No. 04-623

In the Supreme Court of the United States

JOHN ASHCROFT, ATTORNEY GENERAL, ET AL.,
PETITIONERS

v.

STATE OF OREGON, ET AL.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

PARTIES TO THE PROCEEDING

Petitioners are John Ashcroft, Attorney General of the United States; Karen Tandy, Administrator of the Drug Enforcement Administration; Kenneth W. McGee, Assistant Special Agent-in-Charge of the Portland Office of the Drug Enforcement Administration; the United States of America; the United States Department of Justice; and the Drug Enforcement Administration.

Respondents are the State of Oregon, Peter A. Rasmussen, David Malcolm Hochhalter, Richard Holmes, James Romney, Melissa Bush, and John Doe #1.

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The Acting Solicitor General, on behalf of the Attorney General of the United States and the other federal parties, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-63a) is reported at 368 F.3d 1118. The order of the district court granting respondents' motion for a preliminary injunction (Pet. App. 64a-97a) is reported at 192 F. Supp. 2d 1077.

JURISDICTION

The judgment of the court of appeals was entered on May 26, 2004. A petition for rehearing was denied on August 11,

2004 (Pet. App. 98a-99a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Relevant provisions of the Controlled Substances Act (CSA or Act), Pub. L. No. 91-513, Tit. II, 84 Stat. 1242 (21 U.S.C. 801 *et seq.*) and the implementing regulation, 21 C.F.R. 1306.04, are set out in an appendix to this petition. Pet. App. 149a-161a. The relevant provisions of the Oregon Death with Dignity Act, Or. Rev. Stat. §§ 127.800 *et seq.* (2003), are also set out in the appendix. Pet. App. 162a-165a.

STATEMENT

1. a. The Controlled Substances Act, 21 U.S.C. 801 *et seq.*, establishes a comprehensive federal scheme to regulate controlled substances. The CSA makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801 *et seq.*]." 21 U.S.C. 841(a)(1). Physicians and other practitioners who dispense[1] controlled substances must "obtain from the Attorney General a registration." 21 U.S.C. 822(a)(2). They may dispense controlled substances only "in the course of professional practice or research," 21 U.S.C. 802(21), and only "to the extent authorized by their registration and in conformity with the other provisions of [the CSA]," 21 U.S.C. 822(b).

The CSA authorizes the Attorney General to deny or revoke the registration of a practitioner "if he determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f), 824(a)(4). In determining the "public interest" for registration purposes, the

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[1] Under the CSA, the term "dispense" includes the issuance of a prescription by a practitioner as well as delivering a controlled substance directly to a patient. 21 U.S.C. 802(10).

Attorney General considers a number of factors including the registrant's compliance with federal, state, and local laws relating to controlled substances, 21 U.S.C. 823(f)(3) and (4), and "such other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). In addition, a physician who dispenses controlled substances outside the "accepted limits" of medical practice is subject to prosecution under 21 U.S.C. 841(a)(1). *United States* v. *Moore*, 423 U.S. 122, 142 (1975).

Under the CSA, each controlled substance is placed in one of five schedules, depending on whether the substance has a currently accepted medical use in treatment in the United States and the relative abuse potential of the substance. The Act imposes varying regulatory restrictions on controlled substances depending on the applicable schedule. Substances in Schedule I—the most restricted schedule—have "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B), and may not be prescribed by a physician. 21 U.S.C. 829. Human consumption of Schedule I controlled substances is permissible only in a research setting where the research has been approved by the Food and Drug Administration and the researcher has obtained from the Drug Enforcement Administration (DEA) a registration authorizing the specific research protocol. 21 U.S.C. 823(f). Substances in Schedules II through V have a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B)), and therefore may be dispensed for medical use. 21 U.S.C. 829.

When the CSA was enacted in 1970, Congress made an initial assignment of controlled substances to the schedules it believed appropriate. 21 U.S.C. 812(c). Congress authorized the Attorney General, in consultation with the Secretary of Health and Human Services, to add or remove substances or to transfer substances from one schedule to another based upon statutory criteria that take into account changes in

medical and scientific understanding and shifts in patterns of abuse. 21 U.S.C. 811, 812. In addition, Congress provided the Attorney General with broad authority to promulgate "rules and regulations * * * relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances," 21 U.S.C. 821, and "any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions" under the CSA, 21 U.S.C. 871(b). The Attorney General has delegated his functions under the Act to the Administrator of DEA. 28 C.F.R. 0.100(b).

States remain free to enact their own laws relating to controlled substances, such as their own criminal penalties, but state laws are preempted to the extent of any "positive conflict" between a provision of state law and the CSA such that the two "cannot consistently stand together." 21 U.S.C. 903.

b. When the CSA became effective in 1971, DEA's predecessor (the Bureau of Narcotics and Dangerous Drugs) issued regulations through notice-and-comment rulemaking to implement the Act. One of those regulations, now found at 21 C.F.R. 1306.04(a), requires 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." A purported prescription that is not issued "in the usual course of professional treatment or in legitimate and authorized research" does not qualify as a "prescription" for purposes of 21 U.S.C. 829 and, if issued knowingly, will subject the practitioner "to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. 1306.04(a). As this Court indicated in *Moore*, this legitimate medical purpose requirement is implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13.

2. In November 1994, Oregon voters passed a ballot initiative referred to as the Oregon Death with Dignity Act (DWDA), Or. Rev. Stat. §§ 127.800 *et seq.* (2003). The DWDA allows the prescribing and dispensing of "medication" for the purpose of enabling an individual with a terminal disease to commit suicide. *Id.* § 127.800(11). It requires the physician prescribing or dispensing the lethal substance to ensure that the patient is a resident of Oregon, is competent, has a terminal disease, and is making a voluntary and informed decision to obtain the drugs for the purpose of ending his or her life. See *id.* §§ 127.800, 127.815. A second physician must also verify most of those facts. *Id.* §§ 127.815(d), 127.820. The DWDA provides that a physician who prescribes or dispenses a lethal amount or combination of drugs in accordance with the DWDA shall not, for that reason, "be subject to civil or criminal liability or professional disciplinary action." *Id.* § 127.885(1). Oregon is the only State in the Union that purports to authorize physician-assisted suicide.

3. In 2001, the Attorney General sought an opinion from the Office of Legal Counsel (OLC) in the Department of Justice on the question whether a prescription for a drug to assist in a person's suicide, as contemplated in Oregon's DWDA, is a valid prescription pursuant to the CSA and its implementing regulation.[2] On June 27, 2001, OLC issued a memorandum concluding that "assisting in suicide is not a

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[2] No interpretive rule had previously been issued by the Attorney General on this subject. The Administrator of the DEA had previously concluded that assisting suicide in accordance with the DWDA would violate the CSA, E.R. 17, but then-Attorney General Janet Reno reached a different conclusion, see Pet. App. 109a (quoting Letter from Janet Reno, Attorney General of the United States, to Henry J. Hyde, Chairman, Committee on the Judiciary, U.S. House of Representatives (June 5, 1998)). Neither of those previous documents was published in the *Federal Register*.

'legitimate medical purpose' that would justify a physician's dispensing controlled substances consistent with the CSA." Pet. App. 130a; see *id.* at 106a-148a.

The OLC memorandum explained that "[t]he CSA establishes a uniform, nation-wide statutory scheme for regulating the distribution of controlled substances," Pet. App. 130a, and that this Court had held, in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), that a California voter initiative purporting to recognize a medical use for marijuana could not provide the basis for an implied "medical necessity" exception or defense in the CSA in the face of Congress's placement of marijuana on Schedule I, which is reserved for substances with "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B). Pet. App. 131a-133a. The OLC memorandum concluded that Oregon's ballot initiative likewise could not immunize a physician from prosecution or loss of registration under the CSA, if the Attorney General determined, pursuant to the regulatory authority granted to him in the CSA, that assisting an individual to commit suicide does not constitute a "legitimate medical purpose" for which controlled substances may be prescribed. *Id.* at 133a-134a.

The OLC memorandum also canvassed the views of medical and nursing associations, federal and state law, and judicial opinions and concluded, based on that review, that despite the Oregon voters' approval, physician-assisted suicide is not a "legitimate medical purpose." The memorandum noted that "state law and policy, with the sole exception of Oregon's, emphatically oppose assisted suicide," Pet. App. 117a, and that federal law likewise prohibits such conduct in federal medical facilities and denies federal financial assistance in support of it, *id.* at 119a-122a. For example, the memorandum noted that the Health Care Financing Administration in the Department of Health and Human Services had determined that physician-assisted suicide is not eligible

for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." *Id.* at 120a-121a (internal quotation marks omitted).[3] In addition, the OLC memorandum reviewed the position of leading organizations of the medical profession, including the American Medical Association, American Nurses Association, and American Psychiatric Association, all of which took the view that physician-assisted suicide was "fundamentally incompatible with the physician's role as healer." *Id.* at 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)).

On November 9, 2001, the Attorney General published an interpretive rule in the *Federal Register* (66 Fed. Reg. 56,607 (2001)), that adopted the analysis of the OLC Memorandum. Pet. App. 100a-105a. The Attorney General determined that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR § 1306.04," and therefore that "prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA." *Id.* at 102a. The Attorney General made clear that these conclusions "appl[y] regardless of whether state law authorizes or permits such conduct by practitioners or others." *Ibid.*

4. The State of Oregon and others challenged the interpretive rule in the United States District Court for the District of Oregon. That court held the interpretive rule invalid and enjoined its application. Pet. App. 64a-97a. The Attorney General and the other federal parties appealed. The court of appeals first held that the district court had lacked

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[3] The Health Care Financing Administration is now called the Centers for Medicare and Medicaid Services (CMS). CMS maintains this policy at present, and it is currently reflected in the Health & Human Servs., *Medicare Benefit Policy Manual*, ch. 16, § 20 (visited Nov. 5, 2004) <http://www.cms.hhs.gov/ manuals/102_policy/bp102c16.pdf>.

jurisdiction over respondents' suit. *Id.* at 2a-3a & n.1, 56a-61a. Instead, the court of appeals treated the action as a petition for review under 21 U.S.C. 877 that had been mistakenly filed in district court and transferred to the court of appeals. Pet. App. 2a-3a & n.1. On the merits, a divided panel granted the petitions for review.

a. The majority concluded that the interpretive rule was invalid absent an "unmistakably clear" indication of congressional intent to regulate physician-assisted suicide, because, in the majority's view, the rule "invokes the outer limits of Congress' power" by altering "the usual constitutional balance between the States and the Federal Government." Pet. App. 12a-13a (quoting *Solid Waste Agency* v. *United States Army Corps of Eng'rs*, 531 U.S. 159, 172-173 (2001), and *Gregory* v. *Ashcroft*, 501 U.S. 452, 461 (1991) (internal quotes omitted)). The court also held that the interpretive rule violated "the plain language of the CSA," *id.* at 13a, which, according to the majority, (1) only addresses "drug abuse," *id.* at 13a-14a, (2) entrusts medical decisions to the Secretary of Health and Human Services (not the Attorney General), *id.* at 15a, and (3) requires the Attorney General to address all five statutory factors in Section 823(f) that are relevant to registration of a physician under the CSA, including, in particular, whether the physician's conduct complies with state law, before adopting an interpretive rule such as the one here at issue, *id.* at 16a. The panel granted the petitions for review and "continued" the district court's injunction. *Id.* at 25a.

b. Senior Judge Wallace dissented. Pet. App. 25a-63a. He relied upon the presumption that Congress does not make the application of federal statutes dependent on state law, *id.* at 36a (citing *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)), and noted that, while a physician's compliance with state law is relevant under the CSA in determining whether his or her registration would

be consistent with the public interest, *id.* at 37a (citing 21 U.S.C. 823(f)(3) and (4)), other factors, including whether the physician's conduct "may threaten the public health and safety," are not dependent on state law, *ibid.* (citing 21 U.S.C. 823(f)(5)). The dissent further noted that, while the Secretary of Health and Human Services is specifically delegated certain functions under the CSA, responsibility under the Act for determining whether a physician's registration serves the public interest is assigned to the Attorney General alone. *Id.* at 39a-40a. The dissent also rejected the majority's suggestion that application of the CSA to the dispensing of controlled substances to assist suicide is at the limits of Congress's power or would alter federal-state relations, *id.* at 45a, and pointed out that, to the contrary, Congress's authority under the Commerce Clause to regulate the distribution of controlled substances is well-established, *id.* at 49a-50a. Finally, the dissent observed that the Attorney General's conclusion that physician-assisted suicide is not a legitimate medical purpose is well supported by an "overwhelming historical, legal, and medical consensus." *Id.* at 56a.

c. The court of appeals denied the government's petition for rehearing or rehearing en banc. Pet. App. 98a-99a

REASONS FOR GRANTING THE PETITION

The Ninth Circuit held in this case that the Attorney General's ability to administer and enforce the Controlled Substances Act is subordinate to the views of each of the 50 States regarding the permissible uses of scheduled substances. That holding is erroneous and stands the proper relationship between the federal and state governments under the Constitution on its head. Moreover, the court of appeals' ruling conflicts with this Court's recognition in *United States* v. *Moore*, 423 U.S. 122 (1975), that a physician's prescription violates the CSA unless made "in

the usual course of a professional practice and in accordance with a standard of medical practice *generally recognized and accepted in the United States*," *id.* at 139 (emphasis added). The court of appeals' ruling also conflicts with this Court's more recent decision in *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), which gave effect to the determination set forth in the CSA that marijuana has "no currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(1)(B), in the face of a State's contrary determination of that disputed medical question, 532 U.S. at 486, 493.

The court of appeals reached this erroneous result only by misconstruing and dramatically expanding the scope of this Court's decision in *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), and by finding, contrary to this Court's well-established jurisprudence, that federal regulation of the distribution of controlled substances alters the usual constitutional balance between the States and the federal government because of its effect on the practice of medicine. By relying on constitutional avoidance principles to avoid a plainly reasonable interpretation of the CSA by the Attorney General, the court of appeals' holding threatens to undermine federal authority to regulate in numerous other areas that may have an effect on the practice of medicine. This Court's review is warranted to correct this serious misconception of the relative powers of state and federal governments under the Constitution and the CSA.

I. THE NINTH CIRCUIT ERRED IN HOLDING THAT A SINGLE STATE'S LAW RENDERED INVALID THE ATTORNEY GENERAL'S REASONABLE INTERPRETATION OF THE CONTROLLED SUBSTANCES ACT AND ITS IMPLEMENTING REGULATIONS TO BAR THE DISPENSING OF CONTROLLED SUBSTANCES TO FACILITATE SUICIDE

A. The Attorney General's Reasonable Interpretation Of The Comprehensive Federal Statute Must Prevail Over The Determination By A Particular State That Departs Radically From Long-Accepted Legal And Ethical Norms

The court of appeals acknowledged that the CSA prohibits practitioners from prescribing or dispensing controlled substances except for a "legitimate medical purpose" and "in the usual course of professional treatment." Pet. App. 5a (quoting 21 C.F.R. 1306.04). Thus, as the court of appeals recognized, the issue presented in this case is "who gets to decide," *id.* at 9a, whether a practitioner's conduct comports with that federal requirement under the CSA—the Attorney General, pursuant to a uniform national standard, or each of the 50 States, according to 50 different views regarding the proper use of controlled substances. The text and structure of the CSA, as well as general principles of federalism, compel the conclusion that the CSA, and the Attorney General's regulation implementing it, establish a single national standard.

1. In the interpretive ruling under challenge here, the Attorney General concluded that dispensing drugs to assist another individual in taking his or her life does not constitute a "legitimate medical purpose" in the course of medical "treatment." 21 C.F.R. 1306.04(a). Because the Attorney General has primary responsibility for enforcing the CSA, his interpretation of the Act is entitled to deference under

Chevron U.S.A. Inc. v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984), and his interpretation of his own regulation is entitled to even greater deference under *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997), and *Thomas Jefferson University* v. *Shalala*, 512 U.S. 504, 512 (1994). The Attorney General clearly acted reasonably in concluding that dispensing drugs to assist a person to commit suicide is not for a "legitimate medical purpose" or for "treatment" within the meaning of the CSA and his implementing regulation.

Indeed, the Attorney General's conclusion is the position maintained by 49 States, the federal government, and leading associations of the medical profession. As the Court noted in *Washington* v. *Glucksberg*, 521 U.S. 702 (1997), "[i]n almost every State—indeed, in almost every western democracy—it is a crime to assist a suicide." *Id.* at 710. With specific reference to Oregon's DWDA, the Court made clear that the Oregon statute was contrary both to longstanding historical practices and to contemporary trends in the law. *Id.* at 717-718. Thus, contrary to the dominant theme of the court of appeals' decision, the Attorney General did not ignore the laws of the States in interpreting the CSA to bar the dispensing of controlled substances to facilitate suicide. His interpretation is consistent with the position of the overwhelming majority of the States.

Numerous health care experts have agreed that physician-assisted suicide is not a legitimate medical treatment. In *Glucksberg*, the Court noted that New York State's Task Force on Life and the Law—a commission composed of doctors, ethicists, lawyers, religious leaders and interested laypersons—had unanimously concluded that "[l]egalizing assisted suicide and euthanasia would pose profound risks to many individuals who are ill and vulnerable. . . . [T]he potential dangers of this dramatic change in public policy would outweigh any benefit that might be achieved." 521

U.S. at 719 (quotation marks and citation omitted). Likewise, as the OLC memorandum noted, the American Medical Association, American Nurses Association, and American Psychiatric Association filed a joint brief in *Glucksberg* taking the position that physician-assisted suicide is "fundamentally incompatible with the physician's role as healer." Pet. App. 124a (quoting AMA Br. at 5, *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (No. 96-110)). Within the federal government as well, the Department of Health and Human Services' Health Care Financing Administration similarly has determined that physician-assisted suicide is not eligible for reimbursement under Medicare because it is "not reasonable and necessary to the diagnosis and treatment of disease or injury." Pet. App. 120a-121a (internal quotes omitted).

There can be no question, then, that the Attorney General's interpretive ruling is consistent with the prevailing views regarding medical practice and on that basis is, at the very least, reasonable and entitled to deference.

2. It is also clear, from the text and structure of the CSA, that the Attorney General's responsibility for enforcing the CSA required him to resolve the question whether the use of controlled substances to facilitate suicide is a "legitimate medical purpose" for "treatment." The principle that controlled substances may be dispensed only for a "legitimate medical purpose" in "treatment" is central to the CSA and is reflected throughout its provisions. The starting point of the Act (indeed, its first provision) is the recognition that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1). The federal regulatory scheme is built upon the dual principles that the dispensing of controlled substances should be allowed for such "legitimate

medical purposes" but that distribution for illegitimate purposes should be prohibited.

The Attorney General is charged under the CSA, 21 U.S.C. 811(a), with assigning a controlled substance to the appropriate "schedule" according to whether it has a "currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b), as well as with ensuring that there is an "adequate * * * supply" of Schedule I and Schedule II substances "for legitimate medical, scientific, research, and industrial purposes," 21 U.S.C. 823(a)(1). Those substances for which the Attorney General has determined there is "no currently accepted medical use in treatment in the United States" are placed in Schedule I, 21 U.S.C. 812(b)(1)(B), and may not be prescribed or dispensed except pursuant to a research protocol specifically approved by the Attorney General and the Secretary of Health and Human Services with respect to the medical merits of the proposal and its security against diverting the substance from "legitimate medical or scientific use," 21 U.S.C. 823(f). Substances in other Schedules may be dispensed by practitioners only because they have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(2)-(5), and a legitimate "medical use" in "treatment" therefore is a prerequisite to such dispensing.

Other provisions of the Act also confine a practitioner's latitude in dispensing drugs on Schedules II through V to legitimate medical uses in the course of treatment. See, *e.g.*, 21 U.S.C. 829(c) ("No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose."); *Moore*, 423 U.S. at 137 n.13 (indicating that the same requirement is implicit in 21 U.S.C. 829(a) for Schedule II substances). The Act authorizes the prescription of controlled substances only by a practitioner acting "in the course of professional practice or research," 21 U.S.C. 802(21), and, as a general matter, only by written

"prescription," 21 U.S.C. 829. The Attorney General's unchallenged regulation clarifies that a prescription, to be valid, must be "for a legitimate medical purpose" and issued "in the usual course of professional treatment or in legitimate and authorized research." 21 C.F.R. 1306.04(a). Certain reporting requirements imposed by the CSA similarly define a "valid prescription" as one "issued for a legitimate medical purpose by an individual practitioner * * * acting in the usual course of the practitioner's professional practice," 21 U.S.C. 830(b)(3)(A)(ii).

3. a. The centrality of the concepts of "legitimate medical purpose" and medical "treatment" in the text and structure of the CSA leaves no doubt that those standards are to be established and enforced at the federal, rather than state, level. This Court's decisions confirm that conclusion. There is no question, for example, that the determination whether a drug has a "currently accepted medical use in treatment in the United States," for purposes of scheduling the substance under 21 U.S.C. 812(b), is a federal decision that is binding on the States, rather than vice-versa. In *Oakland Cannabis*, the voters in California had passed a ballot initiative that established, for purposes of state law, that seriously ill Californians could "use marijuana for medical purposes." 532 U.S. at 486 (quoting Cal. Health & Safety Code Ann. § 11362.5(b)(1)(A) (West Supp. 2001)). Nonetheless, this Court rejected the marijuana cooperative's reliance on the state law as supporting a "medical necessity" defense to prosecution under the CSA. The Court held that such a defense would be inconsistent with Congress's finding, in classifying marijuana in Schedule I, that it has "no currently accepted medical use in treatment in the United States." *Id.* at 492. See *id.* at 493 (notwithstanding state law, "Congress has made a determination that marijuana has no medical benefits worthy of an exception," and the Court

could not "override a legislative determination" to that effect).

Although Congress, rather than the Attorney General, made the determination whether marijuana has a generally accepted medical use in treatment, a determination by the Attorney General would be no less binding on the States. The CSA expressly grants the Attorney General authority to assign substances to the appropriate schedule, and to move substances—including those originally classified by Congress—among schedules. 21 U.S.C. 811(a). In fact, in *Oakland Cannabis*, the Court specifically recognized that "[t]he Attorney General can include a drug in schedule I * * * if the drug 'has no currently accepted medical use in treatment in the United States,'" 532 U.S. at 492 (quoting 21 U.S.C. 812(b)(1)), and one issue raised in the case was whether Congress's assignment of marijuana to Schedule I, without making specific findings about its medical usefulness, was entitled to as much deference as the Attorney General's assignment would be. *Ibid.* The Court specifically rejected the challenge to Congress's classification of marijuana, holding that "the statute consistently treats all schedule I drugs alike," whether placed there by Congress or the Attorney General. *Id.* at 492-493.

Just as California's ballot initiative purporting to recognize a "use [for] marijuana for medical purposes," Cal. Health & Safety Code § 11362.5(b)(1)(A) (West Supp. 2001), did not compel recognition in *Oakland Cannabis* of an *exception* to the currently applicable rule under the CSA that a Schedule I substance has no "currently accepted medical use in treatment in the United States," neither would the state law be binding on the Attorney General for purposes of compelling him to *reclassify* marijuana to a different schedule under the CSA. Rather, such a determination must be based upon an independent *federal* assessment of the medical and scientific evidence and, if supported

by substantial evidence, is binding upon the entire Nation for purposes of the CSA. See *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131 (D.C. Cir. 1994) (upholding DEA's refusal to reschedule marijuana as supported by substantial evidence). As the D.C. Circuit held in *Alliance for Cannabis*, "only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." *Id.* at 1137. There is no basis in the CSA for substituting a ballot initiative, such as California voters' approval of medical marijuana or Oregon voters' endorsement of physician-assisted suicide, for the requisite "rigorous scientific proof" regarding a substance's "accepted medical use."

Nor is there any reason to conclude, as the Ninth Circuit in this case did, that the Attorney General's determination whether a *particular* use of a controlled substance constitutes a "legitimate medical use" "in the usual course of professional treatment," 21 C.F.R. 1306.04(a), is any less binding in the States for purposes of the CSA than his determination whether a substance has *any* accepted medical use. If, as is evident from *Oakland Cannabis*, the Attorney General could reclassify the Schedule II substances used by Oregon physicians to assist suicide[4] to Schedule I if the medical and scientific evidence warranted—despite the passage of the assisted suicide initiative in Oregon—then he likewise can determine that, while those Schedule II substances have *other* generally accepted medical uses in treatment, deliberately assisting a person to commit suicide is not one.

This Court's decision in *Moore* strongly supports that conclusion. *Moore* involved the prosecution of a physician who

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[4] According to the Oregon Department of Human Services, the three drugs dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are Schedule II depressants. See http://www.dhs.state.or.us/publichealth/chs/pas/ar-tbl-4.cfm; 21 C.F.R. 1308.12(e).

prescribed large quantities of methadone tablets with little or no medical assessment or supervision. See 423 U.S. at 126. He was convicted under the CSA for prescribing controlled substances outside the usual course of his professional practice. This Court held that the CSA was intended to limit a physician's distribution of controlled substances to actions "as a physician" and in the course of "professional practice." 423 U.S. at 140, 141. The Court made clear that Moore's conviction, which it affirmed, was based on a uniform nationwide standard for deciding whether the prescriptions were valid and permissible under the CSA: whether they were "in accordance with a standard of medical practice generally recognized and accepted *in the United States*." *Id.* at 139 (quoting jury instructions) (emphasis added).[5]

b. The conclusion evident from the text and structure of the CSA—that Congress intended the Act to be applied in a uniform manner across the Nation—is further confirmed by the well-established principle of statutory construction 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 on state law." *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43, 47 (1989) (quoting *Jerome* v. *United States*, 318 U.S. 101, 104 (1943), and holding that the word "domicile" used in a federal law should have a uniform meaning and is not defined by

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[5] With the exception of the decision below, the courts of appeals have followed *Moore* and applied a national standard for professional practice under the CSA. See *United States* v. *Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (standard of professional practice "generally recognized and accepted in the United States"), cert. denied, 479 U.S. 1036 (1987); *United States* v. *Norris*, 780 F.2d 1207, 1209 & n.2 (5th Cir. 1986) (same); *United States* v. *Daniel*, 3 F.3d 775, 778 (4th Cir. 1993) (same), cert. denied, 510 U.S. 1130 (1994); Kevin F. O'Malley et al., *Federal Jury Practice and Instructions (Criminal)* § 64.16, at 428 (5th ed. 2000) (same).

state law). See *United States* v. *Turley*, 352 U.S. 407 (1957) (word "stolen," used in federal criminal statute, has a uniform nationwide meaning and is not defined by state law); *United States* v. *Pelzer*, 312 U.S. 399 (1941) (same for phrase "future interests" in federal tax statute). Nothing in either the CSA or its implementing regulation makes the definition of "legitimate medical purpose" depend upon state law. To the contrary, there are strong indications, as *Moore* and *Oakland Cannabis* recognize, that Congress did *not* intend the concepts of legitimate medical purpose, medical treatment, or public health and safety to be determined solely by reference to state law.

The *Mississippi Band* presumption is particularly appropriate with respect to the CSA. Congress made clear that it intended the CSA to establish a national, comprehensive, and uniform law governing the use of controlled substances in this country. The need for national control was so great that Congress specifically found it necessary to regulate purely intrastate conduct relating to controlled substances. See 21 U.S.C. 801(6) (finding that "[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic"). Thus, as in *Mississippi Band*, the application of federal law must not (and does not) depend on state law because "the application of federal legislation is nationwide and at times the federal program would be impaired if state law were to control." *Dickerson* v. *New Banner Inst., Inc.*, 460 U.S. 103, 119-120 (1983). If, for example, one State's voters were of the view that marijuana has a medical use in treating mild depression, and that view was binding on the Attorney General for purposes of scheduling and ensuring adequate supplies for legitimate medical uses, the federal scheme to control the lines of distribution of that drug—including in other States that did not share the maverick view—would be severely undermined. The CSA's

scheme to control *all* manufacturing, possession, and distribution of any scheduled drug unquestionably constitutes "federal legislation, administered by a national agency, intended to solve a national problem on a national scale," the success of which cannot depend upon the vagaries of state law. *NLRB* v. *Natural Gas Util. Dist.*, 402 U.S. 600, 603-604 (1971) (quoting *NLRB* v. *Randolph Elec. Membership Corp.*, 343 F.2d 60, 63 (4th Cir. 1965)).

B. The Ninth Circuit's Reliance On *Gregory* v. *Ashcroft* And Related Principles To Defeat The Application Of The CSA To Private Conduct In Dispensing Drugs Is Fundamentally Flawed

1. The court of appeals failed to follow *Oakland Cannabis*, *Moore*, and *Mississippi Band*, and instead concluded that this Court's decision in *Gregory* v. *Ashcroft*, 501 U.S. 452 (1991), compelled a holding that state law controls the question whether a physician's conduct is for a legitimate medical purpose under the CSA. The court of appeals even went so far as to conclude that the Attorney General's interpretive ruling that dispensing a federally controlled substance to assist a person to commit suicide is not permitted under the CSA "invokes the outer limits of Congress's power by encroaching on state authority to regulate medical practice." Pet. App. 12a (citing *Linder* v. *United States*, 268 U.S. 5, 18 (1925)). Because, in the court of appeals' view, the effect of the CSA on Oregon law "alter[s] the usual constitutional balance between the States and the Federal Government" by exercising control over "an area of law traditionally reserved for state authority," *id.* at 11a (quoting *Gregory*, 501 U.S. at 461 (additional internal quotes omitted)), the court required that the CSA make "unmistakably clear" the Attorney General's authority to adopt the interpretive rule, *ibid.*

The court of appeals' conclusion that federal regulation of the distribution of controlled substances "alter[s] the usual constitutional balance between the States and the Federal Government" in a manner that requires an "unmistakably clear" statement by Congress fundamentally misunderstands the constitutional rule. The decision in *Gregory* turned on the fact that the federal statute at issue threatened to intrude upon a State's determination of the qualifications of its own judges, which this Court characterized as a constitutionally protected "decision of the most fundamental sort for a sovereign entity." 501 U.S. at 460. As the courts of appeals have recognized, *Gregory* must be limited to such basic threats to state sovereignty. See *United States* v. *Lot 5, Fox Grove*, 23 F.3d 359, 362 (11th Cir. 1994) (noting that "the *Gregory* plain statement preemption rule is limited to federal laws impacting a state's self-identification as a sovereignty"), cert. denied, 513 U.S. 1076 (1995); *Gately* v. *Massachusetts*, 2 F.3d 1221, 1230 (1st Cir. 1993) (noting that *Gregory* is limited to protecting "a core function going to the 'heart of representative government'"). The *Gregory* principle does not apply to the effect an Act of Congress may have on a State's views about *private* conduct that is otherwise within the scope of Congress's power to regulate. Furthermore, there is no merit to the court of appeals' notion that the application of the CSA here encroaches on "an area of law traditionally reserved for state authority," Pet. App. 11a, because, as *Glucksberg*, makes clear, there *is* no tradition of States authorizing physician-assisted suicide, 521 U.S. at 710.

The court of appeals' suggestion that Congress's regulation of the distribution of controlled substances in these circumstances raises significant constitutional problems also flies in the face of history and this Court's precedent. Congress has regulated prescriptions for controlled substances nationwide for almost a century under the CSA and its pre-

decessor, the Harrison Act of 1914, ch. 1, 38 Stat. 785. The court of appeals cited *Linder* as authority for the proposition that "direct control of medical practice in the states is beyond the power of the federal government," Pet. App. 10a, and for the further conclusion that the Attorney General's interpretive ruling "invokes the outer limits of Congress' power by encroaching on state authority to regulate medical practice," *id.* at 12a. Notably, the Court's *Lochner*-era decision in *Linder* relied upon the then-prevailing view, articulated in such cases as *Hammer* v. *Dagenhart*, 247 U.S. 251 (1918), that Congress could not employ its enumerated powers to accomplish more general purposes relating to health and welfare that were believed to be the exclusive province of the States. *Linder*, 268 U.S. at 17 (citing *Hammer*, among others, for the proposition that "an act of Congress ostensibly enacted under power granted by the Constitution, not naturally and reasonably adapted to the effective exercise of such power but solely to the achievement of something plainly within power reserved to the States, is invalid and cannot be enforced"). That holding of *Hammer* was expressly overruled in *United States* v. *Darby*, 312 U.S. 100, 115-117 (1941), which upheld the authority of Congress to regulate interstate commerce for the purpose of improving the working conditions of laborers, *id.* at 115.

Moreover, this Court's subsequent decisions establish that *Linder*'s suggestion that the federal government could not supplant wholesale the States' "control of medical practice" does not preclude federal regulation of interstate commerce in controlled substances despite the effects such regulation may have on unorthodox practices by physicians. See *Oakland Cannabis*, 532 U.S. at 492-493 (upholding CSA determination that marijuana lacked an acceptable medical use); *Moore*, 423 U.S. at 143 (affirming federal criminal conviction of physician engaged in unauthorized "experiment[al] * * * theory of detoxification"); *Minor* v. *United States*, 396 U.S.

87, 98 n.13 (1969) (ban on sale of narcotics is within Congress's constitutional power); *Reina* v. *United States*, 364 U.S. 507, 511 (1960) (Congress had "undoubted power to enact the narcotics laws").

Thus the court of appeals erred in concluding that the Attorney General's adoption of a national rule regarding the distribution of controlled substances to facilitate suicide upset the usual balance between the state and federal governments.

2. The other reasons the court of appeals gave in support of its holding are likewise flawed and are, to a significant degree, infected with the court of appeals' erroneous view that *Gregory*'s clear statement rule provided the applicable standard. Under the appropriate framework of affording *Chevron* deference to the Attorney General's construction of the CSA, rather than *Gregory*'s reverse presumption, none of the court of appeals' other points undermines the reasonableness of the Attorney General's interpretive ruling.

a. The court of appeals erred, for example, in relying on the notion that Congress intended "to limit federal authority under the CSA to the field of drug abuse," Pet. App. 14a, and that the CSA's "legitimate medical purpose" requirement must be construed to address that concern alone. In the first place, the taking of drugs to commit suicide *is* "drug abuse," and prohibiting the dispensing of a drug to facilitate suicide therefore falls within the purposes of the Act even as the court of appeals understood them. Moreover, Congress expressly stated broad goals in enacting the CSA, which was designed to combat "illegal importation, manufacture, distribution, and possession and *improper use* of controlled substances." 21 U.S.C. 801(2) (emphasis added). There is no doubt that Congress viewed the use of controlled substances to commit suicide to be a form of improper use. Congress specifically referred to the "[m]isuse of a drug in suicides and attempted suicides," and noted that "injuries resulting from

unsupervised use are regarded as indicative of a drug's potential for abuse." H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1., at 35 (1970). See *id.* at 34 (potential for abuse indicated by "evidence that individuals are taking the drug * * * in amounts sufficient to create a hazard to their health"); 21 U.S.C. 801(1) (noting congressional purpose "to maintain the health and general welfare of the American people"); 21 U.S.C. 823(f)(5) (requiring the Attorney General to consider threats to "the public health and safety" in issuing and revoking registrations to physicians to distribute controlled substances).

b. The court of appeals also cited the role of the Secretary of Health and Human Services as a reason why the Attorney General was not the appropriate officer within the federal government to make determinations under the CSA that affect the practice of medicine. Pet. App. 15a. While it is true that the CSA assigns certain functions with respect to its implementation to the Secretary, the Attorney General shares a role in many of those functions. *E.g.*, 21 U.S.C. 823(f) (assigning to both the Secretary and Attorney General roles in assessing proposed research projects relating to Schedule I drugs). Many other responsibilities under the CSA that require making determinations respecting the legitimate medical use of substances are assigned to the Attorney General alone. *E.g.*, 21 U.S.C. 823(a)(1) (Attorney General to ensure adequate supply of Schedule II substances for "legitimate medical * * * purposes"); 21 U.S.C. 823(f)(5) (listing "the public health and safety" among factors the Attorney General may consider in determining whether to revoke a practitioner's registration under the CSA). In any event, the determination whether dispensing drugs to facilitate suicide constitutes a "legitimate medical purpose" turns on an interpretation of the CSA and a regulation of the Attorney General, and does not require an assessment of

medical or scientific evidence of the sort that the CSA has assigned to the Secretary.[6]

c. The court of appeals' conclusion that the Attorney General violated 21 U.S.C. 823(f) by failing to consider all of the factors addressed in that section is also flawed. As an initial matter, Section 823(f) applies, by its terms, only to actions by the Attorney General to deny or revoke a CSA registration. The Attorney General's ruling at issue here is not such a denial or revocation. It is, rather, an interpretation of the *substantive* provisions of the Act, violation of which may in turn lead to a revocation of registration. In any event, Section 823(f) requires the Attorney General to consider a number of factors, including not only compliance with state laws, 21 U.S.C. 823(f)(4), but others, such as "[c]ompliance with applicable * * * Federal * * * laws relating to controlled substances," 21 U.S.C. 823(f)(4), and any threat to "the public health and safety," 21 U.S.C. 823(f)(5), that plainly call for an independent determination by the Attorney General. The court of appeals' ruling would preclude the Attorney General from exercising his statutory responsibility to ascertain whether a physician's registration is consistent with the public interest by making one factor—compliance with state law—determinative of that question. Indeed the court of appeals would make state law determinative of the question whether dispensing drugs to facilitate suicide even violates the CSA to begin with. There

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[6] The court of appeals cited (Pet. App. 15a) this Court's reference in *Moore* to the Secretary's function in determining "the appropriate methods of professional practice in the medical treatment of . . . narcotic addiction." 423 U.S. at 144 (quoting 42 U.S.C. 257a (1970) (currently 42 U.S.C. 290bb-2a)). That provision is not directly at issue here, and the fact that certain health-related determinations are assigned to the Secretary does not negate the Attorney General's independent responsibilities under the CSA to ensure that controlled substances are prescribed only for a "legitimate medical purpose."

is no support in the statute's text for those extraordinary conclusions.

II. THE COURT OF APPEALS' DECISION WARRANTS REVIEW BECAUSE IT CONFLICTS WITH DECISIONS OF THIS COURT AND IMPROPERLY ALLOWS STATES TO DICTATE THE CONTENT OF FEDERAL LAW.

The court of appeals' decision warrants review by this Court. The holding below is yet another in a series of decisions in which the Ninth Circuit has undermined the federal government's ability to enforce the comprehensive federal law to control dangerous substances by subordinating federal authority to that of the States. In *Oakland Cannabis*, the Ninth Circuit held that in light of California's medical marijuana initiative, the United States could not enforce the CSA against individuals who purport to use marijuana for medical purposes, despite the federal determination in the CSA itself that no generally accepted medical use exists for marijuana. *United States* v. *Oakland Cannabis Buyers' Coop.*, 190 F.3d 1109, 1111, 1114 (9th Cir. 1999), rev'd, 532 U.S. 483 (2001). More recently, in *Raich* v. *Ashcroft*, 352 F.3d 1222 (2003), cert. granted, 124 S. Ct. 2909 (2004), the Ninth Circuit held that Congress could not, pursuant to the Commerce Clause (U.S. Const. Art. 1, § 8, Cl. 3), regulate "the intrastate, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient's physician pursuant to valid California state law," because, in the court's view, that sub-class of activity did not have a sufficient impact on interstate commerce. 352 F.3d at 1228, 1231.

The Ninth Circuit's decision in this case is equally dismissive of the comprehensive federal regulatory scheme. It makes that scheme for controlling substances depend not on a uniform national standard, but on the vagaries of each State's notions of what constitutes a "legitimate medical

purpose" or "treatment," no matter how far outside the mainstream of accepted medical practice a particular State's views may be.

Moreover, the reasoning by which the court of appeals reached that conclusion is dramatic in its potential scope—as evidenced by its reliance on a *Lochner*-era case as defining the limits on Congress's authority to regulate matters that may indirectly affect the practice of medicine. The court of appeals' failure to apply this Court's presumption of national uniformity established in *Mississippi Band* and its invocation, instead, of the *Gregory* v. *Ashcroft* clear statement rule based on the mere fact that the practice of medicine is implicated could have far-reaching consequences if applied to other federal statutory schemes. *E.g.*, 21 U.S.C. 355(d) (requiring FDA to deny application for new drug if not safe and effective for its intended purpose); 21 U.S.C. 352(j) (drug is "misbranded" if "it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof"); 42 U.S.C. 1320a-7(a) and (b)(6)(B) (authorizing Secretary to exclude from participation in "any Federal health care program" a doctor (or anyone else) who furnishes services "substantially in excess of the needs of * * * patients," regardless of whether those patients were eligible for or participated in any federal programs); 42 U.S.C. 1320c-5(a)(1) and (b) (requiring any "health care practitioner" participating in Medicare to provide only "medically necessary" services to Medicare beneficiaries, and allowing the Secretary to bar violators from participating in the Medicare program); 42 U.S.C. 1395y(a)(1)(A) (2000 & Supp. I 2001) (authorizing Medicare to reimburse only "reasonable and necessary" medical services).

In short, Congress often attaches consequences under federal statutes to a determination by a federal official regarding what constitutes proper, necessary, safe, or effective

medical care. The uniform application of such statutory schemes is cast into doubt by the court of appeals' decision in this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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