BOARD OF PHARMACY EXAMINERS

Petition by Carl Olsen)	
for the rescheduling of marijuana)	PETITION FOR
pursuant to Iowa Code 124.201)	RULE MAKING
and 657 IAC Chapter 26)	OR ACTION

Iowa Board of Pharmacy 400 SW Eighth Street, Suite E Des Moines, Iowa 50309-4688

Both state and federal law require that marijuana be transferred from schedule 1 to a lower schedule of Iowa's version of the Uniform Controlled Substances Act, Iowa Code Chapter 124.

Marijuana is incorrectly classified, Iowa Code § 124.204(4)(m), because it no longer fits the criteria for inclusion in schedule 1 as set forth in Iowa Code § 124.203(2):

Has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision.

GROUNDS FOR RESCHEDULING

Twelve states accept the safety of marijuana for medical use, Alaska Statutes § 17.37 (2007), California Health & Safety Code § 11362.5 (2006), Colorado Constitution Article XVIII, Section 14 (2006), Hawaii Revised Statutes § 329-121 (2006), 22 Maine Revised Statutes § 2383-B (2005),

Montana Code Annotated § 50-46-101 (2006), Nevada Constitution Article 4 § 38 (2006) - Nevada Revised Statutes Annotated § 453A.010 (2006), New Mexico Statutes Annotated § 30-31C-1 (2007), Oregon Revised Statutes § 475.300 (2006), Rhode Island General Laws § 21-28.6-1 (2006), 18 Vermont Statutes Annotated § 4471 (2006), Revised Code Washington (ARCW) § 69.51A.005 (2006). All of these states allow medical marijuana use, possession, and cultivation.

Federal drug law, 21 U.S.C. § 903, gives the states the authority to determine accepted medical use. See, *Gonzales v. Oregon*, 546 U.S. 243, 269-270 (2006):

The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States "great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756, 105 S. Ct. 2380, 85 L. Ed. 2d 728 (1985)).

"The Government, in the end, maintains that the prescription requirement delegates to a single Executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general

standards of medical practice in every locality. The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it."

Gonzales v. Oregon, 546 U.S. at 275.

The Iowa Board of Pharmacy Examiners has an affirmative obligation to recommend changes in the schedules. Iowa Code § 124.201.

The 8 factors to be considered by the Iowa Board of Pharmacy
Examiners, Iowa Code 124.201(1)(a)-(h), were considered In The Matter of
Marijuana Rescheduling, DEA Docket No. 86-22, September 6, 1988
(attached as Exhibit #1), which resulted in a finding that, "Marijuana, in its
natural form, is one of the safest therapeutically active substances known
to man." Id. at pages 58-59. Please note that Carl Olsen was one of the
petitioners in the DEA rescheduling petition.

Because no state accepted marijuana's medical use in 1988, the DEA Administrator was able to reject the conclusion of the Administrative Law Judge in DEA Docket No. 86-22 that marijuana must be transferred from schedule 1 to schedule 2 of the federal controlled substances act.

Because marijuana now has currently accepted medical use in 12 states, because federal law defines accepted medical use to be whatever the states say it is, and because the DEA's own Administrative Law Judge

has already determined that marijuana is safe for use under medical supervision, the lowa definition for a schedule I controlled substance, Iowa Code § 124.203(2), no longer applies to marijuana and state law must be amended to reflect these changes.

Carl Olsen 130 E Aurora Ave Des Moines, IA 50313-3654 515-288-5798

Dated this 12th day of May, 2008.

BOARD OF PHARMACY EXAMINERS

MEMORANDUM OF LAW
IN SUPPORT OF PETITION
FOR RULE MAKING OR
OR ACTION

INTRODUCTION

In *State v. Bonjour*, 694 N.W.2d 511 (2005), the Iowa Supreme Court said the Iowa Board of Pharmacy Examiners was responsible for condemning an innocent man to death ("one could say that marijuana might have been lifesaving in this particular case"). 694 N.W.2d at 511.

The scheduling of marijuana in Iowa's Controlled Substances Act, Iowa Code §§ 124 et seq., is inconsistent because marijuana is scheduled in both schedule 1, IC 124.204(4)(m), and schedule 2, IC 124.206(7)(a).

IC 124.203 Substances listed in schedule I -- criteria.

The board shall recommend to the general assembly that it place in schedule I any substance not already included therein if the board finds that the substance:

- 1. Has high potential for abuse; and
- 2. Has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision.

If the board finds that any substance included in schedule I does not meet these criteria, it shall recommend that the general assembly place the substance in a different schedule or remove it from the list of controlled substances, as appropriate.

IC 124.205 Substances listed in schedule II -- criteria.

The board shall recommend to the general assembly that it place in schedule II any substance not already included therein if the board finds that:

- 1. The substance has high potential for abuse;
- 2. The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and
- 3. Abuse of the substance may lead to severe psychic or physical dependence.

If the board finds that any substance included in schedule II does not meet these criteria, it shall recommend that the general assembly place the substance in a different schedule or remove it from the list of controlled substances, as appropriate.

Because marijuana has "accepted medical use in treatment" in 12 states ("in the United States") the Iowa Board of Pharmacy Examiners must remove marijuana from schedule 1, IC 124.203. For the purposes of this Petition, the petitioner does not take any position on whether marijuana is properly scheduled in schedule 2, but reserves the right to challenge any scheduling decision the Iowa Board of Pharmacy Examiners might make if it is inconsistent with the scheduling criteria.

IOWA CONTROLLED SUBSTANCES ACT IOWA CODE CHAPTER 124

Iowa's Controlled Substances Act (**Iowa CSA** hereafter) is based on the Uniform Controlled Substances Act (**UCSA** hereafter). Iowa Code §§ 124.601 and 124.602. The **UCSA** is a creation of The National Conference of Commissioners on Uniform State Laws (http://www.nccusl.org/).

The **UCSA** is modeled after the federal Controlled Substances Act (Federal CSA hereafter). The **UCSA** web site states that, "UCSA provides fundamental law in the fight against narcotic and dangerous drugs, and achieves uniformity between state and federal drug laws."

(http://www.nccusl.org/Update/DesktopDefault.aspx?tabindex=2&tabid=60; search results for "Controlled Substances Act" accessed on May 21, 2008).

As a result of conformity to federal law, the **lowa CSA** automatically adopts changes in federal law unless the lowa Board of Pharmacy Examiners objects. Iowa Code § 124.201(4):

If any new substance is designated as a controlled substance under federal law and notice of the designation is given to the board, the board shall similarly designate as controlled the new substance under this chapter after the expiration of thirty days from publication in the Federal Register of a final order designating a new substance as a controlled substance, unless within that thirty-day period the board objects to the new designation.

In *State v. Bonjour*, 694 N.W.2d at 515-516 (Wiggins, J., and Lavorato, C.J., dissenting), Justice Wiggins details the history of the current scheduling of marijuana in Iowa and the Iowa Board of Pharmacy's role in that scheduling:

In 1971, the legislature repealed the Uniform Narcotic Drug Act and enacted the Uniform Controlled Substances Act. Unif. Controlled Substances Act, prefatory note, 9 U.L.A. 10 (1994). While Iowa's enactment of the Uniform Controlled Substances Act is a substantial adoption of the major provisions of the

uniform act, lowa's act contains some provisions not contained in the uniform act. Id. One such provision at variance with the uniform act occurred by amendment in 1979.

lowa's act, as originally enacted, classified marijuana as a Schedule I controlled substance without exception. Iowa Code § 204.204(4)(j) (1973). A Schedule I substance "has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision." Id. § 204.203(2). The original enactment was consistent with the uniform act. In 1979, the legislature amended lowa's act classifying marijuana as a Schedule I substance "except as otherwise provided by the rules of the board of pharmacy examiners for medical purposes." Id. § 204.204(4)(j) (1981). In the same amendment, the legislature added a new provision to the list of Schedule I substances providing, "this section does not apply to marijuana . . . when utilized for medical purposes pursuant to rules of the state board of pharmacy examiners." Id. § 204.204(6).

In the session laws adopting the 1979 amendments, the legislature also provided funding for the board of pharmacy examiners to establish "a research program for the medicinal use of marijuana." 1979 lowa Acts ch. 9, § 3. In 1979, the board of pharmacy examiners adopted rules establishing a research program investigating the medical use of marijuana. lowa Admin. Code r. 620--12.1 (1979). The rules clearly recognized the legislature did not preclude the medical use of marijuana in lowa's Controlled Substances Act by stating: "Nothing in these rules will preclude the use of any available dosage forms of marijuana or tetrahydrocannabinols." Id. The rules defined "marijuana" as the legislature defined it in lowa's Controlled Substances Act. Id. r. 620--12.2(3).

In 1987, the board of pharmacy examiners rescinded its rules establishing a research program into the medical use of marijuana because the legislature amended lowa's Controlled Substances Act classifying marijuana as a Schedule II substance.² Feb. 25, 1987 Iowa Admin. Bull. at 1444 (ARC 7383). The provision amending the Code classifying marijuana

as a Schedule II substance provided in relevant part: "marijuana is deemed to be a Schedule II substance when used for medicinal purposes pursuant to rules of the board of pharmacy examiners." Iowa Code § 204.206(7) (1987). A Schedule II substance "has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions." Id. § 204.205(2). Millions of people use Schedule II substances each day to relieve their symptoms. Other Schedule II substances include pain medications with codeine (Tylenol with codeine), oxycodone-based pain medications (Percocet), fentynal-based pain medications (Duragesic), and amphetamines (Adderall and Dexedrine).

² By statute, the board of pharmacy examiners has the duty to recommend revisions to the schedules of controlled substances. Iowa Code §§ 204.201(1); 204.205 (1987).

In 1990, the legislature amended this section of the Code one more time. The legislature continued to classify marijuana as a Schedule II substance, when used for medical purposes pursuant to rules of the board of pharmacy examiners. Id. § 204.206(7) (1991). It provided:

Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances [is a Schedule II substance]:

- a. Marijuana when used for medicinal purposes pursuant to rules of the board of pharmacy examiners.
 - c. Nabilone.3

Id. The 1990 amendment continues to be the law today. See lowa Code § 124.206(7) (2003).

³ Nabilone is a synthetic derivative of the chemicals found in marijuana.

FEDERAL CONTROLLED SUBSTANCES ACT UNITED STATES CODE TITLE 21 CHAPTER 13

The **Federal CSA** is almost identical to the **Iowa CSA**. For the purposes of this Petition, the important facts to note about the **Federal CSA** are:

- (1) Congress had doubts about where to place marijuana in the schedules of the **Federal CSA** ("... that marihuana be retained within schedule I at least until the completion of certain studies ... section 601 of the bill provides for the establishment of a Presidential Commission on Marihuana ... recommendations of the Commission will be of aid in determining the appropriate disposition of this question ...",

 Comprehensive Drug Abuse Prevention and Control Act of 1970, 1970

 USCCAN 4566, at page 4579); and
- (2) Congress appointed the Commission on Marihuana to review marijuana's temporary placement in schedule I of the **Federal CSA**(Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, Oct. 27, 1970, 84 Stat. 1236, § 601); and
- (3) The Report of the Commission on Marihuana found that "no sufficiently compelling social reason, predicated on existing knowledge, justifies intrusion by the criminal justice system into the private lives of individuals who smoke marihuana" and "marihuana use is not such a grave

problem that individuals who smoke marihuana, and possess it for that purpose, should be subject to criminal procedures" (Marihuana, A Signal of Misunderstanding, March 22, 1972, at page 150).

STATE AND FEDERAL SCHEDULING CRITERIA

The scheduling criteria for the **lowa CSA**, lowa Code 124.201(1), are as follows:

- a. The actual or relative potential for abuse;
- b. The scientific evidence of its pharmacological effect, if known;
- c. State of current scientific knowledge regarding the substance;
- d. The history and current pattern of abuse;
- e. The scope, duration, and significance of abuse;
- f. The risk to the public health;
- g. The potential of the substance to produce psychic or physiological dependence liability; and
- h. Whether the substance is an immediate precursor of a substance already controlled under this division.

The scheduling criteria for the Federal CSA, 21 USC 811(c), are as

follows:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history and current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The findings of the Commission on Marihuana are relevant to the scheduling criteria in the **Iowa CSA**, Iowa Code 124.201(1), and scheduling criteria in the **Federal CSA**, 21 U.S.C. 811(c).

FEDERAL ADMINISTRATIVE ACTIONS

Congress created an administrative procedure to update and maintain the schedules of controlled substances under 21 U.S.C. § 811 according to current knowledge, 21 C.F.R. § 1308. This process has resulted in findings of fact which affirm the findings of the Commission on Marihuana (attached as Exhibit 1 to this Petition). In the Matter of Marijuana Rescheduling, DEA Docket No. 86-22, Sept. 6, 1988, the Administrative Law Judge found, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." Recommend Ruling (attached as Exhibit 1 to this Petition) at pages 58-59.

A petition filed with the Drug Enforcement Administration (**DEA** hereafter), The 2002 Cannabis Rescheduling Petition, contains a detailed summary of the scientific and medical findings in the late 1990s that support the medical use of cannabis (marijuana) in the United States. The 2002 petition was written by Jon Gettman, Franjo Grotenherman, and Gero Leson and filed with the DEA on October 9, 2002 by the Coalition for

Rescheduling Cannabis (http://www.drugscience.org/ accessed on May 23, 2008).

The pharmaceutically pure, primary psychoactive ingredient in marijuana (delta-9-THC) has been rescheduled twice, from schedule I to schedule II in 1986 (51 Fed. Reg. 17,476, May 13, 1986), and from schedule II to schedule III in 1999 (64 Fed. Reg. 35,928, July 2, 1999).

INTERNATIONAL CONVENTION ON PSYCHOTROPIC SUBSTANCES

The Convention on Psychotropic Substances, 21 U.S.C. § 801a(2), was modified in 1991 to allow for the medical use of the pharmaceutically pure, primary psychoactive ingredient in marijuana, delta-9-THC. Official Records of the Economic and Social Council, 1991, Supplement No. 4 (E/1991/24, Supp. No. 4):

At its 1045th meeting, on 29 April 1991, the Commission on Narcotic Drugs, in accordance with article 2, paragraphs 5 and 6, of the Convention on Psychotropic Substances, 1971, decided that delta-9-tetrahydrocannabinol (also referred to as delta-9-THC) and its stereochemical variants should be transferred from Schedule I to Schedule II of that Convention.

(Report of the Commission on Narcotic Drugs on its Thirty-Fourth Session, Vienna, 29 April to 9 May 1991, E/CN.7/1991/26).

VEGETABLES FROM WHICH DRUGS ARE OBTAINED

Plants are not typically scheduled in schedules more restrictive than the psychoactive substances which are obtained from them. The coca

plant, from which cocaine is extracted, is in schedule II. The opium poppy, from which morphine is extracted, is in schedule II. Both cocaine and morphine are in schedule II.

COMPASSIONATE USE PROGRAM

For over 30 years, the Federal government has supplied marijuana to medical patients. Two of those patients, George McMahon (a resident of Bode, Iowa) and Barbara Douglass (a resident of Storm Lake, Iowa), serve on the Board of Directors of Iowans for Medical Marijuana. Carl Olsen, the Petitioner, is the original incorporator of Iowans for Medical Marijuana (a nonprofit corporation incorporated in the State of Iowa) and also serves as the President of its Board of Directors.

Another Iowan, Ladd Huffman (a resident of Sutherland, Iowa), who was approved to receive marijuana from the Federal government, was a participant in *Kiromiya v. United States*, 37 F. Supp. 2d 717 (E.D. Pa. 1999).

Given these considerations, the fact that some individuals continued to receive marijuana after the termination of the program as a whole does not constitute an equal protection violation. The government emphasized that these individuals had relied on the government-supplied marijuana for many years and that it did not wish to harm those individuals by abruptly cutting off their supply. The government's efforts to persuade these patients and their doctors to utilize alternative treatments is also consistent with its overall goal of limiting its role in distributing marijuana. While there is obviously tension

between the government's repeated statements that marijuana has not been proven to provide any beneficial results and its decision to continue supplying it to eight individuals for medical needs, the government has argued that there is a difference between individuals who have used government-supplied marijuana for many years, in some cases, and those who have not.

Kiromiya v. United States, 78 F.Supp.2d 367, 372 (E.D. Pa. 1999).

Barbara Douglass' primary care physician has recently retired and she has been unable to find another primary care physician willing to prescribe marijuana because of the stigma attached to marijuana's continued unlawful classification as a schedule 1 controlled substance under both state and federal law.

PRIOR CASE LAW

As the result of an administration petition to reschedule marijuana filed by the National Organization for the Reform of Marijuana Laws (NORML hereafter) in 1972, the U.S. Court of Appeals for the District of Columbia Circuit summarized the duties of the DEA under the Federal CSA.

Congress contemplated that the classification set forth in the Act as originally passed would be subject to continuing review by the executive officials concerned, notably in the Department of Justice and the Department of Health, Education and Welfare. Provision was made for further consideration, one taking into account studies and data not available to Congress when the Act was passed in 1970. Section 202 of the CSA, 21 U.S.C. § 812, establishing the schedules of controlled

substances, provides that "such schedules shall initially consist of the substances listed." (Emphasis added.) Subsection (c) provides "Schedules I, II, III, IV and V shall, unless and until amended pursuant to [21 U.S.C. § 811] consist of the following drugs. . . . " In subsection (a) of § 201 of the Act, 21 U.S.C. § 811, Congress provides that the Attorney General shall apply the provisions of the Act to the controlled substances listed in the schedules (in § 202) and other drugs added to such schedule, and "may, by rule," add substances to a schedule, transfer them between schedules, or "remove any drug or other substance from the schedule."

Section 201(a) of the Act, 21 U.S.C. § 811(a), provides that such rules shall be made on the record after opportunity for hearing, pursuant to the rulemaking procedures prescribed by 5 U.S.C. ch. 5, subch. II. It further provides that proceedings for adding, transferring, or deleting substances may be initiated by the Director on his own motion, at the request of the Secretary of Health, Education, and Welfare, or on the petition of any interested party. 21 U.S.C. § 811(a). The Act provides that the Attorney General, before initiating proceedings to either control a substance or to remove one from the schedules, shall "request from the Secretary [of HEW] a scientific and medical evaluation and recommendations". The Secretary is directed to consider certain factors listed in § 201(c) -- pharmacological effect, risk to the public health, psychic or psychological dependence. He is also directed to consider any scientific or medical considerations involved in other listed factors -- such as actual or relative potential for abuse; history and current pattern of abuse; scope, duration and significance of abuse. The statute provides that the Secretary's recommendations "shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance." § 201(b) CSA, 21 U.S.C. § 811 (b).

Put in a larger setting, the provisions for modification of Schedules betoken the same approach of ongoing research, study, and supplemental consideration that characterize other provisions. The Controlled Substances Act is the short title for Title II (Controls and Enforcement) of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Other provisions of the legislation provided for studies and researches by HEW or contracting agencies, for coordination of ongoing studies and programs in the White House under the Special Action Office for Drug Abuse, and for establishment, see § 601, CSA, of a Presidential Commission on Marihuana and Drug Abuse. The House Report recommending that marihuana be listed in Schedule I notes that this was the recommendation of HEW "at least until the completion of certain studies now under way," and projects that the Presidential Commission's recommendations "will be of aid in determining the appropriate disposition of this question in the future." H.R. Rep. No. 91-1444 (Part 1), 91st Cong., 2d Sess. (1970) at p. 13.

NORML v. Ingersoll, 497 F.2d 654, 656-657 (D.C. Cir. 1974). The U.S. Court of Appeals remanded the petition to the **DEA** for administrative hearings. *Id*.

After administrative hearings, the U.S. Court of Appeals again reviewed the administrative action taken by the **DEA** and made the following comment: "The [**DEA** Administrator] seems to be saying that even though the treaty does not require more control than Schedule V provides, he can on his own say-so and without any reason insist on schedule I. We doubt that this was the intent of Congress." *NORML v. DEA*, 559 F.2d 735, 741 (D.C. Cir. 1977). The U.S. Court of Appeals again remanded the petition to the **DEA** for further administrative hearings. *Id*.

Immediately prior to the recommended ruling of the Administrative

Law Judge in 1988 resulting from *NORML v. DEA* (see Exhibit 1 attached to this petition), the U.S. Court of Appeals for the First Circuit rejected the DEA's interpretation of the scheduling criteria of "currently accepted medical use in treatment in the United States" and "accepted safety for use under medical supervision" as used in 21 U.S.C.S. § 812(b)(1) in *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987).

We find this argument to be strained and unpersuasive. The CSA's definition of "United States" plainly does not require the conclusion asserted by the Administrator simply because section 802(28) defines "United States" as "all places subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Congress surely intended the reference to "all places" in section 802(28) to delineate the broad jurisdictional scope of the CSA and to clarify that the CSA regulates conduct occurring any place, as opposed to every place, within the United States. As petitioner aptly notes, a defendant charged with violating the CSA by selling controlled substances in only two states would not have a defense based on section 802(28) if he contended that his activity had not occurred in "all places" subject to United States jurisdiction. We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "in the United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.

Nor does the dictionary definition of "accepted" offered by the Administrator convince us that Congress intended FDA approval to be the equivalent of the second and third Schedule

I criteria. Use of the term "accepted" in sections 812(b)(1)(B) and 812(b)(1)(C) may indicate that Congress intended the medical use or safety of the substance to be "generally agreed upon," but this alone does not inform us as to who must generally be in agreement. The Administrator reads "accepted" to mean that the FDA must have approved the drug for interstate marketing. Dr. Grinspoon, on the other hand, prefers to interpret "accepted" as meaning that the medical community generally agrees that the drug in question has a medical use and can be used safely under medical supervision. Our conclusion is that the term "accepted" does not cure the statute's ambiguity. We are simply unable to extrapolate from the drafters' choice of the word "accepted" and thereby ascertain a general congressional intention favoring the interpretation advanced by the Administrator.

In another argument focusing upon the language of the statute, the Administrator urges us to adopt his interpretation of the CSA because it is entirely consistent with the interpretation of the phrase "accepted medical use in treatment in the United States" employed in the Commissioners' Notes to the Uniform Controlled Substances Act, §§ 203-12, 9 U.L.A. 221-35 (1979) ("Uniform CSA").8 At first glance, this argument appears to have considerable merit. The Uniform CSA, like its federal counterpart, creates five schedules of controlled substances and, indeed, was modeled on the federal CSA. 9 U.L.A. 187. 188 (1979).9 But, while we agree that the Uniform CSA offers an interesting comparison, we fail to see how the interpretation of the Uniform CSA offered by the Commissioners has any bearing at all on the intent of Congress, which enacted the federal CSA prior to the creation of the Uniform CSA. We can only conclude, therefore, that this argument, despite its facial appeal, has no bearing on the claim that the language of the federal CSA evidences congressional intent to adopt the construction of the statute favored by the Administrator.

Experimental substances found to have a potential for abuse in early testing will also be included in Schedule I. When those substances are accepted by the Federal Food and Drug

⁸The Commissioners' Notes provide:

Administration as being safe and effective, they will then be considered to have an accepted medical use for treatment in the United States, and thus, will be eligible to be shifted to an appropriate schedule based upon the criteria set out in Sections 205, 207, 209, and 211.

9 U.L.A. at 221.

⁹The Uniform CSA was approved for adoption by the states in 1970. To date, 48 states, the District of Columbia, Guam, and the Virgin Islands have adopted the Uniform CSA. 9 U.L.A. Supp. 123-24 (1986).

Grinspoon v. DEA, 828 F.2d 881, 886-887 (1st Cir. 1987).

Another possible reason for failure to obtain FDA new drug approval is that the manufacture, distribution, and use of a substance might not involve interstate marketing. 10 Unlike the CSA scheduling restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate. Compare 21 U.S.C. § 801(5) with 21 U.S.C. § 321(b), 331, 355(a). Thus, it is possible that a substance may have both an accepted medical use and safety for use under medical supervision, even though no one has deemed it necessary to seek approval for interstate marketing. Indeed, as Dr. Grinspoon argues, there is no economic or other incentive to seek interstate marketing approval for a drug like MDMA because it cannot be patented and exploited commercially. The prospect of commercial development, of course, is irrelevant to one who, like Grinspoon, seeks only to do research.

Grinspoon v. DEA, 828 F.2d 881, 887-888 (1st Cir. 1987).

In the first appeal from the **DEA** Administrator's denial of the 1988
Recommended Ruling of the Administrative Law Judge (attached to this
Petition as Exhibit 1), the U.S. Court of Appeal for the District of Columbia
noted that there is no federal definition for "accepted medical use".

Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991) ("The difficulty we find in petitioners' argument is that neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable."). The second appeal simply affirmed the first, *Alliance for Cannabis Therapeutics v.* **DEA**, 15 F.3d 1131, 1137 (D.C. Cir. 1994) ("The Administrator reasonably accorded more weight to the opinions of these experts than to the anecdotal testimony of laymen and doctors on which petitioners relied."). What is important to note here is that there was no evidence that any state, within the meaning of *Grinspoon v. DEA*, had accepted marijuana's medical use during the span of 22 years in which this rescheduling petition took place (1972 to 1994).

The United States Supreme Court has recently clarified the meaning and scope of the **Federal CSA** in *Gonzales v. Oregon*, 56 U.S. 243 (2006). The power to define medical practice is given to the states, and the federal authorities must defer to the states' determinations on issues of medical practice. The **DEA** is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law. *Gonzales v. Oregon* at 258. What

constitutes "legitimate" medical practice is not subject to interpretation by the **DEA**. *Gonzales v. Oregon* at 260.

TWELVE STATES ACCEPT MEDICAL USE OF MARIJUANA

Twelve states accept the safety of marijuana for medical use:

- 1. Alaska Alaska Stat. § 17.37.070(8) (2008): "medical use" means the acquisition, possession, cultivation, use or transportation of marijuana or paraphernalia related to the administration of marijuana to alleviate a debilitating medical condition under the provisions of this chapter and AS 11.71.090
- 2. **California** Cal Health & Saf Code § 11362.5 (2008): Use of marijuana for medical purposes
- 3. **Colorado** Colo. Const. Art. XVIII, Section 14(b) (2007): "Medical use" means the acquisition, possession, production, use, or transportation of marijuana or paraphernalia related to the administration of such marijuana to address the symptoms or effects of a patient's debilitating medical condition, which may be authorized only after a diagnosis of the patient's debilitating medical condition by a physician or physicians, as provided by this section.
- 4. **Hawaii** HRS § 329-121(3)(paragraph 3) (2008): "Medical use" means the acquisition, possession, cultivation, use, distribution, or transportation of marijuana or paraphernalia relating to the administration of marijuana to alleviate the symptoms or effects of a qualifying patient's debilitating medical condition.
- 5. **Maine** 22 M.R.S. § 2383-B(5) (2008): MEDICAL USE OF MARIJUANA
- 6. **Montana** Mont. Code Anno., § 50-46-102(5) (2007): "Medical use" means the acquisition, possession, cultivation, manufacture, use, delivery, transfer, or transportation of marijuana or paraphernalia relating to the consumption of marijuana to alleviate the symptoms or effects of a qualifying patient's debilitating medical condition.

- 7. **Nevada** Nev. Rev. Stat. Ann. § 453A.120 (2007): "Medical use of marijuana" means: 1. The possession, delivery, production or use of marijuana; 2. The possession, delivery or use of paraphernalia used to administer marijuana; or 3. Any combination of the acts described in subsections 1 and 2, as necessary for the exclusive benefit of a person to mitigate the symptoms or effects of his chronic or debilitating medical condition.
- 8. **New Mexico** N.M. Stat. Ann. § 26-2B-2 (2008): The purpose of the Lynn and Erin Compassionate Use Act [26-2B-1 NMSA 1978] is to allow the beneficial use of medical cannabis in a regulated system for alleviating symptoms caused by debilitating medical conditions and their medical treatments.
- 9. **Oregon** ORS § 475.302(8) (2007): "Medical use of marijuana" means the production, possession, delivery, or administration of marijuana, or paraphernalia used to administer marijuana, as necessary for the exclusive benefit of a person to mitigate the symptoms or effects of the person's debilitating medical condition.
- 10. **Rhode Island** R.I. Gen. Laws § 21-28.6-3(4) (2008): "Medical use" means the acquisition, possession, cultivation, manufacture, use, delivery, transfer, or transportation of marijuana or paraphernalia relating to the consumption of marijuana to alleviate a registered qualifying patient's debilitating medical condition or symptoms associated with the medical condition.
- 11. Vermont 18 V.S.A. § 4472(10) (2007): "Use for symptom relief" means the acquisition, possession, cultivation, use, transfer, or transportation of marijuana or paraphernalia relating to the administration of marijuana to alleviate the symptoms or effects of a registered patient's debilitating medical condition which is in compliance with all the limitations and restrictions of this subchapter. For the purposes of this definition, "transfer" is limited to the transfer of marijuana and paraphernalia between a registered caregiver and a registered patient.
- 12. **Washington** Rev. Code Wash. (ARCW) § 69.51A.010(2) (2008): "Medical use of marijuana" means the production, possession, or administration of marijuana, as defined in RCW 69.50.101(q), for

All of these 12 states allow medical marijuana use, possession, and cultivation.

MEDICAL NECESSITY AND COMMERCE CLAUSE CASES

The issue of who defines medical practice under 21 U.S.C. § 903 was not considered in *United States v. Oakland Cannabis Buyers* Cooperative, 532 U.S. 483 (2001) (OCBC hereafter). The only question presented to the Supreme Court was whether the **Federal CSA** contains a "medical necessity defense". The Supreme Court declined to rule on whether the prohibition of medical marijuana exceeded Congress' Commerce Clause powers. **OCBC**, 532 U.S. at 494 ("Because the Court of Appeals did not address these claims, we decline to do so in the first instance."); OCBC, 532 U.S. at 495 ("Nor are we passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause."). State v. **Bonjour**, 694 N.W.2d 511 (lowa 2005) was also limited to the question of whether the lowa CSA contains a "medical necessity defense" (citing **OCBC**, 694 N.W.2d at 513).

The issue of who defines medical practice under 21 U.S.C. § 903 was not considered in *Gonzales v. Raich*, 545 U.S. 1, 9 (2005):

The case is made difficult by respondents' strong arguments that they will suffer irreparable harm because, despite a congressional finding to the contrary, marijuana does have valid therapeutic purposes. The question before us, however, is not whether it is wise to enforce the statute in these circumstances; rather, it is whether Congress' power to regulate interstate markets for medicinal substances encompasses the portions of those markets that are supplied with drugs produced and consumed locally. Well-settled law controls our answer. The CSA is a valid exercise of federal power, even as applied to the troubling facts of this case.

The **Federal CSA**, 21 U.S.C. § 903, gives the states the authority to determine accepted medical use. Because the **Federal CSA** recognizes the sovereignty of the states to determine accepted methods of medical practice there is no conflict with federal law. See, *Gonzales v. Oregon*, 546 U.S. 243, 269-270 (2006):

The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States "'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756, 105 S. Ct. 2380, 85 L. Ed. 2d 728 (1985)).

"The Government, in the end, maintains that the prescription requirement delegates to a single Executive officer the power to effect a radical shift of

authority from the States to the Federal Government to define general standards of medical practice in every locality. The text and structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it."

Gonzales v. Oregon, 546 U.S. at 275.

THE RIGHT TO DEFEND LIFE AND LIBERTY

In *State v. Bonjour*, 694 N.W.2d 511, 517-518 (2005) (Wiggins, J., and Lavorato, C.J., dissenting), Justice Wiggins said the board of pharmacy examiners has failed to act:

Article I, section 1 of the Iowa Constitution provides:

All men and women are, by nature, free and equal, and have certain inalienable rights--among which are those of enjoying and defending life and liberty, acquiring, possessing and protecting property, and pursuing and obtaining safety and happiness.

Iowa Const. art. I, § 1.

If this court recognizes article I, section 1's inalienable rights in the context of the necessity defense, the right of a person to defend his or her life and pursue and obtain safety and happiness is just as important, if not more important, than the right to defend one's crops from hungry deer. If we are willing to allow a farmer to realize the full value of his crops by allowing him to kill a foraging deer, when the law authorized only a game warden or his deputy to kill that deer, we should allow an individual to seek relief from the agonizing symptoms caused by an incurable disease that will eventually lead to death, even though the board of pharmacy examiners has not enacted rules regarding the medical use of marijuana.

The failure of the board of pharmacy examiners to act is not an excuse for this court to refuse to recognize the defense when the legislature clearly recognizes there are legitimate medical uses for marijuana. We do not have to wait for the legislature or the board to negotiate the political minefield regarding the medical use of marijuana. As long as the legislature has not precluded the defense by a clear and deliberate choice, this court has an obligation to allow a defendant to use a necessity defense if the facts support such a defense. Otherwise, this court could always cite to a legislature's ambiguous pronouncement on a subject as grounds for rejecting the defense.

CONCLUSION

We now know from *Gonzales v. Oregon* that "accepted medical use" is what the states say it is and not what the **DEA** thinks it is.

It is clear from *Gonzales v. Oregon* and *State v. Bonjour* that the state of lowa can make its own, independent determination of "accepted medical use." However, it is equally clear from *Grinspoon v. DEA* that the state of lowa cannot say that marijuana has "no accepted medical use in treatment in the United States", because 12 states ("in the United States") have made the determination that marijuana does have accepted "medical use".

The Iowa Board of Pharmacy Examiners must move marijuana out of schedule 1 of the Iowa CSA or change the definition for schedule 1 of the Iowa CSA, IC 124.203, from "no accepted medical use in treatment in the

United States" to "no accepted medical use in treatment in Iowa". The principle of comity requires the state of Iowa to respect the laws of the other states, as well as the Supreme Court's interpretation of the **Federal CSA** in *Gonzales v. Oregon*.

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Dated this 25th day of May, 2008.