No. 25-7141

IN THE SUPREME COURT OF THE UNITED STATES

THOMAS KELLER, PETITIONER

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

D. JOHN SAUER
Solicitor General
Counsel of Record

A. TYSEN DUVA
Assistant Attorney General

TORY D. ROBERTS
Attorney

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether the delegation of authority in the Controlled Substances Act to the Attorney General to issue regulations under 21 U.S.C. 821 and 871(b), which the Attorney General has exercised in 21 C.F.R. 1306.04(a) using language that Congress then included in the Act, violates the nondelegation doctrine.

ADDITIONAL RELATED PROCEEDINGS

United States Court of Appeals (9th Cir.):

United States v. Keller, No. 23-656 (June 27, 2025)

United States District Court (N.D. Cal.):

United States v. Keller, No. 18-cr-462 (Apr. 10, 2023)

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-38a) is reported at 142 F.4th 645.

JURISDICTION

The judgment of the court of appeals was entered on June 27, 2025. A petition for rehearing was denied on November 5, 2025 (Pet. App. 39a). On February 3, 2026, Justice Kagan extended the time within which to file a petition for a writ of certiorari to and including March 20, 2026, and the petition was filed on that date. 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 Northern District of California, petitioner was convicted of unlawfully distributing oxycodone, carisoprodol, and diazepam, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); unlawfully distributing diazepam, in violation of 21 U.S.C. 841(a)(1) and (b)(2); unlawfully distributing oxycodone, in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C); and unlawfully distributing carisoprodol, in violation of 21 U.S.C. 841(a)(1) and (b)(2). Judgment 1. He was sentenced to 30 months of imprisonment, to be followed by three years of supervised release. Judgment 2-3. The court of appeals affirmed. Pet. App. 1a-38a.

1. Beginning in 2011, petitioner worked as a solo practitioner physician specializing in pain management. Pet. App. 5a. Petitioner possessed a license from the Drug Enforcement Administration (DEA) allowing him to prescribe controlled substances pursuant to 21 U.S.C. 829(a) and (b). Ibid. Between 2011 and 2018, petitioner was in the 99th percentile of pain specialists in terms of the quantity of opioids he was prescribing per patient per day. Pet. App. 5a. Petitioner's prescription practices eventually caused one pharmacy to refuse to fill prescriptions written by him and caused another doctor to report him to the state medical board. Id. at 5a-6a.

In March 2013, Keller began to treat A.M. for low back pain. Pet. App. 6a. Although A.M. presented no physical issues that justified prescribing her large amounts of opiates, petitioner nevertheless prescribed many. Ibid. In December 2013, A.M. attempted suicide. Ibid. Petitioner briefly stopped his treatment of A.M. but ultimately resumed treatment and, contrary to accepted professional practice, continued to prescribe A.M. opiates and other controlled substances. Ibid. Over the next four years, petitioner prescribed A.M. thousands of pills of oxycodone, OxyContin, carisoprodol, and diazepam. Ibid. In 2017, A.M. committed suicide by overdosing on prescription drugs, including multiple drugs that petitioner had prescribed. Ibid.

2. A grand jury in the Northern District of California charged petitioner with ten counts of unlawfully distributing controlled substances, in violation of 21 U.S.C. 841(a)(1), (b)(1)(C), and (b)(2), and one count of healthcare fraud, in violation of 18 U.S.C. 1347. Superseding Indictment 1-6.

The Controlled Substances Act (CSA or Act) criminalizes the unauthorized distribution and dispensation of controlled substances, "[e]xcept as authorized by this subchapter." 21 U.S.C. 841. The Act's exceptions to the prohibition against drug distribution include an exception for physicians who are "registered by" the DEA and who prescribe controlled substances 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(f). The Act accordingly authorizes the Attorney General, who oversees the DEA, to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. 821; see 21 U.S.C. 871(b).

In 1971, the Attorney General promulgated a regulation specifying that every prescription for a controlled substance "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). Congress then adopted similar language in the Act itself. For example, for purposes of dispensing controlled substances over the internet, 21 U.S.C. 829 defines a "'valid prescription'" as "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by" a qualifying practitioner. 21 U.S.C. 829(e)(2)(A); see, e.g., 21 U.S.C. 830(b)(3)(A)(ii) (similar definition of "valid prescription" applicable to certain reporting requirements for mail-order prescriptions).

Before trial, petitioner moved to dismiss the distribution counts, contending inter alia that to the extent his conviction depended on the language included in 21 C.F.R. 1306.04(a), it rested on an unconstitutional delegation of Congress's legislative authority to the Attorney General "without giving sufficient guidance to confine the discretion of the Attorney General in defining to what standard physicians should be held when determining whether their prescribing conduct is illegal." D. Ct. Doc. 148, at 4 (Oct. 12, 2021). The district court denied petitioner's motion and the case proceeded to trial. D. Ct. Doc. 242 (Nov. 5, 2021).

The jury found petitioner guilty on four counts related to the distribution of oxycodone, carisoprodol, and diazepam to A.M. on four occasions in 2016 and 2017. Judgment 1; see Superseding Indictment 2-5. The jury did not reach a verdict on the remaining distribution counts, which the government then dismissed, and the district court granted petitioner's motion for a judgment of acquittal on the healthcare-fraud count. Pet. App. 8a; see Judgment 1. The court sentenced petitioner to 30 months of imprisonment, to be followed by three years of supervised release. Judgment 2-3.

3. The court of appeals affirmed. Pet. App. 1a-38a. Among other things, the court rejected petitioner's contention that the CSA's delegation of authority to the Attorney General to promulgate regulations implementing the practitioner exception violates the nondelegation doctrine. Id. at 16a-22a.

Citing this Court's precedent, the court of appeals recognized that Congress may delegate authority to the executive branch "so long as Congress articulates an 'intelligible principle' by which the actor empowered to exercise delegated authority can conform." Pet. App. 17a (citation omitted). The court then explained that the "general policy outlined within the CSA is 'the efficient execution' of the Attorney General's 'functions under' that statute," which "are defined as 'controlling the manufacture, distribution, and dispensing of controlled substances.'" Id. at 19a (brackets, citations, ellipsis, and emphasis omitted). And the court observed that "[t]his kind of mandate -- limited in terms of the subject area in which delegated authority may be exercised, yet broad as to how the delegated authority may be exercised -- is the type of delegation of authority long upheld as permissible." Id. at 20a.

The court of appeals also explained that the CSA's delegation of authority to the Attorney General "is both clear and bounded" because that delegation is limited to "rules and regulations 'relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals,'" and rules "in support of the execution of [those] functions." Pet. App. 20a-21a (citation omitted). The court further observed that the challenged regulation, 21 C.F.R. 1306.04, "borrows directly from the CSA in declaring that for 'a prescription for a controlled substance 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.'" Pet. App. 21a (brackets and citation omitted). The court explained that the parallelism "reinforces [its] conclusion that section 1306.04 operates within the limits of delegated authority." Ibid.

Finally, the court of appeals rejected petitioner's argument that "something greater than an intelligible principle" is required when Congress imposes criminal penalties for violating executive-branch regulations, observing that the argument was foreclosed by circuit precedent. Pet. App. 22a (citing United States v. Pheasant, 129 F.4th 576, 583 (9th Cir. 2025), petition for cert. pending, No. 25-6911 (filed Feb. 20, 2026)).

ARGUMENT

Petitioner renews his contention (Pet. 4-18) that 21 U.S.C. 821 and 871(b), and 21 C.F.R. 1306.04(a), together effect an unconstitutional delegation of legislative authority to the executive branch. The court of appeals correctly rejected that contention, and its decision does not conflict with any decision of this Court or another court of appeals. Petitioner alternatively requests (Pet. 18-19) that the petition for a writ of certiorari be held pending the disposition of the pending petition for a writ of certiorari in Pheasant v. United States, No. 25-6911 (filed Feb. 20, 2026), which raises a similar issue. No further review is warranted, and the petition should be denied.

1. This Court has explained that while the Constitution "permits no delegation of [legislative] powers" to the executive branch, Whitman v. American Trucking Associations, 531 U.S. 457, 472 (2001), Congress does not run afoul of the nondelegation doctrine so long as Congress sets forth "an intelligible principle to which the person or body authorized to [act] is directed to conform." J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928).

Under that intelligible-principle test, Congress must delineate "both 'the general policy' that the agency must pursue and 'the boundaries of its delegated authority.'" FCC v. Consumers' Research, 606 U.S. 656, 673 (2025) (brackets and citation omitted). The assessment is contextual; "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." Ibid. (quoting American Trucking, 531 U.S. at 475); cf., e.g., United States v. Miller, 604 U.S. 518, 533 (2025) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme.") (citation omitted). Read in context, the statute must provide "sufficient standards to enable both 'the courts and the public to ascertain whether the agency' has followed the law." Consumers' Research, 606 U.S. at 673 (brackets and citation omitted).

The court of appeals correctly determined that the delegation in this case did not violate nondelegation principles. As this Court has recognized, "[t]he CSA gives the Attorney General limited powers, to be exercised in specific ways." Gonzales v. Oregon, 546 U.S. 243, 259 (2006). Congress set forth "'the general policy' that the agency must pursue," Consumers' Research, 606 U.S. at 673 (citation omitted) -- namely, the "registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. 821; see 21 U.S.C. 871(b) (directing the Attorney General to promulgate rules "for the efficient execution of his functions under" the CSA). Congress likewise defined "the boundaries of [the] delegated authority." Consumers' Research, 606 U.S. at 673 (citation omitted). As this Court has observed, by limiting the Attorney General's rulemaking authority to the items listed above, "Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, he can promulgate rules relating only to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute." Oregon, 546 U.S. at 259 (citation omitted).

The CSA also limits the Attorney General's discretion to regulate on those topics. To deny, revoke, or suspend a physician's registration to dispense controlled substances, the Attorney General must make factual findings based on specific factors listed in the CSA. 21 U.S.C. 823(f), 824(a). Similarly, to exercise the delegated authority to add or remove a controlled substance from the schedules established by the CSA, the Attorney General must follow specific procedures and consider a list of eight enumerated factors. 21 U.S.C. 811, 812. This Court has found that those provisions "painstakingly described the Attorney General's limited authority" under the CSA, and has relied on them to reject a claim of authority for the Attorney General simply "to decide whether a physician's actions are inconsistent with the 'public interest.'" Oregon, 546 U.S. at 262.

2. Petitioner no longer contends that the CSA's delegation to the Attorney General to promulgate regulations, standing alone, fails to satisfy the intelligible-principle test. Instead, he contends (Pet. 5) that the delegation is problematic to the extent it allows the Attorney General to "defin[e] the elements of a federal crime." But as the court of appeals recognized (Pet. App. 21a), it was Congress -- not the Attorney General -- that made it a federal crime to "knowingly or intentionally * * * distribute * * * a controlled substance" in a manner not "authorized by [the CSA]." 21 U.S.C. 841(a)(1).

Indeed, in United States v. Moore, 423 U.S. 122 (1975), this Court focused on the statutory provisions in the CSA itself in holding that a registered physician was appropriately convicted under 21 U.S.C. 841 for prescribing controlled substances outside "the bounds of 'professional practice.'" Id. at 142 (citation omitted); see id. at 138-143; see also id. at 137 n.13 (observing, in context of possible prosecution under a different statute, that the regulatory language that today is located in 21 C.F.R. 1306.04(a) made "explicit" the "medical purpose requirement" that was both implicit and explicit in other relevant provisions of the CSA).

In any event, this Court has made clear that "[t]here is no absolute rule * * * against Congress' delegation of authority to define criminal punishments." Loving v. United States, 517 U.S. 748, 768 (1996). Such delegations are appropriate so long as the "agency defines by regulation what conduct will be criminal, * * * Congress makes the violation of regulations a criminal offense and fixes the punishment, and the regulations 'confine themselves within the field covered by the statute.'" Ibid. (brackets omitted) (quoting United States v. Grimaud, 220 U.S. 506, 518 (1911)).

Accordingly, the Department of Homeland Security does not "defin[e] the elements of a federal crime" (Pet. 5) when it designates ports of entry at which aliens may lawfully enter the United States -- even though its designation affects the scope of criminal liability. See 8 U.S.C. 1325(a)(1) (prescribing criminal punishment for any alien who "enters or attempts to enter the United States at any time or place other than as designated by immigration officers"); see also United States v. Melgar-Diaz, 2 F.4th 1263, 1266-1269 (9th Cir. 2021), cert. denied, 142 S. Ct. 813 (2022). Nor does the Secretary of Agriculture create a crime when he promulgates regulations prohibiting the grazing of sheep without a license in a public forest preserve under his statutory authority "to regulate the occupancy and use and to preserve the forests from destruction," even though violation of those regulations carries criminal penalties. United States v. Grimaud, 220 U.S. 506, 522 (1911) (citation omitted).

The same principle applies to the CSA, where Congress made the unauthorized dispensation of Schedule II drugs without a valid prescription "a criminal offense and fixe[d] the punishment," Loving, 517 U.S. at 768. Indeed, in Touby v. United States, 500 U.S. 160 (1991), this Court rejected a nondelegation challenge to a CSA provision authorizing the Attorney General to temporarily schedule a controlled substance, 21 U.S.C. 811(h), even though such scheduling could result in criminal penalties for violators. Touby, 500 U.S. at 164-169; see 21 U.S.C. 811(a)(1) and (2), 841(a).

That precedent, which petitioner does not seek to overrule, applies a fortiori here. The challenged delegation does not (unlike in Touby) authorize the Attorney General to temporarily render unlawful the distribution of a previously lawful substance. It instead simply authorizes the Attorney General to clarify when a concededly unlawful substance may nevertheless be distributed by a practitioner under an exception to the general statutory prohibition against distributing controlled substances.

Indeed, in doing so, the challenged regulation barely says more than what the statute says (as exemplified by the conviction in Moore). The CSA allows for the prescription of controlled substances only if they have a "currently accepted medical use," 21 U.S.C. 812(b); defines a "valid prescription" in the context of online or mail-order dispensing as one "that is issued for a legitimate medical purpose in the usual course of professional practice," 21 U.S.C. 829(e)(2)(A); and defines a "practitioner" to include a physician authorized to dispense a controlled substance "in the course of professional practice," 21 U.S.C. 802(21). By announcing that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" in order to be "effective," 21 C.F.R. 1306.04(a), the regulation "does little more than restate the terms of the statute itself," Oregon, 546 U.S. at 257. And that Congress expressly incorporated the regulation's language when amending the CSA to address online and mail-order dispensing underscores that the regulation falls well within the bounds of permissible regulatory action by the DEA. See Loving, 517 U.S. at 768.

3. Petitioner does not contend that the decision below conflicts with any decision of this Court or another court of appeals. Instead, he suggests (Pet. 8-17) that courts should apply some standard stricter than the intelligible-principle test when addressing congressional delegations to issue regulations the violation of which might trigger criminal penalties. Although this Court stated in Touby that it is "not entirely clear as to whether more specific guidance is in fact required" when Congress delegates authority "to promulgate regulations that contemplate criminal sanctions," 500 U.S. at 165-166, the Court has never adopted any such higher standard.

As illustrated by Grimaud and Loving v. United States (among other examples), this Court has, in substance, "routinely applied the 'intelligible principle' test even when the challenged statute authorized regulations backed by criminal penalties." United

States v. Pheasant, 129 F.4th 576, 583 (9th Cir. 2025), petition for cert. pending, No. 25-6911 (filed Feb. 20, 2026); see, e.g., Grimaud, 220 U.S. at 521; Loving, 517 U.S. at 771-772. And because Congress has adopted the regulatory language in the statute itself, this would be a particularly inappropriate case for considering whether some heightened standard should apply. Courts of appeals likewise have "decline[d] to abandon the well-settled 'intelligible principle' standard" when reviewing "a statute with criminal consequences." United States v. Nichols, 775 F.3d 1225, 1232 (10th Cir. 2014), rev'd on other grounds, 578 U.S. 104 (2016); accord Pheasant, 129 F.4th at 582-583; United States v. Cooper, 750 F.3d 263, 270-271 (3d Cir.), cert. denied, 574 U.S. 866 (2014).

Petitioner attempts to bolster his nondelegation challenge (Pet. 12-14) by claiming ambiguity or vagueness regarding the dividing line between authorized and unauthorized prescribing conduct under 21 U.S.C. 841. But any ambiguity or vagueness would implicate the CSA itself, which employs near-identical terminology to define a valid prescription in the context of online or mail-order dispensing. And in any event, petitioner's own words belie his claim that he was unaware that his prescribing conduct exceeded the bounds of accepted medical practice and therefore violated the plain text of 21 U.S.C. 841. Petitioner's writings show that he viewed himself as a "legal drug dealer" treating "stupid" "high-level addicts"; dropped his malpractice insurance "because the druggies are stupid and just want drugs," and thus "won't sue me";

and callously celebrated the suicide of A.M: "Psycho bitch girl high-level addict killed herself Thursday. Her second suicide attempt and successful. Adios motherfucker." Trial Tr. 1857-1858, 1880; see Moore, 423 U.S. at 140-142 (rejecting a similar vagueness challenge).

4. This case also is an especially unsuitable vehicle for addressing whether a heightened standard applies to delegations implicating criminal penalties. First, there is no sound basis for concluding that petitioner's conviction actually rests on the regulation that he challenges. The operative indictment cites only the CSA statutory provisions; it does not even mention the regulation. See Superseding Indictment 1-5. And the portion of the jury instructions that echoes the regulatory language (without citing the regulation) was proposed by petitioner himself. Compare Trial Tr. 1838 ("outside the usual course of professional practice, and, without a legitimate medical purpose"), with D. Ct. Doc. 208, at 59 (Oct. 22, 2021) ("outside the usual course of professional practice and without legitimate medical purpose"). If this Court wishes to consider whether a heightened standard applies to a delegation that implicates criminal penalties, it should do so in a case where the exercise of delegated authority clearly forms the basis for the defendant's criminal liability -- not a case (like this one) where the defendant was convicted directly under the statute, and the regulatory and statutory language parrot each other. Cf. Oregon, 546 U.S. at 257 (explaining that 21 C.F.R.

1306.04 "just repeats two statutory phrases" and its interpretation thus presents a question of "the meaning of the statute").

Second, this case presents a highly unusual nondelegation claim because the challenged delegation concerns the scope of an exception to a generally applicable criminal prohibition. If the delegated authority to define the scope of that exception were held unconstitutional, that would at most require severing the exception; the statutory prohibition would be unaffected and remain enforceable. Cf. Barr v. American Association of Political Consultants, 591 U.S. 610, 630 (2020) (severing a statutory "exception, [which was] the constitutionally offending provision"). Such a holding would hardly inure to petitioner's benefit.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

D. JOHN SAUER
Solicitor General

A. TYSEN DUVA
Assistant Attorney General

TORY D. ROBERTS
Attorney

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