# In the Supreme Court of the United States

SAAD SAKKAL, PETITIONER

v.

UNITED STATES OF AMERICA

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

### BRIEF FOR THE UNITED STATES IN OPPOSITION

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## **QUESTION PRESENTED**

Whether the court of appeals was required to vacate petitioner's convictions for unlawful drug distribution under 21 U.S.C. 841(a) following a remand from this Court based on a theory—never raised by petitioner and not reflected in his own proposed jury instructions—that jury instructions relating to his "authoriz[ation]" to distribute drugs, *ibid.*, erred by incorporating the language in 21 C.F.R. 1306.04(a) that defines the scope of that authorization.

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## In the Supreme Court of the United States

No. 23-130 Saad Sakkal, petitioner

2)

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#### BRIEF FOR THE UNITED STATES IN OPPOSITION

#### **OPINIONS BELOW**

The opinion of the court of appeals (Pet. App. 1a-19a) is unreported but is available at 2023 WL 3736778. A previous order of this Court (Pet. App. 20a) is reported at 143 S. Ct. 298. A previous opinion of the court of appeals (Pet. App. 21a-33a) is unreported but is available at 2022 WL 557520.

#### JURISDICTION

The judgment of the court of appeals was entered on May 31, 2023. The petition for a writ of certiorari was filed on August 7, 2023. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

#### **STATEMENT**

Following a jury trial in the United States District Court for the Southern District of Ohio, petitioner was convicted on 30 counts of unlawfully distributing a controlled substance, in violation of 21 U.S.C. 841(a)(1); one count of distributing a controlled substance resulting in death, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); and six counts of using the registration number of another person to dispense a controlled substance, in violation of 21 U.S.C. 843(a)(2) and (d)(1). Judgment 1-2. The district court sentenced petitioner to 240 months of imprisonment, to be followed by three years of supervised release. Judgment 3-4. The court of appeals affirmed. Pet. App. 21a-33a. This Court granted a petition for a writ of certiorari, vacated, and remanded. *Id.* at 20a. On remand, the court of appeals affirmed. *Id.* at 1a-19a.

1. Section 841(a) of Title 21, which is part of the Controlled Substances Act (CSA or Act), 21 U.S.C. 801 *et seq.*, prohibits the knowing or intentional distribution of controlled substances "[e]xcept as authorized by" the Act. The CSA's exceptions to the prohibition against drug distribution include an exception for physicians who are "registered by" the Drug Enforcement Administration (DEA) and who prescribe controlled substances—but the exception applies only "to the extent authorized by their registration and in conformity with the other provisions" of the Act. 21 U.S.C. 822(b); see 21 U.S.C. 823(b) and (f). And controlled substances generally may be dispensed only pursuant to a "written prescription of a practitioner." 21 U.S.C. 829(a).

A federal regulation, 21 C.F.R. 1306.04(a), limits the scope of the authorization by specifying that 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." Section 1306.04(a) specifies that "[a]n order purporting to be a prescription issued not in

the usual course of professional treatment" is deemed "not a prescription," and the "person issuing it[] shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Ibid.* And in *United States* v. *Moore*, 423 U.S. 122 (1975), this Court "h[e]ld that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *Id.* at 124.

2. Petitioner was a DEA-registered physician who practiced medicine at Lindenwald Medical Association. Pet. App. 3a. The DEA began to investigate petitioner after a referral from the Ohio Medical Board, which had received several complaints from pharmacists about petitioner's issuance of problematic prescriptions. *Ibid.* Petitioner prescribed high amounts of controlled substances; dangerous combinations of controlled substances; and multiple substances that served the same purpose as one another (known as "therapeutic duplication"), which risked "respiratory sedation and death." *Ibid.* Petitioner also ignored warning signs about the dangers of his prescribing practices, such as drug screens showing that his patients were taking unprescribed controlled substances or not taking their prescriptions. Id. at 4a. And he failed to use the Ohio Automated Rx Reporting System to monitor whether his patients were receiving controlled substances prescriptions from other doctors. *Ibid*.

Petitioner prescribed one of his patients, Ashley Adkins, 17 medications after seeing her for the first time and "conduct[ing] an examination in 'medical student type fashion.'" Pet. App. 24a. A month later, Lindenwald received an anonymous call reporting "that Adkins was abusing her medications and looking to sell or trade them." *Id.* at 25a. That same day, petitioner saw Adkins

again; her medical record noted that "[s]he appears to be under the influence of either drugs or alcohol" and that "[h]er speech is very slurred, her balance is off." *Ibid.* Despite those signs, petitioner prescribed Adkins benzodiazepine and oxycodone—a dangerous combination of drugs. *Ibid.*; see *id.* at 3a. Adkins immediately filled the prescriptions; she died the next day as a result of "benzodiazepine and oxycodone toxicity." *Id.* at 25a.

At one point, several pharmacies called Lindenwald to discuss their concerns about petitioner's prescribing practices. Pet. App. 4a. Petitioner met with at least three pharmacies to discuss their concerns, but he did not change his practices. *Id.* at 4a-5a. Some pharmacies stopped filling petitioner's controlled substances prescriptions. *Id.* at 5a.

3. In 2018, a federal grand jury returned an indictment charging petitioner with 30 counts of unlawfully distributing a controlled substance, in violation of 21 U.S.C. 841(a)(1); two counts of distributing a controlled substance resulting in death, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); and seven counts of using the registration number of another person to dispense a controlled substance, in violation of 21 U.S.C. 843(a)(2) and (d)(1). Indictment 10-14; see Judgment 1-2.

At the close of trial, petitioner proposed jury instructions that incorporated the regulatory language in Section 1306.04(a) as the touchstone for Section 841(a) liability. See D. Ct. Doc. 42 (Mar. 29, 2019). Petitioner represented to the district court that, "[t]o convict a practitioner under [Section] 841(a), the government must prove \*\*\* [t]hat the distribution of th[e] controlled substances was outside the usual course of professional practice and without a legitimate medical purpose." *Id.* at 5; see *id.* at 1, 3, 6, 11. Petitioner also

asked to instruct the jury that Section 841(a) requires the government to prove that a physician "acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice" and that a physician does not violate Section 841 if he prescribed the substances in "good faith"—that is, "in accordance with what the physician should reasonably believe to be a proper medical practice." *Id.* at 5-6. Petitioner additionally requested a deliberate indifference instruction. *Id.* at 10-11.

The district court rejected petitioner's proposed subjective-intent instruction but did issue an instruction incorporating the regulatory standard. See Pet. App. 5a-7a. The court instructed the jury that:

In order to find the defendant guilty of a violation of 21 U.S.C. 841(a)(1), the government must prove beyond a reasonable doubt each of the following elements:

- (1) The defendant distributed or dispensed a controlled substance as alleged in these counts of the Indictment;
- (2) The defendant acted knowingly and intentionally in distributing that controlled substance; and
- (3) The defendant's act was not for a legitimate medical purpose in the usual course of his professional practice.

*Id.* at 6a (brackets omitted). The court also instructed the jury using petitioner's good-faith and deliberate-indifference instructions. See *id.* at 5a-7a. As to deliberate indifference, the court told the jury that:

[t]he term "knowingly" means that the act was done voluntarily and intentionally and not because of a mistake or accident. Although knowledge of the defendant cannot be established merely by demonstrating that 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 substances alleged in these counts were distributed or dispensed outside the course of professional practice and not for a legitimate medical purpose, then you may find that the defendant knew 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 outside the course of professional practice and not for a legitimate medical purpose, 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 any of these counts.

Id. at 7a. Petitioner raised a single objection to the relevant instructions—and the court credited that objection and accordingly modified its instructions before giving them—but otherwise did not object to the court's mens rea instructions. Id. at 6a.

The jury found petitioner guilty of all 30 counts of unlawfully distributing a controlled substance; one count of distributing a controlled substance resulting in death; and six counts of using another person's registration number to dispense a controlled substance. Judgment 1-2. The district court sentenced petitioner to 240 months of imprisonment, to be followed by three years of supervised release. Judgment 3-4.

4. The court of appeals affirmed. Pet. App. 21a-33a. In doing so, the court declined to consider a claim that petitioner's counsel had provided ineffective assistance by failing to object to the jury instructions on mens rea, explaining that the "court generally does not entertain ineffective-assistance-of-counsel claims on direct appeal because there has not been an opportunity to develop an adequate record to evaluate the merits of the allegations." *Id.* at 30a; see *id.* at 30a n.2.

Before petitioner's time to file a petition for a writ of certiorari expired, this Court decided Ruan v. United States, 597 U.S. 450 (2022). In Ruan, this Court held that the "knowingly or intentionally' mens rea" in Section 841(a) "applies to the [statute's] 'except as authorized' clause," such that, "once a defendant meets the burden of producing evidence that his or her conduct was 'authorized,' the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." Id. at 457 (citation omitted). The Court reasoned, inter alia, that "a lack of authorization is often what separates wrongfulness from innocence." Id. at 458. "In addition," the Court noted, 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," and a "strong scienter requirement helps to diminish the risk of 'overdeterrence'" of medical practitioners. Id. at 459 (brackets and citations omitted).

This Court granted petitioner's petition for a writ of certiorari, vacated, and remanded for further consideration in light of *Ruan*. Pet. App. 20a.

5. On remand, the court of appeals affirmed. Pet. App. 1a-19a. Applying plain error review, see id. at 10a-11a, the court rejected petitioner's claim that "the district court's scienter instruction [did not] compl[y] with the holding of Ruan," id. at 10a; see id. at 14a-19a.

Petitioner argued that the district court's jury instructions were erroneous because they specifically tied the "knowingly or intentionally" mens rea to the act of dispensing, but not to the requirement that a prescription be "not for a legitimate medical purpose in the usual course of his professional practice." Pet. App. 7a; see *id.* at 14a-15a. The court of appeals found that its recent decision in *United States* v. *Anderson*, 67 F.4th 755 (6th Cir. 2023), petition for cert. pending, No. 23-238 (filed Sept. 5, 2023), "forecloses this negative implication argument" because, as in *Anderson*, the district court had further elaborated on the mens rea requirement through a deliberate ignorance instruction. Pet. App. 15a.

As in *Anderson*, the court of appeals here observed that the "'more detailed instructions'" provided to the jury went "beyond an objective view of the 'usual course of professional practice' and instead directed the jury's attention to [petitioner's] subjective mindset in issuing the prescriptions." Pet. App. 17a, 19a (citation omitted). The court therefore found that the instruction for deliberate ignorance that petitioner received "ensured that the instructions comported with *Ruan's* holding." *Id.* at 19a (citing *Anderson*, 67 F.4th at 766). And it accordingly saw no basis for plain-error relief. *Ibid*.

#### **ARGUMENT**

Relying on the most recent petition for a writ of certiorari in Ruan v. United States, cert. denied, No. 22-1175 (2023), petitioner now contends (Pet. 12-13) that the jury instructions at his trial erred by using language from Section 1306.04(a) as the measure of whether his drug-prescribing practices were "authorized" under the CSA. 21 U.S.C. 841(a). That is a new argument that petitioner never raised before. See Pet. C.A. Supp. Br. 15-20; Pet. C.A. Supp. Reply Br. 6-11. Indeed, in the court of appeals petitioner asserted the opposite of what he now argues in this Court. See Pet. C.A. Supp. Reply Br. 6 n.3 ("Whether or not a physician is 'authorized' to prescribe controlled substances under Section 841(a) is governed by 21 C.F.R. § 1306.04(a), which defines an 'authorized' prescription as one that is 'issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."); see also Pet. C.A. Supp. Br. 2-3.

This Court recently denied the second petition for a writ of certiorari in *Ruan*, see *Ruan*, supra (No. 22-1175), on which the petition here relies for the substance of its argument. For the reasons explained in the government's brief in opposition to the petition in *Ruan*, a copy of which is being served on petitioner, petitioner's new, cross-referenced claim lacks merit and does not warrant further review. See Br. in Opp. at 12-22, *Ruan*, supra (No. 22-1175). As with the same claim in *Ruan*, petitioner's new argument was never passed upon below. See *id*. at 12-14. Petitioner's claim is also foreclosed by precedent and rests on a misapprehension of the CSA and this Court's decision in *Ruan*. See *id*. at 14-19. And petitioner has not identified any circuit

conflict that would warrant review by this Court. See id. at 19-22.

## CONCLUSION

The petition for a writ of certiorari should be denied. Respectfully submitted.

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