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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

STATE OF OREGON,

Plaintiff,

&

PETER A. RASMUSSEN, M.D.; and
DAVID MALCOM HOCHHALTER, RPh,

Plaintiffs-Intervenors,

&

KARL STANSEL; **RICHARD HOLMES**; **JANE DOE #1**; and **JAMES ROMNEY** (patients),

Plaintiffs-Intervenors,

v.

JOHN ASHCROFT, in his official capacity as United States Attorney General, **ASA HUTCHINSON**, in his official capacity as Administrator of the Drug Enforcement Administration, **KENNETH W. MAGEE**, in his official capacity as the Director of the Drug Enforcement Administration, Portland Office; **THE UNITED STATES OF AMERICA; THE UNITED STATES DEPARTMENT OF JUSTICE**; and **THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION**,

Defendants.

Civil No. CV-01-1647-JO

MOTION AND MEMORANDUM OF *AMICUS CURIAE* ACLU FOUNDATION OF OREGON, INC.

I. Motion

ACLU Foundation of Oregon, Inc., respectfully moves for leave to submit the following memorandum as *amicus curiae*, in support of the relief sought by plaintiff State of Oregon.

II. Interest of Amicus Curiae

The ACLU Foundation of Oregon, Inc., is the educational and litigation arm of the American Civil Liberties Union of Oregon, which is, in turn, an affiliate of the national American Civil Liberties Union ("ACLU"). The ACLU is a nonprofit, nonpartisan organization with nearly 300,000 members throughout the United States, dedicated to preserving the principles of liberty and equality embodied in the Constitution. Since its founding in 1920, the ACLU has participated in numerous cases in federal and state courts across the country, including many of the significant cases involving physician-assisted death. When Oregon's Death With Dignity Act was challenged in an action filed in this court in 1994, the ACLU represented intervenors in support of the Act, both in the proceedings in this court and before the Ninth Circuit. *Lee v. State of Or.*, 891 F Supp 1421, 1429, 1439 (D Or 1995), *vacated* 107 F3d 1382 (9th Cir), *cert denied* 522 US 927 (1997). In addition, the ACLU appeared as *amicus* both before the Ninth Circuit and before the Supreme Court in *Compassion in Dying v. Washington*, 79 F3d 790 (9th Cir 1996), *rev'd sub nom. Washington v. Glucksberg*, 521 US 702, 117 S Ct 2258, 138 L Ed2d 772 (1997).

The ACLU seeks to appear as *amicus* in this case to urge the court to grant the relief requested by plaintiff State of Oregon The many issues in the case have been thoroughly briefed by other parties and *amici*, and the ACLU will address only two of them: (1) the scope of the Drug Enforcement Agency's authority under the Controlled Substances Act, and (2) the equal protection argument made by *amici* National Right to Life Committee and Oregon Right to Life.

III. Argument

A. The Controlled Substances Act Does Not Confer Authority on the DEA to Regulate the Practice of Medicine.

The Controlled Substances Act ("CSA") grants the Drug Enforcement Agency ("DEA") authority to regulate the "manufacture," "dispensing" and "distribution" of controlled substances. *See* 21 USC §§822(a) and 812(c). The CSA does not purport to regulate the practice of medicine in general and it provides no authority for the DEA to interfere with a state's regulation of the practice of medicine. *See* 21 USC § 801 (in support of statutory purpose, Congress finds that "illegal importation, manufacture, distribution and possession and improper use of controlled substances" are harmful); *Linder v. United States*, 268 US 5, 18, 45 S Ct 446, 69 L Ed 819 (1924) ("Obviously, direct control of medical practice in the states is beyond the power of the federal government."); *American Pharmaceutical Assn. v. Weinberger*, 377 F Supp 824, 830 (D DC 1974) (CSA governs "permissible distribution" of controlled drugs), *aff'd* 530 F2d 1054 (DC Cir 1976).

Defendants claim, however, a radical expansion of CSA's regulatory scope by virtue of a 1984 amendment and a DEA regulation. The statutory language, legislative history and case law all contradict defendants' theory, but defendants nonetheless insist that Congress has implicitly granted DEA authority to prevent Oregon from deciding whether physician-assisted death is a medically legitimate practice. According to defendants, the CSA "authorizes the Attorney General to preclude physicians from prescribing federally-controlled substances for patient suicide" under the public interest standards set forth in 21 U.S.C. § 823. Defs' Opp. To Prel. Inj., at 15. Defendants additionally contend that federal case law and 21 C.F.R. § 1306.04(a) provide the Attorney General with authority to determine whether the provision of a controlled substance for physician-assisted suicide is a "legitimate medical purpose." Defs' Opp. To Prel. Inj., at 16. Defendants overstate their authority under both grounds.

First, the "public interest" standard for license revocation was never intended to allow DEA to assume a role as the national arbiter of what constitutes acceptable medical standards, effectively displacing medical boards and the states. The "public interest" standard was added to the statute in 1984 when Congress enacted the Dangerous Drug Diversion Control Act (PL 98-473, 98 Stat. 2070) and was aimed at controlling illegal drug distribution. The statutory amendment sought to address "prescription drugs [being] *diverted* by legitimate medical distributors to the illicit drug market," and so sought expanded authority to punish physicians "who write or dispense prescriptions in a way that is threatening to the public health or

safety." 130 Cong Rec H9681 (daily ed. Sept. 18, 1984) (remarks of Rep. Gilman) (emphasis added). Federal regulation of physician prescription licenses "under the Controlled Substances Act is a matter entirely separate from a physician's State license to practice medicine." Legislative History, S Rep No. 225, 98th Cong, 2d Sess, reprinted in 1984 USCAAN. 3182, 3449 n.40, and to the extent that the federal government is concerned with the overall practice of medicine, the government "will continue to give deference to the opinions of the State licensing authorities." *Id*. at 3449.

Defendants are correct that the phrase "public interest" in the CSA has a specific statutory definition – one that turns on the existence of five enumerated factors. See 21 USC § 823(f)(1)-(5). However, each factor asks DEA to focus on whether the issuance of a license to a *particular applicant* is inconsistent with the public interest, and not on establishing nation-wide standards for the practice of medicine. See *id*. (Attorney General shall consider whether applicant has been recommended by State medical authorities, § 823(f)(1), the applicant's experience, § 823(f)(2), the applicant's compliance with federal and state laws regarding controlled substances, § 823(f)(3)-(4), and other conduct by applicant which may threaten the public health and safety, § 823(f)(5)). *See also* H Rep No. 98-835, 98th Cong 2d Sess 6 (June 12, 1984) ("This bill is intended to help prevent prescription drugs which are capable of being abused from being 'diverted' from legitimate channels of medical distribution and administration to illegitimate channels for purposes of abuse.") What defendants' argument actually proves is the unremarkable proposition that DEA can revoke a physician's registration for improper prescription or dispensing practices that divert drugs to illicit markets, even when the physician has not been disciplined by the state or convicted of a drug felony. No support whatsoever exists for defendants' inventive suggestion that, through inclusion of the "public interest" provision, Congress created an unlimited DEA authority, implicitly federalizing the regulation of the medical practice.

In contrast to the federal government, Oregon, like every other state, does regulate the practice of medicine, and requires that any advice or information provided by a physician be consistent with the standard of medical care in the community. *See Zavalas v. State By and Through Dept. of Corrections,* 124 Or App 166, 172, 861 P2d 1026, 1028 (1993) ("[ORS 677.095] holds physicians to the degree of care, skill and diligence of ordinarily careful physicians in the community of the physician or a similar community.");

see also St. George's School v. Dept. of Registration, 640 F Supp 208, 211 (ND Ill 1986) ("The authority to license medical doctors belongs to the state"). With the adoption of the Death with Dignity Act, the State of Oregon has formally sanctioned physician-assisted death as a permissible means of providing compassionate end-of-life care. *See* ORS 127.885 ("No professional organization or association, or health care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership or other penalty for participation or refusing to participate in good faith compliance with [the Oregon Death with Dignity Act]").

In sum, it is the State of Oregon, not the federal government, that is the proper entity to ensure that physician advice constitutes an appropriate medical practice within the borders of this State. In defining what constitutes appropriate medical practices for Oregon residents, the State of Oregon has decided to permit physician-assisted death, so long as the physician complies with the safeguards provided for under state law. The federal government has no authority to second-guess that decision.

Second, neither 21 C.F.R. § 1306.04 nor federal case law provide DEA with a broader grant of authority. Defendants principally rely on *Unites States v. Moore*, 423 US 122 (1975), and lower circuit court cases decided under its authority, for the proposition that "it is the federal Drug Enforcement Administration that determines whether a particular physician dispenses a controlled substance for a legitimate medical purpose, not the relevant state's medical authority." Def. Opp. Prel. Inj. at 19 (citing *Noell v. Bensinger*, 586 F2d 554, 557 (5th Cir 1978)). However, the Supreme Court in *Moore* was "concerned with the diversion of drugs from legitimate channels to illegitimate channels", *Moore*, 423 US at 135, because "[Congress] was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *Id*. Indeed, the House Committee Report on the bill that later became the CSA explains: "The bill provides for the control . . . of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H.R.Rep.No. 91-1444, p. 3, U.S.Code Cong. & Admin.News 1970, p. 4569, quoted in *Moore*, 423 US at 135. Thus, the "legitimate medical purpose" language of § 1306.04 and *United States v. Moore* contemplated that the DEA would possess authority to oversee physician

dispensation practices that fall outside of legitimate channels of distribution; it plainly did not intend to provide DEA the power to effectively resolve the nation-wide debate over physician-assisted death. Defendants do not appear to argue otherwise. *See* Def. Opp. To Prel. Inj., Ex. 1, at 22 ("[I]t is also misleading to say that Congress did not intend to assign the DEA the role of resolving the national debate over physician-assisted suicide. Of course Congress did not intend to do that.").

That the federal regulatory scheme does not prohibit a state from authorizing physician-assisted death is shown by the fact that physicians have wide discretion to discuss, recommend, and prescribe drugs to patients for uses other than those for which the drugs were approved. *See*, *e.g., Weaver v. Reagen*, 886 F2d 194, 198 (8th Cir 1989) ("FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient."); Foreword to Physicians' Desk Reference (51st ed. 1997) ("Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."). Allowing physicians to prescribe drugs for such "off- label" usage "is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiff's Legal Comm.*, 531 US 341, 350, 121 S Ct 1012, 148 Led2d 854 (2001). For example, even though Tributerol has been approved by the FDA only for the treatment of high blood pressure, physicians have discovered that it is effective in postponing labor in pregnant women who enter labor too early, and so it is often prescribed in that situation as well. In other words, federal law is not a bar to a physician administering services that have not met with federal approval. *U.S. ex rel. Franklin v. Park Davis, Div. of Warner Lambert Co.,* 147 F Supp 2d 39, 44 (D Mass 2001) ("Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA.").

Defendants' strained reading of the "public interest" provision of the CSA and 21 C.F.R. § 1306.04 not only ignores every indicia of the statute's meaning and turns the state-federal relationship on its head, but it also violates the interpretive principle that courts should construe statutes to avoid constitutional problems. Defendants' proposed construction – allowing punishment of physicians for conducting a medical procedure that has been expressly approved by state law – raises profound federalism issues. *See*

Linder, 268 US at 17-18 (in order to avoid constitutional issues, court interpreted federal statute regulating drug distribution as not authorizing federal government to usurp state power to regulate practice of medicine). "[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *DeBartolo v. Florida Gulf Coast Building & Constr. Trades Council*, 485 US 568, 575, 108 S Ct 1392, 99 LEd2d 645 (1988).

Three-quarters of a century ago, the Supreme Court declared that "Congress cannot, under the pretext of executing delegated power, pass laws for the accomplishment of objects not intrusted to the federal government." *Linder v. United States*, 268 US at 17. And long before that, in one of the foundational opinions of American constitutional law, the Court made the same point:

"Should Congress, in the execution of its powers, adopt measures which are prohibited by the constitution; or should Congress, under the pretext of executing its powers, pass laws for the accomplishment of objects not intrusted to the government; it would become the painful duty of this tribunal, should a case requiring such a decision come before it, to say, that such an act was not the law of the land." *McCulloch v. Maryland*, 4 Wheat. (17 US) 316, 423, 4 L Ed 579 (1819).

In this case, of course, it is not Congress that is attempting to regulate the practice of medicine in Oregon; it is the Executive Branch that is doing so, by attempting to extract a meaning from the CSA that Congress never intended. But whether the defendants' current interpretation of the CSA is their own invention, or whether it is authorized, as they contend, by that statute, the principle is the same: the federal government cannot use the "pretext" of enforcing laws aimed at preventing the illicit use of controlled substances to intrude into an area that has always been regarded (both as a matter of tradition and as a matter of federalism) as within the exclusive responsibility and prerogative of the states (namely, regulation of the practice of medicine). No one seriously doubts that this is what is occurring in the present case, and Chief Justice Taft's famous words in *Bailey v. Drexel Furniture Co.*, 259 US 20, 37, 42 S Ct 449, 66 L Ed 817 (1922), are equally applicable here: "a court must be blind not to see [the true reason for a particular law]. All others can see and understand this. How can we properly shut our minds to it?" Or, as Justice Frankfurter later put it, "there comes a point where this Court should not be ignorant as judges of what we know as men." *Watts v. State of Indiana*, 338 US 49, 52, 69 S Ct 1347, 93 L Ed 1801 (1949) (plurality opinion). Defendants' efforts to intrude into the medical practices of Oregon physicians, a realm in which

the states have historically been sovereign and a matter on which the citizens of Oregon have resoundingly spoken, should be rejected.

B. The Equal Protection Argument Set Out in the "Brief of Amici Curiae National Right to Life Committee & Oregon Right to Life" Is Without Merit.

Although neither the complaint nor any other pleading filed by any party raises an equal protection issue, *amici* National Right to Life Committee and Oregon Right to Life devoted more than a third of their brief filed on or about November 16, 2001, in connection with plaintiff's application for a temporary restraining order, to a contention that "Oregon fails to provide *** equal protection [of the laws] with its 'Death With Dignity Act.'" (Brief of Amici Curiae NRLC & ORL at 16.) The court should disregard that argument, since no party to this case has alleged any claim based on the Equal Protection Clause of the Fourteenth Amendment.

However, if the court were to consider that argument, it should summarily reject it. The argument is based primarily on the equal protection analysis set out in *Lee v. State of Or.*, 891 F Supp 1429 (D Or 1995), *vacated* 107 F3d 1382 (9th Cir), *cert denied* 522 US 927 (1997). While the *amici* acknowledge that the Ninth Circuit "vacated and reversed" the district court decision in that case, *amici* nevertheless contend that the court's analysis in that case "is instructive" with respect to the equal protection issue. (Brief of Amici Curiae NRLC & ORL at 17.) That contention overlooks the fact that the Ninth Circuit expressly repudiated that analysis in *Compassion in Dying v. Washington*, 79 F3d 790 (9th Cir 1996), *rev'd sub nom. Washington v. Glucksberg*, 521 US 702, 117 S Ct 2258, 138 LEd2d 772 (1997). The Ninth Circuit stated that "Judge Hogan clearly erred" in his equal protection analysis in *Lee v. State of Or.*, that "the rationale on which *Lee* was decided was clearly erroneous," and that the equal protection holding of *Lee* was "highly irregular." 79 F3d at 838 and 838 nn. 138, 139.[1]

The Ninth Circuit's description of the court's equal protection analysis in *Lee* was accurate. The district court in *Lee* began its opinion by correctly noting that "[l]egislation is presumed valid if a classification drawn by a statute is rationally related to a legitimate state interest." 891 F Supp at 1432. The classification in the Death With Dignity Act that was challenged by the *Lee* plaintiffs is the classification of persons who are authorized by the statute to request medication for the purpose of ending their lives. ORS

127.805 defines that classification as "adult[s] who [are] capable, [are] resident[s] of Oregon, and ha[ve] been determined by the attending physician and consulting physician to be suffering from a terminal disease, and who ha[ve] voluntarily expressed his or her wish to die ***." ORS 127.800(3) defines "capable" to mean having "the ability to make and communicate health care decisions to health care providers," and ORS 127.800(12) defines "terminal disease" to mean "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months."

Thus, the "class" that was challenged in *Lee* as a violation of the Equal Protection Clause is the class of terminally ill, competent, adult residents of Oregon whose physicians have determined that they will die within six months. In his opinion relating to the equal protection issues, Judge Hogan expressly held that this classification does not violate the Equal Protection Clause, for he concluded that "[i]t is 'rational' to conclude that competent terminally ill persons may not want protection from their suicidal impulses." 891 F Supp at 1434. To be sure, Judge Hogan went on to hold that the Death With Dignity Act violates the Equal Protection Clause, but the equal protection identified by Judge Hogan had nothing to do with the classification made by the Act; rather, Judge Hogan concluded that "the procedures designed to differentiate between the competent and the incompetent are not sufficient," *id*., and it was for that reason that he concluded that the Act violates the Equal Protection Clause.

The Ninth Circuit was correct in asserting, in *Compassion in Dying*, that this conclusion by Judge Hogan was clearly erroneous. That conclusion was based on a fundamental misunderstanding of the principles of equal protection analysis. A leading treatise explains:

"The equal protection guarantee has nothing to do with the determination of whether a specific individual is properly placed within a classification. Equal protection tests whether the classification is properly drawn. It is the guarantee of procedural due process that determines what process is necessary to find that an individual falls within or outside of a specific classification. Equal protection deals with legislative line drawing; procedural due process deals with the adjudication of individual claims." J. Nowak and R. Rotunda, *Constitutional Law* § 14.2 at 635 (6th ed 2000) (footnote omitted).

That summary of the law is fully supported by Supreme Court opinions. In *Personnel Adm'r of Massachusetts v. Feeney*, 442 US 256, 99 S Ct 2282, 60 LEd2d 870 (1979), for example, the Court held as follows:

"When the basic classification is rationally based, uneven effects upon particular groups within a class are ordinarily of no constitutional concern. *** The calculus of effects, the manner in which a particular law reverberates in a society, is a legislative and not a judicial responsibility. *** In assessing an equal protection challenge, a court is called upon only to measure the basic validity of the legislative classification." 442 US at 272 (citations omitted).

Therefore, once the district court in *Lee* made the determination, as it did, that the classification in the Act was "rationally based," its equal protection analysis was completed, and it should have rejected plaintiffs' equal protection claim, for "equal protection is not a license for courts to judge the wisdom, fairness, or logic of legislative choices. In areas of social and economic policy, a statutory classification that neither proceeds along suspect lines nor infringes fundamental constitutional rights must be upheld against equal protection challenge if there is any reasonably conceivable state of facts that could provide a rational basis for the classification. *** 'The Constitution presumes that, absent some reason to infer antipathy, even improvident decisions will eventually be rectified by the democratic process and that judicial intervention is generally unwarranted no matter how unwisely we may think a political branch has acted.'" *FCC v. Beach Communications, Inc*., 508 US 307, 313-314, 113 S Ct 2096, 124 LEd2d 211 (1993) (footnote and citations omitted).

It is clear from these authorities that the classification of persons embodied in the Death With Dignity Act does not violate the Equal Protection Clause; indeed, as noted above, Judge Hogan expressly held that the classification was "rational." *Lee v. State of Or*., 891 F Supp at 1434. The equal protection analysis put forth in the present case by *amici* National Right to Live Committee and Oregon Right to Life should therefore be rejected.

IV. Conclusion

The ACLU respectfully urges the court to grant the relief requested by plaintiff State of Oregon.

DATED: January 22, 2002 .

Respectfully submitted,

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DATED: January 22, 2002

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[1] The Supreme Court subsequently reversed the Ninth Circuit decision in *Compassion in Dying*, but in doing so it expressly stated that "it offer[ed] no opinion" on the Equal Protection analysis of either the district court opinion in *Lee v. State of Or.* or the court of appeals opinion in *Compassion in Dying*. *Washington v. Glucksberg*, 521 US at 709 n 7.