2002 WL 32290872 (C.A.9) (Appellate Brief)
For opinion see 368 F.3d 1118

Briefs and Other Related Documents

United States Court of Appeals,
Ninth Circuit.
STATE OF OREGON, et al., Plaintiffs-Appellees,
v.
John ASHCROFT, in his official capacity as United States Attorney General, et al., Defendants-Appellants.
No. 02-35587.
November 7, 2002.

On Appeal from the United States District Court for the District of Oregon

Amicus Curiae Brief of the American College of Legal Medicine in Support of Plaintiffs-Appellees

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***1** Now comes the American College of Legal Medicine ("ACLM"), by and through its legal counsel, Miles J. Zaremski, Esq. and Maxwell J. Mehlman, Esq. and submits this brief as *amicus curiae* in support of Plaintiffs-Appellees in this case.

Consent of the Parties

The ACLM has received consent from all parties to file this brief.

Interest of Amicus

The American College of Legal Medicine is uniquely qualified to advise the Court on this subject. Founded in 1960, the American College of Legal Medicine (ACLM) is a non-profit organization dedicated to scholarship, education and policy in law, medicine, and healthcare. The ACLM is the only organization in the United States where the majority of its 1,300 Fellows and members possess both medical and juris doctor degrees. These healthcare and legal professionals' diverse education, training, and experience enable the ACLM to promote interdisciplinary cooperation and an understanding of issues where law and medicine converge.

*2 Argument

In a Directive to the Department of Drug Enforcement on 6 November 2001, the Attorney General of the United States declared that the use of Schedule II controlled substances under Oregon's Death with Dignity Act was not a "legitimate medical purpose," and that therefore physicians who complied with that act were violating the Controlled Substances Act ("CSA"). 66 Fed. Reg. 5,607, 5,608 (Nov. 9, 2001). A key issue in this case, consequently, is the meaning of the term, "legitimate medical purpose," and more importantly, what process the CSA, and the law in general, require for establishing what is and is not a legitimate medical use.

The Attorney General takes the position that he can declare what is and is not a legitimate medical purpose under the CSA. This is plainly contrary to the CSA. In the District Court's opinion in this case, Judge Robert E. Jones held that nothing in the CSA grants the Attorney General ". . .the authority to decide, as a matter of national policy, a question of such magnitude as whether physician-assisted suicide constitutes a legitimate medical purpose or practice." *Oregon v. Ashcroft*, 192 F. Supp. 1077, 1089 (D. Ore. 2002). We concur.

The CSA does not give the Attorney General the power to unilaterally decide what is and is not a currently accepted medical use for scheduling purposes. Controlled substances are scheduled according to whether they have a "currently *3 accepted medical use" or "no currently accepted medical use," with varying levels of restrictions. 21 USC § 812(b). But 21 USC § 811(b) provides:

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. . . .

The recommendations of the Secretary shall include recommendations with respect to the appropriate

schedule, if any, under which such drug or other substance should be listed. . . .

The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.

Thus, according to the CSA, a determination of what is and is not a currently accepted medical use can only be made by the Attorney General based on a scientific and medical evaluation *from* the Secretary of Health and Human Services (HHS).[FN1] The Secretary of HHS must also include recommendations as to where a *4 substance should be scheduled. The recommendations of HHS are binding on the Attorney General as to scientific and medical matters, including where a drug is scheduled and whether or not a drug ought to be controlled. In short, the CSA does not give the Attorney General the authority to declare, *sua sponte,* what is and is not a currently accepted medical use. Instead, he must defer to the expert medical judgment of the Department of Health and Human Services, embodied in a "scientific and medical evaluation."

> FN1. *See*, in general, Joranson DE. "Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances" In: Cooper JR, et al. Evaluation of the Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Possible Implications for Future Research. National Institute on Drug Abuse Technical Research Monograph 131. Rockville, MD: NIDA, 1993. Also available at:
>
> *http://www.medsch.wisc.edu/painpolicy/publicat/93nLda.htm*. Joranson states: "When Congress adopted the final version of the CSA in October 1970, the Secretary of Health, Education, and Welfare, and not the Attorney General, had been given the responsibility for making medical and scientific decisions concerning drug control..." (at p. 14). Joranson quotes Congressman Paul Rogers of the House Subcommittee on Health and the Environment, as follows:
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> "'As Members may recall, the scientific and medical community of this Nation were greatly upset over the fact that scientific and medical decisions in the Senate bill were centered in the Department of Justice, with the Attorney General having the responsibility to make scientific and medical determinations which were not in the competency of the Department, and admittedly so. We have changed that so that the Department of Health, Education and Welfare will determine scientific and medical decisions. This is a most important change in the whole approach as it came from the Senate.' Congressman Paul Rogers, *Congressional Record*, September 23, 1970." *Id.*
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> Joranson states further:
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> "The intent of Congress to avoid interference with medical practice and drug availability was restated in 1978 when Congress enacted the Psychotrophic Substances. Act to satisfy U.S. obligations under the Convention on Psychotropic Substances. Congress amended the CSA to say that control of psychotrophic substances in the U.S. 'should be accomplished within the framework of the procedures and criteria for classification of substances provided in the (CSA)' to ensure that 'availability [of FFDCA drugs]... for useful and legitimate medical and scientific purposes will not be unduly restricted.... Furthermore, the Congress said that nothing in the treaties is to "interfere with ethical medical practice in this country as determined by the Secretary of Health and Human Services on the basis of a consensus of the American medical and scientific community' (21 USC § 801)."
>
> *Id.*, at p. 7.

The only relevant discretion the Attorney General is given under the CSA is to determine whether to

schedule a derivative drug in the same schedule or a ***5** higher numerical schedule than its immediate precursor, 21 USC § 811 (e) and, if there is an imminent hazard to public safety, to move a controlled substance to schedule I (no currently accepted medical use) for no more than eighteen months, 21 USC § 811(h). Neither of these decisions involve a determination of what is or is not a legitimate medical use. The former relates to the potential for abuse, while the latter involves the much less precise judgment that a substance has *no* legitimate medical use at all. These limited exceptions to the Attorney General's power under the CSA emphasize his lack of competence to determine on his own what the legitimate medical uses are for a controlled substance that has some legitimate medical use (i.e., not Schedule I).

The CSA does not provide a definition of "legitimate medical purpose" in its extensive definitions. Court decisions, however, uniformly confirm the notion that the Attorney General must defer to expert medical judgment in determining what is and is not a legitimate medical use. The Attorney General relies on two cases in his brief, *U. S. v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975) and *U.S. v. Moore*, 423 U.S. 122 (1975) for the proposition that the CSA prohibits physicians from prescribing drugs except for legitimate medical purposes. Both cases demonstrate that expert medical judgment is required in order to determine what is and is not a legitimate medical purpose. In *Rosenberg*, the Ninth Circuit held that Dr. Rosenberg violated the CSA by prescribing Schedule II, III, and IV controlled ***6** substances to patients he had not examined, or in some cases not met, because expert medical testimony showed that this was outside the "usual course of professional practice." *Rosenberg* 515 F.2d at 193. *Moore* was relied on by the Attorney General, 66 Fed. Reg. 5,607, 5,608 (Nov. 9, 2001), and by the Office of Legal Counsel ("OLC") of the U.S. Department of Justice's Memorandum on which he based his directive, (*OLC Memo*, June 27, 2001, pp.5-6). In *Moore*, a physician prescribed methadone, a Schedule II controlled substance, in large quantities, charging by the pill, to patients not in detoxification or maintenance programs. *U.S. v. Moore*, 505 F.2d 426, 447 (D.C. Cir. 1974) (dissent). Reversing the Court of Appeals, the Supreme Court held that the physician could be held liable for failing to use controlled substances within the course of professional practice and for legitimate medical purposes. *U. S. v. Moore*, 423 U.S. at 142. What is significant is that expert medical testimony was necessary to prove that this was not a legitimate medical practice and, therefore, violated the. CSA.

In fact, case law makes it clear that expert medical knowledge is required in all jurisdictions to determine legitimate medical use for purposes of proving that a physician has violated the GSA in the course of professional practice. "The general rule is that the propriety or impropriety of particular medical treatment can be established only by expert medical testimony." *Church v. Bloch*, 182 P.2d 241, 245 (Cal. 1947). *See, e.g., U. S. v. Boettjer*, 569 F.2d 1078, 1079 (9th Cir. 1978) ***7** ("The testimony of the government's expert witness . . . supported the conclusion that Dr. Boettjer had dealt with the investigator-patients in an unprofessional manner without the application of sound medical criteria and the prescriptions were not issued for legitimate medical purposes."); *Farney v. Anderson*, 372 N.E.2d 151, 154 (Ill. 1978) ("The method employed by Farney might be the accepted one for treating addicts; perhaps not, but it is not for a layman, uneducated in medicine, to say. Expert testimony, whether coming down on the positive or negative side of Farney's treatment, is essential."). *See also U.S. v. Tran Trong Cuong, M.D.*, 18 F.3d 1132, 1137-38 (4th Cir. 1994) ("In making a medical judgment concerning the right to treatment for an individual patient physicians have discretion to choose among the wide range of available options. Therefore, in determining whether defendant acted without a legitimate medical purpose, you should examine all the defendant's actions and the circumstances surrounding them. . . . [A]n examination of [expert medical] testimony and the other evidence presented convinces us that Dr. Tran's actions in dispensing narcotics and other controlled substances violated the criminal standard and were outside the bounds of his professional medical practice."); *White v. United States*, 399 F.2d 813, 820 (8th Cir. 1968) ("It would seem that one whose area of expertise is the study of the beneficial and harmful effects of drugs within the human body is in an especially advantageous position to testify as to the relationship which should ***8** exist between a doctor and patient, or what a doctor should know about his patient before prescribing a particular drug. He, as a student of drugs, can evaluate their potential effect in the human body. His testimony is along a line not generally known to laymen and jurors. Consequently, Dr. Burton is a proper expert and his testimony was within the range of his expertise.").

A requirement that the Attorney General defer to expert medical judgment is consistent with the manner in which the law establishes what is and is not a legitimate medical use in contexts outside of the CSA as well. The Supreme Court, in *Davis v. Virginian Railway Co.*, 361 U.S. 354 (1960), articulated the standard for proof of malpractice as requiring two elements of evidence, "evidence as to the recognized standard of care of the medical community in the particular kind of case, and a showing that the physician in question negligently departed from this standard in his treatment of the plaintiff." 361 U.S. at 357 (1960). Expert medical testimony is necessary to prove both elements. *See also State v. Warden*, 813 P.2d 1146, 1151 (Utah 1991) ("Since the negligence occurred in the context of medical treatment, it is necessary to view the circumstances from the viewpoint of a member of the medical profession. Expert testimony established that Warden, by not examining Young prior to the time birth was imminent and not hospitalizing the infant immediately after the birth, deviated from the standard of care which physicians using ordinary care exercise in the delivery and care of newborns."); ***9** *People v. Klvana*, 15 Cal.Rptr.2d 512, 536 (1992) (Expert medical testimony was necessary "on the prevailing standards of obstetrical care and what knowledge a person with Dr. Klvana's medical training and experiences would be expected to possess."); *Rudick v. Prineville Memorial Hospital*, 319 F.2d 764 (9th Cir. 1963) (holding that the dismissal of appellee radiologist was improper because there no expert testimony that he had acted negligently or improperly or in any way not in conformity with the medical practice of experts in his specialty).

Expert medical knowledge, whether from outside experts or based on the physician board members' own expertise, is also necessary to determine what is and is not a legitimate medical use in disciplinary hearings before state medical boards. See *Dotson v. Texas State Bd. of Medical Examiners*, 612 S.W.2d 921, 923 (Tex. 1981) ("The problem is that there is no expert testimony to support the Board's factual conclusion that these drugs were non-therapeutic in the manner such drugs were prescribed by either of these doctors. It should be recognized at the outset that each of these controlled drugs (Preludin, Valium, Ritalin and Elavil) is a legitimately manufactured prescription drug authorized for use by the Food and Drug Administration and that both doctors were authorized to prescribe each."); *Loffredo v. Sobol*, 195 A.D.2d 757, 759 (N.Y. 1993) ("[Expert medical] testimony adequately supported the finding of gross negligence with respect to patient A. The contrary medical evidence presented by petitioner merely created a ***10** credibility issue which respondents were free to and did resolve against him."); *McKay v. State Board of Medical Examiners*, 86 P.2d 232, 236 (Colo. 1938) ("In the case before us there is no expert testimony disclosed in the record that proves or tends to prove a failure properly to diagnose or to treat the disease of the various persons with respect to whom malpractice was charged. It is not enough that the board may be composed of experts who applied their knowledge of diagnosis and treatment to the case in which malpractice is alleged."); and *Smith v. Department of Registration*, 106 N.E.2d 722, 730-31 (Ill. 1952) ("This court possesses neither medical learning nor powers of telepathy. We are, therefore, unable to medically evaluate the testimony in this record or to know what scientific appraisal of it was made by the medical committee."). See also *Arlen v. State Medical Board*, 399 N.E.2d 1251, 1254 (Oh. 1980) ("[E]xpert testimony as to a standard of practice is not mandatory in a license revocation hearing and the board may rely on its own expertise to determine whether a physician failed to conform to minimum standards of care.").

Indeed, the Attorney General appears to recognize the appropriateness of deferring to expert medical judgment when he refers to the views of the American Medical Association on the Oregon Death with Dignity Act. "The American Medical Association and the American Nurses Association...regard the practice of assisted suicide as 'fundamentally inconsistent with the physician's role as healer,' ***11** and have informed the Supreme Court that '[t]he ethical prohibition against physician-assisted suicide is a cornerstone of medical ethics." *Defendants' Memorandum In Support of Motion to Dismiss*, p. 34, (citing *OLC Memo* at 11). Yet, it is important to realize that the AMA's and ANA's views, themselves, do not settle the question of what is a legitimate medical use. The law recognizes that the practice of medicine is complex and that reasonable physicians may differ on what is legitimate and appropriate. The law is thus careful to allow room for disagreement among reasonable practitioners, as reflected, for example, in the "respectable minority doctrine," which recognizes medical practices that are not the norm, but are, nonetheless, a legitimate medical use, in that they are acceptable and supported by a school of expert medical thought. *See In re Williams*, 60 Ohio St.3d 85 (1991) (overturning a State Medical Board determination that the physician had failed to meet the minimum standards of

medical practice because the two medical experts who testified stated that, although they supported the majority opinion on the duration of prescription stimulants for weight loss, "Dr. Williams's application of the 'minority' protocol was not substandard medical practice."); *Chumbler v. McClure*, 505 F.2d 489,492 (6th Cir. 1974) ("Where two or more schools of thought exist among competent members of the medical profession concerning proper medical treatment for a given ailment, each of which is supported by responsible medical authority, it is not malpractice to be among the ***12** minority in a given city who follow one of the accepted schools."); and *Downer v. Veilleux*, 322 A.2d 82, 87 (Me. 1974) ("[A] physician does not incur liability merely by electing to pursue one of several recognized courses of treatment. It is incumbent upon the plaintiff to show by expert testimony that the treatment pursued by the defendant was something other than that which the average and reasonably skilled physician would have employed.").

In fact, a substantial percentage of Oregon physicians, including the governor of Oregon, John A. Kitzhaber, MD, believe that the Oregon Death with Dignity Act reflects legitimate medical practice. A survey for the *Journal of the American Medical Association*, for example, found that 51% of responding physicians (66% of practicing Oregon, physicians) strongly support or support the Death with Dignity Act and legalization of physician-assisted suicide. Linda Ganzini, MD, et al., *Oregon Physicians' Attitudes About and Experiences With End-of-Life Care Since Passage of the Oregon Death with Dignity* Act, 285 JAMA, 2363, 2365 (May 9, 2001).

The only exception to the need to defer to expert medical judgment occurs when, in the case of a controlled substance that has a legitimate medical purpose, a state declares what is and is not a currently accepted medical use within that state. As the U.S. Supreme Court held in ***13** *Washington v. Glucksberg*, 521 U.S. 702 (1997), a state is free to make this "considered policy choice." *See* 521 U.S. at 704, 723. This is what Oregon has done here.

Justice O'Connor stated in her concurrence in *Glucksberg*: "As the Court recognizes, states are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues [citations omitted]. In such circumstances, ". . .the... challenging task of crafting appropriate procedures for safeguarding . . . liberty interests is entrusted to the 'laboratory' of the states... in the first instance [citation omitted]." 521 U.S. 702, 737. Oregon has chosen to set up its own laboratory and has crafted statutory language voted upon twice by its electorate. Oregon's statutory framework has confirmed the legitimacy of the medical purpose at issue - a legitimacy which, as has already been demonstrated by appellees, withstood the test of time and courtroom challenges. *See Oregon v. Ashcroft*, 192 F.Supp.2d 1077, 1081 (2002).

Moreover, *in Rush Prudential HMO, Inc. v. Moran*, 122 S. Ct. 2151 (2002), the Court held that, absent clear Congressional intent to the contrary, matters of health care are left to states to regulate. *Id.*, at 2171. A *sine qua non* of the regulation of health care is establishing parameters for the practice of medicine, including standards of care and treatment; subsumed within this (regulation of medical practice) is the determination of what is, or is not, a legitimate medical purpose. As previously pointed out in this brief and in the record below, Congress ***14** did not give the Attorney General the authority to determine, on his own, what is or is not a legitimate medical purpose. Absent such clearly expressed guidance from Congress, the legitimacy of a medical purpose is a matter for the states -- here, the State of Oregon -- to establish in its own laboratory, in order to ensure that the rights of its citizenry are appropriately safeguarded with respect to physician-aid-in-dying.

Conclusion

In summary, the Attorney General does not have the medical expertise required to determine what is and is not a legitimate medical purpose in order to penalize physicians for acting in conformity with Oregon's Death with Dignity Act. For controlled substances that have a legitimate medical use, this determination can be made only with the aid of medical expertise or by states making considered choices about public policy consistent with their role to regulate matters of health care where Congress is silent on the subject.

*15 WHEREFORE for the reasons expressed in this *amicus* filing, the ACLM respectfully requests that this Honorable Court affirm the decision below.

STATE OF OREGON, et al., Plaintiffs-Appellees, v. John ASHCROFT, in his official capacity as United States Attorney General, et al., Defendants-Appellants.
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