also*, *Abramski v. United States*, 573 U.S. 169, 191 (2014) (addressing ATF circular and prior version of ATF form, and stating, "[t]he critical point is that criminal laws are for courts, not the Government, to construe" (citing *Apel*, 571 U.S. at 369)).

The Sixth Circuit's substitution of 21 C.F.R. § 1306.04(a) is made all the more problematic given that the regulatory language is "ambiguous" and "open to varying constructions." *See*, *Ruan,* 142 S. Ct. at 2377. "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(a). When is a course of treatment "usual"? Does it require at least 50.1% of providers to adopt or use the treatment? Does a course of treatment become illegitimate if used in conjunction with other medications? If the government can prosecute and

convict a physician, branding them as a "drug dealer" simply because that physician knows that most, or maybe just many, other doctors disagree with them, 21 C.F.R. § 1306.04(a) just reestablishes the very problem this Court sought to resolve in *Ruan*. Indeed, in *Ruan*, the Court was emphatic that even though the government may rely on "circumstantial evidence . . . by reference to objective criteria such as 'legitimate medical purpose' and 'usual course' of 'professional practice,'" the ultimate question—the one the jury must be asked to decide—is whether "a defendant knew or intended that his or her conduct was unauthorized." *Ruan,* 142 S. Ct. at 2382.

The Sixth Circuit ignored the principles set forth by this Court in *Ruan*. Instead, in its view, Dr. Anderson was justly convicted for prescribing "without a legitimate medical purpose and outside the course of professional practice." *Anderson*, 67 F.4th at 766. Whatever those terms mean, to whichever lay jurors are deciding a physician's fate.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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