No. 24-

IN THE

Supreme Court of the United States

JOHN L. STANTON, M.D.,

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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QUESTIONS PRESENTED

The Circuits have applied vastly different interpretations of the ambiguous phrase "outside the usual course of his professional practice, other than for a legitimate medical purpose." *Ruan v. United States*, 597 U.S. 450, 459 (2022); *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006); *United States v. Moore*, 423 U.S. 122, 135 (1975). Circuits applying this phrase in the disjunctive have convicted physicians of a "knowing or intentional" deviation from an unenumerated "standard of care." The questions presented are:

Whether the phrase to measure authorization under 21 U.S.C. § 841(a) can be applied in the disjunctive.

If the phrase is applied in the disjunctive, whether the prosecution of a physician for a deviation of an unenumerated "standard of care" is an improper exercise of the Commerce Clause.

Whether the phrase can be applied in the disjunctive to calculate drug weight.

PARTIES TO THE PROCEEDING

Petitioner, defendant-appellant below, is Dr. John Stanton.

Respondent is the United States of America, appellee below.

RELATED PROCEEDINGS

United States v. John Stanton, No. 23-5394, United States Court of Appeals for the Sixth Circuit. Judgments entered June 6, 2024 and August 8, 2024.

United States v. Maccarone et. al., No. 6:21-cr-00019-REW-HAI, United States District Court for the Eastern District of Kentucky, Judgment entered April 18, 2023.

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The opinion of the Court of Appeals is reported at 103 F.4th 1204. See Petitioner's Appendix ("Pet. App."), *infra*, 1a-16a. The order of the Sixth Circuit denying rehearing is not reported. See Pet. App., *infra*, 34a-35a.

JURISDICTION

The Sixth Circuit entered judgment on June 5, 2024. The court of appeals denied rehearing on August 8. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Section 841(a)(1) of the Controlled Substances Act ("CSA"), 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[.]

21 C.F.R. § 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.

INTRODUCTION

The Controlled Substances Act ("CSA"), in particular 21 U.S.C. § 841(a), was enacted to target drug trafficking. In *United States v. Moore*, 423 U.S. 122 (1975), the Court affirmed that Congress deemed the harsh penalties for unlawful distribution under Section 841(a) appropriate sanction for drug trafficking by a registered physician. *Id.* at 137. That's exactly the way in which the CSA was initially enforced. From when the Act was first passed in 1970 through the early 2000s, the CSA was used to prosecute physicians whose prescribing deviated so visibly from the "usual course of professional practice" that it followed that their prescribing was for "other than a legitimate medical

purpose." *See United States v. Rottschaefer*, 178 Fed. Appx. 145, 147-148 (3d Cir.) (noting that "[s]everal courts have held that 'there is no difference in the meanings'" of the two phrases) (citation omitted), cert. denied, 549 U.S. 887 (2006); *United States v. Daniel*, 3 F.3d 775, 778 (4th Cir. 1993) (equating the two phrases), cert. denied, 510 U.S. 1130 (1994). And it was these cases, soon after the CSA's enactment, that formed the basis for the *Rosen* factors. *See United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978). There, the Fifth Circuit compiled a list of factors that it found to coincide with drug trafficking. *Id.* at 1036.[1] The Drug Enforcement Administration ("DEA") found that list persuasive and it was added to the Federal Register. 71 Fed. Reg. 52,720 (Sept. 6, 2006) (codified 21 C.F.R. 1306). The DEA cautioned, however, that the existence of any of the *Rosen* factors alone should not automatically lead to the conclusion that a physician acted improperly. *See Id.* "Rather, each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient." *Id.*

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1. (1) An inordinately large quantity of controlled substances was prescribed; (2) Large numbers of prescriptions were issued; (3) No physical examination was given; (4) The physician warned the patient to fill prescriptions at different drug stores; (5) The physician issued prescriptions knowing that the patient was delivering the drugs to others; (6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment; (7) The physician involved used street slang rather than medical terminology for the drugs prescribed; (8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; and (9) The physician wrote more than one prescription on occasions in order to spread them out. *Rosen*, 582 F.2d at 1036.

Over time, however, the connective tissue between prescribing outside the usual course of professional practice and other than for a legitimate medical purpose has atrophied. The government now instead prosecutes physicians based on standards of professional practice that are increasingly disconnected from prescribing for other than a legitimate medical purpose. The DEA, for example, has crafted "general practice standards" in restricting the way in which medicine is practiced.[2] These "general practice standards" include: failing to perform an appropriate physical examination; failing to utilize appropriate diagnostic testing; failing to devise and document a written treatment plan; failing to periodically reassess the effectiveness of treatment; continuing to prescribe controlled substances without pursuing alternative therapies; repeatedly and continually prescribing without referring the patient to appropriate specialists; and failing to keep and maintain records which contain adequate findings to support a diagnosis and the need to prescribe one or more medications.[3] Compare these "general practice standards" to the *Rosen* factors which the Fifth Circuit found coincided with drug trafficking. *See Rosen*, 582 F.2d at 1036. The comparison is jarring. What used to be a targeted approach aimed at preventing drug trafficking is now an exercise in restricting the way in which medicine is practiced.

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2. John J. Mulrooney II and Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 385-86 (2017), https://scholarship.law.marquette.edu/mulr/vol101/iss2/3.

3. Id.

The government's errant enforcement of the CSA has broadened the scope of the Act's harsh penalties which were intended for physicians engaged in drug trafficking. *Moore*, 423 U.S. at 137. Because the government has moved away from targeting drug trafficking, opting instead to prosecute physicians even where their prescribing is for a legitimate medical purpose, the government's enforcement of the CSA is no longer a valid exercise of its power under the Commerce Clause. *See Gonzales v. Raich*, 545 U.S. 1, 24-26 (2005) (finding that the CSA was designed to balance the beneficial use of medications while preventing their misuse for which there is an established interstate market of illegitimate channels).

The Court's intervention is needed to restore the boundaries that Congress intended to surround and limit the CSA.

STATEMENT OF THE CASE

A. Factual Background

Petitioner, Dr. John Stanton, was a physician who held a valid DEA registration to prescribe controlled substances and was licensed to practice medicine in Tennessee. Stanton Br. 11. He provided medical care to a wide range of patients while practicing at various medical clinics. Part of that care was his employment at Gateway Medical Associates, P.C. ("GMA"). Id.

GMA was a pain management medical clinic that was owned by Dr. Maccarone. See Id. In 2016, Tennessee began requiring pain management clinics to employ medical directors. This meant that GMA, pursuant to Tenn. Code

§ 63-1-306(a), had to retain a medical director. Because Dr. Maccarone lacked the credentials to qualify for the position, he hired Petitioner, who had the appropriate credentials to serve as the medical director. See Id.

Petitioner began to take on a more active role at GMA when Dr. Maccarone was forced to take medical leave in November 2018 and then again in March 2020. Id. Petitioner immediately started to treat GMA patients, carrying on Dr. Maccarone's prescriptions to not disturb patient continuity of care. Pet. App. 2a-4a. Petitioner did, however, encourage patients to try alternative treatments such as physical therapy or injections, and if a patient declined alternative treatment, Petitioner reduced their prescriptions pending results from their urine drug screen. Id. When Dr. Maccarone returned from leave, Petitioner made sure to warn him of red flags that he observed while filling in for him. Id.

The government indicted Petitioner along with Dr. Maccarone and two GMA patient "sponsors," Jeffrey Ghent and Terry Prince, in 2021. Petitioner was charged in a single count for conspiring to distribute controlled substances in violation of 21 U.S.C. § 846. Id. He proceeded to trial in the Eastern District of Kentucky. Id.

B. The Federal Criminal Trial

Petitioner's trial lasted seven days and he took the stand to testify in his case-in-chief. Id. The jury also heard from nineteen government witnesses, including Dr. Maccarone, the "sponsors," Ghent and Prince, and GMA patients and employees. Id. "The government also planned to offer expert testimony that [Petitioner's] prescription

practices *lacked a legitimate medical basis*." Id. On the second day of trial, however, the government asked the district court to substitute a new expert witness, Dr. Timothy King, after it had second thoughts about its existing expert. Id. The trial court held that this late disclosure would prejudice Petitioner. But the district court did allow Dr. King to testify as a rebuttal witness solely in response to Petitioner's own testimony. Id. Dr. King's rebuttal testimony *was* rebuttal testimony. It did not include any review of medical records, diagnostic imaging, or prescribing histories. Dr. King testified *solely* based on what he heard in open court from Petitioner.[4] Stanton Br. 21-22. In fact, Dr. King testified that pertinent medical information that was not discussed in court was wholly omitted from his rebuttal testimony. Id.

Petitioner challenged the sufficiency of the evidence, moving for judgment of acquittal, both at the close of the government's case-in-chief and again at the end of proof. Stanton Br. 24 n.6. The district court denied both motions and Petitioner was found guilty of the drug conspiracy charge and sentenced to 120 months of imprisonment. Pet. App. 5a-6a. That sentence was based on the 21

4. Petitioner consented to Dr. King sitting in court to listen to his testimony. 08/26/2022 Tr. 12. Counsel, to be sure, made the strategic decision to not call Petitioner's expert to testify and so he had "no objection to [Dr. King] being in here. I'm not sure what he would be rebutting if we're not advancing Hilgenhurst." Id. Counsel was wrong because the district court allowed Dr. King to evaluate whether Petitioner used his "best medical judgment" in working at GMA. Pet. App. 10a-11a. Typically, such testimony on the defendant's state of mind is prohibited under Federal Rule of Evidence 704(b). See Pet. for Reh'g 5-8. Not in the Sixth Circuit, however. See Pet. App. 10a-11a.

patient files introduced at trial, totaling a converted drug weight of at least 21,524 kilograms. Id. The district court thus found every prescription provided to the 21 patients was unauthorized under the CSA. It did so despite the government failing to provide expert testimony on whether the prescriptions "lacked a legitimate medical basis," Pet. App. 4a-5a, and Petitioner having his medical expert, Dr. James Patrick Murphy, testify that the prescriptions were provided for a legitimate medical purpose. Stanton Br. 36-38.

C. The Court of Appeals' Decision

Petitioner appealed raising, *inter alia*, that the government did not prove that any controlled substances were unauthorized under the CSA. He highlighted to the court of appeals that the government did not provide expert testimony to establish that prescriptions were issued for other than a legitimate medical purpose: "The government also planned to offer expert testimony that [Petitioner's] prescription practices *lacked a legitimate medical basis*." Pet. App. 4a-5a. In place of that expert testimony, Dr. King testified on rebuttal, where he evaluated Petitioner's testimony that he "used his best medical judgment in working at GMA." Id. But Dr. King never testified that prescriptions were issued for other than a legitimate medical purpose. Stanton Br. 21-22. Nor could he have, given that his testimony was not based on any medical records in the case. Id. Petitioner thus argued that there was insufficient evidence to prove his involvement in a drug conspiracy because the government did not prove that any controlled substances were unauthorized under the CSA, nor that he joined an agreement to accomplish the same.

Petitioner also argued that the district court erred in calculating drug weight for the same reason. Stanton Br. 36-38. In fact, Petitioner reminded the court of appeals that while the government failed to provide expert testimony on the prescriptions at issue, he provided to the district court expert testimony from Dr. Murphy. Id. Petitioner urged the court of appeals that the district court had to consider whether GMA prescriptions were issued other than for a legitimate medical purpose and not only rely on if the prescriptions were issued outside the usual course of professional practice. Because the only expert testimony on the matter directed that the prescriptions were issued for a legitimate medical purpose, Petitioner argued that the district court erred in sentencing him. Id.

The court of appeals was unmoved. It found that not only was the evidence sufficient to convict Petitioner but that "[t]he question before the jury thus was not whether a drug conspiracy existed; it was whether Dr. Stanton agreed to join it." Pet. App. 6a-10a. In so doing, the court of appeals referenced red flags that it found Petitioner failed to cure, for example, long and unusual clinic hours, high narcotics dosages without individualization or tapering, and continued prescriptions to patients who failed drug screens. Id. Whether or not there was a legitimate medical purpose for the "high narcotics dosages" and "continued prescriptions to patients who failed drug screens" was irrelevant. See Id.

The court of appeals also found that "[a]lthough expert testimony would have been useful" in calculating drug weight, the record "presents a far cry from the situation that [Petitioner] posits, in which the government fails to introduce any evidence, expert or otherwise, to show that a physician's careful treatment of patients violated *accepted*

medical standards." Id. 16a. Again, whether controlled substances were issued for other than a legitimate medical purpose was irrelevant. The court of appeals was instead focused on whether Petitioner violated "medical standards." Id.

Petitioner sought rehearing, petitioning the court of appeals to reconsider the decision. Pet. for Reh'g 1-3. He argued that to convict for conspiracy under 21 U.S.C. § 846 the government had to prove that controlled substances were unauthorized under the CSA, or that he conspired to accomplish the same. Id. 3-5. This necessarily means that there had to be an agreement to distribute controlled substances for other than a legitimate medical purpose. Because the government failed to prove so, Petitioner urged the court of appeals to vacate his conviction. Id.

Rehearing was denied without comment. Pet. App. 34a-35a.

REASONS FOR GRANTING THE PETITION

A medical doctor may be convicted under the CSA, 21 U.S.C. § 841(a)(1), if the government proves that he or she prescribed drugs "outside the usual course of professional practice." *Moore*, 423 U.S. at 124. This Court, however, has repeatedly found that phrase to be "ambiguous" and "open to varying constructions." *Ruan*, 597 U.S. at 459. That ambiguity has been the government's playground.

Indeed, the government has continually moved the goal post on what constitutes the "usual course of professional practice."[5] See Lubetsky Petition for

5. John J. Mulrooney II and Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in*

Certiorari (No. 24-137). What's more, the government has done away with proving that a physician distributed controlled substances other than for a legitimate medical purpose. Whether or not a physician is drug trafficking is now beside the point. *See United States v. Volkman*, 797 F.3d 377, 386 (6th Cir. 2015) (holding that instructing the jury that a physician engaged in drug dealing and trafficking would have "*needlessly* narrowed the scope of the jury's inquiry."). This has allowed the government to use the harsh penalties under Section 841(a), intended for drug trafficking, *Moore*, 423 U.S. at 137, to restrict medicine in whatever way it sees fit. Physicians that fail to fall in line are subject to lengthy periods of imprisonment.

The government's enforcement of the CSA is no longer a legitimate exercise of its power. This Court found in *Gonzales* that the CSA was valid under the Commerce Clause in part because it targeted drug trafficking—i.e., the illegitimate channels of controlled substances for which there was an established and lucrative interstate market. See 545 U.S. at 26. Drug trafficking, however, is separate and distinct from the practice of medicine. *Id.* at 48 (O'Connor, J., dissenting, joined by Rehnquist, C.J., and Thomas, J.) ("Both federal and state legislation—including the CSA itself, the California Compassionate Use Act, and other state medical marijuana legislation—recognize that medical and nonmedical (i.e., recreational) uses of drugs are realistically distinct and can be segregated, and regulate them differently.").

Shallow, Murky, Drug-Infested Waters, 101 Marq. L. Rev. 333, 385-86 (2017), https://scholarship.law.marquette.edu/mulr/vol101/iss2/3.

As the government's enforcement of the CSA is increasingly removed from State-specific medical and prescribing requirements, it continues to test the outer limits of its authority under the Commerce Clause. See Lubetsky Petition for Certiorari (No. 24-137). In circuits that employ the disjunctive reading to measure authorization, like the Sixth Circuit, the government is particularly successful at spreading the outer limits of its authority. In those circuits physicians are convicted of unlawful distribution based only on whether they deviate from the federal government's heightened standard for prescribing in the usual course of professional practice—regardless of how disconnected that heightened standard is from State-specific prescribing requirements or prescribing for other than a legitimate medical purpose.

The Court should grant certiorari to decide exactly how far the government's authority under the Commerce Clause extends and to resolve the circuit split on the disjunctive versus conjunctive reading in unlawful distribution cases and conspiracy to commit the same.

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

Every circuit court measures authorization using 21 C.F.R. § 1306.04(a)'s requirement that for a prescription to be effective it 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). Some circuits, however, read that requirement in the disjunctive whereas others read the requirement in

the conjunctive. Still, others oscillate between the two different readings providing some physicians the benefit of the conjunctive formulation but convicting others if they deviate from either prescribing in the usual course of professional practice or prescribe for other than a legitimate medical purpose.

The Sixth Circuit seems to have adopted the disjunctive reading; however, it is not clear given that it has vacillated between the disjunctive and conjunctive reading. *United States v. Bothra*, No. 2:18-cr-20800, 2022 U.S. Dist. LEXIS 84971, at *10-*13 (E.D. Mich. May 11, 2022) (discussing how decades of convoluted Sixth Circuit case law muddied the waters on the disjunctive versus conjunctive paradigm); *United States v. Kirk*, 584 F.2d 773, 784 (6th Cir. 1978) (holding that two essential elements of unlawful distribution are that prescriptions are "'not in the usual course of professional practice'" and 'not for a legitimate medical or research purpose.'"); *but see id* (finding that there is no difference in the meanings of the statutory phrases); *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (finding that a conviction under § 841(a)(1) requires the government to prove beyond a reasonable doubt that the drugs were distributed outside the usual course of professional practice); *compare United States v. August*, 984 F.2d 705, 712 (6th Cir. 1992) (holding that a prescription must be not for a legitimate medical purpose *and* not in the usual course of professional practice for a doctor to be found guilty of a controlled substances violation).

The disjunctive reading is in sharp conflict with the conjunctive reading of many other circuit courts. As detailed below, that conflict is only growing deeper

as circuit courts are encouraged to reevaluate their disjunctive reading following this Court's decision in *Ruan*. The disjunctive decision is also difficult to square with this Court's precedent.

A. THE COURTS OF APPEALS ARE DIVIDED ON THE DISJUNCTIVE VERSUS CONJUNCTIVE READING

The First, Second, Third, Fifth, and Eleventh Circuits have settled on the disjunctive reading and have remained faithful to that formulation. *United States v. Simon*, 12 F.4th 1, 24 (1st Cir. 2021); *compare United States v. Doe*, 49 F.4th 589, 600 (1st Cir. 2022) (finding that under Massachusetts law unlawful dispensing is the issuance of an invalid prescription . . . *i.e.*, one issued without a legitimate medical purpose and not in the usual course of the physician's professional practice); *United States v. Maye*, 649 Fed. Appx. 15, 16 (2d Cir. 2016); *United States v. Cristobal*, No. 23-6107, 2024 U.S. App. LEXIS 8380, at *5-7 (2d Cir. Apr. 8, 2024) (finding sufficient evidence to sustain unlawful distribution conviction where evidence that prescribing fell outside the usual course of professional practice); *United States v. Belfiore*, No. 22-20, 2024 U.S. App. LEXIS 11311, at *3 (2d Cir. May 9, 2024) (same); *United States v. Rivera*, 74 F.4th 134, 138 (3d Cir. 2023) (binding precedent confirms the disjunctive reading to measure authorization); *compare United States v. Titus*, 78 F.4th 595, 602 (3d Cir. 2023) (finding jury instructions complied with *Ruan* where they required the jury to find defendant knowingly or intentionally distributed controlled substances outside the usual course of professional practice and not for a legitimate medical purpose); *United States v. Lamartiniere*, 100 F.4th 625,

638-43 (5th Cir. 2024); *United States v. Heaton*, 59 F.4th 1226, 1239-40 (11th Cir. 2023).

The Eighth and Ninth Circuits appear to have settled on the conjunctive reading. *See United States v. Smith*, 573 F.3d 639, 649 (8th Cir. 2009); *United States v. Feingold*, 454 F.3d 1001, 1012 (9th Cir. 2006); *see also United States v. Wilson*, 850 Fed. Appx. 546, 547 (9th Cir. 2021); *United States v. Kabov*, No. 19-50083, No. 19-50089, 2023 U.S. App. LEXIS 18214, at *15 (9th Cir. Jul. 18, 2023) (finding no issue with district court's conjunctive instruction but remanding for the lower court to decide whether the instruction complied with the required *mens rea* following *Ruan* and *Rehaif*); *United States v. Motley*, No. 21-10296, 2023 U.S. App. LEXIS 34494, at *7 (9th Cir. Dec. 29, 2023) (finding no error with lower court's conjunctive jury instruction). The Eighth Circuit, however, has hinted that it may have moved to the disjunctive reading instead. *See United States v. Elder*, 682 F.3d 1065, 1068-69 (8th Cir. 2012); *United States v. King*, 898 F.3d 797, 807 (8th Cir. 2018) (citing to *Smith*, 573 F.3d at 647-49 and suggesting that the conjunctive reading is appropriate).[6]

The Sixth Circuit, along with the Fourth, Seventh and Tenth Circuits, have vacillated between the disjunctive and conjunctive reading. *See Bothra*, LEXIS 84971, at *10-*13; *United States v. Oppong*, No. 21-3003, 2022 U.S. App. LEXIS 9475, 2022 WL 1055915, at *15 (6th Cir. Apr. 8, 2022) (holding that "binding case law does not support

6. The Eighth Circuit has not published an opinion on the disjunctive versus conjunctive reading following this Court's decision in *Ruan*. There also appears to be no unpublished opinions.

[the conjunctive reading of the] jury-instructions.") *United States v. Bauer*, 82 F.4th 522, 528 (6th Cir. 2023) (holding that registered doctors are among those authorized to prescribe controlled substances but only when issued for a legitimate medical purpose . . . acting in the usual course of his professional practice); *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (holding to convict a physician for unlawful distribution the government must prove, *inter alia*, that the defendant's actions were not for legitimate medical purposes or were beyond the bounds of medical practice); *compare United States v. Smithers*, 92 F.4th 237, 246-47 (4th Cir. 2024) (finding that *Ruan* requires that a physician knowingly or intentionally prescribed in an unauthorized manner but that acting outside the bounds of medical practice is a purely objective standard); *Id.* at 250 n.5 (directing the panel does not reach whether a disjunctive jury instruction is accurate post-*Ruan*); *Jong Hi Bek*, 493 F.3d at 798; *United States v. Chube*, 538 F.3d 693, 699 (7th Cir. 2008); *compare United States v. Mikaitis*, 33 F.4th 393, 402 (7th Cir. 2022) (holding that to convict physician the government was required to prove that he knowingly distributed drugs outside the usual course of professional practice and not for a legitimate medical purpose); *United States v. Hofschulz*, No. 21-3403 & 21-3404, 2024 U.S. App. LEXIS 15366, at *13 (7th Cir. Jun. 25, 2024) (finding the conjunctive reading is an accurate statement of the law and fully compliant with *Ruan*); *United States v. Nelson*, 383 F.3d 1227, 1232-33 (10th Cir. 2004); *but see United States v. Kahn*, 58 F.4th 1308, 1316 (10th Cir. 2023) (finding that "outside the course of professional practice" is an objective measure of a physician's prescribing and that *Ruan* held the government must prove the defendant subjectively knew or intended to prescribe in an unauthorized manner).

Petitioner was one of the less fortunate physicians in the Sixth Circuit. His drug trafficking conspiracy conviction was upheld in the absence of proof that prescriptions were issued other than for a legitimate medical purpose (and proof that he conspired to do the same). Pet. App. 4a-5a ("The government also planned to offer expert testimony that [Petitioner's] prescription practices *lacked a legitimate medical basis*."). But he is hardly the only one. Physicians in the Sixth Circuit are routinely convicted regardless of whether their prescribing was for other than a legitimate medical purpose. *See Volkman*, 797 F.3d at 386 (refusing to narrow the scope of the jury's inquiry to whether the physician was engaged in drug trafficking). Even a "physician on the vanguard of pain management" with "no financial incentive to overprescribe opioids" may be convicted under the Sixth Circuit's disjunctive reading. *Bauer*, 82 F.4th at 533. From there, the Sixth Circuit narrows its inquiry on "medical standards" when evaluating a physician's sentence. See Pet. App. 14a-16a (finding that drug weight can be calculated only based on whether a physician violated "accepted medical standards."). Those harsh penalties under the CSA, *Moore*, 423 U.S. at 137, become even more punitive when a simple departure from accepted medical standards will suffice.

Bottom line is that drug weight must be based on a preponderance of the evidence, reasonable, and a conservative estimate of the amount of drugs involved. Pet. App. 15a-16a (citing *United States v. Woodside*, 895 F.3d 894, 900-02 (6th Cir. 2018)); *see Alleyne v. United States*, 570 U.S. 99, 116 (2013). To ignore whether prescriptions were issued for other than a legitimate medical purpose and solely focus on if those prescriptions were distributed outside the usual course of professional practice fails to

conform with that standard. *See Ruan*, 597 U.S. at 454 (citing 21 C.F.R. § 1306.04(a)). Indeed, whether controlled substances were issued for a legitimate medical purpose directly weighs on whether it is more likely than not that prescriptions were unauthorized under the CSA. *See United States v. Haymond*, 588 U.S. 634, 638 (2019) (confirming that preponderance of the evidence for sentencing means a fact is more likely than not).

The Sixth Circuit is using the disjunctive reading to measure authorization to circumvent the preponderance of the evidence standard for sentencing.

B. THE COURT OF APPEALS' DECISION IS INCONSISTENT WITH THIS COURT'S CASE LAW

Every time this Court has had the opportunity it has been clear that Section 1306.04(a)'s regulatory language defining an authorized prescription is ambiguous, written in generalities, susceptible to more precise definition and open to varying constructions. *Ruan*, 597 U.S. at 459. There, the Court found that "[a] strong scienter requirement helps reduce the risk of 'overdeterrence,' i.e., punishing conduct that lies close to, but on the permissible side of, the criminal line." *Id.* A strong scienter requirement means nothing, however, if the conduct that it is applied to is a moving target, vague and incapable of a common definition. And that's exactly what "the usual course of professional practice" has devolved into under the Sixth Circuit's disjunctive reading. See Lubetsky Petition for Certiorari (No. 24-137). On that basis, the disjunctive reading should be set aside for the conjunctive reading of the regulatory language.

Moreover, the conjunctive reading is required under the rule of lenity. That rule requires that the ambiguity in § 1306.04(a)'s regulatory language, as applied to 21 U.S.C. § 841(a)(1), should be construed narrowly in favor of the defendant—that is, the regulatory language should be read in the conjunctive when measuring authorization. S*ee Ladner v. United States*, 358 U.S. 169, 178 (1958). This is doubtless given that the government has extended prosecution under § 841(a)(1) to prescribing that squarely falls within the usual course of professional practice of specific states but nonetheless exceeds the government's heightened prescribing standard. *See Gonzales*, 546 U.S. at 270 (holding that the structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers); *Gonzales*, 545 U.S. at 48 (O'Connor, J., dissenting, joined by Rehnquist, C.J., and Thomas, J.) (holding that the government's authority under the Commerce Clause should not extend to the medical uses of drugs which should be regulated at the state level). This Court, to be sure, has held that statutes should express the legislative intent in enacting them. *See Ladner*, 358 U.S. at 177-78.

That doesn't matter in the Sixth Circuit. Instead, binding case law instructs that the disjunctive reading is appropriate. *Oppong*, LEXIS 9475, at *14-15. No lenity was, or will be shown, absent this Court's intervention.

II. THIS CASE IS AN IDEAL VEHICLE TO RESOLVE AN IMPORTANT ISSUE

This case is profoundly important. Clear notice to physicians of their legal liability for prescribing decisions is vital to this nation. Millions of patients live with chronic

pain,[7] and while there is a dispute as to the appropriateness of long-term chronic opioid therapy, doctors are entitled to know when their conduct is deemed criminal. Yet, the government in crafting its own unenumerated prescribing standard has encroached on the State's authority to regulate the practice of medicine, thereby depriving physicians of notice of what constitutes unauthorized prescribing. *See Gonzales*, 546 U.S. at 270. This has turned the CSA on its head. Rather than state governments setting the rubric for medicine and prescribing and the federal government enforcing the CSA based on that rubric, the federal government has seized the ambiguity in the "usual course of professional practice" and crafted its own restrictive and unenumerated prescribing standard, forcing physicians to heed that standard or face criminal prosecution. See Lubetsky Petition for Certiorari (No. 24-137).

Dr. King, a regular on the government side,[8] is a perfect example of the government's unenumerated prescribing standard. Indeed, he regularly applies his fifteen point "standard of care" in testifying that

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7. 14. S. Michaela Rikard, et al., *Chronic Pain Among Adults—United States, 2019–2021*, CDC, Apr. 14, 2023, https://www.cdc. gov/mmwr/volumes/72/wr/mm7215a1.htm.

8. *United States v. Anderson*, No. 2:19-cr-0067-ALM-1 (S.D. Oh. 2021); *United States v. Petty et al.*, No. 4:20-cr-00290-O-4 (N.D. Tx. 2021); *United States v. Campbell et al.*, No. 3:17-cr-00087-RGJ-1 (W.D. Ky. 2023); *United States v. Bauer*, No. 3:19-cr-00490-JZ-1 (N.D. Oh. 2022); *United States v. Hofschulz et al.*, No. 2:18-cr-00145-PP-1 (E.D. Wi. 2021); *United States v. Spayd*, No. 3:19-cr-00111-SLG-MMS-1 (D. Ak. 2023); *United States v. Kistler*, No. 2:22-cr-00067-ALM-1 (S.D. Oh. 2023); *United States v. Wagoner et al.*, No. 2:17-cv-00478-HAB (N.D. In. 2021).

physicians have departed from prevailing "medical standards." In *United States v. Anderson*, 67 F.4th 755 (6th Cir. 2023), for example, Dr. King used his "fifteen standards of care commonly applied to pain management practices" in evaluating a physician's prescribing. *Id.* at 767. *Anderson* concerned a physician's prescribing in Ohio. *Id.* at 759. Dr. King then applied the same fifteen-point standard in *United States v. Spayd*, No. 23-1303 (9th Cir. 2023), where the appeal is pending before the Ninth Circuit. Appellant Br., Dkt. 18 (Feb. 5, 2024). There, however, it was an advanced nurse practitioner that was prosecuted for her prescribing in Alaska. Whether it's Ohio or Alaska, a physician or nurse practitioner, Dr. King is ready to use his fifteen-point standard of care. *See United States v. Hofschulz*, 105 F.4th 923, 926, 931 (7th Cir. 2024) (Dr. King using his fifteen-point standard to evaluate a nurse practitioner's prescribing in Wisconsin). In this case, Dr. King used his fifteen-point standard to evaluate Petitioner's prescribing in Tennessee. The federal government, through its experts like Dr. King and Dr. Rubenstein, Lubetsky Petition for Certiorari (No. 24-137), has advanced its own heightened and unenumerated prescribing standard unmoored from State-specific prescribing requirements.

The real victims, however, are the patients. Indeed, chronic pain patients have "become collateral casualties in the government's war on drugs."[9] In response, state lawmakers and attorney generals are pushing for change: For the federal government to stop forcing physicians to set aside their role as healer. Shaun Boyd,

9. Jeffrey A. Singer, *The War on Drugs is Also a War on Pain Patients*, Cato Institute, Apr. 1, 2024, https://www.cato.org/blog/war-drugs-also-war-pain-patients.

Colorado Lawmaker Introduces Bill to Provide Easier Access to Opioids for Chronic Pain Sufferers, CBS News, Mar. 3, 2023, https://www.cbsnews.com/colorado/news/lawmaker-introduces-bill-provide-easier-access-opioids-chronic-pain-sufferers/ ("For more than a year, Ginal has worked with doctors, pharmacists, and patient advocates to draft a bill that protects providers who prescribe high-dose opioids from disciplinary action, prevents them from denying treatment based on a prescription, and prohibits them from forcibly tapering a prescription."); Letter of 30 State Attorneys General to Administrator of DEA, 151 Cong. Rec. 6974 (2005).

The government may be well-intentioned in its initiatives to combat an ongoing crisis with the distribution of *illegal* opioids. Nonetheless, controlled substances play a crucial role in treating and managing many patients' pain. These patients and their physicians will continue to suffer at the hands of the government's errant enforcement of the CSA together with the Sixth Circuit's disjunctive reading to measure authorization. The Court's intervention is needed to add balance to what often seem to be competing interests: The need to protect against the illegal use of opioids and the genuine need for access to opioids to treat pain.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

TABLE OF APPENDICES

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APPENDIX A — OPINION AND JUDGMENT OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT, FILED JUNE 5, 2024

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

File Name: 24a0126p.06

No. 23-5394

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

JOHN L. STANTON, M.D.,

Defendant-Appellant.

May 28, 2024, Argued
June 5, 2024, Decided;
June 5, 2024, Filed

Appeal from the United States District Court
for the Eastern District of Kentucky at London.
No. 6:21-cr-00019-4—Robert E. Wier, District Judge.

Before: SUTTON, Chief Judge;
CLAY and BUSH, Circuit Judges.

Appendix A

OPINION

SUTTON, Chief Judge. Dr. John Stanton served as the medical director for a pain clinic in northern Tennessee. The federal government alleged that the clinic operated as a pill mill and charged Dr. Stanton with conspiring to violate federal drug laws. After a seven-day trial, a jury convicted him. On appeal, Dr. Stanton challenges the sufficiency of the evidence to support the jury's verdict and several rulings by the trial court. We affirm.

I.

In 2000, Dr. James Maccarone opened Gateway Medical Associates as a primary care medical practice in Clarksville, Tennessee. After a dozen years in operation, Gateway began to serve more patients seeking treatment for pain management. Over time, Dr. Maccarone came to realize that his clinic had gained a "reputation" as a "pill mill" where patients could "walk in, . . . pay whatever it is that it costs, and . . . walk out with narcotics." R.307 at 190. Patients drove as long as five hours each way to reach the clinic, drove by several other pain management clinics along the way, then waited in the parking lot past midnight to be seen, all while claiming (in many cases) to suffer from back pain. Drug dealers "sponsored" many of these patients so they could obtain prescription narcotics. R.306 at 270.

"[D]rowning in debt" and recognizing that he could charge more than twice as much for a pain visit as he did for primary care, Dr. Maccarone leaned into the

clinic's growing reputation as a "pill mill." R.307 at 218. Disregarding medical standards, Dr. Maccarone prescribed opioids even after patients failed drug tests, and on the rare occasions when he discharged patients for testing positive, he would allow them back into the practice if they paid an extra fee.

In July 2016, Tennessee began requiring pain management clinics to employ medical directors. *See* Tenn. Code § 63-1-306(a). Dr. Maccarone lacked the credentials to qualify for this position. But he knew Dr. Stanton. Stanton practiced orthopedic surgery at the facility next door and had received certification in pain management. Dr. Stanton already served as the medical director for another clinic, and he agreed to serve this role at Gateway as well in return for a salary of $1,500 per week.

As Gateway's medical director, Dr. Stanton oversaw its pain management services and safeguards, including state mandated policies for urine screening and pill counts. Dr. Stanton eventually warned Dr. Maccarone that Gateway's unusual hours, long-distance patient population, and high levels of medication raised "red flags." R.307 at 226, 228. But Dr. Maccarone ignored Dr. Stanton's recommendations to taper off high narcotics doses, and Dr. Stanton continued to sign off on state compliance reports despite his concerns.

When Dr. Maccarone took an emergency medical leave of absence in November 2018, Dr. Stanton assumed responsibility for his patients. Dr. Stanton would see

as many as three dozen patients in a single afternoon. He maintained Dr. Maccarone's practice of prescribing narcotics to patients who failed drug screens. But he did reduce these prescriptions by a standard amount of five or ten pills when patients refused his advice to try injections or physical therapy as alternatives. After Dr. Maccarone returned to the practice, Dr. Stanton continued to see his patients. Between November 2018 and October 2020, Dr. Stanton wrote roughly 5,800 narcotics prescriptions, and Dr. Maccarone wrote about 9,000 prescriptions.

Gateway's prescription practices, together with large numbers of patients "tailgating" in the parking lot for hours, led state and federal investigators to scrutinize the clinic. R.305 at 103. After conducting a warrant-authorized search of Gateway, the government indicted Dr. Stanton, Dr. Maccarone, and two patient sponsors, Jeffrey Ghent and Terry Prince, for conspiring to distribute controlled substances without a legitimate medical purpose. Dr. Maccarone and the sponsors pleaded guilty. Dr. Stanton went to trial.

Over the course of seven days, the jury heard from nineteen government witnesses, including Dr. Maccarone, the sponsors, and several clinic patients, as well as from Dr. Stanton and two other defense witnesses. The government also planned to offer expert testimony that Dr. Stanton's prescription practices lacked a legitimate medical basis. On the second day of trial, it asked the court to substitute a new expert witness, Dr. Timothy King, after it had second thoughts about its existing expert. The trial court held that this late disclosure would prejudice

Dr. Stanton. But the court did allow Dr. King to testify as a rebuttal witness solely in response to Dr. Stanton's own testimony.

The jury found Dr. Stanton guilty of the drug conspiracy charge. At sentencing, the court concluded that the files for 21 patients introduced at trial showed Dr. Stanton had prescribed a converted drug weight of at least 21,524 kilograms. On that basis, the Sentencing Guidelines recommended a minimum sentence of 188 months. The trial court varied downward to 120 months.

II.

On appeal, Dr. Stanton challenges his conviction and sentence in five ways: (1) insufficient evidence to convict him for conspiracy; (2) reversible error in allowing Dr. King to testify on rebuttal; (3) abuse of discretion in instructing the jury on deliberate ignorance; (4) reversible error in responding to the jury's questions about the jury instructions; and (5) insufficient evidence to support the drug weight calculation at sentencing.

Sufficiency of the evidence. In reviewing this challenge, we make all reasonable inferences from the testimony and trial record in favor of the jury verdict. *United States v. Anderson*, 67 F.4th 755, 768 (6th Cir. 2023) (per curiam). We will reverse only if no "trier of fact" could have found that the government proved the elements of this crime beyond a reasonable doubt. *Id.*

To prove its case, the government had to establish that two or more people agreed to violate federal drug laws and that Dr. Stanton knowingly and voluntarily participated in the agreement. *See United States v. Wheat*, 988 F.3d 299, 306 (6th Cir. 2021). The government may establish these elements of the crime through circumstantial evidence, including knowledge of unusual prescribing practices or knowledge of unusual patient protocols. *United States v. Volkman*, 797 F.3d 377, 390 (6th Cir. 2015); *see United States v. Fowler*, 819 F.3d 298, 309 (6th Cir. 2016).

The evidence sufficed to make this finding. The jury heard considerable evidence from Dr. Maccarone and other witnesses that Gateway operated as a pill mill and violated federal law in doing so. The question before the jury thus was not whether a drug conspiracy existed; it was whether Dr. Stanton agreed to join it. Ample evidence showed that Dr. Stanton agreed to join the conspiracy.

Dr. Stanton agreed to help Dr. Maccarone operate Gateway by serving as its medical director. He saw plenty of red flags that Gateway operated as a pill mill and declined to cure them: the long and unusual clinic hours; patients traveling long distances from out of state; high narcotics dosages without individualization or tapering; and continued prescriptions to patients who failed drug screens. *See United States v. Lang*, 717 F. App'x 523, 544 (6th Cir. 2017) (affirming a clinic owner's conviction for drug conspiracy when "it was clear to even casual observers that [the clinic] was a pill mill").

Even after seeing these red flags, he continued to sign off on compliance reports, and he continued to see the high-dosage patients whose prescriptions Dr. Maccarone refused to lower.

The jury also could have found that Dr. Stanton's prescriptions furthered the conspiracy. He spent only a few minutes with each of his own patients before signing off on pre-printed prescriptions. His medical assistant testified that neither doctor used the clinic's electronic medical records, and a pharmacy expert testified that Dr. Stanton's prescriptions lacked the dosage individualization of legitimate pain management practices. Even after Dr. Maccarone returned to Gateway, Dr. Stanton continued to see patients and wrote almost 40% of Gateway's prescriptions between November 2018 and October 2020.

The jury also could have found that Dr. Stanton's unconvincing efforts to clear his name with investigators amounted to an effort to cover up his participation in the drug conspiracy. Dr. Stanton, for instance, told an investigator from the Drug Enforcement Agency that Gateway discharged patients who tested positive for heroin and cocaine, even though Gateway's records showed otherwise. *Cf. United States v. Gardiner*, 463 F.3d 445, 462-63 (6th Cir. 2006) (distinguishing acts of concealment that further an ongoing conspiracy from those that cover up previous crimes).

Dr. Stanton replies that the government failed to prove that he wrote any prescriptions at Gateway without proper medical authorization. But that proof would have mattered only if the government had charged Dr. Stanton with distributing controlled substances under 21 U.S.C. § 841(a). *See Ruan v. United States*, 597 U.S. 450, 457, 142 S. Ct. 2370, 213 L. Ed. 2d 706 (2022). It did not. It instead charged him with conspiring to distribute drugs, 21 U.S.C. § 846, a crime that targets the agreement to commit the unlawful act and a crime that does not turn on whether any one conspirator completed the underlying substantive crime. *Wheat*, 988 F.3d at 306. The government proved its case by showing that Dr. Stanton knowingly agreed to help Gateway and Dr. Maccarone illegally distribute controlled substances.

Dr. Stanton points out that the jury heard evidence that he never knowingly agreed with any other conspirator to dispense narcotics. For instance: Dr. Maccarone testified that he never spoke with Dr. Stanton about operating Gateway as a pill mill; Ghent testified that Dr. Stanton evaluated his shoulder and recommended surgery before prescribing narcotics; and Prince testified he never spoke with Dr. Stanton at all. But the jury could reasonably credit Dr. Maccarone's testimony that he hired Dr. Stanton with the "mutual understanding of what [Dr. Maccarone] was doing and of what [Dr. Stanton] was doing." R.307 at 247. It could view Dr. Stanton's examination of Ghent as pretextual and, even if not, as one that still involved a pre-printed prescription, as with many other patients.

And it makes no difference that he did not speak to *one* of the sponsors. Once the jury heard testimony from Dr. Maccarone and other witnesses defining the scope of the conspiracy and providing circumstantial evidence of the conspiracy, it needed only to find a connection between that crime and Dr. Stanton as well as an agreement to join the conspiracy. Ample evidence supported the jury's finding on this score. *See United States v. Sadler*, 24 F.4th 515, 542 (6th Cir. 2022).

Dr. Stanton insists that the government may not bootstrap his regulatory violations as Gateway's medical director into criminal liability. But the government did not charge Dr. Stanton with conspiracy to violate Tennessee's clinical guidance. It charged him with conspiring to violate federal drug laws. Because the government may use circumstantial evidence to support that charge, it was fair game to introduce evidence that Dr. Stanton failed to follow Tennessee's regulatory requirements, as this evidence supported the theory that he knowingly joined an illegal scheme. *See United States v. Bauer*, 82 F.4th 522, 529 (6th Cir. 2023) (inferring knowledge of illegal prescriptions from evidence that provider practices violated clinic policies and exceeded state and federal dosage guidance); *cf. United States v. Brown*, 553 F.3d 768, 791 (5th Cir. 2008) (acknowledging "the irreproachable, commonplace use of duly issued regulations in clarifying the scope and contour of criminal laws" against drug conspiracy). The government, moreover, informed Dr. Stanton that it would reference these Tennessee rules

prior to trial, and he never objected to this evidence when prompted by the court. Nor did Dr. Stanton object at trial when a Tennessee official testified about these rules, or when the government introduced copies of the regulations seized from Gateway. Sufficient evidence, all in all, supported the conviction.

Expert testimony. Dr. Stanton separately challenges the district court's decision to permit Dr. King to testify as an expert witness on rebuttal. Abuse-of-discretion review applies to a trial court's "control [over] the scope of rebuttal testimony." *Geders v. United States*, 425 U.S. 80, 86, 96 S. Ct. 1330, 47 L. Ed. 2d 592 (1976).

A party may offer rebuttal testimony to counter evidence offered by the defense. And that is true even when the party, the government in this instance, could have anticipated the defense and offered the same evidence as part of its case in chief. *Toth v. Grand Trunk R.R.*, 306 F.3d 335, 345 (6th Cir. 2002); *Martin v. Weaver*, 666 F.2d 1013, 1020 (6th Cir. 1981).

The court did not abuse its discretion in handling Dr. King's rebuttal testimony. After Dr. Stanton testified that he had used his best medical judgment in working at Gateway, the government called Dr. King to evaluate that testimony. Dr. King explained that it fell "outside the standard of care" to schedule as many patients in as short of a time as Dr. Stanton did, to continue to prescribe narcotics to patients who failed drug screens, and to

treat another doctor's patients without "an independent medical evaluation." R.309 at 288-91. In each instance, this testimony rebutted Dr. Stanton's testimony about the relevant medical standards, and in each instance it impeached his credibility on these fronts. *See United States v. Hofstetter*, 31 F.4th 396, 428 (6th Cir. 2022), *vacated on other grounds by* 143 S. Ct. 351, 214 L. Ed. 2d 168 (2022). Although Dr. Stanton's evidence was not "new" in the sense that the government understood Dr. Stanton likely would raise this defense, Dr. King's testimony qualifies as fair-game rebuttal evidence because it challenged defenses that entered the trial through Dr. Stanton's testimony. *See Benedict v. United States*, 822 F.2d 1426, 1428-30 (6th Cir. 1987).

Dr. Stanton replies that Dr. King's rebuttal testimony unfairly surprised him after the government withdrew its original expert. But Dr. King did not come out of nowhere. The government identified him as a potential expert witness when the original expert could not testify. Nor did Dr. Stanton request a continuance in the face of this late disclosure. The government, at any rate, did not have an obligation to anticipate how Dr. Stanton would defend himself when it crafted its own case in chief. *Hofstetter*, 31 F.4th at 428. In response to that testimony, Judge Weir carefully cabined Dr. King's testimony to ensure that it responded only to Dr. Stanton's own testimony. No abuse of discretion occurred.

Jury instruction. Dr. Stanton challenges the district court's deliberate-ignorance instruction. We review the instruction for an abuse of discretion and will reverse only if the instructions as a whole prove confusing, misleading, or prejudicial. *United States v. Frei*, 995 F.3d 561, 565 (6th Cir. 2021).

A deliberate-ignorance instruction prevents a defendant from avoiding the consequences of his actions by closing his eyes to the obvious. *United States v. Mitchell*, 681 F.3d 867, 876 (6th Cir. 2012); *United States v. Geisen*, 612 F.3d 471, 485-86 (6th Cir. 2010). In pill-mill conspiracies, the instruction prevents clinic owners and providers from claiming a lack of knowledge of illegal operations despite awareness of serial red flags. *See, e.g.*, *United States v. Ashrafkhan*, 821 F. App'x 428, 435 (6th Cir. 2020); *United States v. Gowder*, 841 F. App'x 770, 783 (6th Cir. 2020); *United States v. Leman*, 574 F. App'x 699, 705-06 (6th Cir. 2014). To prevent juries from confusing the high standard of willful blindness with mere "negligence, carelessness[,] or ignorance," trial courts should provide this instruction only when the record could support this inference and the defendant claims a lack of knowledge. *Mitchell*, 681 F.3d at 876.

The court's instruction fits that standard. The jury heard copious evidence suggesting that Dr. Stanton knew about Gateway's unusual patient population, Dr. Maccarone's lack of concern about drug testing, and other telltale signs of a pill mill. To all of this, Dr. Stanton claimed a lack of knowledge about any criminal conduct

at Gateway. The jury could permissibly find from that evidence that Dr. Stanton deliberately avoided learning of Gateway's illicit practices. *Cf. Leman*, 574 F. App'x at 706 (observing that evidence of a "large percentage of patients . . . [who] drove for hours in large groups" and received "very high dosages of narcotics" supported giving deliberate ignorance instruction).

Dr. Stanton replies that the instruction fails to follow *Ruan*, which held that the government must prove that a doctor knowingly acted outside the authorized practice of medicine to violate 21 U.S.C. § 841(a). 597 U.S. at 459-60. But *Ruan* does not prevent the government from proving knowledge "through circumstantial evidence." *Id.* at 467. A deliberate ignorance instruction satisfies *Ruan* when, as here, it reminds the jury that this standard sits well above carelessness, negligence, and mistake. *Anderson*, 67 F.4th at 766; *see also United States v. Hofstetter*, 80 F.4th 725, 731 (6th Cir. 2023). Nor did the court impermissibly allow the jury to use deliberate ignorance to infer Dr. Stanton's intent to join the conspiracy. *See United States v. Matthews*, 31 F.4th 436, 450 (6th Cir. 2022). It instead instructed the jury that it could infer Dr. Stanton's knowledge of the conspiracy's aims based on what he did, how he acted, the natural results of his conduct, and other circumstantial evidence.

Jury questions. Dr. Stanton argues that the trial court erred in its response to the jury's questions during deliberations. But the government, Dr. Stanton, and the

court all agreed to do what the court did: refer the jury to the instructions as already given. Dr. Stanton's counsel informed the court that the supplemental instructions appeared "fine" to him. R.310 at 123. That agreement to the form of the instruction waives our review of this issue. *See United States v. Daneshvar*, 925 F.3d 766, 786-87 (6th Cir. 2019).

Even if we reviewed the supplemental instruction for plain error, as Dr. Stanton requests, no such mistake occurred in referring the jury to legally correct statements of the law. *See United States v. Combs*, 33 F.3d 667, 670 (6th Cir. 1994). The existing conspiracy instruction, which followed the contours of the Sixth Circuit Pattern Jury Instructions, fully covered the legal questions the jury raised. *See United States v. Hines*, 398 F.3d 713, 718-19 (6th Cir. 2005) (affirming jury instructions that "essentially tracked the language and organization of the Sixth Circuit Pattern Jury Instruction regarding conspiracy"). Dr. Stanton replies that the jury expressed confusion about the elements of conspiracy, but the supplemental instruction clarified that the jury must find "both" previously listed elements satisfied. R.239 at 8.

Sentencing. Dr. Stanton argues that the government failed to prove the converted drug weight used to sentence him by a preponderance of the evidence. The sentencing guideline for a criminal drug conspiracy instructs the trial court to calculate a base offense level based on the "converted drug weight" of the illegal prescriptions. *See*

U.S.S.G. § 2D1.1(a)(5), (c). The calculation may include illegal prescriptions that the defendant personally wrote as well as those attributable to his role in "jointly undertaken criminal activity," *id.* § 1B1.3(a)(1)(B), including the prescriptions Dr. Maccarone wrote as a reasonably foreseeable result of Dr. Stanton's participation in the conspiracy, *see United States v. Sadler*, 750 F.3d 585, 594 (6th Cir. 2014). The court should "show its work" to explain why a preponderance of the evidence supports that reasonable and conservative estimate of the amount of drugs involved. *United States v. Woodside*, 895 F.3d 894, 900-02 (6th Cir. 2018).

The trial court did just that in finding that Dr. Stanton illegally prescribed narcotics to these 21 patients. It recognized that the government had introduced evidence of numerous irregularities in the patient files, including failed drug tests and pill counts, brief patient visits, and standardized dosages. Evidence at trial, including Dr. Maccarone's testimony, explained that these and other activities violated Gateway's own written policies, Tennessee's state regulations, and standard medical practices.

In the alternative, the court reasoned that the identified prescriptions conservatively and reasonably accounted for the total number of prescriptions that Dr. Stanton enabled at Gateway. The court explained that Gateway's "whole operation is highly tainted" and that the 21 patients surely undercounted the total amount

of illicit prescriptions at Gateway. R.358 at 216. It recognized that Dr. Maccarone could not have operated Gateway "without Dr. Stanton's blessing" as medical director, and it attributed Dr. Maccarone's prescriptions to Dr. Stanton. *Id.* at 221. The court properly reasoned that these 21 patients represented only about 4% of the clinic's clientele, 6% of its long-distance travelers, and an unknown number of sponsored patients. The evidence at trial further showed that Dr. Stanton personally wrote about 40% of Gateway's prescriptions in the two years following Dr. Maccarone's medical absence. One way or another, no abuse of discretion occurred. *Cf. Woodside*, 895 F.3d at 901-03.

Dr. Stanton objects that the government did not introduce expert testimony that the prescriptions for these 21 patients were improper and thus could not prove that he knew that he wrote these prescriptions outside the authorized practice of medicine. Although expert testimony would have been useful, the trial record presents a far cry from the situation that Dr. Stanton posits, in which the government fails to introduce any evidence, expert or otherwise, to show that a physician's careful treatment of patients violated accepted medical standards. On this record, the district court could readily find that Dr. Stanton knowingly turned a blind eye to the many red flags surrounding his and Dr. Maccarone's drug-prescription habits and should be sentenced accordingly.

We affirm.

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 23-5394

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

JOHN L. STANTON, M.D.,

Defendant-Appellant.

Before: SUTTON, Chief Judge; CLAY and BUSH, Circuit Judges.

JUDGMENT

On Appeal from the United States District Court
for the Eastern District of Kentucky at London.

THIS CAUSE was heard on the record from the district court and was argued by counsel.

IN CONSIDERATION THEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTERED BY ORDER OF THE COURT

/s/_____
Kelly L. Stephens, Clerk

APPENDIX B — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF KENTUCKY, SOUTHERN DIVISION AT LONDON, FILED APRIL 18, 2023

UNITED STATES DISTRICT COURT
Eastern District of Kentucky –
Southern Division at London

Case Number:
6:2 l-CR-019-S-REW-04

USM Number:
57572-509

UNITED STATES OF AMERICA

v.

JOHN L. STANTON

JUDGMENT IN A CRIMINAL CASE

THE DEFENDANT:

☐ pleaded guilty to count(s) _____

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☒ was found guilty on count(s) 1 of the Superseding Indictment [DE #74] after a plea of not guilty.

Appendix B

The defendant is adjudicated guilty of these offenses:

Title & Section	**Nature of Offense**	**Offense Ended**	**Count**
21:846	Conspiracy to Distribute Controlled Substances, to include Oxycodone, Oxymorphone, and Methadone, Schedule II Controlled Substances, and certain Benzodiazepines, Including Alprazolam, Schedule IV Controlled Substances	March 2021	1

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s) _____

☐ Count(s) _____ ☐ is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments

imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

April 17, 2023
Date of Imposition of Judgment

/s/ RW
Signature of Judge

Honorable Robert E. Wier, U.S. District Judge
Name and Title of Judge

4.18.2023
Date

Appendix B

DEFENDANT: John L. Stanton
CASE NUMBER: 6:21-CR-019-S-REW-04

IMPRISONMENT

The defendant is hereby committed to the custody of the Bureau of Prisons to be imprisoned for a total term of:

ONE HUNDRED TWENTY (120) MONTHS

The Court intends for defendant to receive credit toward his federal sentence for all time he spent in custody related to this case, if consistent with § 3585.

☒ The court makes the following recommendations to the Bureau of Prisons:

That defendant receive a full medical assessment and screening that specifically addresses his need for a knee replacement surgery, and that he be given access to any and all necessary treatment.

That defendant be designated to the camp at McCreary or at Manchester, Kentucky. If the defendant docs not qualify for either facility, it is recommended that he be designated to the facility otherwise closest to his home in Clarksville, Tennessee.

☒ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at ____ ☐a.m. ☐ p.m. on _____

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____ at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

Appendix B

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of:

THREE (3) YEARS

STATUTORILY MANDATED CONDITIONS

1. You must not commit another federal, state or local crime.

2. You must not unlawfully possess or use a controlled substance.

3. You must submit to a drug test within 15 days of supervision commencement. USPO shall subsequently test Defendant at least twice thereafter and may test Defendant as frequently as ***monthly/weekly/biweekly*** during the supervision term. USPO may seek Court permission for more frequent testing, if warranted. USPO may re-test if any test sample is invalid.

   ☒ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(Check, if applicable.*

4. ☐ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(Check, if applicable.)*

5. ☒ You must cooperate in the collection of DNA as directed by the probation officer. *(Check, if applicable.)*

6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq.)* as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(Check, if applicable.)*

7. ☐ You must participate in an approved program for domestic violence. *(Check, if applicable.)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached pages. The Court has considered § 3583(d)(1)-(3) in formulating all additional conditions.

Appendix B

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment unless the probation officer instructs you to report to a different probation office or within a different time frame.

2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.

3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.

4. You must answer truthfully the questions asked by your probation officer.

5. You must live at a place approved by the probation officer. If you plan to change where you live or

anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.

6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.

7. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.

8. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.

9. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).

10. You must not act or make any agreement with a law enforcement agency to act as a confidential

human source or informant without first getting the permission of the court.

11. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.

12. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions,* available at: www.uscourts.gov.

Defendant's Signature _____

Date _____

Appendix B

SPECIAL CONDITIONS OF SUPERVISION

1. Should the defendant seek a DEA registration license to prescribe controlled substances, he shall first give notice to the probation office.

2. Should the defendant intend to work in any capacity in a medical setting that prescribes controlled substances, he shall first notify the probation office.

Appendix B

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	**Restitution**	**Fine**	**AVAA Assessment***	**JVTA Assessment****
TOTALS	$100.00	$Community Waived	$100,000.00	$ N/A	$ N/A

☐ The determination of restitution is deferred until after such determination. An *Amended Judgment in a Criminal Case (A0245C)* will be entered after such detetmination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

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* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Pub. L. No. 115-299.

** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.

Appendix B

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage

TOTALS $ _____ $ _____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

Appendix B

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☒ Lump sum payment of $100,100.00 due immediately, balance due

- ☐ not later than _____, or
- ☒ in accordance with ☐ C, ☐ D, ☐ E, or ☒ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g. weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years),* to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g. weekly, monthly, quarterly)* installments of $ _____ over a period of *(e.g. months or years),* to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☒ Special instructions regarding the payment of criminal monetary penalties:

Criminal monetary penalties are payable to:
Clerk, U. S. District Court, Eastern District of Kentucky
310 S. Main Street, Room 215,
London, KY 40741

INCLUDE CASE NUMBER WITH ALL CORRESPONDENCE

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number
Defendant and Co-Defendant Names

(including defendant number)	Total Amount	Joint and Several Amount	Corresponding Payee, if appropriate

Appendix B

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☒ The defendant shall forfeit the defendant's interest in the following property to the United States:
The defendant's Tennessee medical license [DE #253] and a money judgment of $318,300 is now final [DE #273].

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) AVAA assessment, (5) fine principal, (6) fine interest, (7) community restitution, (8) JVT A assessment, (9) penalties, and (10) costs, including cost of prosecution and court costs.

APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT, FILED AUGUST 8, 2024

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 23-5394

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

v.

JOHN L. STANTON, M.D.,

Defendant-Appellant.

ORDER

BEFORE: SUTTON, Chief Judge; CLAY and BUSH, Circuit Judges.

The court received a petition for rehearing en banc. The original panel has reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. The petition then was circulated to the full court. No judge has requested a vote on the suggestion for rehearing en banc.

Therefore, the petition is denied.

Appendix C

ENTERED BY ORDER OF THE COURT

/s/ Kelly L. Stephens, Clerk
Kelly L. Stephens, Clerk