

No. 04-623

In the Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

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

REPLY BRIEF FOR THE PETITIONERS

PAUL D. CLEMENT
*Solicitor General
Counsel of Record
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217*

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I. THE ATTORNEY GENERAL REASONABLY CONCLUDED THAT ASSISTING A PERSON'S SUICIDE IS NOT A "LEGITIMATE MEDICAL PURPOSE" FOR WHICH DRUGS CAN BE DISTRIBUTED UNDER THE CONTROLLED SUBSTANCES ACT

A. The Attorney General's Interpretive Rule Is Reasonable And Is Entitled To Deference

1. Respondents challenge the Attorney General's regulatory interpretation that dispensing drugs for the purpose of hastening a person's death is not within "the usual course of professional treatment" or for a "legitimate medical purpose" within the meaning of the longstanding regulation that establishes the prerequisites for a lawful prescription under the Controlled Substances Act. See 21 C.F.R. 1306.04(a). The Attorney General's interpretation of his own regulation is "controlling unless 'plainly erroneous or inconsistent with the regulation.'" *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). That precondition for deference is amply satisfied here. The Attorney General's interpretation of the regulation is supported by the thrust of the Act it implements (which combats drug abuse, including overdoses), this Court's decisions under the Harrison Act and the CSA, the ordinary meaning of the terms "medical" and "medicine," centuries of tradition, federal law in other contexts, the position of 49 States, and the judgment of the American Medical Association that assisting suicide is "fundamentally incompatible" with a physician's role as healer. See Gov't Br. 21-24; p. 19, *infra*.

Patient-respondents suggest (at 9-12) that the Attorney General's interpretation is not entitled to deference under *Auer* because it was not issued after notice-and-comment rulemaking. That contention is mistaken. The underlying *regulation* the Attorney General interpreted *was* issued though notice and comment, 36 Fed. Reg. 4948, 7777, 7799

(1971), and respondents do not challenge the regulation’s validity under *Chevron*. Nor could they because the regulation is firmly supported by the longstanding requirement—dating to the Harrison Act, which, as amended, excepted from its scope drugs obtained pursuant to “a prescription, written for legitimate medical uses,” Revenue Act of Feb. 24, 1919, § 1006, 40 Stat. 1131, and reaffirmed in the CSA and *United States v. Moore*, 423 U.S. 122 (1975)—that a prescription must be for an accepted medical purpose in treatment, not for a non-medical purpose such as maintaining the habit of an addict. And there is no independent requirement that the interpretation of a notice-and-comment regulation also be the product of notice and comment. Such interpretations rarely follow notice and comment, and indeed *Auer* and its predecessors involved interpretations that were not the product of notice and comment. See *Auer*, 519 U.S. at 462; *Thomas Jefferson Univ.*, 512 U.S. at 510, 512; *Martin v. OSHRC*, 499 U.S. 144, 156-157 (1991). Accordingly, the regulation itself is concededly valid and the Attorney General’s interpretation of it plainly qualifies for *Auer* deference. That is a sufficient basis to decide this case and reverse the decision below.

2. The Attorney General’s rule is equally valid, however, even if respondents are somehow permitted to ignore the regulation and *Auer* and their suit is viewed as one challenging an interpretation of the Act itself. The interpretation embraced in the Attorney General’s rule reflects an entirely reasonable construction of the Act, and therefore must be upheld under *Chevron*.

The CSA makes clear in its very first section that it permits the distribution of controlled substances only for “legitimate medical purposes”—those intended to “maintain the health and general welfare of the American people,” 21 U.S.C. 801(1). The Act’s clearly stated purpose is to enhance and maintain life, not to end it. This Court’s decisions under the Harrison Act, which the CSA was intended to strengthen, *Gonzales v. Raich*, 125 S. Ct. 2195, 2202-2203 (2005),

made that central principle clear more than 80 years ago. See *Webb v. United States*, 249 U.S. 96, 99-100 (1919) (To call a doctor’s order for morphine that was “not * * * issued * * * in the course of professional *treatment* in the attempted *cure* of the habit” “a physician’s prescription would be so plain a perversion of meaning that no discussion of the subject is required.”) (emphasis added); accord *Jin Fuey Moy v. United States*, 254 U.S. 189, 194 (1920); *United States v. Behrman*, 258 U.S. 280, 286, 288-289 (1922). And this Court followed the interpretation of those cases in *Moore*, 423 U.S. at 132, in a prosecution under the CSA.

Moreover, the CSA directs that substances be scheduled according to whether they have a “currently accepted medical use *in treatment*” and an “accepted *safety* for use * * * under medical supervision.” 21 U.S.C. 812(b)(1)(B) and (C) (emphasis added). There can be little doubt that a substance that had no utility in curing, treating, or alleviating disease, but was perfectly suited to causing a painless death, would be placed among the substances in schedule I as one having “no currently accepted medical use in treatment in the United States,” 21 U.S.C. 812(b)(1)(B). That scheduling decision would be made as a matter of federal law, and would bind physicians, even if state law were to the contrary. *Raich*, 125 S. Ct. at 2211-2213; *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 486, 492-493 (2001). While the schedule II substances prescribed under Oregon’s Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800 *et seq.* (2003), do have some accepted medical uses, facilitating suicide is not one of them. A prescription issued for that purpose therefore is not for a legitimate medical purpose under the Act. The legislative history of the CSA confirms that using controlled substances to commit suicide is “misuse” under the CSA and a critical aspect of the pattern of abuse—including overdoses—that the Act was enacted to prevent. H.R. Rep. No. 1444, 91st Cong., 2d Sess. 35 (1970). This interpretation of the Act is eminently reasonable and therefore is controlling under *Chevron*.

3. That validity of the Attorney General's interpretation of the Act is unaffected by the fact that it was not issued after notice and comment. This Court has made clear that notice-and-comment rulemaking is not a prerequisite for *Chevron* deference. *Barnhart v. Walton*, 535 U.S. 212, 219-220, 221-222 (2002). And any such inflexible requirement would be contrary to the Administrative Procedure Act, the basic statutory framework for judicial review of agency action, which specifically exempts interpretive rules from the requirement of notice and comment. See 5 U.S.C. 553(b)(3)(A).

The patient-respondents' other objections to deference (at 10-28) are without merit. Respondents first object to the interpretation as "informal." See Patient Br. 11. But the interpretive rule was issued by the Attorney General himself, after considering the lengthy legal analysis of the Office of Legal Counsel, and his determination was published in the Federal Register. Pet. App. 100a-105a; *id.* at 106a-148a. No greater formality could be expected. This case therefore is a far cry from the cases the patient-respondents cite: *United States v. Mead Corp.*, 533 U.S. 218, 233 (2001) ("46 different * * * offices issue 10,000 to 15,000" rulings per year); *Alaska Department of Environmental Conservation*, 540 U.S. 461, 487 (2004) ("internal guidance memorandum"); *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (opinion letter).

The patient-respondents also contend (at 13-15) that the Attorney General's rule is not entitled to deference because he lacks medical expertise. They cite the role assigned to the Secretary of Health and Human Services in the CSA with respect to the scheduling of controlled substances. *Id.* at 15 (citing 21 U.S.C. 811(b)). But as the practitioner-respondents realize (at 20-33), this case does not implicate the authority to schedule controlled substances, which may touch upon technical scientific and medical matters. Rather, it presents a legal question for the Attorney General to resolve by interpreting one of his own regulations and the

provisions of the CSA it implements. Nor is there anything anomalous about a scheme that requires broader input on the ultimate question of scheduling a drug than on a decision that particular practices are abusive or illegitimate. In cases such as *Webb* and *Moore*, the Court sustained criminal prosecutions initiated by the Department of Justice based on the Department's judgment that the prescriptions were improper, with no suggestion that prior approval by some other federal agency was required.

Even as to scheduling, respondents overstate the role of the Secretary. His views are binding on the Attorney General only as to "such scientific and medical matters" as are specifically referred to the Secretary in the scheduling process. See 21 U.S.C. 811(b) and (c). The statute makes clear that the Secretary's comments about a substance's "potential for abuse," "pattern of abuse," or "significance of abuse," 21 U.S.C. 811(b), (c)(1), (4) and (5), are binding on the Attorney General *only* as to any "scientific and medical considerations," 21 U.S.C. 811(b). Congress thus recognized that even in the scheduling process, determinations about a substance's "abuse" may not be scientific or medical in nature, but might instead involve legal or other considerations that are for the Attorney General to resolve.

Respondents also emphasize that the interpretive rule at issue here is contrary to the views of the preceding Attorney General. Patient Br. 16, 21-22, 27-28. This Court's recent decision in *National Cable & Telecommunications Ass'n v. Brand X Internet Services*, 125 S. Ct. 2688 (2005), provides a complete legal answer to that argument. "Agency inconsistency is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework." *Id.* at 2699. In addition, the position of the Attorney General that respondents challenge, unlike the views of his predecessor set forth in a letter to Members of Congress, took the form of agency action, after a thorough legal analysis, published in the Federal Register.

Finally, respondents object (Patient Br. 16-19, 20-21, 30-35) that the thorough analysis on which the Attorney General’s decision was based did not discuss Oregon’s experience under the DWDA or other views supportive of assisted suicide as a policy matter. But, because that analysis focused on what constitutes a “legitimate medical purpose” as a *legal* matter and on the judgment that suicide, including physician-assisted suicide, is *itself* harmful to public health and safety, Oregon’s data concerning the experience of persons who receive drugs and commit suicide as permitted by the DWDA were irrelevant. The patient-respondents’ other evidence consists of a few opinion polls, the support of specialized professional groups and associations, and recent legal developments in a few foreign countries. Patient Br. 30-35. Even respondents concede that, at most, that evidence indicates that public opinion is “divided” on this issue, Patient Br. 30.¹

B. The CSA Establishes A Uniform National Standard For Distributing Controlled Substances

Apart from their challenge to the Attorney General’s interpretation on deference grounds, respondents offer three statutory arguments why the CSA should be construed to take the determination out of federal hands altogether and make state law the arbiter of whether distribution of a drug is for a “legitimate medical purpose” under the CSA. None is persuasive.

¹ Certain of respondents’ amici, but not respondents, argue that the Attorney General’s interpretive ruling should be rejected because of the “rule of lenity.” Briffault Br. 19-22. In *Babbitt v. Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687 (1995), the Court rejected the suggestion “that the rule of lenity should provide the standard for reviewing facial challenges to administrative regulations whenever the governing statute authorizes criminal enforcement.” *Id.* at 704 n.18. There is no question that the Attorney General’s interpretive rule gives “[a]dequate notice of potential liability” to practitioners if they use their federal registration to assist someone to commit suicide. *Ibid.* The rule of lenity is therefore inapplicable.

1. Practitioner-respondents argue (at 13-14, 23) that it is the statutory phrase “in the course of professional practice,” 21 U.S.C. 802(21), rather than the regulatory phrase “legitimate medical purpose,” 21 C.F.R. 1306.04, that governs, and that the former necessarily incorporates medical practice under state law. That argument simply ignores the fact that the CSA itself uses the term “legitimate” to modify “medical purpose” or medical “use” in at least four different provisions, including the Act’s very first declaration of congressional purpose, 21 U.S.C. 801(1). See also 21 U.S.C. 830(b)(3)(A)(ii) (defining “valid prescription” as one “issued for a legitimate medical purpose”), 823(a)(1), 823(f). It also ignores the absence of any language even in “the course of professional practice” phrase that ties it to practice in a particular state or locality.

More broadly, the practitioners fail to grasp that the CSA does not merely regulate the conduct of doctors in particular localities; it imposes affirmative nationwide duties on the Attorney General to act based upon his determination whether an asserted medical purpose is “legitimate” or “accepted.” For example, the Attorney General must schedule substances according to whether they have a “currently accepted medical use in treatment *in the United States*,” 21 U.S.C. 812(b)(1)-(5) (emphasis added), and must regulate the manufacture of controlled substances to ensure “an adequate and uninterrupted supply” for “legitimate medical, scientific, research and industrial purposes,” 21 U.S.C. 823(a)(1). It is untenable, especially in light of this Court’s recent decision in *Raich* upholding the CSA’s blanket prohibition on marijuana use despite California’s recognition of its medicinal utility, to maintain that the Attorney General is constrained to adopt a particular State’s policy regarding what is an “accepted” or “legitimate” medical purpose or use. 125 S. Ct. at 2211; *Oakland Cannabis*, 532 U.S. at 486, 492-493. The Attorney General would not need to remove a drug from schedule I because one State recognized an idiosyncratic use for an otherwise banned substance. There is no more reason

for the Attorney General to have to treat a prescription that would be unlawful and improper as a matter of federal law in 49 States as legitimate because of the idiosyncratic view of a single State. That would be true of a State that purported to allow prescriptions of the sort at issue in *Moore*, and is no less true of a State that allows prescriptions for a use (facilitating a lethal overdose) that amounts to abuse in 49 States and as a matter of federal law.

2. Alternatively, the practitioner-respondents argue (at 25) that Congress was concerned only with doctors “diverting drugs outside of legitimate channels.” To the extent respondents mean that Congress was *not* concerned with the purposes for which a doctor prescribes medicine to a patient, except to the extent the patient might *resell* the drugs outside “legitimate channels,” that contention is simply wrong. As the Court recognized in *Raich*, “the CSA is a comprehensive regulatory regime specifically designed to regulate which controlled substances can be utilized for medicinal purposes, *and in what manner*,” 125 S. Ct. at 2211 (emphasis added). See *Moore*, 423 U.S. at 143 (CSA establishes “limits on free experimentation with drugs” by physicians). Indeed, diversion from legitimate uses to illegitimate uses via otherwise legitimate channels (*e.g.*, prescriptions from a doctor to a patient) was a primary concern of the Harrison Act prosecutions and *Moore*. Similarly in this case, the diversion of schedule II substances from legitimate uses as medicine to what in every other State and under federal law amounts to abuse and the facilitation of a lethal overdose *is diversion* for purposes of the CSA.²

² Moreover, Oregon’s representation (at 23 n.9) that prescriptions under DWDA pose no risk of diversion to others is not borne out. A lethal dose under DWDA is approximately 90 to 100 times the therapeutic dose. Oregon Br. 43. And it appears that a high percentage of persons for whom a lethal dose is prescribed do not end up taking the prescribed drugs, Patient Br. 39, thus leaving a large quantity of strictly regulated schedule II substances unaccounted for and outside the CSA’s closed system.

After criminal prosecutions such as *Moore* confirmed the basic legal distinction under the CSA between legitimate medical *treatment* of addicts and illicit dispensing of drugs to maintain an addict's habit, the Act was amended to provide for the Secretary to articulate more specific criteria for when a physician can prescribe narcotic drugs to patients for "maintenance treatment or detoxification treatment." 21 U.S.C. 823(g)(1); see Gov't Br. 33-34. But that mechanism for fleshing out the established *legal* standard in a particular context simply confirms that the CSA itself more generally embodies a basic federal statutory limitation on what constitutes a "legitimate medical purpose." If prescribing controlled substances to sustain addiction during life is not such a purpose, then *a fortiori* prescribing drugs to cause death crosses the statutory line. No medical or scientific expertise of the Secretary is required for the Attorney General to resolve that basic question of statutory interpretation.

3. Respondents contend that the CSA's reference to state licensing decisions in 21 U.S.C. 823(f) indicates a congressional intent that state, rather than federal, law provide the sole reference point for determining whether a particular physician's dispensing of drugs is permissible under the CSA. Practitioner Br. 29-33; Oregon Br. 35-38. Section 823(f) governs the granting of federal registration to dispense controlled substances, not the conduct of physicians after they are registered. Gov't Br. 34-35. Nonetheless, its history is instructive. When the CSA was adopted, Congress piggybacked on state licensing boards to determine who would obtain a federal registration in the first instance. See 21 U.S.C. 823(f) (1970). But even then the State's licensing decision was not dispositive with respect to federal registration, because registration could be revoked if the registrant was convicted of a felony under the CSA or any other law of the United States (or of any State) relating to a controlled substance. 21 U.S.C. 824(a)(2) (1970). Neither Section 823(f) nor any other provision of the CSA was ever understood to require that the federal government await a

determination by a state licensing board before prosecuting a doctor under the CSA or revoking the federal registration based on a conviction. Gov't Br. 31-33.

Significantly, moreover, Congress amended the Act in 1984 to allow the Attorney General to deny, suspend, or revoke a practitioner's registration on other *federal* grounds as well. See 21 U.S.C. 823(f), 824(a). Now, the Attorney General must also consider "[t]he applicant's experience in dispensing * * * controlled substances," "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," and "[s]uch other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(2), (4), and (5).

Congress revised the earlier provisions in part because States were not adequately regulating physicians' abuses of their prescription-writing authority. See S. Rep. No. 225, 98th Cong., 1st Sess. 262 (1983) (noting that it "may clearly be contrary to the public interest" to require federal registration of any practitioner licensed under state law); *id.* at 266. Thus, the 1984 amendments granted the Attorney General considerably *broader* authority to take administrative action on independent federal grounds. It is also clear that the references to violations of federal, state, *or* local law are in the disjunctive and that any one of the enumerated factors in Section 823(f) can be dispositive. See, *e.g.*, *Shatz v. United States Dep't of Justice*, 873 F.2d 1089 (8th Cir. 1989). It is clear, for example, that the Attorney General may now revoke the registration of a physician who engages in improper prescription practices of the sort involved in *Moore*, without waiting for a federal criminal conviction much less a state-law conviction or action by state registration authorities.

The patient-respondents suggest (at 42-44) that the Attorney General's interpretive rule violates Section 823(f) because it gives insufficient weight to Oregon law. The Attorney General's rule is not, however, an application of the registration provisions in Section 823(f), but an interpretation of the *substantive* federal law requirements (under 21 C.F.R. 1306.04) for a valid prescription. Because compliance with

federal law, *viz* the CSA (including the prescription requirement), is itself a consideration in registration decisions under Section 823(f), the interpretive rule puts registrants on notice of an important determination of the Attorney General regarding federal law that *could* affect their registrations. In short, Sections 823 and 824 make clear that a doctor can lose his or her federal license by violating state law, local law *or* federal law. A doctor might lose federal registration based on violations of state laws that have no federal analog because the state-law violation may demonstrate indirectly that a doctor is unfit for federal-law purposes. A violation of federal law demonstrates unfitness more directly and can occur even if state law does not regulate or criminalize the conduct.

II. THERE IS NO REQUIREMENT OF A CLEAR STATEMENT APPLICABLE HERE

For the reasons stated above, the Attorney General’s ruling is clearly sound under normal rules of statutory construction. Respondents urge, however, that the usual principles do not apply here. Rather, they contend that the CSA can restrict conduct that state law would permit only if the statute contains a “clear statement” to that effect. This Court has already recognized that the CSA reflects a comprehensive regime that does not need to yield just because a State has chosen to remove state-law prohibitions on certain conduct independently prohibited by federal law. *Raich*, 125 S. Ct. at 2203. And respondents cannot point to any authority requiring federal authorities to identify a “clear statement” of legislative intent before applying a comprehensive scheme to such conduct.

A. A Presumption Against Federal Preemption Does Not Apply Because The CSA Does Not Preempt The DWDA

Oregon contends that a “presumption against preemption” applies—and a “clear statement” is required—whenever a federal regulation would “prevent” a more permissive “state

law from operating as state lawmakers intended.” Oregon Br. 20-21. That argument is flatly wrong and, if accepted, would dramatically alter the relationship between state and federal law.

Respondents’ reliance on the presumption against preemption suffers a singular flaw: This is not a preemption case. Preemption refers to those circumstances in which “the Supremacy Clause invalidates state laws that ‘interfere with or are contrary to the laws of Congress.’” *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)). The combined effect of federal law and the Supremacy Clause renders such state statutes unconstitutional. The CSA does not preempt Oregon law. The CSA prohibits physicians from prescribing federally-controlled substances for the purpose of assisting a person to commit suicide. The DWDA removes pre-existing state-law sanctions on facilitating suicide in certain circumstances. See *Kane v. Kulonogoski*, 871 P.2d 993, 998 (Or. 1994). Nothing in the CSA invalidates the DWDA or prevents the use of means other than federally-controlled substances for the commission of suicide.

When “Congress has chosen to prohibit an act which [the State] has chosen not to prohibit; there is no conflict,” *Hylland v. Fukuda*, 580 F.2d 977, 981 (9th Cir. 1978), and any presumption against preemption is therefore inapposite. Respondents’ reliance (Oregon Br. 26-27; Practitioner Br. 45-46) on the CSA’s preemption clause, 21 U.S.C. 903, is thus misplaced. That provision clarifies Congress’s intent not to preempt the entire *field* of controlled substances. But, since the Attorney General’s interpretive ruling does not “preempt” Oregon law in any way, let alone the field, Section 903 is simply irrelevant.

What Oregon actually proposes (Br. 20-21), then, is a radical new presumption that would effectively invert the Supremacy Clause and, in the absence of a clear statement, bar federal regulation whenever it would “frustrat[e]” a State’s

choice to permit conduct that federal law prohibits. That proposition has no support in the cases Oregon cites,³ and would either completely invert the constitutional relationship between the federal and state governments or at a minimum resurrect the cramped notions of federal power that the Court definitively rejected in *United States v. Darby*, 312 U.S. 100 (1941). In *Darby*, the respondent challenged the Fair Labor Standards Act of 1938, 29 U.S.C. 201 *et seq.*, on the ground that it “undertakes to regulate wages and hours within the state contrary to the policy of the state which has elected to leave them unregulated.” 312 U.S. at 114. The Court rejected that contention, ruling that Congress is “free to exclude from commerce” conduct that “it may conceive to be injurious to the public health, morals or welfare, even though the state has not sought to regulate their use.” *Ibid.*

Although *Darby* concerned Congress’s constitutional authority, other cases reject the same proposition as a matter of statutory construction. For example, in *Caron v. United States*, 524 U.S. 308 (1998), the Court interpreted a federal statute to prohibit an individual from possessing rifles and shotguns, *id.* at 316-317, even though the State specifically allowed such possession, *id.* at 311. Similarly, in *Dickerson v. New Banner Institute Inc.*, 460 U.S. 103 (1983), the Court held that, for purposes of federal gun laws, the determinations whether an individual had been “convicted” in state court and whether that conviction had later been nullified were “question[s] of federal, not state, law,” *id.* at 111-112, even though the respondent’s gun rights might have been restored as a matter of state law, *id.* at 114 n.9.

³ Two of those cases, *Jones v. United States*, 529 U.S. 848 (2000), and *United States v. Bass*, 404 U.S. 336 (1971), involved the doctrine of constitutional avoidance, which we address below. See pp. 14-16, *infra*. The other two involved classic questions of preemption. See *Department of Revenue v. ACF Indus., Inc.*, 510 U.S. 332, 335-336 (1994); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 508 (1992).

B. Because The CSA, As Interpreted By The Attorney General, Is Clearly Constitutional, The Doctrine Of Constitutional Avoidance Does Not Apply

Respondents invoke the doctrine of constitutional avoidance, under which courts prefer an interpretation of an ambiguous statute that avoids “a serious constitutional question.” *Verizon Communications, Inc. v. FCC*, 535 U.S. 467, 523 (2002). Oregon Br. 42; see Patient Br. 23; Practitioner Br. 47-50. As explained above, however, the CSA is not ambiguous. Nor is its constitutionality, as interpreted by the Attorney General, doubtful.

Respondents’ contention that Congress lacks authority under the Commerce Clause to regulate the distribution of schedule II controlled substances in Oregon is foreclosed, *a fortiori*, by this Court’s decision in *Raich*, which rejected a Commerce Clause challenge to Congress’s authority to regulate even the home cultivation and consumption of marijuana, including marijuana that is to be used for purported medicinal purposes on the basis of a physician’s recommendation as authorized by state law. 125 S. Ct. at 2207. The class of conduct at issue in *Raich* was “purely intrastate activity that is not itself ‘commercial,’ in that it is not produced for sale.” *Id.* at 2206. Here, by contrast, the CSA directly regulates the commerce between physician and patient or pharmacist and customer in schedule II controlled substances that, by Oregon’s own admission (Br. 43 & n.18), are produced commercially and have, in all likelihood, “traveled in interstate commerce.”

Respondents assert that the Attorney General’s interpretive rule is nonetheless unconstitutional because there is no evidence that controlled substances prescribed under the DWDA “have or will enter into the stream of *illicit* commerce.” Practitioner Br. 49 (emphasis added). But that argument is both circular and unpersuasive. The prescription of drugs for the purpose of enabling a person to take his own life is “illicit” *under the CSA*, and its legality and consequent regulation (to an extent) under Oregon law does not diminish

federal authority. *Raich*, 125 S. Ct. at 2213 n.38; *id.* at 2219-2220 (Scalia, J., concurring in the judgment). Nor, in any event, is Congress's Commerce Clause authority limited by the licit or illicit nature of the activity regulated. The CSA is equally constitutional in its prohibition of schedule I substances and its regulation of sometimes lawful schedule II substances. Oregon also errs in suggesting that because a relatively small number of individuals can avail themselves of the DWDA, the total amount of drugs at issue is too "insignificant" for Congress to regulate. Oregon Br. 45. "[W]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power to excise, as trivial, individual instances of the class." *Raich*, 125 S. Ct. at 2209 (quotation marks omitted). It is the class of activities that Congress has forbidden—not the class of activities that state law decriminalizes—that must have the requisite impact on interstate commerce, and that standard is satisfied here, just as it was in *Raich*. *Id.* at 2208.

Oregon contends that Congress's power under the Commerce Clause is limited to regulating the "commercial aspects" of a transaction, and that it cannot make the application of federal law turn on "a physician's or patient's intentions about the ultimate use of the drugs" at issue. Oregon Br. 43-44. However, the Court made clear long ago that Congress's Commerce Clause power is not limited to some narrow category of concerns about the "commercial aspects" of transactions, but may be exercised, based on Congress's "own conception of public policy," to prohibit what it "may conceive to be injurious to the public health, morals or welfare." *Darby*, 312 U.S. at 114; see also *The Lottery Case*, 188 U.S. 321, 354 (1903). There is nothing unusual, let alone constitutionally suspect, about federal laws that regulate conduct based on the actor's purpose or intent. In *Moore*, for example, the Court upheld a physician's conviction under the CSA precisely because he had prescribed methadone to feed his patients' habits, rather than for "detoxification purposes," the only purpose allowed under the Act. 423 U.S. at

144-145.⁴ Nor does the fact that a physician acts “pursuant to affirmative state law,” Oregon Br. 47, shield his activity from Congress’s constitutional reach, for “state action cannot circumscribe Congress’ plenary commerce power.” *Raich*, 125 S. Ct. at 2213; *Wickard v. Filburn*, 317 U.S. 111, 124 (1942); *Darby*, 312 U.S. at 114. Indeed, the logic of respondents’ Commerce Clause argument is that the federal government lacks the authority to revoke a doctor’s license for prescribing controlled substances for purposes of assisting suicide not just in Oregon, but in the 49 States that prohibit the conduct.

C. There Is No Requirement That Congress Make A Particularly “Clear Statement” Whenever It Addresses An Issue That Is Also Within “Traditional State Authority”

Respondents finally suggest that a clear statement is necessary because the CSA, as interpreted by the Attorney General, “would intrude upon the historic powers of the States” and “alter the usual state-federal balance.” Oregon Br. 28, 30 (quotation marks omitted). See Practitioner Br. 47-50; Patient Br. 23-24. That proposition is singularly inapposite here: the federal government has regulated the distribution of controlled substances for 90 years, *Raich*, 125 S. Ct. at 2202, whereas, prior to 1994, no State had ever purported to allow physicians to dispense controlled substances for the purpose of assisting a person’s suicide.

More broadly, Oregon asserts (Br. 34 & n.15) that a “clear statement” is required whenever federal regulation would have an impact on “States’ regulation of the health, welfare, and comfort of their citizens.” But that category of state authority encompasses everything not forbidden by the Con-

⁴ Similarly, federal law prohibits interstate travel only when done with specified intent, such as “for the purpose of engaging in any illicit sexual conduct with another person,” PROTECT Act, Pub. L. 108-21, Title I, § 105(a), 117 Stat. 654 (to be codified at 18 U.S.C. 2423(b)), with intent to commit murder for hire, 18 U.S.C. 1958(a), with intent to avoid prosecution, 18 U.S.C. 1073, and with intent to incite a riot, 18 U.S.C. 2101(a)(1).

stitution. See *Hodel v. Virginia Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 311 (1981). Respondents' broad anti-federal-regulation presumption therefore would mark a sea-change in the Court's jurisprudence. None of the cases cited by respondents (Oregon Br. 27-34, 38-42) support such a sweeping rule.

Oregon primarily relies (Br. 31-34) on *Gregory v. Ashcroft*, 501 U.S. 452 (1991), but *Gregory* stands for no such proposition. The question presented was one of federal *preemption* of state law—whether the federal Age Discrimination in Employment Act prohibited Missouri from enforcing a state constitutional requirement that judges retire at seventy. See *id.* at 455, 460. Moreover, because the state law at issue concerned “[t]he authority of the people of the States to determine the qualifications of their government officials,” preemption by federal law would have encroached upon “how a State defines itself as a sovereign” and presented a “potential constitutional problem,” under the Guarantee Clause, U.S. Const., Art. IV, § 4, and the Tenth Amendment. *Gregory*, 501 U.S. at 460, 463-464; see *City of Edmonds v. Oxford House, Inc.*, 514 U.S. 725, 732 n.5 (1995) (emphasizing that Missouri's interest in setting the qualifications of judicial office went “*beyond* an area traditionally regulated by the States,” to the core of state sovereignty) (quoting *Gregory*, 501 U.S. at 460) (emphasis added). This case implicates neither basis for triggering a clear-statement requirement.

Oregon contends (Br. 31-34) that, even if *Gregory* is not directly applicable, other decisions have applied *Gregory*'s clear statement requirement more broadly. But the other cases Oregon cites are likewise inapposite. Most are yet further examples of the presumption against preemption of state law in particular contexts.⁵ Others are instances of the

⁵ See, e.g., *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 359 (2002); *California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 319 (1997); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 714-715 (1985); *Hisquierdo v.*

doctrine of constitutional avoidance.⁶ And two involved the presumption that Congress does not intend to abrogate the States' sovereign immunity—a core aspect of state sovereignty.⁷ None of those canons of construction is implicated by the application of the CSA to commercial transactions in controlled substances among physicians, pharmacists, and their customers, even if, as in *Raich*, the CSA prohibits transactions that state law would allow.

Respondents' inability to cite examples of the Court's applying a clear-statement rule merely because federal law regulates private conduct in a manner more restrictive than state law is not surprising. Giving effect to more stringent federal law does not “alter the usual state-federal balance,” Oregon Br. 30. Rather, that *is* the usual state-federal balance under the Constitution, which permits Congress to legislate according to “its own conception of public policy.” *Darby*, 312 U.S. at 114. Thus, as we discussed in our opening brief, the “general assumption” is that the terms of a federal statute do not depend upon state law but instead should be given “uniform nationwide application.” *Mississippi Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989).

The Court has, moreover, applied the presumption of federal uniformity to statutes that legislate in areas within “traditional state regulatory powers,” Oregon Br. 28. In *Mississippi Band* itself, the Court held that a uniform federal definition should be given to the ambiguous term “domicile” in the Indian Child Welfare Act, even though the sub-

Hisquierdo, 439 U.S. 572, 581, 590 (1979); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 236 (1947).

⁶ See, e.g., *Raygor v. Regents of the Univ. of Minn.*, 534 U.S. 533, 543-544 (2002); *Solid Waste Agency v. United States Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001); *Jones v. United States*, 529 U.S. 848, 857-858 (2000); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *United States v. Bass*, 404 U.S. 336, 339 n.4 (1971). See also *United States v. Lopez*, 514 U.S. 549, 562 (1995) (characterizing *Bass* as an example of constitutional avoidance).

⁷ See *Raygor*, 534 U.S. at 543; *Will v. Michigan Dep't of State Police*, 491 U.S. 58 (1989).

ject matter—family law, specifically child custody—is near the epicenter of conduct traditionally regulated by the States. See *Elk Grove Unified School Dist. v. Newdow*, 124 S. Ct. 2301, 2309 (2004).⁸ Likewise, in *Caron* the Court gave a uniform federal meaning to the gun statute in light of the federal government’s “interest in a single, national, protective policy, broader than required by state law.” 524 U.S. at 316.

Respondents cite numerous cases that comment on the States’ historic role in regulating medicine (Practitioner Br. 44; Oregon Br. 47 & n.22; Patient Br. 24 n.11), but none—apart from long-ago-overruled language in *Linder v. United States*, 268 U.S. 5 (1925), see Gov’t Br. 40-41—suggests that a federal law concerning medicine is somehow more suspect than statutes in other areas like family law or gun possession that States have also traditionally regulated. And the Court’s decisions in *Raich* and *Oakland Cannabis* positively refute that proposition specifically with respect to the CSA. See also *Lambert v. Yellowley*, 272 U.S. 581, 596 (1926) (“[T]here is no right to practice medicine which is not subordinate to * * * the power of Congress to make laws necessary and proper” to its constitutional authority.).

Although respondents refer repeatedly to the tradition of state regulation of medicine, the DWDA and its approach to assisted suicide does not resemble any traditional regulation of “medicine.” Assisting in a person’s suicide is, as the American Medical Association ethics guidelines recognize, “fundamentally incompatible with the physician’s role as healer.” AMA, *Current Opinions of the Council of Ethical*

⁸ Oregon characterizes (at 16 n.7) *Mississippi Band* as involving a “clearly demonstrated [congressional] intent to displace state court jurisdiction.” But that is not how the Court described its own reasoning. Rather, the opinion states that “[w]e start * * * with the *general* assumption that ‘in the absence of a plain indication to the contrary, . . . Congress when it enacts a statute is not making the application of the federal act dependent upon state law.’” 490 U.S. at 43 (emphasis added) (quoting *Jerome v. United States*, 318 U.S. 101, 104 (1943)).

and Judicial Affairs, Opinion No. E-2.211, Physician-Assisted Suicide, (last visited Aug. 25, 2005) <<http://www.ama-assn.org/ama/pub/category/print/8459.html>>. Moreover, the DWDA regulates assisted suicide differently from Oregon's own regulation of medicine. The DWDA's allowance of prescriptions for assisted suicide, while prohibiting physicians from actually administering the lethal drugs (see Oregon Br. 2, Practitioner Br. 15), which presumably reflects Oregon's own apparent discomfort with the idea of physicians directly causing death, is unique. Respondents point to no other circumstance, and we are aware of none, in which a doctor "may prescribe, but not administer," a substance. Oregon Br. 2. That simply does not happen when the controlled substance is being dispensed as "medicine." Moreover, that anomaly only underscores that the DWDA relies not on the physician's medical knowledge (the lethal substances and the required dosages have been well publicized in Oregon's DWDA reports, see Oregon Br. 43 & n.20.), but on the physician's federal-law status as a distributor of schedule II substances. The Attorney General's interpretation thus represents not an effort to reverse a state-law judgment about assisted suicide (which remains valid in Oregon to the extent it does not involve federally-controlled substances), but an effort to prevent a State from commandeering a federal-licensee's ability to dispense schedule II substances for ends that are contrary to federal law and bear little resemblance to traditional medicine.

* * * * *

For the foregoing reasons and those stated in the opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

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