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10 On Behalf of the Association of the  
Bar of the City of New York

13 UNITED STATES DISTRICT COURT  
14 DISTRICT OF OREGON

No. CV01-1647-JO

15 STATE OF OREGON,

16 Plaintiff,

18 &

19 RICHARD HOLMES; KARL STANSELL;  
20 JAMES ROMNEY; JANE DOE #1; PETER A.  
RASMUSSEN, M.D.; and DAVID MALCOME  
21 HOCHHALTER, PhD,

22 Plaintiffs-Intervenors,

23 v.

24 JOHN ASHCROFT, in his official capacity as  
United States Attorney; ASA HUTCHINSON, in  
25 his official capacity as Administration of the Drug  
Enforcement Administration; KENNETH W.  
26 MAGEE, in his official capacity as Director of the

ASSOCIATION OF THE BAR OF THE  
CITY OF NEW YORK'S AMICUS  
BRIEF IN SUPPORT OF OREGON'S  
MOTION FOR SUMMARY  
JUDGMENT

1 Drug Enforcement Administration, Portland Office;) )  
2 UNITED STATES OF AMERICA; UNITED )  
3 STATES DEPARTMENT OF JUSTICE; and )  
4 UNITED STATES DRUG ENFORCEMENT )  
5 ADMINISTRATOR, )

6 Defendants. )

## 7 INTRODUCTION

8 This brief is being submitted on behalf of the Association of the Bar of the City of New York (the  
9 "Association"). As set forth below, the Association objects to the unprecedented action of Attorney  
10 General John Ashcroft to proclaim, in his November 8, 2002 directive (the "Ashcroft Directive"), that he  
11 has the authority to determine what is a "legitimate medical purpose" in the context of Oregon's Death  
12 with Dignity Act. The Association does not take a position regarding the merits of the Oregon statute.  
13 Instead, the Association focuses on the impermissible action of the Attorney General to usurp the  
14 traditional authority of the individual states to regulate the practice of medicine within their own borders,  
15 and the negative implications the Ashcroft Directive will have on patients and healthcare practitioners.  
16 The Ashcroft Directive would have the effect of precluding the use of federally controlled substances even  
17 if lawful under the Oregon Death With Dignity Act.

18 First, the Association objects to the Attorney General's interpretation of the Controlled  
19 Substances Act ("CSA") – an act created to address illegal drug trafficking in the United States – as  
20 giving him the authority to decide what is a "legitimate medical purpose." Second, the Ashcroft Directive  
21 is objectionable because it exposes patients, medical practitioners, and the public at large to the personal  
22 philosophy of the individual appointee who holds the office of Attorney General at any particular time.  
23 Third, the Association objects to the Attorney General's failure to comply with publication and comment  
24 requirements of the Administrative Procedures Act in issuing the Ashcroft Directive. Fourth, the  
25 Association objects to the Ashcroft Directive because it will have far reaching adverse implications for  
26 healthcare practitioners, and their patients, across the country. Fifth, the Association objects to General  
Ashcroft's action as being inconsistent with the traditional deference given to the states to make

1 | determinations regarding the legitimate practice of medicine.

2 | **BACKGROUND**

3 | Controlled Substances Act

4 | Attorney General Ashcroft alleges that he is vested with the authority to declare physician-  
5 | assisted suicides illegal (if assisted by controlled substances) based on the authority granted to him under  
6 | “The Controlled Substances Act” (the “CSA”). The CSA sets forth the regulatory scheme whereby the  
7 | federal government regulates the use and administration of controlled substances.<sup>1</sup> It was established by  
8 | Congress for the specific purpose of prohibiting and controlling “[t]he illegal importation, manufacture,  
9 | distribution, possession and improper use of controlled substances [that] have a substantial and  
10 | detrimental effect on the health and general welfare of the American people.” At the same time, the CSA  
11 | expressly recognizes that many controlled substances have useful and legitimate medical purposes, for  
12 | which they may appropriately be used to “maintain the health and general welfare of the American  
13 | people.”<sup>2</sup>

14 | The CSA is enforced by the federal Drug Enforcement Administration (the “DEA”), which is  
15 | “responsible for controlling abuse of narcotics and dangerous drugs, while ensuring adequate supplies for  
16 | legitimate medical purposes. . . . DEA accomplishes its objectives through coordination with state, local,  
17 | and other federal officials in . . . regulation of legitimate controlled substances.”<sup>3</sup> Clearly, the DEA’s  
18 | focus is on illegal drug trafficking, not regulation of the legitimate practice of medicine. But now, as a  
19 | direct result of recent action taken by the Attorney General, the DEA’s role may change to improperly  
20 | encompass the regulation of the practice of medicine.

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23 | \_\_\_\_\_  
24 | <sup>1</sup> 21 U.S.C.S. Section 801, et seq.

25 | <sup>2</sup> 21 U.S.C.S. Section 801.

26 | <sup>3</sup> Fed. Reg., Vol. 66, No. 232, Monday, December 3, 2001 (publication of Department of  
Justice Statement of Regulatory Priorities).

1 Oregon's Death with Dignity Act  
2 And Subsequent Federal Legislation

3 Underlying the instant litigation is Oregon's Death with Dignity Act. In 1994 the people of  
4 Oregon, through a public referendum, enacted the Death with Dignity Act (the "Oregon Act"). In 1997,  
5 the Oregon Act went into effect after a referendum to repeal the Oregon Act was rejected by the Oregon  
6 voters.<sup>4</sup> The Oregon Act, permits, under certain conditions, providers to prescribe medications in  
7 dosages that will assist terminally-ill patients to "end his or her life in a humane and dignified manner."<sup>5</sup>  
8 The Oregon Act is the only statute of its kind in the United States.

9 For obvious reasons, the Oregon Act has generated much debate. In 1998 (following the  
10 effective date of the Oregon Act), former Attorney General, Janet Reno, "concluded that adverse action  
11 against a physician who has assisted in a suicide in full compliance with the Oregon Act would not be  
12 authorized by the CSA."<sup>6</sup> This conclusion overruled an earlier opinion by the head of the DEA. Attorney  
13 General Reno's ruling was met with strong opposition. Representative Henry Hyde introduced two bills  
14 in the House of Representatives condemning Attorney General Reno's endorsement of the Oregon  
15 statute, and prohibiting physicians from prescribing controlled substances for assisting in suicide.

16 The first bill, the Lethal Drug Abuse Prevention Act of 1998, would have amended the CSA to  
17 directly authorize the suspension or revocation of a practitioner's DEA registration if the registrant  
18 intentionally dispensed or distributed a controlled substance for the purpose of assisting the suicide or  
19 euthanasia of another individual.<sup>7</sup> The second bill, the Pain Relief Promotion Act, attempted to clarify the  
20 CSA to provide that the alleviation of pain is a legitimate medical purpose, but that the CSA did not  
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22

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23 <sup>4</sup> ORS 127.800 through 127.995.

24 <sup>5</sup> ORS 127.800 (7), 127.800 (11), 127.805 (1), 127.815 (1)(k); 127.830.

25 <sup>6</sup> *Statement of Attorney General Janet Reno on Oregon's Death with Dignity Act* (visited  
26 Mar. 4, 2002) <<http://www.usdoj.gov/opa/pr/1988/June/259ag.htm.html>> (emphasis added).

<sup>7</sup> Lethal Drug Abuse Prevention Act of 1998, H.R. 4006, 105<sup>th</sup> Cong. (1998).

1 permit the use of controlled substances to cause death or assist in a suicide.<sup>8</sup> While the second bill  
2 passed the House, neither bill passed the Senate, nor was either signed into law.

3 The Ashcroft Directive

4 Accordingly, the Oregon Act generated substantial debate at the federal level, but Congress has  
5 not definitively responded to it. Nonetheless, the current Attorney General, on his own initiative and  
6 without notice or formal rule-making, reversed the prior position of the Department of Justice with  
7 respect to the Oregon Act. He did so by issuing an “interpretive rule” which states that prescribing  
8 federally controlled substances to assist in an individual’s suicide will subject a physician’s DEA  
9 registration to possible suspension or revocation as being “inconsistent with the public interest,” even if  
10 this activity is authorized by the Oregon Act.<sup>9</sup>

11 This is an unbridled attempt to define the “legitimate” practice of medicine -- without the benefit  
12 of congressional action, without the benefit of empirical findings, and without the benefit of formal rule-  
13 making. For the reasons set forth below, the Attorney General’s directive must not withstand judicial  
14 scrutiny.

15 **ARGUMENT**

16 **POINT I**

17 **THE ATTORNEY GENERAL CANNOT CIRCUMVENT**  
18 **THE NEED FOR LEGISLATIVE ENACTMENT OR FORMAL**  
19 **RULE-MAKING BY ISSUING A MEMORANDUM THAT LIMITS**  
20 **THE STATES’ ABILITY TO DETERMINE WHAT CONSTITUTES**  
21 **“A LEGITIMATE MEDICAL PURPOSE”**

22 *A. The Potential Political*  
23 *Nature Of The Ashcroft Directive*

24 The Ashcroft Directive exposes patients, medical providers, medical/pharmacy regulators, and  
25 the public at large to the personal philosophy, subjectivity and whim of the individual political “appointee”

26 <sup>8</sup> Pain Relief Promotion Act, H.R. 2260, 106<sup>th</sup> Cong. (1999).

<sup>9</sup> Fed. Reg., Vol. 66, No. 218, Friday, November 8, 2001 (publication of the Ashcroft  
Directive as an “interpretive rule”).

1 who then holds the office of United States Attorney General. As such, this kind of action holds potential  
2 for abuse, from which Americans are entitled, and expect, to be protected. While the Ashcroft Directive  
3 politicizes a narrow medical-practices issue concerning physician-assisted suicide as presently legalized  
4 by statute in the State of Oregon, this kind of rule-making, as a precedent, allows this Attorney General,  
5 or any future Attorney General, to politicize any other aspect of medical practice - regardless of whether  
6 a treatment or practice is conventional or controversial, whether the implications are narrow or broad,  
7 and whether or not it involves end-of-life decisions. The Ashcroft Directive is devoid of any reference to  
8 medical, empirical or other objective analysis or data while, at the same time, in the context of the  
9 evolving area of palliative care, it purports to create a bright line distinguishing between the appropriate  
10 use of controlled substances to manage pain (which in some instances may increase the risk of death),  
11 and an inappropriate use of controlled substances to assist in a suicide.<sup>10</sup>

12 The Ashcroft Directive has the effect of defining the term "legitimate medical purpose" where  
13 Congress, in enacting the CSA, elected to remain silent. Further, without the benefit of public hearings,  
14 or the apparent input of state medical and pharmacy licensing boards, hospice care providers, pain or  
15 mental health specialists, patients or affected members of the public, the Ashcroft Directive authorizes,  
16 and is designed to expose otherwise-licensed and qualified physicians to, possible suspension or  
17 revocation of their DEA registration to prescribe controlled substances in the practice of their profession.  
18 While the Department of Justice might typically be called upon to offer enforcement guidance in  
19 connection with a federal statute, Attorney General Ashcroft's action crosses the line from guidance to  
20 legislation.

21 In contrast, former Attorney General Reno, when faced with precisely the same issue, declined to  
22 legislate a definition of "legitimate medical purpose," where Congress had failed to do so. In her June 5,  
23 1998 statement, Attorney General Reno acknowledged that she was bound by the CSA, and concluded  
24 that the CSA did not authorize the imposition of her personal, and political philosophy on Americans  
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26 <sup>10</sup> *Id.*

1 (notwithstanding the stated position of the Clinton administration against physician-assisted suicide).<sup>11</sup>

2 The affirmative intent of Congress not to nullify Oregon's Death with Dignity Act was further  
3 evidenced and reinforced in its failure after public hearings to pass the Pain Relief Promotion Act of 1999  
4 (the "PRPA")<sup>12</sup> - which was introduced and considered after Oregon's legislation and Attorney General  
5 Reno's 1998 statement. Under the proposed PRPA, the CSA would have been amended by, among  
6 other things, adding to Section 303 of 21 U.S.C. 823 the following:

7 "Notwithstanding any other provision of this Act, in determining whether a registration is  
8 consistent with the public interest under this Act, the Attorney General shall give no force  
and effect to State law authorizing or permitting assisted suicide or euthanasia."

9 Moreover, Rep. Henry J. Hyde, Chairman of the Committee conducting the House hearings on  
10 June 24, 1999, acknowledged, in addressing his colleague Rep. Barney Frank, that "But we are trying to  
11 establish a national standard where you can know what the law is from State to State, and that is the  
12 effort."<sup>13</sup> By not enacting the Pain Relief Promotion Act of 1999, Congress specifically declined the  
13 opportunity to nullify Oregon's statute and/or to create a national standard on the issue.<sup>14</sup>

14 *B. Need For Formal Rule-Making*

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16 <sup>11</sup> *Statement of Attorney General Janet Reno on Oregon's Death with Dignity Act* (visited  
Mar. 4, 2002) <<http://www.usdoj.gov/opa/pr/1988/June/259ag.htm.html>>.

17  
18 <sup>12</sup> *Pain Relief Promotion Act of 1999: Hearing on H.R. 2260 Before the Subcomm. on the*  
*Constitution of the House Comm. on the Judiciary, 106th Cong. (1999)* [hereinafter *House Comm.*  
19 *Hearings*]; *Pain Management and Improving End of Life Care: Hearing on S. 1272 Before S.*  
*Comm. on Health, Education, Labor and Pensions, 106th Cong. (1999)* [hereinafter *Senate*  
20 *Hearings*].

21 <sup>13</sup> *House Comm. Hearings, supra* note 12, at 111.

22 <sup>14</sup> One of the expressed objections to the PRPA was that it would politicize medical standards  
and nullify the will of the people:

23 PRPA would nullify the will of the people of Oregon as expressed through two ballot  
24 referenda ... Congress and the courts have long recognized the importance of the  
laboratory of State experimentation on complicated matters of social policy. . . . a side  
25 effect of this contravention of federalism is the politicization of medical standards, which  
currently are decided on a State-by-State basis. In effect, the federal government,  
through the Justice Department and the Drug Enforcement Administration, would come  
26 closer to establishing itself as a 'national medical board.'

H.R. Rep. No. 378, 106th Cong., 1<sup>st</sup> Sess., pt. 1, p.33 (1999) (emphasis added).

1 The Administrative Procedure Act (“APA”) requires agency-created rules to be subject to public  
2 criticism before they are “chiseled into bureaucratic stone.”<sup>15</sup> Under the APA, notice of proposed rule-  
3 making must be published in the Federal Register, and interested parties must be given an opportunity to  
4 comment and participate in the rule-making process.<sup>16</sup> In *Alcaraz v. Block*, the court, in describing the  
5 APA’s informal, notice and comment rule-making, stated:

6 “This framework creates a pre-publication dialogue which allows the rule-making agency  
7 to educate itself on the full range of interests the rule affects, and reintroduces a  
8 representative public voice, thus ensuring fairness to affected parties after governmental  
9 authority has been delegated to unrepresentative agencies, through sensitive efficient  
10 governmental decision making.”<sup>17</sup>

11 However, there is an exception to the public notice and comment requirements for “interpretive  
12 rules, general statements of policy, or rules of agency organization, procedure or practice.”<sup>18</sup> In an effort  
13 to circumvent the rule-making process, the Ashcroft Directive has been labeled an “interpretative rule” by  
14 the Defendants. As an interpretive rule, Defendants contend that they properly dispensed with the  
15 APA’s public notice and comment requirements.

16 While there is no bright-line distinction between substantive “legislative rules” (which require  
17 notice and comment) and “interpretive rules,”<sup>19</sup> interpretative rules have been defined, generally, to:

18 “merely clarify or explain existing laws or regulations, and do not  
19 foreclose alternate courses of action or conclusively affect rights of  
20 private parties.”<sup>20</sup>

21 The Ashcroft Directive does not fall under this definition of an interpretative rule. Rather, the  
22 Ashcroft Directive is an attempt by the Department of Justice to intrude into the area of medical regulation

23 <sup>15</sup> *Alcaraz v. Block*, 746 F.2d 593, 610-611 (9th Cir. 1984).

24 <sup>16</sup> 5 U.S.C. §553(b) and (c).

25 <sup>17</sup> *Alcaraz v. Block*, 746 F.2d 593, 611 (9th Cir. 1984).

26 <sup>18</sup> 5 U.S.C. §553(b)(A).

<sup>19</sup> *Alcaraz*, 746 F.2d at 613.

<sup>20</sup> *Malone v. Bureau of Indian Affairs* 38 F.3d 433, 438 (9th Cir. 1994), quoting, *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983) and *Linoz v. Heckler*, 800 F.2d 871, 877 (9th Cir. 1986).



1 by deciding what constitutes a legitimate medical purpose. It is not a clarification of existing federal law  
2 or policy. The Ashcroft Directive attempts to preempt existing state law, and substantially affects the  
3 rights of Oregon medical practitioners and patients.

4 For these simple reasons alone, the Ashcroft Directive cannot be construed as an interpretative  
5 rule, and must be invalidated because it was promulgated without public notice and comment, in violation  
6 of APA requirements.

7 **POINT II**

8 **FAR-REACHING NEGATIVE**  
9 **CONSEQUENCES OF THE ASHCROFT DIRECTIVE**  
10 **ON PRACTITIONERS AND PATIENTS**

11 **A. Practitioner Implications**

12 The ability of the Attorney General to determine the legitimacy of a particular medical practice is  
13 extremely dangerous. The practice of medicine is based on state standards, and doctors, until now, were  
14 assured that they would not be subject to liability if they practiced within the confines of those standards.

15 The potential loss of a DEA registration is of no small consequence to a practitioner. Revocation  
16 or suspension of DEA registration may subject a practitioner to investigation by state licensing or medical  
17 boards.<sup>21</sup> Whenever a practitioner is called into question by a state medical board, that physician runs  
18 the risk of losing his or her license to practice medicine.<sup>22</sup> Any adverse action by a state medical board  
19 also threatens a practitioner's ability to participate in Medicare, Medicaid and other federally funded  
20 programs.<sup>23</sup> Should a practitioner be excluded from participation in such federal programs, that  
21 practitioner is likely to find himself unable to practice in most hospitals and medical institutions, which rely  
22 on such federal funding..

23 The practitioner is faced with a Hobson's choice between practicing in accord with the Oregon

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24 <sup>21</sup> N.Y. EDUC LAW § 6530 (McKinney, 2001); N.Y. PUB. HEALTH § 3390 (McKinney,  
25 2001); ORS 677.190.

26 <sup>22</sup> *Id.*

<sup>23</sup> 42 CFR §1001.501 (2001).

1 state law and standards, and federal law and standards as articulated in the Ashcroft Directive. This issue  
2 was articulated in the Congressional debate over the proposed PRPA: One of the dissents in a House  
3 Committee Report on the proposed PRPA almost seemed to anticipate the Ashcroft Directive, in writing  
4 that the PRPA would allow federal law enforcement agents to “second-guess the considered medical  
5 judgment of physicians, pharmacists, and patients,” threaten medical professionals “with long prison  
6 sentences and strict liability,” and “inhibit physicians from aggressively treating pain.”<sup>24</sup>

7 *B. Patient Implications*

8 The Ashcroft Directive also allows unprecedented federal intrusion into the protected relationship  
9 between patients and their physicians. Fear of federal investigation and prosecution will make physicians  
10 hesitant to make decisions and prescribe drugs according to their best medical judgment. This result will  
11 undoubtedly harm patient care because the Ashcroft Directive’s intrusion into state medical practice  
12 under cover of the CSA has implications for pain management generally, not just in the context of  
13 physician-assisted suicide..

14 For example, while the trend in medical education is to provide adequate pain management to  
15 terminally ill patients, patients will no longer be likely to receive adequate pain treatment. But, in reality, if  
16 a practitioner exercises his or her professional judgment in prescribing a pain medication to a terminally ill  
17 patient, and that patient succumbs to death, there is absolutely nothing to prevent that practitioner’s  
18 medical judgment from being second-guessed by the DEA. In fact, there has already been testimony  
19 before the United States Senate Committee on Health, Education, Labor and Pensions that “some  
20 clinicians are reluctant to use sufficient dosages of opioids to relieve pain because they fear that this may  
21 hasten death and that the clinically appropriate use of pain medications could be confused with physician-  
22 assisted suicide.”<sup>25</sup> The fear of investigation and penalties will erode progress in the evolving area of life  
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24 <sup>24</sup> H.R. Rep. No. 378, 106th Cong., 1st Sess., pt. 1, p. 31 (1999).

25 <sup>25</sup> *Senate Hearings, supra* note 12, (written testimony of Joseph J. Fins, M.D., F.A.C.P.,  
26 Associate Professor of Medicine in Psychiatry, Weill Medical College of Cornell University and  
Director of Medical Ethics, New York Presbyterian Hospital - Cornell Campus).

1 care and pain management and cause dying patients and their families to needlessly suffer.<sup>26</sup> By allowing  
2 the Attorney General and the DEA to make decisions which involve the practice of medicine and science,  
3 the balance that Congress established between the federal objective to regulate the abuse of controlled  
4 substances and the states' ability to regulate medical practice, will be upset.<sup>27</sup> "When balance in  
5 controlled substance policy is upset, the chances for conflict between law enforcement and medicine  
6 increases, as does the likelihood that patient care will be harmed."<sup>28</sup>

7 The Ashcroft Directive, should it be permitted to stand, also sets the stage for future federal  
8 intrusions aimed at curtailing other medical practices and procedures that are viewed as objectionable by  
9 the current Attorney General or Administration.<sup>29</sup>

10 For example, if the Attorney General can declare the use of certain controlled substances to  
11 hasten the death of a terminally-ill patient's death to be an illegal, non-legitimate medical practice, then it is  
12 fair to assume that the Attorney General, if so inclined, can issue another directive declaring the use of  
13 certain anesthetics to perform late-term abortions to be an illegal, non-legitimate medical practice.<sup>30</sup>  
14 While some states have laws banning late-term abortions under certain conditions,<sup>31</sup> and others are still

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16 <sup>26</sup> *Id.*

17 <sup>27</sup> *Senate Hearings, supra* note 12, (testimony of David E. Joranson, Senior Scientist and  
18 Director of the Pain Studies Group, University of Wisconsin Comprehensive Cancer Center, Madison).

19 <sup>28</sup> *Id.*

20 <sup>29</sup> "The directive establishes a clear precedent by putting the Attorney General's office in the  
21 position of regulating the practice of medicine. If the provisions of the memorandum are permitted to  
22 stand, Ashcroft or a future Attorney General could decide to use this precedent to justify restrictions on  
23 other medically approved drugs or practices viewed as objectionable." Edward Lowenstein, M.D.,  
24 *The U.S. Attorney General's Intrusion Into Medical Practice*, 346 *New England Journal of*  
25 *Medicine*, 447, 447-448 (2002).

26 <sup>30</sup> On April 10, 1996 President Clinton vetoed the proposed federal "Partial-Birth Abortion  
27 Ban Act of 1995," which would have banned partial-birth abortions. A new Attorney General cannot  
28 be allowed to override prior President veto by declaring the use of controlled substances in connection  
29 with this procedure to be a non-legitimate medical practice – effectively banning the procedure. If this  
30 were allowed, this nation's system of checks and balances would be seriously jeopardized.

31 Ala. Code § 26-23-1 to 26-23-6 (2001); Ariz. Rev. Stat. Ann § 13-3603.01 (2001); Ga.  
Code Ann. § 16-12-144 (2001); N.J. Stat. Ann. § 2A: 65A-6 (2001); Ohio Rev. Code Ann. §

1 debating the issue,<sup>32</sup> the Attorney General may conceivably ban this controversial procedure without any  
2 regard to existing or proposed state laws regulating the procedure.<sup>33</sup>

3 Given the above serious negative implications to practitioners and their patients, the Ashcroft  
4 Directive cannot be permitted to stand.

### 5 POINT III

#### 6 THE ATTORNEY GENERAL DOES NOT HAVE THE 7 AUTHORITY TO DETERMINE WHAT CONSTITUTES A 8 "LEGITIMATE MEDICAL PURPOSE," A FUNCTION 9 TRADITIONALLY LEFT TO THE STATES TO DECIDE

##### 10 A. Deference Is Traditionally Given To States Concerning 11 Regulation Of The Practice of Medicine

12 For obvious reasons, the practice of medicine is a highly regulated profession. However, the  
13 practice of medicine is regulated generally by state law, not federal law.<sup>34</sup> Each state has its own medical  
14 licensing board, standards of professional conduct and licensing requirements.<sup>35</sup>

15 State sovereignty with respect to the regulation of medicine is well-established, and for that  
16 reason, Congress has not created a national standard for the practice of medicine. To the contrary, the

17 2919.15.

18 <sup>32</sup> NY A.B. 3688, 224<sup>th</sup> Legis. Sess. (N.Y. 2001); NY A.B. 2826, 224 Legis. Sess. (N.Y.  
19 2001); OR S.B. 750, 71<sup>st</sup> Legis. Assemb. (OR 2001).

20 <sup>33</sup> Another example concerns the use of misoprotol, which has been recognized as an effective  
21 abortifacient in combinations with other FDA-approved drugs. This legitimate medical use of  
22 misoprotol may be jeopardized if the Ashcroft Directive is allowed to stand because "it would be a  
23 simple matter of using his memorandum as a precedent to declare illegitimate this or any other off-label  
24 use of an approved medicine," which are common and recognized by the FDA. Edward Lowenstein,  
25 M.D., *The U.S. Attorney General's Intrusion Into Medical Practice*, 346 New England Journal of  
26 Medicine, 447, 447-448 (2002).

27 <sup>34</sup> In *Linder v. United States*, the United States Supreme Court stated that "[o]bviously,  
28 direct control of medical practice in the states is beyond the power of the federal government." 268  
29 U.S. 5, 18, 45 S.Ct. 446, 449 (1925).

30 <sup>35</sup> States are authorized to regulate medicine by setting up licensing boards and may determine  
31 the qualifications of who may practice medicine in the state. *See Peckman v. Thompson*, 745 F. Supp.  
32 1388, 1391 (C.D. Ill. 1990); *See also Dent v. West Virginia*, 129 U.S. 114, 122, 9 S.Ct. 231, 233  
33 (1889) (deferring to state medical licensing laws and stating that the "nature and extent of the  
34 qualifications required [to practice medicine] must depend primarily upon the judgment of the state as to  
35 their necessity").

1 United States Supreme Court has held that a state's ability to regulate medicine within its borders is  
2 "elemental" and vital to the state's police powers.<sup>36</sup> The Supreme Court has also consistently given  
3 deference to physicians' medical judgments.<sup>37</sup>

4 B. *In Enacting the CSA, Congress Did Not Intend To*  
5 *Determine What Constitutes a "Legitimate Medical Purpose"*

6 The Ashcroft Directive effectively usurps the well-established authority of the states to regulate  
7 the practice of medicine. In place of physicians and medical experts, the Attorney General, having no  
8 medical expertise, will now be able to determine whether a particular medical treatment or practice is, or  
9 is not, legitimate.

10 This result was not intended by Congress when it enacted the CSA. The CSA was enacted by  
11 Congress for the specific purpose of combating illegal manufacturing, dispensing and distributing of  
12 controlled substances.<sup>38</sup> Because Congress recognized that many of these substances have legitimate  
13 medical uses, the CSA contains an elaborate registration and reporting scheme that enables registered  
14 practitioners to legally prescribe and dispense controlled substances without fear of prosecution.<sup>39</sup> Under  
15 the CSA's registration and reporting scheme, physicians and pharmacists apply to the DEA for a federal  
16 license to prescribe and administer controlled substances. Any prescription for a controlled substance  
17 "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of

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19 <sup>36</sup> *Barsky v. Bd. of Regents*, 347 U.S. 442, 449, 74 S.Ct. 650 (1954) ("It is elemental that a  
20 state has broad power to establish and enforce standards of conduct within its borders relative to the  
21 health of everyone. It is vital to the state's police powers.").

22 <sup>37</sup> See, e.g., *Parham v. J.R.*, 442 U.S. 584, 608, 99 S.Ct. 2493, 2507 (1979) (mode and  
23 procedure of medical diagnostic procedures is not the business of judges); *Addington v. Texas*, 441  
24 U.S. 418, 429, 99 S.Ct. 1804, 1811 (1979) (whether a person is mentally ill turns on the meaning of  
25 facts which must be interpreted by psychiatrists and psychologists); *Youngberg v. Romeo*, 457 U.S.  
26 307, 322-23, 102 S.Ct. 2452, 2461-62 (1982) (deference to medical judgment requires that  
physicians be permitted to consider factors that the medical community accepts as relevant in the  
making of such judgments.).

<sup>38</sup> 21 U.S.C. § 801. See e.g., *United States v. Moore*, 423 U.S. 122, 135, 96 S.Ct. 335,  
342 (1975); *United States v. Rosenberg*, 515 F.2d 190, 193 (9th Cir. 1975), *cert. denied*, 423 U.S.  
1031, 96 S.Ct 562 (1975).

<sup>39</sup> 21 U.S.C. §§ 821-830.

1 his professional practice . . . .”<sup>40</sup> Only when a registered practitioner’s “activities fall outside the usual  
2 course of professional practice,” may he or she be prosecuted under the CSA.<sup>41</sup>

3 However, the CSA and its implementing regulations do not define or address what constitutes the  
4 “usual course of professional practice” or “legitimate medical purpose.” This was not an oversight by  
5 Congress, but rather a choice by Congress not to intrude into an area traditionally regulated by the states.  
6 The intent of Congress to defer to the states on issues of medical practice was confirmed by a 1997 Act  
7 of Congress that restricts the use of federal funds to furnish services in support of assisted suicide,  
8 euthanasia and mercy killing, while expressly recognizing that such activities, “because of recent  
9 developments, may still become lawful in areas of the United States.”<sup>42</sup>

10 C. The Supreme Court Has Deferred To The States To  
11 Explore The Issue of Physician-Assisted Suicide

12 The Supreme Court has already considered two state laws – one enacted by New York and the  
13 other by Washington – declaring physician-assisted suicides illegal.<sup>43</sup> While the Supreme Court found  
14 both of these state laws to be constitutional, the Court did not hold that a state law legalizing physician-  
15 assisted suicide is necessarily unconstitutional.

16 In *Washington v. Glucksburg*, five justices joined in the opinion of the Court written by Chief  
17 Justice Rehnquist, who wrote:

18 “Throughout the Nation, Americans are engaged in an earnest and profound debate  
19 about the morality, legality, and practicality of physician-assisted suicide. Our holding  
20 permits this debate to continue, as it should in a democratic society.”<sup>44</sup>

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21 <sup>40</sup> 21 C.F.R. § 1306.04.

22 <sup>41</sup> *United States v. Moore*, 423 U.S. 122, 124, 96 S.Ct. 335, 337 (1975); *U.S. v. Ekinci*,  
101 F.3d 838 (2d Cir.1996).

23 <sup>42</sup> *See*, Assisted Suicide Funding Restriction Act of 1997, 42 U.S.C. § 14401(a)(2)-(3).

24 <sup>43</sup> *Washington v. Glucksburg*, 521 U.S. 702, 117 S.Ct. 2258 (1997); *Vacco v. Quill*, 521  
25 U.S. 793, 117 S.Ct. 2293 (1997).

26 <sup>44</sup> *Glucksburg*, 521 U.S. at 735, 117 S.Ct. at 2275. Justice Rehnquist also noted that States  
are already engaged in “serious, thoughtful examinations of physician-assisted suicides and other  
issues.” 521 U.S. at 719, 117 S.Ct. at 2267.

1 Similarly, Justice O'Connor (joined by Justice Ginsburg and Justice Breyer, in part) agreed that  
2 the decision on this issue should be "entrusted to the 'laboratory' of the States in the first instance."<sup>45</sup> In  
3 the companion case of *Vacco v. Quill*, dealing with the issue of physician-assisted suicide, the Supreme  
4 Court agreed with the district court's determination that "[u]nder both the U.S. Constitution and the  
5 federal system it establishes, the resolution of this issue is left to the normal democratic processes within  
6 the state."<sup>46</sup>

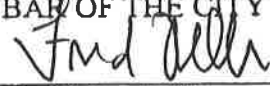
7 Given the Supreme Court's decision urging continued debate by the states on this issue, it is not  
8 appropriate for the Attorney General to resolve such debate by administrative fiat.

9 **CONCLUSION**

10 For the foregoing reasons, we respectfully request the Court to issue an order granting Plaintiff's  
11 motion for summary judgment.

12 Dated: March 1, 2002

13 THE ASSOCIATION OF THE  
14 BAR OF THE CITY OF NEW YORK

15 By:  \_\_\_\_\_

16 Fredrick I. Miller  
17 Leo T. Crowley  
18 Matha Golar  
19 Ruth Kalibtzer  
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25 of the City of New York

26 By:  \_\_\_\_\_

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the City of New York

27 issues." 521 U.S. at 719, 117 S.Ct. at 2267.

28 <sup>45</sup> *Glucksburg*, 521 U.S. at 737, 117 S.Ct. at 2303.

29 <sup>46</sup> *Vacco v. Quill*, 521 U.S. at 798, 117 S.Ct. at 2297.

CERTIFICATE OF SERVICE

I hereby certify that I served the foregoing *ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK'S AMICUS BRIEF IN SUPPORT OF OREGON'S MOTION FOR SUMMARY JUDGMENT* on the following party(ies):

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Portland, OR 97205

by mailing a true and correct copy by first class mail thereof to said party(ies) on the date stated below.

DATED this 7th day of March, 2002.



---

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9 On behalf of the Association of the Bar of the City of New York

10 UNITED STATES DISTRICT COURT  
11 DISTRICT OF OREGON

12 STATE OF OREGON )  
13 Plaintiff, )  
14 & )  
15 RICHARD HOLMES; KARL STANSELL; )  
JAMES ROMNEY; JANE DOE #1; PETER )  
16 A. RASMUSSEN, M.D.; and DAVID )  
MALCOMÉ HOCHHALTER, PhD, )  
17 Plaintiffs-Intervenors, )  
18 v. )  
19 JOHN ASHCROFT, in his official capacity )  
as United States Attorney; ASA )  
20 HUTCHINSON, in his official capacity )  
as Administration of the Drug Enforcement )  
21 Administration; KENNETH W. MAGEE, in )  
his official capacity as Director of the Drug )  
22 Enforcement Administration, Portland )  
Office; UNITED STATES OF AMERICA; )  
23 UNITED STATES DEPARTMENT )  
OF JUSTICE; and UNITED STATES )  
24 DRUG ENFORCEMENT )  
ADMINISTRATOR, )  
25 Defendants. )  
26

Case No. CV01-1647-JO  
MOTION OF ASSOCIATION OF THE  
BAR OF THE CITY OF NEW YORK TO  
FILE AMICUS CURIAE MEMORANDUM  
EXPEDITED CONSIDERATION  
REQUESTED  
DECISION REQUESTED BEFORE  
MARCH 7, 2002

Page MOTION OF ASSOCIATION OF THE BAR OF THE CITY OF  
NEW YORK TO FILE AMICUS CURIAE MEMORANDUM

LINDSAY, HART, NEIL & WEIGLER, LLP  
1300 S.W. FIFTH AVENUE, SUITE 3400  
PORTLAND, OREGON 97201-5696  
(503) 226-7677

1 **L.R. RULE 7.1 CERTIFICATION**

2 The parties made a good faith effort through personal or telephone conferences to resolve the  
3 dispute, and each of the parties has consented to this motion, with the exception of the defendants. One  
4 letter, one e-mail, two voice mails, and a message left with the secretary for Joseph W. LaBue, U.S.  
5 Justice Department, Senior Trial Counsel, have gone unanswered.

6 **MOTION**

7 The Association of the Bar of the City of New York ("ABCNY") is aligned with the position of  
8 the State of Oregon and the Plaintiffs-Intervenors in this case. The ABCNY is prepared to file its  
9 amicus curiae memorandum by March 7, 2002, the deadline set by the court for such submissions. The  
10 ABCNY respectfully requests that the court expedite its consideration of this motion for leave to appear  
11 as amicus curiae, and issue an order before March 7, 2002.

12 Based on the inherent powers of the Court, the ABCNY requests that the Court allow the  
13 submission of an amicus curiae memorandum in the above-captioned matter. The ABCNY believes that  
14 it has unique and helpful information that will assist the Court in ruling on this important case.

15 The ABCNY was founded in 1870 and has grown to more than 22,000 members. Since its  
16 formation it has engaged in public policy and reform of the law, working through its committees, which  
17 presently are 180 in number.

18 Through the work of its Health Law Committee, the ABCNY seeks to file an amicus brief. The  
19 Health Law Committee is the bar association's committee that addresses legal and policy issues affecting  
20 health care and public health. The Health Law Committee, as is the case with other ABCNY  
21 committees, routinely prepares position statements and, on occasion, amicus briefs (in both state and  
22 federal courts, at all levels), on issues that it believes are relevant to members of the legal profession and  
23 in the public interest.

24 This Committee has noted the potential relevance of the subject matter of Attorney General  
25 Ashcroft's recent directive with regard to the Controlled Substances Act and its application to Oregon  
26 law. It further has noted the potential impact that this directive, or similar directives in this area, may

1 have on medical practitioners, patients, and the regulation of medical practice in the states.

2 Accordingly, the ABCNY seeks permission to present its position, which focuses to a large  
3 extent on these issues of state medical practice and state medical regulation, and believes that this should  
4 be a part of any consideration of the issues at hand.

5 Dated: March 1, 2002

6 Respectfully submitted,

7 LINDSAY, HART, NEIL & WEIGLER LLP

8 By: 

9 Roy Pulvers, OSB No. 83357  
10 Attorney for Association of the Bar of the  
11 City of New York

12 GARFUNKEL, WILD & TRAVIS, P.C.

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Page

CERTIFICATE OF SERVICE

I hereby certify that I served the foregoing MOTION OF THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK TO FILE AMICUS CURIAE MEMORANDUM on the following party(ies):

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Portland, OR 97205

by mailing a true and correct copy by first class mail thereof to said party(ies) on the date stated below.

DATED this 1st day of March, 2002.



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