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## IN THE UNITED STATES DISTRICT COURT

## FOR THE DISTRICT OF OREGON

STATE OF OREGON,	)	
Plaintiff, and	) ) )	ivil No. 01-1647-JO
PETER A. RASMUSSEN; ET AL.,	)	
Plaintiff-Intervenors,	)	
v.	) ) <u>C</u>	PINION AND ORDER
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 Director of the Drug	)	
Enforcement Administration, Portland Office;	)	
UNITED STATES OF AMERICA; UNITED	)	
STATES DEPARTMENT OF JUSTICE; and	)	
UNITED STATES DRUG ENFORCEMENT	)	
ADMINISTRATION,	)	
	)	
Defendants.	)	

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JONES, Judge:

## **INTRODUCTION**

After surviving voter and legal challenges, the 1994 Oregon Death with Dignity Act ("Oregon Act"), O.R.S. 127.800 et seq, finally went into effect in October 1997. On November 6, 2001, with no advance warning to Oregon representatives, Attorney General John Ashcroft (herein referred to as "Ashcroft") fired the first shot in the battle between the state of PAGE 2 - OPINION AND ORDER

Oregon and the federal government over which government has the ultimate authority to decide what constitutes the legitimate practice of medicine, at least when schedule II substances regulated under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 et seq, are involved. Ashcroft began the battle by issuing the so-called "Ashcroft directive," -- a few paragraphs published in the Federal Register on November 9, 2001, in which Ashcroft declares, in relevant part, that

- controlled substances may not be dispensed to assist suicide, thus reversing the position taken by his predecessor, Attorney General Janet Reno, in June 1998.
- assisting suicide is not a "legitimate medical purpose" and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.
- prescribing, dispensing, or administering federally controlled substances to assist suicide may "render [a physician's] registration \* \* \* inconsistent with the public interest" and therefore subject to possible suspension or revocation under 21 U.S.C. § 824(a)(4).

66 FR 56608 (Nov. 9, 2001).

Through his directive, Ashcroft evidently sought to stifle an ongoing "earnest and profound debate" in the various states concerning physician-assisted suicide. Washington v. Glucksberg, 521 U.S. 702, 735 (1997). In Glucksberg, the Supreme Court was called upon to decide whether the state of Washington's statutory ban on assisted suicide violated the Due Process Clause. In a thoughtful opinion, the Court acknowledged that "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality and practicality of physician-assisted suicide." The Court recounted the various states' "serious, thoughtful examinations" of the issues in this difficult debate, including Oregon's 1994 enactment of the Oregon Act. See 521 U.S. at 716-19. The Court declined to "strike down the

considered policy choice" of the State of Washington, deferring instead to that state's resolution of the debate. 521 U.S. at 719, 724, 735.

In her concurring opinion in Glucksberg, Justice O'Connor further elaborated that

[t]here is no reason to think the democratic process will not strike the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure. \* \* \* States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues. \* \* \* 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."

Glucksberg, 521 U.S. at 737 (O'Connor, J., concurring)(citations omitted).

As the Court acknowledged in <u>Glucksberg</u>, the citizens of Oregon, through their democratic initiative process, have chosen to resolve the moral, legal, and ethical debate on physician-assisted suicide for themselves by voting - not once, but twice - in favor of the Oregon Act. The Oregon Act attempts to resolve this "earnest and profound debate" by "strik[ing] the proper balance between the interests of terminally ill, mentally competent individuals who would seek to end their suffering and the State's interests in protecting those who might seek to end life mistakenly or under pressure." <u>Glucksberg</u>, 521 U.S. at 737 (O'Connor, J., concurring).

With publication of the Ashcroft directive, Ashcroft essentially nullified the Oregon Act and four years of Oregon experience in implementing it. In response to what it perceived as an unwarranted and unauthorized intrusion into the sovereign interests of Oregon, the medical practices of Oregon physicians, and the end-of-life decisions made by terminally-ill Oregonians, plaintiff state of Oregon ("plaintiff") immediately commenced this lawsuit to, among other

things, enjoin Ashcroft and the other defendants<sup>1</sup> from giving the Ashcroft directive any legal effect. A temporary restraining order, issued on November 8, 2001, remains in effect.<sup>2</sup>

Despite the enormity of the debate over physician-assisted suicide, the issues in this case are legal ones and, as pertain to my disposition, are fairly narrowly drawn. My resolution of the legal issues does not require any delving into the complex religious, moral, ethical, medical, emotional or psychological controversies that surround physician-assisted suicide or "hastened death" (as the parties sometimes describe it), because in Oregon, those controversies have been for now - put to rest.

The case presently is before me on several motions: (1) plaintiff's motion for summary judgment (# 111); (2) intervenors' motions for summary judgment or partial summary judgment (## 85, 101); and (3) defendants' motion to dismiss and alternative motion for summary judgment (# 133). For the reasons stated below, I grant plaintiff's and intervenors' motions for summary judgment in part and today enter a permanent injunction enjoining defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive at issue in this case. Those portions of plaintiff's and intervenors' motions not addressed in this opinion are denied as moot.<sup>3</sup> Defendants' motion to dismiss and alternative motion for summary judgment

The defendants are John Ashcroft, Asa Hutchinson in his official capacity as Administrator of the Drug Enforcement Agency ("DEA"), Kenneth Magee in his official capacity as Director of the DEA in Portland, Oregon, the United States, the United States Department of Justice, and the DEA.

The procedural history of this case is discussed more fully below.

The patient intervenors also filed a motion for class certification (# 41). During the hearing on March 22, 2002, defendants agreed not to object to the addition or substitution of new patient plaintiffs as needed to continue the viability of patient-plaintiffs' claims in this action.

(continued...)

are denied.

#### FACTUAL AND PROCEDURAL BACKGROUND

## 1. The Controlled Substances Act

Congress enacted the CSA, 21 U.S.C. §§ 801-950, as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA provides a comprehensive federal scheme for regulation and control of certain drugs and other substances. The congressional findings supporting Title II reveal that Congress' overarching concern in enacting the CSA was the problem of drug abuse and illegal trafficking in drugs. See 21 U.S.C. § 801.

The CSA establishes five schedules of controlled substances, ranging from schedule I substances, which have no accepted medical use and can be utilized only in very limited contexts, to schedules II, III, IV, and V substances, which have recognized uses and can be manufactured, distributed, possessed and used, subject to the restrictions of the CSA. See 21 U.S.C. § 812, 841. The CSA sets forth initial schedules, 21 U.S.C. § 812(c), and specifies procedures by which the Attorney General may add, remove, or transfer substances to or between schedules. 21 U.S.C. § 811.

The CSA makes it unlawful for any person to manufacture, distribute, or dispense any controlled substance "[e]xcept as authorized by [the CSA]." 21 U.S.C. § 841(a)(1). As pertinent in this case, physicians who prescribe controlled substances and pharmacists who fill the prescriptions are considered "practitioners" who "dispense" controlled substances. 21 U.S.C.

<sup>&</sup>lt;sup>3</sup>(...continued)

Patient-plaintiffs remain concerned, however, so I have included in the injunction language prohibiting defendants from objecting to additions or substitutions of patients during the pendency of this case. In view of defendants' agreement and the injunction, the motion for class certification is denied.

§ 802(10) and (21). To obtain authorization to do so, practitioners must register with the Attorney General and obtain a Drug Enforcement Agency ("DEA") certificate of registration. 21 U.S.C. § 822.

Under the CSA as originally enacted, state-licensed practitioners were entitled to be registered with the DEA as a matter of right. See 21 U.S.C. § 823(f)(1983)("Practitioners shall be registered to dispense \* \* \* controlled substances in schedule II, III, IV, or V if they are authorized to dispense \* \* \* under the law of the State in which they practice"); see also United States v. Moore, 423 U.S. 122, 140-41 (1975)(registration mandatory if applicant authorized under state law). The Attorney General could suspend or revoke a practitioner's registration only if the registrant (1) materially falsified an application; (2) was convicted of a felony relating to controlled substances; or (3) had his or her state license or registration suspended or revoked.

See 21 U.S.C. § 824(a)(1983).

Congress has amended the CSA many times since 1970. See Oregon's Memorandum in Support of Motion for Summary Judgment, p. 4 n.22 (amendments cited). With each amendment, Congress further attempted to address the problems of drug abuse and illegal trafficking in drugs. In 1984, apparently concerned with the domestic diversion of otherwise legitimate medical controlled substances into the illegal market by registered practitioners, Congress again amended the CSA. As pertinent here, the 1984 amendment empowered the Attorney General to deny, suspend, or revoke a practitioner's DEA registration if the Attorney General "determines that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. § 823(f); see also 21 U.S.C. § 824(1)(4).

In 1971, under authority delegated by the Attorney General pursuant to 21 U.S.C. § 871(a), the predecessor to the Administrator of the DEA<sup>4</sup> adopted formal regulations implementing the CSA. One of the regulations, now codified at 21 C.F.R. § 1306.04, provides, in relevant part:

A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the usual course of his professional practice. \* \* \* An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a)(emphasis added).

## 2. The Oregon Death with Dignity Act

In November 1994, Oregon voters enacted the Oregon Act through the initiative process. Having survived legal challenges, see Lee v. State of Or., 891 F.Supp. 1429 (D.Or. 1995)(Oregon Act does not provide sufficient safeguards for terminally ill persons and therefore violates the Equal Protection Clause), vacated 107 F.3d 1382 (9th Cir. 1997), and an initiative that would have repealed it, the Oregon Act went into effect in October 1997.

The Oregon Act provides a detailed procedure by which a mentally competent, terminally ill patient may make a written request for medication "for the purpose of ending his or her life in a humane and dignified manner \* \* \*." O.R.S. 127.805(1). Once a valid request has been properly documented and all waiting periods have expired, the attending physician may prescribe, but not administer, medication to enable the patient to take his or her own life.

The predecessor agency was the Bureau of Narcotics and Dangerous Drugs.

PAGE 8 - OPINION AND ORDER

Physicians and pharmacists are immune from civil and criminal liability and any adverse disciplinary action for participating in good faith compliance with the Oregon Act. See generally O.R.S. 127.805-.885; see also Affidavit of Stephen Bushong ("Bushong Aff."), Exh. 5, pp. 1-2.

Since 1997, the Oregon Act has been utilized by approximately 70 terminally ill Oregonians. Although defendants quibble somewhat with the data,<sup>5</sup> the parties appear to agree that these patients all utilized medications that are listed as schedule II controlled substances under the CSA.

## 3. Events Giving Rise to This Action

On July 27, 1997, Senator Orrin Hatch and Representative Henry Hyde sent a letter to the Administrator of the DEA advocating an interpretation of the CSA that would, in effect, permit the DEA to revoke the registrations of physicians and pharmacists who take actions authorized by the Oregon Act. See Bushong Aff., Exh. 1. In late October 1997, Hatch and Hyde sent a second letter to the DEA, expressing "heightened \* \* \* urgency" resulting from the United States Supreme Court's decision to deny certiorari in Lee v. State of Or., supra, which had, until then, kept the Oregon Act from going into effect. Bushong Aff., Exhibit 2. The second letter included a memorandum that purported to provide a legal basis for a proposed interpretation of the CSA that would make it illegal to prescribe controlled substances for the purpose of assisted suicide. Bushong Aff., Exh. 2, pp. 4-7.

On November 5, 1997, then-DEA Administrator Thomas Constantine wrote Hyde a letter in which he expressed the opinion that

Defendants state that they have not been provided data from which they can verify whether controlled substances were utilized by all patients. See Defts.' Response to Plaintiff State of Oregon's Concise Statement of Material Facts, ¶ 2.

delivering, dispensing or prescribing a controlled substance with the intent of assisting a suicide would not be under any current definition a "legitimate medical purpose." As a result, the activities that you described in you[r] letter to us would be, in our opinion, a violation of the CSA.

\* \* \*

DEA must examine the facts on a case-by-case basis to determine whether a physician's actions conflict with the CSA. If the facts indicate that a physician has acted as set forth in your letter, however, then DEA would have a statutory basis to initiate revocation proceedings.

## Bushong Aff., Exh. 3.

By letter dated December 3, 1997, Oregon Deputy Attorney General David Schuman, Ph.D., J.D., a noted constitutional scholar and former Professor of Law, University of Oregon, wrote to Jonathan Schwartz of the United States Department of Justice ("USDOJ") urging USDOJ to reconsider the DEA's position. Bushong Aff., Exh. 4. After considering Oregon's response and making her own evaluation, on June 5, 1998, then-Attorney General Janet Reno responded to Hyde's "request concerning the question whether the Department of Justice, through the [DEA], may invoke the [CSA] \* \* \* to take adverse action against any physicians who assist patients in ending their lives by prescribing controlled substances." Bushong Aff., Exh. 5. Reno stated that the USDOJ "has reviewed the issue thoroughly" and has concluded that "the federal government's pursuit of adverse actions against Oregon physicians who fully comply with that state's Death with Dignity Act would be beyond the purpose of the CSA." Bushong Aff., Exh. 5, pp. 1, 4. USDOJ's opinion was confirmed by letter to Oregon Attorney General Hardy Myers the same day. See Bushong Aff., Exh. 6.

Between 1998 and 2000, two separate federal legislative attempts to preempt the Oregon Act failed to pass.<sup>6</sup> On February 2, 2001, Hardy Myers wrote to newly-appointed Attorney General John Ashcroft asking that "[i]f the current interpretation of the CSA in relation to [the Oregon Act] is to be reexamined," Oregon representatives be given an opportunity to meet with USDOJ representatives to discuss the issue. Bushong Aff., Exh. 7. Two months later, on April 17, 2001, a representative of USDOJ wrote Myers on behalf of Ashcroft, stating that

I am aware of no pending legislation in Congress that would prompt a review of the Department's interpretation of the CSA as it relates to physician-assisted suicide. Should such a review be commenced in the future, we would be happy to include your views in that review.

Bushong Aff., Exh. 8 (emphasis added).

On June 27, 2001, two USDOJ attorneys, Sheldon Bradshaw and Robert Delahunty, sent a "Memorandum for the Attorney General" that reexamined, in great detail, the then-existing USDOJ interpretation of the CSA in relation to the Oregon Act. Bushong Aff., Exh. 9. Notwithstanding the assurances made on Ashcroft's behalf in April 2001, that "we would be happy to include [Oregon's] views in that review," the 24-page memorandum evidently was researched and written without any request for or consideration of Oregon data or comments of Oregon representatives. The memorandum was not disclosed to Oregon Attorney General Myers until November 6, 2001. Bushong Aff., ¶ 10. Thus, the Attorney General of the United States completely ignored his earlier promise to the Oregon Attorney General to ascertain Oregon's views. In doing so, he lost the opportunity to evaluate carefully the scientifically conducted

The Lethal Drug Abuse and Prevention Act of 1998, which was introduced in Congress in 1998 and which would have preempted the Oregon Act, failed to reach the floor of either the House or the Senate. The Pain Relief Promotion Act of 1999 passed the House in 1999, but failed to reach the Senate floor for a vote. See Bushong Aff., ¶ 8.

epidemiological studies of the Oregon Act, and the excellent analysis of the multiple issues as set forth in the briefs submitted by plaintiff and intervenors in these proceedings.

On November 6, 2001, Ashcroft issued a memorandum to DEA Administrator Asa Hutchinson. This memorandum, the so-called "Ashcroft directive," relies on the June 27, 2001, Bradshaw/Delahunty memorandum as "the legal basis for my [Ashcroft's] decision." Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction, Exhibit 1, p. 1. The Ashcroft directive reinstates the "original DEA determination," and directs the DEA to "enforce and apply this determination" upon publication in the Federal Register. <u>Id</u>. at p. 2. Significantly for purposes of the present proceeding, the Ashcroft directive states:

I hereby determine that assisting suicide is not a "legitimate medical purpose" within the meaning of 21 C.F.R. § 1306.04 (2001), and that the prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA.

<u>Id</u>. at p. 1.

The Ashcroft directive was published in the Federal Register on November 9, 2001. See Bushong Aff., Exhibit 10. Before publication, defendants did not consult with Oregon public officials, provide any notice to them or to the Oregon general public, or provide any opportunity for any public comment anywhere.

#### PROCEDURAL BACKGROUND

On November 7, 2001, plaintiff state of Oregon commenced this action by filing a complaint for declaratory and injunctive relief together with a motion for a temporary restraining order ("TRO") or a preliminary injunction to enjoin defendants from enforcing, applying, or otherwise giving any legal effect to the Ashcroft directive pending further order of the court.

Following a hearing on November 8, 2001, I granted plaintiff's motion and entered a TRO. I also PAGE 12 - OPINION AND ORDER

granted motions to intervene filed by Peter Rasmussen, M.D., and David Hochhalter, Rph, and by certain terminally-ill patients<sup>7</sup> (together, the "intervenors").

On November 20, 2001, I held a full hearing on plaintiff's and intervenors' motions for preliminary injunction. Following the hearing, I continued the TRO and established a briefing schedule for the parties' dispositive motions. In mid-January 2002, a second group of patients sought and were granted leave to intervene.

On March 22, 2002, I held a full hearing on the merits of the pending motions. Following the hearing, I took the motions under advisement. I have reviewed and thoroughly considered the parties' arguments and submissions, as well as the submissions of the numerous amici curiae.<sup>8</sup>

As I suggested to the parties during the March hearing, the resolution of this case turns on the CSA and does not require constitutional analysis. As did former Attorney General Reno almost four years ago, I conclude that Congress did not intend the CSA to override a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Although I granted the individual patients' motion to intervene, I denied intervenor status to the organization, Compassion in Dying of Oregon.

Amici curiae briefs have been filed on behalf of the following: New York Physicians, ACLU Foundation of Oregon, Inc., Association of the Bar of the City of New York, Surviving Family Members, Autonomy, Inc., et al, American Academy of Pain Management, et al, Coalition of Mental Health Professionals, Not Dead Yet, et al, National Right to Life Committee and Oregon Right to Life, and the Family Research Council. The court thanks all amici for their valuable and insightful submissions.

Moreover, while I tend to agree with plaintiff and intervenors that the Ashcroft directive fails to pass muster as a matter of administrative law, I decline to resolve this case on that basis. Whether characterized as a substantive or an interpretative rule, the fact remains that the Ashcroft directive exceeds the authority delegated to the defendants under the CSA.

#### DISCUSSION

## I. Defendants' Motion to Dismiss

For the first time in this proceeding, defendants challenge this court's subject matter jurisdiction over plaintiff's and intervenors' claims. Defendants maintain that under 21 U.S.C. § 877, exclusive jurisdiction to review the Ashcroft directive rests with the courts of appeals. Section 877 provides:

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within 30 days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.

According to defendants, the Ashcroft directive is a "final determination" within the meaning of that provision.

There is little pertinent authority to inform my decision on this issue. Two matters, however, are certain. First, defendants do not contend and could not maintain any argument that

The Ashcroft directive bears little similarity to another alleged "interpretive rule" recently issued under the CSA. That rule, which was brought to the court's attention as supplemental authority by defendants, serves to underscore how hastily the Ashcroft directive appears to have been crafted and published. See Notice of Filing Supplemental Authority in Support of Defendants' Motion to Dismiss (Order in Hemp Industries Associationl v. DEA, No. 01-71662 (9th Cir. March 7, 2002)); see also 66 FR 51530, 51535, and 51539 (Oct. 9, 2001).

plaintiff did not initiate this action within 30 days after notice of Ashcroft's decision. See

Transcript of Proceedings ("TR") (March 22, 2002), pp. 51-52. Second, although in their

motion, defendants insist that this action must be dismissed, they now agree that if this court

should decide that section 877 divests jurisdiction, transfer to the Ninth Circuit Court of Appeals

pursuant to 28 U.S.C. § 1631 would be appropriate. It at p. 50.

After careful consideration of this question, I conclude that the Ashcroft directive, however it is characterized, is not a final determination, finding, or conclusion within the meaning of section 877. Although the correct answer to this question is by no means clear, in the balance I am persuaded that section 877 applies in situations where the Attorney General makes a quasi-judicial determination that resolves disputed facts in a specific case after some level of administrative proceedings; for example, in classifying a substance under section 811, or in denying, suspending, or revoking a DEA registration under sections 823 or 824, and the like.

See, e.g., Humphreys v. Drug Enforcement Admin., 96 F.3d 658 (3rd Cir. 1996)(appellate court review of DEA revocation of physician's registration); Nutt v. Drug Enforcement Admin., 916

See Nutt v. Drug Enforcement Admin., 916 F.2d 202, 204 n.2 (5th Cir. 1990) (district court could cure jurisdictional defect caused by petitioner's failure to timely file petition for review of agency decision in court of appeals by transferring the petition pursuant to 28 U.S.C. § 1631).

<sup>&</sup>lt;sup>11</sup> 28 U.S.C. § 1631 provides:

Whenever a civil action is filed in a court \* \* \* or an appeal, including a petition for review of administrative action, is noticed for or filed with such a court and that court finds that there is a want of jurisdiction, the court shall, if it is in the interest of justice, transfer such action or appeal to any other such court in which the action or appeal could have been brought at the time it was filed or noticed, and the action or appeal shall proceed as if it had been filed in or noticed for the court to which it is transferred on the date upon which it was actually filed in or noticed for the court from which it is transferred.

F.2d 202 (5th Cir. 1990)(appellate court had jurisdiction to review DEA revocation of physician's registration). Section 877 may also, at least theoretically, apply where the Attorney General undertakes formal rulemaking, which he did not do in this case.<sup>12</sup> Those types of proceedings "under this subchapter" produce administrative records susceptible to review by an appellate court.

In the present case, in contrast, the Attorney General essentially kept his own counsel, did not provide notice or an opportunity for comment, did not take any evidence, did not decide disputed facts, and more importantly, did not produce an administrative record. Instead, the only record with respect to the Ashcroft directive is the one currently being created in this court.

Moreover, even defendants appear to concede that section 877 is not exclusive, recognizing that "plaintiffs can obtain district court review only one way, by demonstrating that the review provision is inapplicable to their particular claim." Memorandum in Support of Defendants' Motion ("Defendants' Memorandum"), p. 10. In McNary v. Haitian Refugee Center, Inc., 498 U.S. 479 (1991), the Supreme Court examined an Immigration and Nationality Act provision that, similar to section 877, provided for only a single level of review in the courts of appeals. In ruling that the district court retained jurisdiction to hear constitutional and statutory challenges to INS procedures, the Court explained:

In this regard, I acknowledge defendants' submission of supplemental authority, Hemp Industries Association v. DEA, No. 01-71662 (9th Cir.), which consists of a Ninth Circuit order staying operation of a DEA "Interpretive Rule" pending a hearing of the appeal on the merits. There is nothing before this court to suggest that the issues in that case and this one are in any respect similar. Moreover, defendants have themselves raised in Hemp the question of whether a DEA interpretive rule is subject to review under section 877. See Oregon Response to Notice of Filing of Supplemental Authority, Exh. 1, p. 5. Finally, it does not appear that the Ninth Circuit has determined that it in fact has jurisdiction to review the DEA interpretive rule under section 877.

[I]t is unlikely that a court of appeals would be in a position to provide meaningful review of the types of claims raised in this litigation. \* \* \* Not only would a court of appeals \* \* \* most likely not have an adequate record \* \* \* but it also would lack the factfinding and record-developing capabilities of a federal district court. \* \* \* [S]tatutes that provide for only a single level of judicial review in the court of appeals "are traditionally viewed as warranted only in circumstances where district court factfinding would unnecessarily duplicate an adequate administrate record -- circumstances that are not present \* \* \* where district court factfinding is essential given the inadequate administrative record."

McNary, 498 U.S. at 497 (citation omitted).

In summary, I conclude that this court has subject matter jurisdiction over plaintiffs and intervenors' broad statutory, procedural, and constitutional challenges to the Ashcroft directive. Because, however, in the inevitable appeal that will follow this decision the Ninth Circuit might decide otherwise, I hereby find that if there is a "want of jurisdiction" in this court, then in the interests of justice transfer to the Ninth Circuit Court of Appeals would be appropriate under 28 U.S.C. § 1631. See Intern. Broth. of Teamsters v. Dept. of Transp., 932 F.2d 1292, 1298 (9th Cir. 1991)("Jurisdictional substance, rather than procedural niceties or magic words, governs the propriety of transfers under section 1631").

## II. The Issue of Oregon's Standing

Earlier in this case, defendants moved to dismiss the state of Oregon for lack of standing.

The parties briefed the issue and I heard argument on it during the November 20, 2001, hearing.

I then entered an order denying the motion "at this juncture."

Defendants have not again raised the issue of Oregon's standing and, despite an invitation to do so (TR at 23), failed to argue or even mention standing during the March 22, 2002, hearing. Although defendants' silence on this issue suggests that they now concede standing, to put this matter firmly to rest, I hereby find that the state of Oregon meets the statutory requirements for

standing under the Declaratory Judgment Act, 28 U.S.C. § 2201, the Administrative Procedures Act, 5 U.S.C. § 702, as well as under any prudential principles that might apply. Oregon also meets the constitutional requirements for standing under Article III of the United States Constitution. Oregon has alleged and proved a sufficient injury to its sovereign and legitimate interest in the continued enforceability of its own statutes. See, e.g., Maine v. Taylor, 477 U.S. 131, 137 (1986)("a State clearly has a legitimate interest in the continued enforceability of its own statutes"); Bowen v. Public Agencies Opposed to Social Sec., 477 U.S. 41, 50 n.17 (1986)(state had "judicially cognizable interest in the preservation of its own sovereignty"); see also State of Alaska v. U.S. Dept. of Transp., 868 F.2d 441, 443 n.1 (D.C. Cir. 1989)("Inasmuch as the States' sovereign interest in law enforcement is sufficient to support standing, we need not delve into the issue of parens patriae standing"). 13

## III. Cross-Motions for Summary Judgment

I now turn to the central substantive issue in this case, whether the Ashcroft directive, which declares that prescribing controlled substances to assist patient suicide is not a "legitimate medical purpose," is authorized under the CSA and its implementing regulations. Having carefully considered this matter, I conclude that nothing in the plain language of the CSA or its legislative history demonstrates Congress' intent to grant defendants the authority under the CSA to determine that prescribing controlled substances for purposes of physician-assisted suicide in

As did the D.C. Circuit, I, too, decline to "delve into the issue of *parens patriae* standing." State of Alaska v. U.S. Dept. of Transp., 868 F.2d 441, 443 n.1 (D.C. Cir. 1989). I also note that defendants do not challenge the patient-intervenors' standing, and, recognizing that five of the initial nine patients in this case have died, have agreed to permit additional patients to join as plaintiff-intervenors to "keep the case alive" and get "this issue resolved." Transcript of Proceedings (March 22, 2002), pp. 90-91.

compliance with Oregon law is not a "legitimate medical purpose" under 21 C.F.R. § 1306.04(a).

I begin with the axiom that an administrative agency's power is limited to the authority delegated by Congress. In re Altabon Foods, Inc., 998 F.2d 718, 719 (9th Cir. 1993), (citing Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988) ("agency's power to promulgate legislative regulations is limited to the authority delegated by Congress")). In defining the bounds of its regulatory authority, "an agency may appropriately look to the legislative history and underlying policies of its statutory grants of authority." Altabon Foods, 998 F.2d at 719 (quoting United States v. Riverside Bayview Homes, Inc., 474 U.S. 121, 132 (1985)). This court's concomitant inquiry must "focus on the language, structure, and legislative history" of the CSA, with the primary goal of "determin[ing] the intent of Congress." Altabon Foods, 998 F.2d at 719-20 (quoting California v. Block, 663 F.2d 855, 860 (9th Cir. 1981)).

1. The Plain Language of the CSA Does Not Support the Ashcroft Directive.

Defendants contend that the CSA authorizes the Ashcroft directive because provisions of the statute "plainly contemplate the existence of federal standards." Defendants' Memorandum, p. 20. According to defendants, certain provisions are "directly controlling here":

that a "practitioner" must dispense controlled substances "in the course of professional practice" [§ 802(21)], that a controlled substance cannot be distributed "other than for a medical purpose" [§ 829(c)], and that a prescription "must be issued for a legitimate medical purpose" (21 C.F.R. § 1306.04) \* \* \*.

Defendants' Memorandum, p. 20. Defendants also point to the rulemaking authority set forth in sections 821 and 871(b), the reference to "federal" control of drug trafficking in section 801(6), the reference to "this subchapter" in section 841(a), and the language that limits registered persons to dispensing controlled substances only "to the extent authorized by their registration and in conformity with the other provisions of this subchapter." 21 U.S.C. § 822(b); see

PAGE 19 - OPINION AND ORDER

Defendants' Memorandum, pp. 20-21. Defendants find further significance in the CSA scheduling provisions, specifically sections 811(a)(1)(Attorney General may by rule assign controlled substances to schedules), and 812(b)(required findings for schedules I-V include consideration of any "currently accepted medical use in treatment in the United States"). Defendants' Memorandum, p. 21.

Defendants urge the court to conclude that taken together, these gleaned bits and pieces of statutory language demonstrate Congress' intent that federal, rather than state, standards control the determination of what medical practices are authorized under the CSA with respect to controlled substances. In this regard, I agree with plaintiff that defendants' analysis, which focuses on "isolated words or sentences" to discern Congress' intent, is contrary to accepted principles of statutory construction. <u>U.S. Nat. Bank of Or. v. Independent Ins. Agents</u>, 508 U.S. 439, 455 (1993).

In <u>U.S. Nat. Bank</u>, the Supreme Court emphasized that it has "over and over \* \* \* stressed that '[i]n expounding a statute, [the court] must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy."

Id. at 455 (quoting <u>United States v. Heirs of Boisdore</u>, 49 U.S. (8 How.) 113, 122 (1849) and noting that <u>Boisdore</u> has been quoted in more than a dozen cases). Indeed, it is a "'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." <u>FDA v. Brown & Williamson Tobacco Corp.</u>, 529 U.S. 120, 133 (2000); <u>see also Lexecon Inc. v. Milberg Weiss Bershad Hynes</u>, 523 U.S. 26, 36 (1998)(central tenet of interpretation is that statute is to be considered in all its parts when construing any one of them). Thus,

[a] court must \* \* \* interpret the statute "as a symmetrical and coherent scheme,"
\* \* \* and "fit, if possible, all parts into an harmonious whole" \* \* \*. In addition,
[a court] must be guided to a degree by common sense as to the manner in which
Congress is likely to delegate a policy decision of such \* \* \* political magnitude
to an administrative agency.

## FDA v. Brown & Williamson, 529 U.S. at 133 (citations omitted).

It is undisputed that under the CSA, the Attorney General and the DEA have broad authority to regulate controlled substances. No provision of the CSA, however, alone (as defendants urge) or viewed as a "symmetrical and coherent scheme" demonstrates or even suggests that Congress intended to delegate to the Attorney General or the DEA 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.

Nor, as defendants propose, did the 1984 amendments to the CSA delegate such authority. As amended, section 823(f) permits the Attorney General to deny an application for registration as "inconsistent with the public interest" after consideration of the following factors:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) such other conduct which may threaten the public health and safety.

The revocation section, § 824(a)(4), as amended, includes as a ground for revocation or suspension "such acts as would render his registration under section 823 \* \* \* inconsistent with the public interest as determined under such section." Defendants read these amendments, together with 21 C.F.R. § 1306.04, as supplying evidence that Congress intended to expand the Attorney General's and the DEA's authority to include the power to define the parameters of legitimate medical practices. I do not, however, read the CSA or the 1984 amendments as containing - either explicitly or implicitly - such a remarkable grant of power.

2. The Legislative History of the CSA Does Not Support the Ashcroft Directive.

As observed by Professor William Funk of the Lewis and Clark Law School in his review of Justice Scalia's essay<sup>14</sup> on legislative interpretation:

The legitimacy of legislative history as a means of interpreting statutes, at least when they are unclear, is, rightly or wrongly, well established. Other than Justice Thomas, no Justice seems interested in adopting Justice Scalia's rejection of legislative history or his rejection of the notion of legislative intent.

William Funk, Review Essay Faith in Texts - Justice Scalia's Interpretation of Statutes and the Constitution: Apostasy for the Rest of Us? 49 Admin. L. Rev. 825 (1997). Both sides in this controversy resort to certain congressional comments and reports to buttress their views of what Congress intended in enacting and amending the CSA. Nothing in the legislative history suggests, however, that anyone in Congress intended the CSA to restrict or proscribe prescriptions for controlled substances that might be used legitimately under state law to assist suicide or hasten death. To the contrary, the legislative history of both the 1970 enactment and

<sup>&</sup>lt;sup>14</sup> AMATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW. An Essay by Antonin Scalia with Commentary by Amy Gutmann, editor, Gordon S. Wood, Laurence H. Tribe, Mary Ann Glendon, and Ronald Dworkin. Princeton: Princeton University Press, 1997.

the 1984 amendments overwhelming support a conclusion that Congress' intent was to address problems of drug abuse, drug trafficking, and diversion of drugs from legitimate channels to illegitimate channels. See <u>United States v. Moore</u>, 423 U.S. 122, 134-35 (1975)("Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant").

The best defendants can produce in the way of supportive legislative history is a vague comment by one congressman, Representative Gillman, to the effect that by amending the CSA, Congress wanted to "make it easier" for the DEA to suspend or revoke the authority of physicians who write or dispense prescriptions in a way that is threatening to public health or safety, and an equally curious reference from the House Committee report, which states:

Although the Committee is concerned about the appropriateness of having federal officials determine the appropriate method of the practice of medicine, it is necessary to recognize that for the last 50 years this is precisely what has happened, through criminal prosecution of physicians whose methods of prescribing narcotic drugs have not conformed to the opinions of federal prosecutors of what constitutes appropriate methods of professional practice.

Defendants' Memorandum, pp. 16-17.

What does this add to the issue at hand? I have already explained that the core objective of the CSA was to permit federal prosecution of drug dealers, drug abusers, and "practitioners" who engage in the illegal diversion and distribution of drugs. Defendants cannot seriously conclude from the above-quoted language that Congress delegated to federal prosecutors the authority to define what constitutes legitimate medical practices. To state the proposition is to

The case law defendants cite belies this conclusion. As discussed in the next portion of this decision, even in cases where a doctor or pharmacist is a "drug pusher" or blatantly operates a "pill mill," the issue of whether the conduct is outside the normal course of professional or medical practice is entrusted to a jury, to decide the issue as mixed subjective-objective question of fact under (continued...)

refute it. Federal prosecutors have never possessed such powers, and the vagueness of the reference would render any alleged violation based on a prosecutor's subjective views about medical practice patently unenforceable.

Having served in the state legislature, I do not give much credence to floor speeches or even committee reports as representing the intent of a legislative body. As many have observed in watching Congress at work, members of Congress often speak about legislative intent to an empty room, or place material prepared by staff, lobbyists and the like into the congressional record. To construe this as revealing legislative intent defies reality and more often than not ignores the plain meaning of the statute in favor of the subjective beliefs of individual members of Congress, an extremely unreliable approach to statutory interpretation. As Justice Scalia observed in his essay<sup>17</sup> and in his concurring opinion in Conroy v. Aniskoff, 507 U.S. 511, 519 (1993):

Judge Harold Leventhal used to describe the use of legislative history as the equivalent of entering a crowded cocktail party and looking over the heads of the guests for one's friends.

Here, neither side has presented any convincing relevant comment from friend or foe to reliably demonstrate that Congress ever considered assisted suicide in enacting or amending the CSA. Moreover, no legislative history supports defendants' theory that Congress intended the

PAGE 24 - OPINION AND ORDER

<sup>&</sup>lt;sup>15</sup> (...continued) instructions based on community standards, not on some national standard adopted as a federal regulation.

In contrast, carefully prepared advisory committee notes, when officially adopted by a legislative body, can be exceedingly helpful in interpreting statutes and rules. <u>E.g.</u>, Federal Rules of Civil Procedure; Federal Rules of Evidence.

See footnote 14, supra.

1984 amendments to "alter[] the federal-state framework by permitting federal encroachment upon a traditional state power." Solid Waste Agency v. Army Corps of Engineers, 531 U.S. 159, 173 (2001)(citation omitted). Thus, I need not determine the merit or lack of merit of the legislative history, simply because there is none on point.

## 3. The Case Law Does Not Support the Ashcroft Directive.

The cases defendants cite as "equally clear that federal law determines what medical practices are authorized by the CSA," United States v. Moore, supra, United States v. Rosenberg, 515 F.2d 190 (9th Cir. 1975), United States v. Hayes, 794 F.2d 1348 (9th Cir. 1986), United States v. Boettjer, 569 F.2d 1078 (9th Cir. 1978), and U.S. v. Leal, 75 F.3d 219 (6th Cir. 1996), do not advance their position. All involved criminal proceedings against DEA registered physicians or pharmacists whose activities fell far outside any definition of the usual or accepted course of professional medical practice. In none of the cases was a doctor or pharmacist prosecuted and convicted under the CSA for legal medical actions taken in compliance with state law, which is precisely what the Ashcroft directive would permit if allowed to stand.

In Moore, for example, the defendant doctor "acted as a large-scale 'pusher' not as a physician," and admitted that he did not observe generally accepted medical practices. 423 U.S. at 126, 143. In Rosenberg, the evidence established that "[w]hen a doctor acts as Dr. Rosenberg did in this case, he can appropriately be called a trafficker in drugs." 515 F.2d at 196. The Rosenberg court was careful to note, however, that the phrase "in the course of professional medical practice" as used in the CSA "clearly means that a doctor is not exempt from the statute when he takes actions that he does not in good faith believe are for legitimate medical purposes,"

PAGE 25 - OPINION AND ORDER

Defendants' Memorandum, p. 21.

plainly a subjective standard. 515 F.2d at 197 (emphasis added).<sup>19</sup>

In both <u>Hayes</u> and <u>Boettjer</u>, the quoted language on which defendants rely for a "federal" standard of medicine actually was part of the trial courts' jury instructions. <u>Hayes</u>, 794 F.2d at 1351; <u>Boettjer</u>, 569 F.2d at 1081. Nothing in either opinion suggests that the Ninth Circuit approved or adopted a federal test for "legitimate medical purpose" or "usual course." The last case defendants cite, <u>United States v. Leal</u>, concerned a "pill mill" operated by a physician and a pharmacy. The <u>Leal</u> court rejected defendant pharmacist's argument that he was entitled to a jury instruction concerning his duties as a pharmacist under state law, because as a DEA registrant, the CSA imposed a "federal duty on Leal to be vigilant in filling prescriptions, so as to avoid filling those that were issued for a non-medical purpose. Whether state law imposes an equivalent civil or criminal duty is irrelevant." <u>Leal</u>, 75 F.3d at 227. The <u>Leal</u> court did not, as defendants would like this court to infer, hold that the federal law gives content to what is or is not a "medical purpose."

Defendants' reliance on <u>Rosenberg</u> for the proposition that federal law determines what medical practices are authorized by the CSA is misleading. In the portion of the opinion that defendants quote, the Ninth Circuit's comments were directed to the doctor's constitutional argument that whether he was acting in the course of his professional practice must be determined by the state court, because "direct control of medical practice in the states is beyond the power of the federal government." <u>Rosenberg</u>, 515 F.2d at 198 (citation omitted). The Ninth Circuit did not hold that the CSA authorizes direct agency determination of what constitutes the ordinary course of professional practice, instead, the court held only that the CSA is constitutional under the Tenth Amendment.

I note that defendants seem to have abandoned the notion, espoused in the Ashcroft directive, that the Supreme Court's decision in <u>United States v. Oakland Cannabis Buyers' Coop.</u>, 532 U.S. 483 (2001), is somehow controlling on the issues presented here.

## IV. Summary

The determination of what constitutes a legitimate medical practice or purpose traditionally has been left to the individual states. State statutes, state medical boards, and state regulations control the practice of medicine. The CSA was never intended, and the USDOJ and DEA were never authorized, to establish a national medical practice or act as a national medical board. To allow an attorney general -- an appointed executive whose tenure depends entirely on whatever administration occupies the White House -- to determine the legitimacy of a particular medical practice without a specific congressional grant of such authority would be unprecedented and extraordinary. As stated, the practice of medicine is based on state standards, recognizing, of course, national enactments that, within constitutional limits, specifically and clearly define what is lawful and what is not.<sup>21</sup> Without doubt there is tremendous disagreement among highly respected medical practitioners as to whether assisted suicide or hastened death is a legitimate medical practice, but opponents have been heard and, absent a specific prohibitive federal statute, the Oregon voters have made the legal, albeit controversial, decision that such a practice is legitimate in this sovereign state.

The Ashcroft directive attempts to define the term "legitimate medical purpose" to exclude use of controlled substances for otherwise legal physician-assisted suicide where Congress failed to do so despite multiple opportunities. Obviously, Congress knows how to do so, as manifested in its abandoned attempts to restrict assisted suicide nationwide. Because

For example, in section 4 of Title I of the 1970 CSA, 42 U.S.C. § 257a, Congress expressly required the Secretary of Health, Education, and Welfare, after consultation with the Attorney General and national addict treatment organizations, to "determine the appropriate methods of professional practice in the medical treatment of ... narcotic addiction ...." <u>United States v. Moore</u>, 423 U.S. 122, 144 (1975).

former Attorney General Reno concluded that the CSA has no application to the Oregon Act, Representative Hyde introduced two bills in the House of Representatives to specifically address the Oregon Act. The first bill, the Lethal Drug Use Prevention Act of 1998, would have amended the CSA to directly authorize the suspension or revocation of a practitioner's DEA registration if the registrant intentionally dispensed or distributed a controlled substance for the purpose of assisting the suicide or euthanasia of another individual. The second bill, the Pain Relief Promotion Act, attempted to clarify the CSA to provide that the alleviation of pain is a legitimate medical purpose, but that the CSA did not permit the use of controlled substances to cause death or assist in a suicide. While the second bill passed the House, neither bill passed the Senate, and neither was signed into law.

Even though both acts failed in Congress, certain congressional leaders made a good faith effort to get through the administrative door that which they could not get through the congressional door, seeking refuge with the newly-appointed Attorney General whose ideology matched their views, and this is precisely what occurred. The Executive Branch immediately began its efforts to re-write the law to achieve its goal of abolishing assisted suicide anywhere. Although congressional action attempting to control matters traditionally left to the state may raise constitutional issues for any future legislation in this field, suffice it to say that at this juncture, neither the U.S. Constitution nor the Bill of Rights speaks to assisted suicide, neither providing for it as a personal right nor prohibiting it.

I again emphasize that I resolve this case as a matter of statutory interpretation, and my interpretation of the statutory text and meaning is that the CSA does not prohibit practitioners from prescribing and dispensing controlled substances in compliance with a carefully-worded

state legislative act. Thus, the Ashcroft directive is not entitled to deference under any standard<sup>22</sup> and is invalid. I also emphasize that my task is not to criticize those who oppose the concept of assisted suicide for any reason. Many of our citizens, including the highest respected leaders of this country, oppose assisted suicide. But the fact that opposition to assisted suicide may be fully justified, morally, ethically, religiously or otherwise, does not permit a federal statute to be manipulated from its true meaning to satisfy even a worthy goal. As the Supreme Court has warned, courts should be "out of the business of reviewing the wisdom of statutes," <u>Usery v. Turner Elkhorn Mining Co.</u>, 428 U.S. 1, 15 (1976), a proposition not to be taken "cum grano salis" (with a grain of salt). <u>Barrick Gold Exploration, Inc.</u>, 47 F.3d 832, 836 (6th Cir. 1995)(commenting on Easterbrook, *The Constitution of Business*, 11 Geo. Mason U.L. Rev. 53 (1988)).

#### CONCLUSION

For the reasons stated, plaintiff's motion for summary judgment (# 111) and intervenors' motions for summary judgment or partial summary judgment (## 85, 101) are granted in part and moot in part; patients-intervenors' motion for class certification (# 41) is denied; and defendants' motion to dismiss and alternative motion for summary judgment (# 133) is denied. The

See Oregon's Memorandum in Support, pp. 16-18, for a discussion of the various levels of deference, none of which governs here.

Permanent Injunction entered concurrently with this Opinion and Order shall be effective immediately upon filing. Any other pending motions are denied as moot.

DATED this <u>(7</u>\* day of April, 2002.

ROBER<del>T E.</del> JOI

U.S. District Judge