IN THE SUPREME COURT OF IOWA

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| CARL OLSEN,<br><br>Petitioner-Appellant,<br><br>v.<br><br>IOWA BOARD OF PHARMACY,<br><br>Respondent-Appellee. | ) | SUPREME COURT NO. 14-2164 |

APPEAL FROM THE IOWA DISTRICT COURT

FOR POLK COUNTY

HONORABLE ELIZA OVROM, JUDGE

# APPENDIX

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## CERTIFICATE OF FILING

On the 14th day of August, 2015, I, the undersigned, do hereby certify that I did electronically file through the Iowa Court System the Appendix.

/s/ Carl Olsen
CARL OLSEN

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IOWA BOARD OF PHARMACY

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| PETITION FOR RECOMMENDATION TO REMOVE MARIJUANA FROM SCHEDULE I OF THE IOWA UNIFORM CONTROLLED SUBSTANCES ACT | ) ) ) ) | **PETITION FOR AGENCY ACTION** |

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

By provision of law:

> Annually, within thirty days after the convening of each regular session of the general assembly, the Board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in sections 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems necessary or advisable.

Iowa Code § 124.201(1) (2013).

> 1. The board shall recommend to the general assembly that the general assembly place a substance in schedule I if the substance is not already included therein and the board finds that the substance:
>
> a. Has high potential for abuse; and
>
> b. Has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision.
>
> 2. If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate.

Iowa Code § 124.203 (2013).

## INTRODUCTION

In 2010, the Iowa Board of Pharmacy (the "**Board**") recommended that marijuana be removed from schedule I and placed in schedule II of the Iowa Uniform Controlled Substances Act (the "**Act**").

Petitioner, Carl E. Olsen, asserts that once the Board deems it necessary and advisable to remove marijuana from schedule I and place it in schedule II, the Board is required to make annual recommendations to the Iowa General Assembly until it acts on the Board's recommendation.

## REQUESTED ACTION

Petitioner requests a recommendation from the Board to the Eighty-Fifth Iowa General Assembly that marijuana be removed from schedule I, Iowa Code § 124.204(4)(m), and such other revisions in the schedules and recommendations which are required by the Act, or deemed necessary or advisable by the Board.

## PRIOR HISTORY

### A. First Ruling from the Board on October 7, 2008

On May 12, 2008, Petitioner requested the Board make a recommendation to the General Assembly that marijuana be removed from schedule I. At that time, twelve states had already established marijuana's

"accepted medical use in treatment in the United States" as a matter of law[1] by enacting laws regarding medical use.

The question of whether marijuana has "accepted medical use in treatment in the United States" was presented as a question of law rather than as a question of science. *See* Board Case No. 2008-105.

On October 7, 2008 the Board denied the request because it did not include any scientific evidence on marijuana's "potential for abuse."[2]

On April 21, 2009 the Iowa District Court remanded the case to the Board because "potential for abuse" is not determinative of whether marijuana should be placed in schedule I. *See McMahon v. Iowa Board of Pharmacy*, Iowa District Court for Polk County No. CV 7415, Ruling on Petition for Judicial Review.[3]

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1. Alaska Statutes § 17.37 (1998); California Health & Safety Code § 11362.5 (1996); Colorado Constitution Article XVIII, Section 14 (2000); Hawaii Revised Statutes § 329-121 (2000); 22 Maine Revised Statutes § 2383-B (1999); Montana Code Annotated § 50-46-101 (2004); Nevada Constitution Article 4 § 38 - Nevada Revised Statutes Annotated § 453A.010 (2000); New Mexico Statutes Annotated § 30-31C-1 (2007); Oregon Revised Statutes § 475.300 (1998); Rhode Island General Laws § 21-28.6-1 (2006); 18 Vermont Statutes Annotated § 4471 (2004); Revised Code Washington (ARCW) § 69.51A.005 (1998).

2. http://resources.iowamedicalmarijuana.org/petition/2012/20081007_pharmacy_board.pdf.

3. http://resources.iowamedicalmarijuana.org/petition/2012/20090421_district_court.pdf. ("Section 124.203 of the Iowa Code requires that any controlled substance have (1) a high potential for abuse, ***and*** (2) no accepted medical use in treatment in the United States before it may be classified under Schedule I. Because the Code imposes both criteria as a prerequisite to Schedule I classification, the failure to meet either would require recommendation to the legislature for removal or rescheduling. *See id*. As such, the Board's statement that it 'would also need to make a finding that marijuana lacks a high potential for abuse' before it could recommend to the legislature that marijuana be moved from Schedule to Schedule II is based upon an erroneous interpretation of law.")

### B. Second Ruling from the Board on July 21, 2009

On July 21, 2009 the Board again denied Petitioner's request because it did not include any scientific evidence on the question of marijuana's medical efficacy.[4]

Petitioner sought judicial review on the ground that the Board misinterpreted the statutory language "accepted medical use in treatment in the United States" to mean "medical efficacy" rather than accepted medical use in 12 states (all of which were "in the United States").[5]

### C. Third Ruling from the Board on February 17, 2010

On July 21, 2009 the Board decided on its own initiative to hold evidentiary hearings on marijuana's medical efficacy, addressing, among other things, the eight factors in Iowa Code § 124.201(1)(a)-(h).[6]

The Board held a series of four, statewide public hearings between August 19, and November 4, 2009. These hearings were transcribed by a certified court reporter.[7]

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4. http://resources.iowamedicalmarijuana.org/petition/2012/20090721_pharmacy_board.pdf
5. http://resources.iowamedicalmarijuana.org/petition/2012/20091030_district_court.pdf
6. http://resources.iowamedicalmarijuana.org/petition/2012/20090721_scheduling_review.pdf; http://www.iowamedical.org/documents/news/081809_MarijuanaHearings.pdf. The eight factors in Iowa Code § 124.201(1)(a)-(h) do not change the meaning of Iowa Code § 124.203(1)(b) to require that marijuana must first have accepted medical use in treatment in the United States before the same can be found in Iowa.
7. http://www.iowamedicalmarijuana.org/pharmacyhearings.aspx

Based on the evidence introduced at these hearings, the Board voted unanimously on February 17, 2010 to recommend that the General Assembly remove marijuana from schedule I.[8]

On May 14, 2010 the Iowa Supreme Court dismissed the appeal as moot. *McMahon v. Iowa Board of Pharmacy*, No. 09-1789, Order.[9]

### D. Subsequent Action by the Board

In November 2010, the Board pre-filed LSB 1274DP with the Iowa Legislature (SSB 1016), recommending, among other things, that the general assembly remove marijuana, Iowa Code § 124.204(4)(m), from schedule I.[10]

### E. Inaction by the General Assembly

To date, the Iowa General Assembly has neither accepted nor rejected the Board's 2010 recommendation.

**THIS ACTION IS NECESSARY TO UPDATE THE RECORD**

The administrative record requires updating because much has happened nationwide since the Board last recommended rescheduling in 2010. As this petition seeks a current recommendation from the Board to the Eighty-Fifth Iowa General Assembly (2013-14), the Board must

8. http://resources.iowamedicalmarijuana.org/petition/2012/20100217_pharmacy_board.pdf

9. http://resources.iowamedicalmarijuana.org/petition/2012/20100514_supreme_court.pdf ("The Board ultimately made the reclassification recommendation sought by the petitioners and the intervenor.")

10. http://resources.iowamedicalmarijuana.org/petition/2012/ssb1016_Introduced.pdf (http://www.iowa.gov/ibpe/pdf/2010_11_24minutes.pdf)

consider the present state of the art regarding the medicolegal aspects of marijuana in renewing its recommendation.

## ADDITIONAL EVIDENCE

Petitioner incorporates by reference the prior petitions filed with the Board on May 12, 2008[11] and August 3, 2012.[12] In addition to the evidence presented to the Board between August 19 and November 4, 2009, as well as that submitted by Petitioner in support of the August 3, 2012 petition, the following is offered in support of this petition.

### A. Other states have accepted the medical use of marijuana in treatment since August 3, 2012

Between the filing of the two petitions, five states[13] accepted the medical use of marijuana in treatment of medical conditions. Since the filing of the last petition on August 3, 2012, two additional states, Massachusetts and New Hampshire,[14] now accept the medical use of marijuana in treatment, which brings the current state total to 19.

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11. The first petition was filed with the Board on May 12, 2008. http://resources.iowamedicalmarijuana.org/imm/petitions/iowa_petition_20080512.pdf; http://resources.iowamedicalmarijuana.org/imm/petitions/iowa_memorandum_20080525.pdf

12. http://resources.iowamedicalmarijuana.org/petition/2012/petition_ibpe_2012_august.pdf

13. Arizona Revised Statutes, Title 36, Chapter 28.1, §§ 36-2801 through 36-2819 (2010); Connecticut Public Act No. 12-55 (2012) (not yet codified); Delaware Code, Title 16, Chapter 49A, §§ 4901A through 4926A (2011); D.C. Law 18-210; D.C. Official Code, Title 7, Chapter 16B, §§ 7-1671.01 through 7-1671.13 (2010); Michigan Compiled Laws, Chapter 333, §§ 333.26421 through 333.26430 (2008); New Jersey Public Laws 2009, Chapter 307, New Jersey Statutes, Chapter 24:6I, §§ 24:61-1 through 24:6I-16 (2010).

14. Massachusetts, November 6, 2012 (effective January 1, 2013), and New Hampshire, July 23, 2013 (effective July 23, 2013).

### B. Scientific Literature

As further support of this petition, copies of the recent scientific literature published since the last filing are provided on the accompanying CD.

## ARGUMENT

### A. Background

With the exception of marijuana, no other controlled substance listed in schedule I of the Iowa Uniform Controlled Substances Act has been accepted for medical use in any state "in the United States."

Marijuana has an extensive history of medical use in the United States. *See James v. City of Costa Mesa*, No. 10-55769 (9th Circuit, May 21, 2012) (Berzon, J., dissenting)[15], Slip. Op. at pages 5309-5310:

> First, while California in 1996 became the first of the sixteen states that currently legalize medical marijuana, the history of medical marijuana goes back much further, so that use for medical purposes was not unthinkable in 1990. At one time, "almost all States . . . had exceptions making lawful, under specified conditions, possession of marihuana by . . . persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person." *Leary v. United States*, 395 U.S. 6, 17 (1969). What's more, the Federal government itself conducted an experimental medical marijuana program from 1978 to 1992, and it continues to provide marijuana to the surviving participants. See *Conant v. Walters*, 309 F.3d 629, 648 (9th Cir. 2002). The existence of these programs indicates

15. http://www.ca9.uscourts.gov/datastore/opinions/2012/05/21/10-55769.pdf

> that medical marijuana was not a concept utterly foreign to Congress before 1996.

Marijuana's placement in federal schedule I remains controversial today. More than forty years ago, a presidential commission recommended decriminalization of marijuana.[16]

> In an effort to secure more information about marijuana, Congress, in section 601 of DAPCA, established the Commission on Marihuana and Drug Abuse to study marijuana use and its effects. The Commission, headed by Governor Raymond P. Shafer, issued its report, Marihuana: A Signal of Misunderstanding, in 1972. The Commission recommended that federal and state penalties for private possession of marijuana be eliminated and that governmental efforts should focus on discouraging marijuana use. Signal of Misunderstanding 134-38, 151-60.

*NORML v. Bell*, 488 F. Supp. 123, 135 (D.D.C. 1980). Subsequent findings were in accord with the Shafer Commission:

> New studies have indicated that the dangers of marihuana use are not as great as once believed. A recent report of a federal panel representing, inter alia, HEW, DEA, the State Department, and the White House, concluded that marihuana use entails a "relatively low social cost," and suggested that decriminalization be considered. Washington Post, Dec. 12, 1976, at A1, col. 1; Washington Star, Dec. 12, 1976, at A7, col. 1. See *United States v. Randall*, supra note 61, at 2254 (characterizing marihuana as "a drug with no demonstrably harmful effects"). Indeed, in NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE, SECOND REPORT, DRUG USE IN AMERICA: PROBLEM IN PERSPECTIVE, Vol. I, at 235 (1973), the Commission recommended that "the United

16. Public Law 91-513, Oct. 27, 1970, 84 Stat. 1280-1281, Part F — Advisory Commission, Establishment of Commission on Marihuana and Drug Abuse.

> States take the necessary steps to remove cannabis from the Single Convention on Narcotic Drugs (1961), since this drug does not pose the same social and public health problems associated with the opiates and coca leaf products."

*NORML v. DEA*, 559 F.2d 735, 751 n.70 (D.C. Cir. 1977). There is also the finding that "[m]arijuana, in its natural form, is one of the safest therapeutically active substances known to man."[17] Despite the historical record of the medical use of marijuana, the DEA Administrator then rejected rescheduling because marijuana had no accepted medical use in treatment in the United States at the time the recommendation was issued.

The issue of safety for use in treatment under medical supervision was once previously considered to be separate from the issue of accepted medical use. This is no longer true.

> Since the Administrator based this determination on his decision that no medical uses are possible (and thus any use lacks "accepted safety"), we do not see that "safety" issue as raising a separate analytical question.

*See Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 n.4 (D.C. Cir. 1991). The following year, the DEA formally announced that previous administrative decisions separating safety from accepted medical use were incorrect and equated both issues for analytical purposes:

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[17.] Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of Administrative Law Judge, DEA Docket No. 86-22 at 58-59 (Sept. 6, 1988). http://resources.iowamedicalmarijuana.org/imm/young.pdf

> The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. 53 FR 5156 (February 22, 1988). In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

Marijuana Scheduling Petition; Denial of Petition; Remand, DEA Docket No. 86-22, Vol. 57, Federal Register at 10504 (Thursday, March 26, 1992). Currently, the issue of marijuana's safety for use under medical supervision is implicit in the analysis of whether marijuana has accepted medical use.

It is no mere coincidence that California became the first state "in the United States" to accept the medical use of marijuana in treatment "in the United States" just two years after the DEA's refusal to reclassify marijuana was upheld in *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

### B. Accepted Medical Use and Treatment in the United States

Marijuana has accepted medical use in treatment in the United States as a matter of law because 19 states[18] now accept the medical use of marijuana. The Iowa Code employs very specific language for the placement of controlled substances in schedule I. In order to remain in schedule I, marijuana cannot have any "accepted medical use in treatment in the United States."

[18.] The District of Columbia also accepts marijuana for medical use with the consent of Congress.

The term “state” is defined as:

> “*State*,” when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession, and any area subject to the legal authority of the United States of America.

Iowa Code § 124.101(29).

Accepted medical use in treatment “in the United States” does not mean accepted medical use “*in every state*.” In the Board’s Supplemental Order of July 21, 2009, Case No. 2008-105, the Board stated “the United States is 50 states, not 12.” This argument has been rejected in *Grinspoon v. DEA*, 828 F.2d 881, 886 (1st Cir. 1987):

> 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.

Accepted medical use in treatment “in the United States” does not mean accepted medical use “*in Iowa*.” If General Assembly intended to make the condition for placement in Schedule I to be accepted medical use “*in Iowa*,” it would have done so. The Board cannot assume the legislature made a mistake in using the phrase “in the United States” and really meant

to say "*in Iowa*." The legislature could have easily provided for "medical efficacy" if that was the intent. The intent of the Iowa legislature is expressed in Iowa Code § 124.601 ("to make uniform the law of those states which enact it").

The choice of the words "in the United States" is consistent with the understanding that states are the primary regulators of medical practice in the United States. *See Conant v. Walters*, 309 F.3d 629, 639 (9th Cir. 2002):

> Our decision is consistent with principles of federalism that have left states as the primary regulators of professional conduct. See *Whalen v. Roe*, 429 U.S. 589, 603 n. 30, 51 L. Ed. 2d 64, 97 S. Ct. 869 (1977) (recognizing states' broad police powers to regulate the administration of drugs by health professionals); *Linder v. United States*, 268 U.S. 5, 18, 69 L. Ed. 819, 45 S. Ct. 446 (1925) ("direct control of medical practice in the states is beyond the power of the federal government"). We must "show[] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country." *Oakland Cannabis*, 532 U.S. at 501 (Stevens, J., concurring) (internal quotation marks omitted).

*See also Gonzales v. Oregon*, 546 U.S. 243, 251 (2006) (noting "the [Controlled Substances Act] explicitly contemplates a role for the States").

In *Gonzales v. Raich*, 545 U.S. 1, 28 n.37 (2005), the Supreme Court acknowledged the doubtful validity of marijuana's current federal classification:

> We acknowledge that evidence proffered by respondents in this case regarding the effective medical uses for marijuana, if found credible after trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I. *See*, *e.g.*, Institute of Medicine, Marijuana and Medicine: Assessing the Science Base 179 (J. Joy, S. Watson, & J. Benson eds. 1999) (recognizing that "[s]cientific data indicate the potential therapeutic value of cannabinoid drugs, primarily THC [Tetrahydrocannabinol] for pain relief, control of nausea and vomiting, and appetite stimulation"); *see also Conant v. Walters*, 309 F.3d 629, 640-643 (CA9 2002) (Kozinski, J., concurring) (chronicling medical studies recognizing valid medical uses for marijuana and its derivatives).

In *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court recognized the limits of the CSA and the role of state police powers vis-à-vis the practice of medicine.

> [T]he CSA . . . 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.'" (citations omitted)

*Id*. at 269-270. "When Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute." *Id.* at 272.

Finally, the phrase "accepted medical use in treatment in the United States" does not mean accepted medical use by the Food and Drug Administration (FDA) and/or the U.S. Drug Enforcement Administration (DEA):

> 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.

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

## CONCLUSION

This petition acknowledges the Board's duty to consider the eight factors in Iowa Code section 124.201(1)(a)-(h). None of those factors is determinative. The Board cannot interpret, however, the eight factors in Iowa Code section 124.201(1)(a)-(h) in a manner which would result in a recommendation that is inconsistent with Iowa Code § 124.203(1)(b).[19]

In 2010, the Board was correct in recommending marijuana be removed from schedule I because marijuana has accepted medical use in treatment in the United States as a matter of law.

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[19.] In his ruling remanding the case to the Board, Judge Novak stated, "A finding of accepted medical use in treatment in the United States alone would be sufficient to warrant recommendation for reclassification or removal pursuant to the terms of Iowa Code section 124.203." *McMahon v. Board of Pharmacy*, No. CV 7415 at 4, fn. 1 (April 21, 2009)

Petitioner requests the Board renew its 2010 recommendation to the General Assembly to remove marijuana from schedule I and place it in schedule II.

Respectfully submitted,

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BEFORE THE IOWA BOARD OF PHARMACY

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| PETITION FOR RECOMMENDATION TO REMOVE MARIJUANA FROM SCHEDULE I OF THE IOWA UNIFORM CONTROLLED SUBSTANCE ACT | ) ) ) ) | **RULING ON PETITION FOR AGENCY ACTION** |

On July 30, 2013, Carl Olsen filed a Petition for Agency Action with the Iowa Board of Pharmacy. The Petition requested that the Board recommend to the Iowa General Assembly that marijuana be rescheduled to a Schedule II controlled substance thereby allowing it to be prescribed for medicinal purposes.

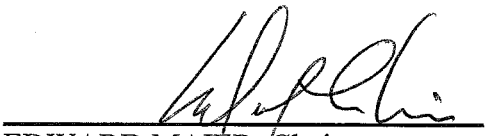
The Board considered the Petition at its bimonthly meeting on November 5 and 6, 2013. The Board voted to deny the Petition. Iowa law provides:

> Annually, within thirty days after the convening of each regular session of the general assembly, the Board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in sections 124.204, 124.206, 124.208, 124.210, or 124.212, ***which it deems necessary or advisable.***

Iowa Code § 124.201(1) (2013) (emphasis added). Iowa Code section 124.203 further provides that if the Board finds that any substance does not meet the definition of a Schedule I controlled substance, the Board shall recommend its rescheduling to the legislature ***as appropriate***. *Id.* § 124.2013(2) (emphasis added).

The Board recommended the rescheduling of marijuana in 2010. The Board recognized at that time and continues to recognize that the scheduling of controlled substances is ultimately a decision for the Iowa Legislature. The General Assembly took no action on the Board's 2010 recommendation. During the 2013 session, the legislature considered but did not act upon two bills calling for the rescheduling of marijuana. On November 6, 2013, the Board concluded that it was not advisable or appropriate to

recommend the rescheduling of marijuana in 2014.



EDWARD MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
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**Iowa District Court**
**Polk County, Iowa**

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| CARL OLSEN, | ) | |
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| Petitioner, | ) | |
| | ) | |
| vs. | ) | |
| | ) | Docket No. _____ |
| IOWA BOARD OF PHARMACY, | ) | |
| | ) | |
| Respondent. | ) | |

## AMENDED PETITION FOR JUDICIAL REVIEW

Carl Olsen respectfully petitions the Court to review the November 6, 2013, decision of the Iowa Board of Pharmacy ("Board" hereafter), attached hereto as **Exhibit #1**.

### Introduction

In 1971, Iowa enacted the Uniform Controlled Substances Act. See Iowa Code § 124.602 ("This chapter may be cited as the 'Uniform Controlled Substances Act'"). The legislative intent of Iowa's Uniform Controlled Substances Act ("IUCSA" hereafter) is to make Iowa's law uniform with those states that have adopted the Uniform Controlled Substances Act. See Iowa Code § 124.601 ("This chapter shall be so construed as to effectuate its general purpose to make uniform

the law of those states which enact it"). See Uniform Controlled Substances Act (1994) (U.L.A.) §§ 101-710 ("UCSA" hereafter).

The USCA is a model act created by the National Conference of Commissioners on Uniform State Laws (http://www.uniformlaws.org/) in 1970. The UCSA was designed to complement the federal Controlled Substances Act (http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf), at page 1 ("The 1970 Uniform Act was designed to complement the federal Controlled Substances Act, which was enacted in 1970"). 9 U.L.A. Pt. II 1 (2007) (Pocket Part current through 2013).

Like the federal Controlled Substance Act ("CSA" hereafter), the UCSA includes an administrative process for scheduling controlled substances. See 21 U.S.C. §§ 811 and 812, and see UCSA, §§ 201, 203, 205, 207, 209, 211, and 213.

The IUCSA contains a truncated, hybrid version of the administrative process in the UCSA and the CSA. See IUCSA, Iowa Code §§ 124.201, 203, 205, 207, 209, and 211. Unlike the UCSA or the CSA, the IUCSA does not give the administrative agency the authority to schedule controlled substances by formal rulemaking (which is why section 213 of the UCSA was not implemented in the IUCSA). Instead, the IUCSA designates the Board as an advisory body to the Iowa legislature. The Iowa legislature makes final decisions on scheduling, after receiving advice from the Board. It's important to note here that the intent of the

USCA as explicitly stated in Iowa Code § 124.601, makes the advice of the Board extremely critical in Iowa's hybrid implementation of the UCSA. Marijuana would have been transferred to Schedule II of the IUCSA in 2010 if Iowa had implemented the same process the CSA and the UCSA use to determine scheduling. It's critical to stress that the Board's decision in 2010, attached hereto as **Exhibit #2**, is a legislative requirement and is not just some anomaly in Iowa law. In 2010, the Board did an exhaustive analysis of the eight (8) statutory factors in Iowa Code § 124.201(1)(a)-(h), as required by Iowa law, and determined that marijuana should no longer be included in Schedule I of the IUCSA.

Here is a simple analogy to help the court understand the context. The IUCSA is a structure designed to protect the public health. The Iowa legislature is the owner of the IUCSA. The Board is the alarm to warn the legislature when the IUCSA is no longer protecting the public health. The alarm went off in 2010 when the Board recommended the reclassification of marijuana[1].

Now, four years later, the public is desperately looking for an escape. The recently enacted cannabis oil legislation, SF 2360 signed by Governor Branstad on May 30, 2014[2] (attached hereto as **Exhibit #3**), is intended to be an escape, but it

[1] On February 17, 2010, the Iowa Board of Pharmacy recommended that the Iowa Legislature remove marijuana from Schedule I of the Iowa Uniform Controlled Substances Act. See **Exhibit #2**, attached hereto.

[2] http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=billinfo&Service=Billbook&menu=false&hbill=sf2360

was crafted without regard for the advice of the Board. Not everyone is being protected by this new law[3] (see **Exhibit #4** and **Exhibit #5**, state of Iowa prosecuting an Iowa man with terminal cancer for using the same cannabis oil, as well as his entire family, his parents, his wife, and his children). Those who are supposedly protected face peril and uncertainty[4] (see **Exhibit #6** and **Exhibit #7**, detailing the perils Iowa families face in going to Colorado to get cannabis oil).

Marijuana is listed as a controlled substance in Schedule I of the Iowa Uniform Controlled Substances Act (Iowa Code Chapter 124). Iowa Code § 124.204(4)(m). Schedule I of the Act is for substances that have no "accepted medical use in treatment in the United States." Iowa Code § 124.203(1)(b). See Ruling on Petition for Judicial Review, McMahon v. Iowa Board of Pharmacy, No. CV 7415, Polk County District Court (April 21, 2009), at page 4, footnote 1 ("A finding of accepted medical use for treatment in the United States alone would be

[3] Des Moines Register, June 7, 2014, *The Register's Editorial: Iowa officials now need to expand marijuana oils to other sufferers* (http://www.desmoinesregister.com/story/opinion/editorials/2014/06/07/registers-editorial-iowa-officials-now-need-expand-marijuana-oils-sufferers/10108805/); Quad City Times, June 4, 2010, *Mackenzie family's marijuana trial date set* (http://qctimes.com/news/local/crime-and-courts/mackenzie-family-s-marijuana-trial-date-set/article_5f4563af-464a-5684-a310-9206c60871ec.html).

[4] Sioux City Journal, June 15, 2014, *New medical cannabis law raises concerns in Siouxland* (http://siouxcityjournal.com/news/local/new-medical-cannabis-law-raises-concerns-in-siouxland/article_5cc5854c-d4c4-5dad-9831-8b9621aaf8ef.html); KCCI TV 8, May 2, 2014, *Iowa families face treacherous trip to get cannabis oil* (http://www.kcci.com/news/iowa-families-face-treacherous-trip-to-get-cannabis-oil/25763938).

sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203"), attached hereto as **Exhibit #8**.

To date, twenty-three (23) jurisdictions, twenty-two (22) states[5] and the District of Columbia[6], have legally recognized that marijuana has accepted medical use in treatment in the United States. Another eight (9) states[7] have recently enacted cannabis oil laws that require citizens to leave their states and travel to one of the twenty-three (23) jurisdictions where the oil can be obtained. Iowa is one of

[5] Alaska Statutes § 17.37 (1998); Arizona Revised Statutes, Title 36, Chapter 28.1, §§ 36-2801 through 36-2819 (2010); California Health & Safety Code § 11362.5 (1996); Colorado Constitution Article XVIII, Section 14 (2000); Connecticut Public Act No. 12-55, Connecticut General Statutes, Chapter 420f (2012); Delaware Code, Title 16, Chapter 49A, §§ 4901A through 4926A (2011); Hawaii Revised Statutes § 329-121 (2000); Illinois Public Act 98-0122 (2013); 22 Maine Revised Statutes § 2383-B (1999); Annotated Code of Maryland Section 13–3301 through 13–3303 and 13–3307 through 13–3311 (2014); Massachusetts Chapter 369 of the Acts of 2012 (2012); Michigan Compiled Laws, Chapter 333, §§ 333.26421 through 333.26430 (2008); Minnesota SF 2470 -- Signed into law by Gov. Mark Dayton on May 29, 2014, Approved: By Senate 46-16, by House 89-40, Effective: May 30, 2014; Montana Code Annotated § 50-46-101 (2004); Nevada Constitution Article 4 § 38 - Nevada Revised Statutes Annotated § 453A.010 (2000); New Hampshire Revised Statutes Annotated Chapter 126-W (2013); New Jersey Public Laws 2009, Chapter 307, New Jersey Statutes, Chapter 24:6I, §§ 24:61-1 through 24:6I-16 (2010); New Mexico Statutes Annotated § 30-31C-1 (2007); Oregon Revised Statutes § 475.300 (1998); Rhode Island General Laws § 21-28.6-1 (2006); 18 Vermont Statutes Annotated § 4471 (2004); Revised Code Washington (ARCW) § 69.51A.005 (1998).

[6] D.C. Law 18-210; D.C. Official Code, Title 7, Chapter 16B, §§ 7-1671.01 through 7-1671.13 (2010).

[7] Alabama, Senate Bill 174, Signed into law by Governor Robert Bentley (Apr. 1, 2014); Florida, Senate Bill 1030, Signed into law by Governor Rick Scott (June 16, 2014); Iowa, Senate File 2360, Signed into law by Governor Terry Branstad (May 30, 2014); Kentucky, Senate Bill 124, Signed into law by Governor Steve Beshear (Apr. 10, 2014); Mississippi, House Bill 1231, Signed by Gov. Phil Bryant (Apr. 17, 2014); South Carolina, Senate Bill 1035, The bill became law because Governor Nikki Haley did not sign or veto the bill within five days of its passage (May 29, 2014); Tennessee, Senate Bill 2531, Signed into law by Gov. Bill Haslam (May 16, 2014); Utah, House Bill 105, Signed into law by Governor Gary Herbert (Mar. 21, 2014); Wisconsin, Assembly Bill 726, Signed by Governor Scott Walker (Apr. 16, 2014).

these nine (9) states. A tenth state is about to enact a cannabis oil law like the one in Iowa[8].

This appeal involves a matter of public importance. See Ruling and Order Respondent's Motion to Dismiss the Petition for Judicial Review, Olsen v. Iowa Board of Pharmacy, No. CV 45505, Polk County District Court (October 23, 2013), at page 5, attached hereto as **Exhibit #9**:

> In reviewing the Petition for Judicial Review, the Petitioner makes allegations that the usage of marijuana has an accepted medical use in the United States and that as of the date of the filing of the Petition 19 jurisdictions, 18 states and the District of Columbia, have legally recognized that marijuana has accepted medical use and treatment of various medical conditions. It would appear that on the face of the Petition, and applying the standards as set out by the Iowa Supreme Court for the review of a motion to dismiss, that the issue has one of public importance.

It is absolutely critical that the Board fulfill its statutory obligation to act in an advisory role to the Iowa legislature at this time and while this issue is evolving.

Iowa Code Chapter 17A gives any interested party the right to appeal from decisions made by the Board in regard to the scheduling of controlled substances.

This petition for judicial review is an appeal from the November 6, 2013, decision of the Iowa Board of Pharmacy not to recommend the rescheduling or removal of marijuana from Schedule I of the IUCSA in 2014 despite the fact the

[8] Missouri, House Bill 2238, Signed by House Speaker and Senate President Pro Tem, and sent to Governor (May 30, 2014).

Board has already concluded that marijuana does not meet the criteria for listing in Schedule I of the IUCSA in 2010, and despite the fact the Board has not made any contrary finding that marijuana now meets the criteria for listing in Schedule I of the IUCSA since recommending the rescheduling of marijuana in 2010.

**Jurisdiction, Parties & Venue**

1. This is an action for judicial review as authorized by Iowa Code § 17A.19 which is part of the Iowa Administrative Procedures Act.

2. The name of the petitioner is Carl Olsen ("Olsen" hereafter).

3. Olsen resides at 130 E. Aurora Ave., Des Moines, Iowa 50313-3654.

4. The Iowa Board of Pharmacy ("Board" hereafter) is the agency named as the Respondent in this action.

5. The Board maintains its principal headquarters in Polk County, Iowa.

6. Subject matter jurisdiction and venue of this matter properly lies in Polk County, Iowa by virtue of Iowa Code § 17A.19(2).

7. This is an appeal from a final order by the Board dated November 6, 2013, indicating that it will not grant Mr. Olsen's request to recommend the removal of marijuana from Schedule I of the Iowa Uniform Controlled Substances Act ("Act" hereafter). A true copy of the order is appended hereto, marked as **Exhibit #1** and by this reference is made a part hereof.

8. The action appealed from is the refusal of the Board to make a recommendation to the Iowa State General Assembly that marijuana be removed from Schedule I of the Act.

9. Mr. Olsen has exhausted his administrative remedies and this is an appeal from a final order of the respondent agency.

## Allegations

10. On February 17, 2010, the Board made a unanimous ruling recommending that the Iowa Legislature remove marijuana from Schedule I of the Act, attached hereto as **Exhibit #2**.

11. Since the Board's unanimous ruling on February 17, 2010, the Board has not made any opposite recommendation that marijuana should not be removed from Schedule I of the Act.

12. The facts have not changed since the Board made its recommendation in 2010 and there are no facts in dispute in this case.

13. There is no disagreement between Olsen and the Board that medical evidence warrants a recommendation for reclassification or removal of marijuana from Schedule I.

14. Olsen agrees with the Board's decision in 2010 to recommend removing marijuana from Schedule I.

15. There is nothing for this court to decide regarding the sufficiency of the medical evidence.

16. Iowa Code § 124.203(2) requires that, "If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate."

17. Because the Board still considers the evidence to support a finding that marijuana should be reclassified, the Board only has two options: recommend rescheduling of marijuana or recommend removal of marijuana from the list of controlled substances.

18. Doing nothing is not an option for the Board, unless facts have changed.

19. Because facts have not changed, the Board must either recommend the general assembly place marijuana in a different schedule or recommend that marijuana be removed from the list of controlled substances.

20. The Board's final ruling on November 6, 2013, is incorrect, because it fails to quote Iowa Code § 124.203(2) accurately.

21. The Board incorrectly reads Iowa Code § 124.203(2) to provide a third option, doing nothing.

22. The statute says the Board must recommend rescheduling marijuana or removing marijuana from the list of controlled substances, and doing nothing is not a valid option.

23. The Board's final ruling on November 6, 2013, says, "if the board finds that any substance does not meet the definition of a Schedule I controlled substance, the Board shall recommend it's rescheduling to the legislature **as appropriate,**" which is not an accurate reading of the statute.

24. The Board incorrectly paraphrases the statute to support a decision to do nothing, when the statute requires the board to do one of two things, recommend rescheduling of marijuana or recommend removing marijuana from the list of controlled substances, as appropriate.

25. The full text of the statute reads as follows:

**124.203. Substances listed in schedule I – criteria**

1. 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:

    a. Has high potential for abuse; and

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

2. 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.

Iowa Code § 124.203 (emphasis added).

26. The use of the word "or" in Iowa Code § 124.203(2) is defined in Webster's Dictionary as, "http://www.merriam-webster.com/dictionary/or -used as a function word to indicate an alternative <coffee or tea> <sink or swim>, the equivalent or substitutive character of two words or phrases <lessen or abate>, or approximation or uncertainty <in five or six days>

27. The Board incorrectly interprets "as appropriate" in Iowa Code 124.203(2) to mean the statute does not require the Board to do anything, even though the word "shall" requires the Board to recommend the general assembly either "place the substance in a different schedule" or "remove it from the list of controlled substances."

28. The Iowa General Assembly is composed of two annual sessions, beginning in odd numbered years.

29. It is not appropriate, necessary, or advisable for the Board to neglect its duty to recommend the general assembly place a substance in a different schedule or remove it from the list of controlled substances if that substance does not meet the criteria for Schedule I.

30. Because marijuana no longer meets all the criteria required by Schedule I of the Act the Board has a legal duty to recommend the general

assembly remove marijuana from Schedule I and either place it in a different schedule or remove it from control altogether. Iowa Code § 124.203(2).

31. The ruling of the Board is:

Iowa Code § 17A.19(10)(a).
Unconstitutional on its face because it violates due process for the board to ignore the provisions of 124.203(2).

Iowa Code § 17A.19(10)(b).
In violation of the law, because the Board has no authority to ignore 124.203(2).

Iowa Code § 17A.19(10)(c).
Based upon an erroneous interpretation of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency, because the Board has no discretion to disobey a statutory command.

Iowa Code § 17A.19(10)(d).
Based upon a procedure or decision-making process prohibited by law or was taken without following the prescribed procedure or decision-making process, because the Board did not find that any facts have changed that would cast doubt on the validity of the unanimous decision it made in 2010 to recommend reclassification of marijuana.

Iowa Code § 17A.19(10)(h).
Inconsistent with the Board's prior practice or precedents, because the Board has not justified that inconsistency by stating credible reasons sufficient to indicate a fair and rational basis for the inconsistency. Pharmacy Board member Jim Miller said the 2010 ruling is precedent at a public hearing on rulemaking held on March 12, 2010.

Iowa Code § 17A.19(10)(j).
The product of a decision-making process in which the agency did not consider a relevant and important matter relating to the propriety or desirability of the action in question that a rational decision maker in similar circumstances would have considered prior to taking that action, because the Iowa legislature required the Board to act in an advisory capacity when the

> Act was created in 1971 and the Board is refusing to perform its duty to advise the legislature without any authorization from the legislature that it can stop acting in this advisory capacity.
>
> Iowa Code § 17A.19(10)(k).
>
> Not required by law and its negative impact on the private rights affected is so grossly disproportionate to the benefits accruing to the public interest from that action that it must necessarily be deemed to lack any foundation in rational agency policy, because the Board has no legal authority to withhold its advice from the legislature and the Board has a duty to protect the public interest by advising the legislature annually.

## Prayer for Relief

WHEREFORE, the Petitioner prays for:

A. A judgment setting aside the November 6, 2013, ruling of the Iowa Board of Pharmacy; and

B. A declaratory ruling from this court, establishing that, as a matter of law, marijuana has "accepted medical use in treatment in the United States"; and

C. A writ of mandamus requiring the Iowa Board of Pharmacy to perform its duty to recommend removal of marijuana from Schedule I of the Iowa Controlled Substances Act, Iowa Code Chapter 124, according to requirements of Iowa Code § 124.203.

Respectfully Submitted:

/s/ Carl Olsen
Carl Olsen, Pro Se
130 E. Aurora Ave.
Des Moines, IA 50313-3654
515-343-9933

# Affidavit of Service

**State of Iowa )**
**) SS:**
**County of Polk )**

I certify under penalty of perjury that on or before June 16, 2014, and in compliance with the notice requirements of Iowa Code Section 17A.19(2), I effected service of notice of this action by mailing copies of this petition to all parties of record in the underlying case before the Iowa Board of Pharmacy addressed to the parties or their attorney of record as follows:

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

Meghan Gavin
Assistant Iowa Attorney General
1305 E. Walnut Street
Des Moines, IA 50319

/s/ Carl Olsen
Carl Olsen, Pro Se Petitioner

BEFORE THE IOWA BOARD OF PHARMACY

| | | |
|---|---|---|
| PETITION FOR RECOMMENDATION TO REMOVE MARIJUANA FROM SCHEDULE I OF THE IOWA UNIFORM CONTROLLED SUBSTANCE ACT | ) ) ) ) | **RULING ON PETITION FOR AGENCY ACTION** |

On July 30, 2013, Carl Olsen filed a Petition for Agency Action with the Iowa Board of Pharmacy. The Petition requested that the Board recommend to the Iowa General Assembly that marijuana be rescheduled to a Schedule II controlled substance thereby allowing it to be prescribed for medicinal purposes.

The Board considered the Petition at its bimonthly meeting on November 5 and 6, 2013. The Board voted to deny the Petition. Iowa law provides:

> Annually, within thirty days after the convening of each regular session of the general assembly, the Board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in sections 124.204, 124.206, 124.208, 124.210, or 124.212, ***which it deems necessary or advisable***.

Iowa Code § 124.201(1) (2013) (emphasis added). Iowa Code section 124.203 further provides that if the Board finds that any substance does not meet the definition of a Schedule I controlled substance, the Board shall recommend its rescheduling to the legislature ***as appropriate***. *Id.* § 124.2013(2) (emphasis added).

The Board recommended the rescheduling of marijuana in 2010. The Board recognized at that time and continues to recognize that the scheduling of controlled substances is ultimately a decision for the Iowa Legislature. The General Assembly took no action on the Board's 2010 recommendation. During the 2013 session, the legislature considered but did not act upon two bills calling for the rescheduling of marijuana. On November 6, 2013, the Board concluded that it was not advisable or appropriate to

recommend the rescheduling of marijuana in 2014.

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

State of Iowa
Board of Pharmacy

RiverPoint Business Park
400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688
http://www.state.ia.us/ibpe
Telephone: (515) 281-5944 Facsimile: (515) 281-4609



# MINUTES

## February 17, 2010

The Iowa Board of Pharmacy met on February 17, 2010, in the conference room at 400 SW Eighth Street, Des Moines, Iowa at 9:00 a.m. Chairperson Benjamin called the meeting to order at 9:02 a.m.

MEMBERS PRESENT
Vernon H. Benjamin, Chairperson
Susan M. Frey, Vice-Chair
Mark M. Anliker
Annabelle Diehl
Edward L. Maier
Peggy M. Whitworth

MEMBERS ABSENT
DeeAnn Wedemeyer Oleson

STAFF PRESENT
Lloyd Jessen, Executive Director
Scott Galenbeck, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary

Compliance Officers Present:
Bernie Berntsen
Jim Wolfe

I. Medical Marijuana.

After the Board held four public meetings and reviewed a substantial amount of medical marijuana material, the Board met to deliberate the possible reclassification of marijuana from Schedule I of the Iowa Controlled Substances Act (Act) into Schedule II of the Act.

Motion (Maier/Anliker) the Iowa Board of Pharmacy recommends that the legislature reclassify marijuana from Schedule I of the Iowa Controlled Substance Act (Act) into Schedule II of the Act with the further recommendation that the legislature convene a task force or study committee comprised of various disciplines including but not limited to the following: a representative of a seriously ill patient; a representative of law enforcement; a representative of the Iowa Attorney General; a representative of an HIV organization or a physician caring for an AIDS patient; a

substance abuse treatment representative; a person living with a serious illness; a hospice or palliative care representative; a representative of the Iowa Board of Nursing; a representative of the Iowa Board of Medicine; and a representative of the Iowa Board of Pharmacy, for the purpose of making recommendations back to the legislature regarding the administration of a medical marijuana program. Roll call vote. Yes: Anliker, Benjamin, Diehl, Frey, Maier, Whitworth; No: None; Abstain: None; Absent: Oleson. Passed: 6-0-0-1.

Motion (Maier/Frey) to adjourn the meeting. Passed: 6-0-0-1. Absent: Oleson. Meeting adjourned at 12:47 p.m. on February 17, 2010.

Becky Hall

Becky Hall
Recording Secretary

Lloyd K. Jessen
Executive Director

Vernon H. Benjamin
Board Chair

APPROVED THIS 9th DAY OF March, ~~200~~ 2010.

TERRY E. BRANSTAD
GOVERNOR

# OFFICE OF THE GOVERNOR

KIM REYNOLDS
LT. GOVERNOR

May 30, 2014

The Honorable Matt Schultz
Secretary of State of Iowa
State Capitol Building
LOCAL

Dear Mr. Secretary:

I hereby transmit:

Senate File 2360, an Act creating the medical cannabidiol act and providing penalties.

The above Senate File is hereby approved this date.

Sincerely,

Terry E. Branstad
Governor

cc: Secretary of the Senate
Clerk of the House

STATE OF IOWA
GENERAL ASSEMBLY

Senate File 2360

AN ACT

CREATING THE MEDICAL CANNABIDIOL ACT AND PROVIDING PENALTIES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.401, subsection 5, Code 2014, is amended by adding the following new unnumbered paragraph after unnumbered paragraph 2:

NEW UNNUMBERED PARAGRAPH. A person may knowingly or intentionally recommend, possess, use, dispense, deliver, transport, or administer cannabidiol if the recommendation, possession, use, dispensing, delivery, transporting, or administering is in accordance with the provisions of chapter 124D. For purposes of this paragraph, "*cannabidiol*" means the same as defined in section 124D.2.

Sec. 2. NEW SECTION. 124D.1 Short title.

This chapter shall be known and may be cited as the "*Medical Cannabidiol Act*".

Sec. 3. NEW SECTION. 124D.2 Definitions.

As used in this chapter:

1. *"Cannabidiol"* means a nonpsychoactive cannabinoid found in the plant Cannabis sativa L. or Cannabis indica or any other preparation thereof that is essentially free from plant material, and has a tetrahydrocannabinol level of no more than three percent.

2. *"Department"* means the department of public health.

3. *"Intractable epilepsy"* means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

4. *"Neurologist"* means an allopathic or osteopathic physician board-certified in neurology in good standing and licensed under chapter 148.

5. *"Primary caregiver"* means a person, at least eighteen years of age, who has been designated by a patient's neurologist or a person having custody of a patient, as being necessary to take responsibility for managing the well-being of the patient with respect to the medical use of cannabidiol pursuant to the provisions of this chapter.

Sec. 4. NEW SECTION. 124D.3 Neurologist recommendation — medical use of cannabidiol.

A neurologist who has examined and treated a patient suffering from intractable epilepsy may provide but has no duty to provide a written recommendation for the patient's medical use of cannabidiol to treat or alleviate symptoms of intractable epilepsy if no other satisfactory alternative treatment options exist for the patient and all of the following conditions apply:

1. The patient is a permanent resident of this state.

2. A neurologist has treated the patient for intractable epilepsy for at least six months. For purposes of this treatment period, and notwithstanding section 124D.2, subsection 4, treatment provided by a neurologist may include treatment by an out-of-state licensed neurologist in good standing.

3. The neurologist has tried alternative treatment options that have not alleviated the patient's symptoms.

4. The neurologist determines the risks of recommending the medical use of cannabidiol are reasonable in light of the potential benefit for the patient.

5. The neurologist maintains a patient treatment plan.

Sec. 5. NEW SECTION. **124D.4 Cannabidiol registration card.**

1. *Issuance to patient.* The department may approve the issuance of a cannabidiol registration card by the department of transportation to a patient who:

*a.* Is at least eighteen years of age.

*b.* Is a permanent resident of this state.

*c.* Requests the patient's neurologist to submit a written recommendation to the department signed by the neurologist that the patient may benefit from the medical use of cannabidiol pursuant to section 124D.3.

*d.* Submits an application to the department, on a form created by the department, in consultation with the department of transportation, that contains all of the following:

(1) The patient's full name, Iowa residence address, date of birth, and telephone number.

(2) A copy of the patient's valid photo identification.

(3) Full name, address, and telephone number of the patient's neurologist.

(4) Full name, residence address, date of birth, and telephone number of each primary caregiver of the patient, if any.

(5) Any other information required by rule.

2. *Patient card contents.* A cannabidiol registration card issued to a patient by the department of transportation pursuant to subsection 1 shall contain, at a minimum, all of the following:

*a.* The patient's full name, Iowa residence address, and date of birth.

*b.* The patient's photo.

*c.* The date of issuance and expiration date of the registration card.

*d.* Any other information required by rule.

3. *Issuance to primary caregiver.* For a patient in a primary caregiver's care, the department may approve the issuance of a cannabidiol registration card by the department of transportation to the primary caregiver who:

*a.* Is at least eighteen years of age.

*b.* Requests a patient's neurologist to submit a written recommendation to the department signed by the neurologist that a patient in the primary caregiver's care may benefit from the medical use of cannabidiol pursuant to section 124D.3.

*c.* Submits an application to the department, on a form

created by the department, in consultation with the department of transportation, that contains all of the following:

(1) The primary caregiver's full name, residence address, date of birth, and telephone number.

(2) The patient's full name.

(3) A copy of the primary caregiver's valid photo identification.

(4) Full name, address, and telephone number of the patient's neurologist.

(5) Any other information required by rule.

4. *Primary caregiver card contents.* A cannabidiol registration card issued by the department of transportation to a primary caregiver pursuant to subsection 3 shall contain, at a minimum, all of the following:

*a.* The primary caregiver's full name, residence address, and date of birth.

*b.* The primary caregiver's photo.

*c.* The date of issuance and expiration date of the registration card.

*d.* The full name of each patient in the primary caregiver's care.

*e.* Any other information required by rule.

5. *Expiration date of card.* A cannabidiol registration card issued pursuant to this section shall expire one year after the date of issuance and may be renewed.

6. *Card issuance — department of transportation.* The department may enter into a chapter 28E agreement with the department of transportation to facilitate the issuance of a cannabidiol registration card pursuant to subsections 1 and 3.

Sec. 6. NEW SECTION. **124D.5 Department duties — rules.**

1. *a.* The department shall maintain a confidential file of the names of each patient to or for whom the department issues a cannabidiol registration card and the name of each primary caregiver to whom the department issues a cannabidiol registration card under section 124D.4.

*b.* Individual names contained in the file shall be confidential and shall not be subject to disclosure, except as provided in subparagraph (1).

(1) Information in the confidential file maintained pursuant to paragraph "*a*" may be released to the following persons under the following circumstances:

(a) To authorized employees or agents of the department and the department of transportation as necessary to perform the

duties of the department and the department of transportation pursuant to this chapter.

(b) To authorized employees of state or local law enforcement agencies, but only for the purpose of verifying that a person is lawfully in possession of a cannabidiol registration card issued pursuant to this chapter.

(2) Release of information pursuant to subparagraph (1) shall be consistent with the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

2. The department, in consultation with the department of transportation, shall adopt rules to administer this chapter which shall include but not be limited to rules to establish the manner in which the department shall consider applications for new and renewal cannabidiol registration cards.

Sec. 7. NEW SECTION. **124D.6 Medical use of cannabidiol — affirmative defense.**

1. *a.* A recommendation for the possession or use of cannabidiol as authorized by this chapter shall be provided exclusively by a neurologist for a patient who has been diagnosed with intractable epilepsy.

*b.* Cannabidiol provided exclusively pursuant to the recommendation of a neurologist shall be obtained from an out-of-state source and shall only be recommended for oral or transdermal administration.

*c.* A neurologist shall be the sole authorized recommender as part of the treatment plan by the neurologist of a patient diagnosed with intractable epilepsy. A neurologist shall have the sole authority to recommend the use or amount of cannabidiol, if any, in the treatment plan of a patient diagnosed with intractable epilepsy.

2. A neurologist, including any authorized agent thereof, shall not be subject to prosecution for the unlawful recommendation, possession, or administration of marijuana under the laws of this state for activities arising directly out of or directly related to the recommendation or use of cannabidiol in the treatment of a patient diagnosed with intractable epilepsy.

3. *a.* In a prosecution for the unlawful possession of marijuana under the laws of this state, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the patient has been diagnosed with intractable epilepsy, used or possessed

cannabidiol pursuant to a recommendation by a neurologist as authorized under this chapter, and, for a patient eighteen years of age or older, is in possession of a valid cannabidiol registration card.

*b.* In a prosecution for the unlawful possession of marijuana under the laws of this state, including but not limited to chapters 124 and 453B, it is an affirmative and complete defense to the prosecution that the person possessed cannabidiol because the person is a primary caregiver of a patient who has been diagnosed with intractable epilepsy and is in possession of a valid cannabidiol registration card, and where the primary caregiver's possession of the cannabidiol is on behalf of the patient and for the patient's use only as authorized under this chapter.

*c.* (1) The defenses afforded a patient under paragraph "*a*" apply to a patient only if the quantity of cannabidiol oil possessed by the patient does not exceed thirty-two ounces.

(2) The defenses afforded a primary caregiver under paragraph "*b*" apply to a primary caregiver only if the quantity of cannabidiol oil possessed by the primary caregiver does not exceed thirty-two ounces per patient.

*d.* If a patient or primary caregiver is charged with the commission of a crime and is not in possession of the person's cannabidiol registration card, any charge or charges filed against the person shall be dismissed by the court if the person produces to the court at the person's trial a cannabidiol registration card issued to that person and valid at the time the person was charged.

4. An agency of this state or a political subdivision thereof, including any law enforcement agency, shall not remove or initiate proceedings to remove a patient under the age of eighteen from the home of a parent based solely upon the parent's or patient's possession or use of cannabidiol as authorized under this chapter.

Sec. 8. NEW SECTION. **124D.7 Penalties.**

A person who knowingly or intentionally possesses or uses cannabidiol in violation of the requirements of this chapter is subject to the penalties provided under chapters 124 and 453B.

Sec. 9. NEW SECTION. **124D.8 Repeal.**

This chapter is repealed July 1, 2017.

Sec. 10. REPORTS. The university of Iowa carver college of medicine and college of pharmacy shall, on or before July 1 of each year, beginning July 1, 2015, submit a report detailing

the scientific literature, studies, and clinical trials regarding the use of cannabidiol on patients diagnosed with intractable epilepsy to the department of public health and the general assembly.

PAM JOCHUM
President of the Senate

KRAIG PAULSEN
Speaker of the House

I hereby certify that this bill originated in the Senate and is known as Senate File 2360, Eighty-fifth General Assembly.

MICHAEL E. MARSHALL
Secretary of the Senate

Approved May 30, 2014

TERRY E. BRANSTAD
Governor

## THE REGISTER'S EDITORIALS

# Iowa officials now need to expand marijuana oils to other sufferers

Iowa parents will no longer face prosecution if they purchase a special marijuana extract for their severely epileptic children. Gov. Terry Branstad signed a bill into law, which takes effect July 1, that allows parents to buy a cannabis oil that may lessen seizures. For that, he and the Legislature deserve credit.

"This bill received tremendous support and truly shows the power of people talking to their legislators and to their governor about important issues to them, to their families and to their children," Branstad said shortly before he signed Senate File 2360.

**Sally Gaer advocates for the legalization medical marijuana in February.**
REGISTER PHOTO

Parents did work relentlessly the past few months to gain support from lawmakers. And that did make all the difference in swaying elected officials. However, this law is only the first step toward changes Iowa needs to make.

The parents who will be legally allowed to purchase the cannabis oil still face obstacles. They need a recommendation from an Iowa neurologist and will have to travel to other states with less restrictive marijuana laws to obtain the oil. They may face waiting lists.

Also, the change in law benefits only a small group of Iowans with the most organized lobbying efforts. Other sick Iowans should have legal access to marijuana extracts, too. These include people with painful and debilitating conditions like cancer, spinal cord injuries and severe arthritis, who may benefit from the drug. But if these people obtain cannabis oil, they will still be considered criminals in this state.

Benton Mackenzie, for example, has been diagnosed with angiosarcoma, a cancer of the blood vessels. The 48-year-old was growing his own marijuana to make cannabis oil to shrink skin lesions caused by the disease. After the plants were confiscated from his parents' home in Long Grove last summer, his lesions have grown enormous and his health has deteriorated.

Mackenzie and his wife are both charged with felony drug possession. His 73-year-old parents are charged with hosting a drug house. His son is charged with misdemeanor possession, and his friend is charged in the drug conspiracy. A Scott County district judge recently ruled Mackenzie won't be able to use his illness as a defense.

"At least the state is now recognizing, with a law, that marijuana has medicinal value," said Mackenzie.

Yes, but the state has much more work to do on this issue.

Quad-City Times

MARIJUANA CASE

# Mackenzie family's marijuana trial date set

JUNE 05, 2014 4:30 AM • BY BRIAN WELLNER

A judge has set a trial date for an Iowa man suffering from terminal cancer after appointing a lawyer to defend the man against marijuana charges.

Scott County District Judge Henry Latham said Wednesday that the trial of Benton Mackenzie will begin June 30. He appointed Joel Walker to defend the man.

The 48-year-old Mackenzie, who has been diagnosed with angiosarcoma, appeared in the courtroom in a wheelchair.

He is charged in a conspiracy to grow marijuana along with his wife, Loretta Mackenzie, and his friend, Stephen Bloomer.

Scott County Sheriff's deputies say they searched Mackenzie's parents' Long Grove property and found 71 marijuana plants last summer.

Mackenzie says he needed all of those plants to extract enough cannabis oil for daily treatments of his cancer and to relieve symptoms of the disease.

His 22-year-old son, Cody Mackenzie, was charged with misdemeanor possession after deputies said they found marijuana in his bedroom. Benton Mackenzie's 73-year-old parents, Charles and Dorothy Mackenzie, are charged with hosting a drug house.

They all appeared in a Scott County courtroom Wednesday. Each had a different attorney present except for Benton Mackenzie.

Lori Kieffer-Garrison was representing him until Friday, when the Iowa Supreme Court suspended her law license for six months, citing multiple violations of the Iowa Rules of Professional Conduct.

The Mackenzies and Bloomer were set to go to trial this week before Kieffer-Garrison's suspension put the case on hold so a new attorney could be appointed for Benton Mackenzie.

Davenport attorney Murray Bell said Friday that Kieffer-Garrison called him about representing Benton Mackenzie. Latham said Wednesday that Bell has declined to do so.

Latham first asked David Treimer to represent Benton Mackenzie, and Treimer appeared at Wednesday's hearing.

"I have no confidence in this attorney," Benton Mackenzie said of Treimer. He said Treimer

represented his wife in a prior drug case.

Both Benton and Loretta Mackenzie were convicted of growing marijuana in 2011.

"Now this is coming back to me," Treimer said. "I represented his wife. They alleged they had a problem with my representation. It was for another marijuana case. I see how it could be a conflict of interest."

After a five-minute break, Latham returned, saying that he had called Walker and that Walker agreed to represent Benton Mackenzie.

After the hearing, Benton Mackenzie said Treimer didn't believe his wife's defense in 2011 — that she was only his caretaker and took no part in growing the marijuana.

She is arguing the same defense this time.

Benton Mackenzie also said that in 2011, like last year, he was growing the marijuana to treat his cancer.

Benton and Loretta Mackenzie have said they regret having pleaded guilty to the 2011 charges.

SIOUX CITY Journal.com

SIOUXLAND HEALTH

# HELP OR HAZARD?

## New medical cannabis law raises concerns in Siouxland

New medical cannabis law raises concerns in Siouxland

4 HOURS AGO • DOLLY A. BUTZ
DBUTZ@SIOUXCITYJOURNAL.COM

SIOUX CITY | A new law that will allow seizure sufferers in Iowa to use a marijuana extract to help control their disease has a local doctor worried about the possible risks to children.

Iowans who can legally possess up to 32 ounces of cannabidiol oil starting July 1 will have to buy the product from out-of-state dispensaries and dealers, and there's no way to know what kinds of impurities it may contain, said Mercy Medical Center emergency room physician Thomas Benzoni.

"More and more we're seeing toxic agents seep into drugs," Benzoni said.

Some cannabidiol contains potentially deadly oil-based insecticides used to treat cannabis plants.

"When something is extracted from cannabis or any plant with oil, then anything that is oil-soluble will be in the oil portion," he said. "Many substances that are very toxic are oil-soluble."

Given the way Iowa's law is configured, allowing patients to possess the medication but requiring them to obtain it out of state, Benzoni said he believes cannabis will "do plenty of harm to children" and adults alike.

The federal Drug Enforcement Administration classifies marijuana and its components as a Schedule I substance, meaning it is illegal and not regulated by the Food and Drug Administration.

### NOWHERE TO GO?

Gov. Terry Branstad signed the Medical Cannabidiol Act into law May 30 at the urging of parents who believe the oil can reduce the frequency of seizures and in some cases eliminate them.

The law allows adults and children who suffer from uncontrollable epilepsy to have the drug in Iowa, where other forms of marijuana are illegal.

The law requires patients with "intractable epilepsy" to get a written recommendation from a neurologist who has treated them for at least six months. Neurologists submit the recommendation to the Iowa Department of Public Health, which then permits the Iowa Department of Transportation to issue a cannabidiol registration card to patients who are at least 18 years old or, in the case of a minor patient, a primary caregiver.

Neurologists have the sole authority to recommend the use and the amount of cannabidiol oil, which can be taken by mouth or rubbed into the skin. The oil is free of THC, the mind-altering ingredient in the cannabis plant.

Once the new law goes into effect, Iowa will be one of 23 states that have decriminalized the drug for medical use.

Some states, including Minnesota, have empowered state regulators to oversee the growing of medical cannabis and its distribution. The law signed by Minnesota Gov. Mark Dayton in May requires the state's commissioner of health to register two in-state marijuana manufacturers by December.

Iowa residents won't be able to buy medical marijuana in Minnesota. The state's law restricts access to Minnesota residents diagnosed with qualifying conditions and registered with the Department of Health.

Iowans can travel to Colorado to buy marijuana and marijuana products from a licensed retail shop but can't legally take it out of the state. According to the Colorado Department of Public Health & Environment, there is no difference between marijuana sold for retail and medical use.

Anyone caught traveling with marijuana through Nebraska, which is between Colorado and Iowa but where the substance is illegal, faces possible arrest.

"Nebraska law has not changed, and marijuana in any form remains illegal," said Deb Collins, spokeswoman for the Nebraska State Patrol.

Only the states of Arizona, Delaware, Maine, Michigan, Nevada, New Hampshire and Rhode Island offer reciprocity for patients with out-of-state medical marijuana identification cards.

Tyler Brock, Siouxland District Health Department deputy director, said local public health offices won't be involved in issuing registration cards for Iowans.

"That's probably why we haven't had much conversation with this at a local level," he said.

**CALLS FOR MORE TESTING**

Steve Fox, 61, of Sioux City, has lived with epilepsy most of his life. A native of Homer, Neb., he has been on multiple medications to help control seizures. He had the first of many brain surgeries at the age of 8 months.

Fox established the Siouxland Epilepsy Support Group in 2004. Four years later, the local organization merged with the Epilepsy Foundation of America's North/Central Illinois, Iowa and Nebraska chapter. He hopes to re-energize a local support group.

Fox agreed the prospect of legalized cannabidiol oil treatment may give parents a glimmer of hope for their children's health.

“I think it’s a new solution,” he said.

However, he said more testing needs to be done to make sure it’s safe and effective. He said he doubted local physicians would be quick to suggest the oil as a treatment option.

A statement from the Epilepsy Foundation’s regional chapter supports the rights of patients and families living with seizures and epilepsy to access medical marijuana but contends, "There is still a lot we don't know about the medical use of marijuana for epilepsy."

"The Epilepsy Foundation calls for an end to Drug Enforcement Administration restrictions that limit clinical trials and research into medical marijuana for epilepsy," the statement by foundation president and CEO Philip Gattone and board chairman Warren Lammert said.

"The Epilepsy Foundation believes that an end to seizures should not be determined by one's ZIP code."

**'COMPASSIONATE USE'**

Justin Johnston, 37, of Sioux City, developed epilepsy at age 15. His treatment has included myriad medications to which his brain eventually becomes accustomed. Although he wasn’t too familiar with Iowa's new cannabidiol law, he said any new treatment option would be beneficial.

“I think it would be a great idea if it would make a younger person much better,” he said.

Linda Kalin, executive director of the Sioux City-based Iowa Poison Control Center, said the federal Schedule I designation hinders medical researchers from performing controlled studies on cannabidiol oil.

"This is compassionate use. It seems reasonable," she said of the law. "We do need more studies. We as a country need objective data from randomized trials."

In the meantime, Benzoni cautioned that no one really knows what's in a vial of marijuana extract made or sold by a dispensary or a lone dealer.

He said he would like to see more studies being done on cannabidiol oil to learn what it contains and whether it offers any medical benefits.

"If people have a scientific inquiry about it, go ahead and study it, but be willing to accept the conclusion before the scientific study is done," he said. "People demand a certain answer before they do the study. If they don't agree with the results of the study, then they say, 'The study's wrong.'"

*Journal staff writer Molly Montag contributed to this report.*

## About the law

Who is affected: People suffering from an epileptic seizure disorder for which standard medical treatment doesn't offer relief or results in harmful side effects.

What they can possess: 32 ounces of cannabidiol oil in Iowa beginning July 1.

Requirements: Patients need a written recommendation from a licensed neurologist to

obtain a cannabidiol registration card issued by the Iowa Department of Public Health through the Iowa Department of Transportation.

What the cards do: Given to patients 18 years of age and a primary caregiver if the patient is a minor. The law requires patients to buy the drug from out-of-state sources.

## Your turn

What do you think? Take part in our Journal poll about cannabidiol oil at siouxcityjournal.com.

Add your voice to our Opinion page by emailing letters@siouxcityjournal.com.

# Iowa families face treacherous trip to get cannabis oil

**UPDATED** 7:32 AM CDT May 02, 2014

**DES MOINES, Iowa -**

While the Iowa legislature has approved a bill to allow cannabis oil's use for some patients, the oil will not be sold in Iowa.

Watch this video forecast

Families will be forced to drive to a state where it is available to get it. That means driving hundreds of miles likely to Colorado and then transporting it back through states where it is not legal to possess, like Nebraska.

Amanda Gregory's six-year-old daughter suffers from a severe form of the neurological disorder.

"Five, six months ago, got diagnosed with Raine 20 Chromosome, which is an extremely rare chromosome disorder which makes her have seizures daily," said Gregory.

If Gov. Terry Branstad signs the bill just approved by the Legislature Thursday, the Gregory family will soon travel to Colorado to obtain up to 32 ounces of cannabis oil -- a last-resort treatment for seizures.

But their journey out of Colorado en route to Iowa may come with a roadblock. Law enforcement in one state may stop you for transporting a product that is legal in another.

"They would still be in possession of a controlled substance one, which is considered not approved in the eyes of the DEA," said Rep. John Forbes.

A representative of the Nebraska State Patrol told KCCI Thursday that any form of marijuana is illegal in their state.

Republican representative and former state trooper Clel Baudler told KCCI caregivers will get a pass in Nebraska as long as they have the proper paper work.

"If they got stopped or they had a breakdown or an accident and they had this product with very little THC, they wouldn't get in trouble," said Baudler.

That would be another relief for Gregory who wouldn't let the threat of a misdemeanor keep her from bringing Colorado cannabis oil back to Altoona.

"Do I got to Colorado and get the things that my child needs or do I put my job on the line, which? My daughter is more important than my job," said Gregory.

**IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY**

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| **GEORGE McMAHON, BRYAN SCOTT and BARBARA DOUGLASS,**<br><br>**Petitioners,**<br><br>**CARL OLSEN,**<br><br>**Intervenor,**<br><br>**v.**<br><br>**IOWA BOARD OF PHARMACY,**<br><br>**Respondent.** | **Case No. CV7415**<br><br>**RULING ON PETITION FOR JUDICIAL REVIEW** |



## Introduction

The above-captioned matter came before the Court for hearing on March 27, 2009. Petitioners were represented by attorney Randall Wilson. Intervenor, Carl Olsen, was present on behalf of himself. Respondent was represented by attorney Scott Galenbeck. Following oral argument and upon review of the court file and applicable law, the Court enters the following:

## Statement of the Case

Petitioners filed a petition with the Iowa Board of Pharmacy on June 24, 2008, seeking removal of marijuana from Schedule I of Iowa's Controlled Substances Act. Petitioners argued that Iowa Code section 124.203 requires the Iowa Board of Pharmacy (hereinafter the "Board") to recommend to the legislature that marijuana be rescheduled because it no longer meets the legislative criteria established for the listing of Schedule I substances. The Board issued a final decision denying Petitioners' request on October 7, 2008. Petitioners have now appealed the Board's decision in this action for judicial review, and argue that the Board's decision is based upon an erroneous interpretation of law.

## Standard of Review

On judicial review of agency action, the district court functions in an appellate capacity to apply the standards of Iowa Code section 17A.19. *Iowa Planners Network v. Iowa State Commerce Comm'n*, 373 N.W.2d 106, 108 (Iowa 1985). The Court shall reverse, modify, or grant other appropriate relief from agency action if such action was based upon an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency. IOWA CODE § 17A.19(10)(c). The Court shall not give deference to the view of the agency with respect to particular matters that have not been vested by a provision of law in the discretion of the agency. IOWA CODE § 17A.19(11)(b). Appropriate deference is given to an agency's interpretation of law when the contrary is true, although "the meaning of any statute is always a matter of law to be determined by the court." *Birchansky Real Estate, L.C. v. Iowa Dept of Public Health,* 737 N.W.2d 134, 138 (Iowa 2007); IOWA CODE § 17A.19(11)(c). The agency's findings are binding on appeal unless a contrary result is compelled as a matter of law. *Ward v. Iowa Dept. of Transp.*, 304 N.W.2d 236, 238 (Iowa 1981).

## Analysis

Marijuana is identified in the Iowa Controlled Substances Act as a Schedule I controlled substance. *See* IOWA CODE § 124.204 (2009). Section 124.203 of the Iowa Code sets forth the criteria for classifying controlled substances under Schedule I. Section 124.203 provides:

> 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.

IOWA CODE § 124.203. This section further provides that the Board "shall recommend" that the general assembly place a listed Schedule I substance in a different schedule or remove it if it does not meet the previously mentioned criteria. *Id.*

Petitioners argued before the Board that marijuana no longer meets the criteria for classification as a Schedule I controlled substance because marijuana now has accepted medical use in treatment in the United States. In support of their argument, Petitioners cited to the laws of other states that have now authorized the use of marijuana for medicinal purposes. The Board addressed Petitioners' argument and request for reclassification in its final order by explaining:

> While neither accepting or rejecting Olsen's assertion that the medicinal value of marijuana is established by legislation adopted in other states, the Board notes that before recommending to the Iowa legislature that marijuana be moved from schedule I to schedule II, the Board would also need to make a finding that marijuana lacks a high potential for abuse. *See* Iowa Code 124.203 (2007). There exists no basis for such a finding in the record before the Board, as Olsen's submission offers no evidence or information on marijuana's potential for abuse. Absent such evidence or information, Olsen's request must be denied.

(Order, p. 2).

Section 124.203 of the Iowa Code requires that any controlled substance have (1) a high potential for abuse, ***and*** (2) no accepted medical use in treatment in the United States before it may be classified under Schedule I. Because the Code imposes both criteria as a prerequisite to Schedule I classification, the failure to meet either would require recommendation to the legislature for removal or rescheduling. *See id.* As such, the Board's statement that it "would also need to make a finding that marijuana lacks a high potential for abuse" before it could recommend to the legislature that marijuana be moved from Schedule I to Schedule II is based upon an erroneous interpretation of law.[1]

[1] Pursuant to Iowa Code section 124.205, Schedule II substances must be found to have "currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions," in order to be classified as such. *See* IOWA CODE § 124.205. Controlled substances must also be found to have a "high

The Board now argues in this action for judicial review that its decision should be affirmed by this Court because Petitioners failed to make an adequate record before the agency. The Board asserts that Petitioners failed to present evidence addressing all of the factors delineated in Iowa Code section 124.201. However, this is not the Board's stated reason for its decision in its written order. The Court may not rely on the Board's post hoc rationalizations for purposes of affirming the agency action at issue. Petitioners were entitled to a written explanation of the reasons for the Board's decision regardless of whether the agency action at issue was taken in response to a request for the adoption of agency rules, taken in response to a request for a declaratory order, or taken in a contested case proceeding. *See* IOWA CODE §§ 17A.7(1), 17A(4)(d), 17A.16; *Ward v. Iowa Dept. of Transp.*, 304 N.W.2d 236, 238 (Iowa 1981). The Court acknowledges that the factors set forth in Iowa Code section 124.201 are relevant in the Board's determination of whether the statutory criteria for Schedule I classification are satisfied.[2] However, Iowa Code section 124.203 clearly requires that the Board recommend removal of marijuana from Schedule I or reclassification under a different schedule if it is found that marijuana "[h]as no accepted medical use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision." If the Board believes that the evidence presented by Petitioners was insufficient to support such a finding, it should have so stated in its order. Remand of the Board's decision is required so that Board may address Petitioners'

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potential for abuse" before they may be classified under Schedule II. *Id.* As such, one of the main characteristics that distinguishes Schedule II substances from those listed in Schedule I is accepted medical use in treatment in the United States. It is therefore erroneous to state that a substance classified under Schedule I cannot be reclassified as a Schedule II substance if the substance is found to present a high potential for abuse. Both Schedule I and Schedule II controlled substances share the same characteristic of having a high potential for abuse. A finding of accepted medical use for treatment in the United States alone would be sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203.

[2] Iowa Code section 124.201 requires that the Board consider these factors before making a rescheduling recommendation to the legislature. The Board is apparently of the position that these factors must also be considered before recommending rescheduling or removal pursuant to the terms of Iowa Code section 124.203.

Petition through proper application of the law. The Board must determine whether the evidence presented by Petitioner is sufficient to support a finding that marijuana has accepted medical use in the Unites States and does not lack accepted safety for use in treatment under medical supervision.

**ORDER**

**IT IS THE ORDER OF THE COURT** that the Ruling on Appeal of the Iowa Board of Pharmacy is hereby **REMANDED.**

**SO ORDERED** this 21 day of April, 2009.

Joel D. Novak

**JOEL D. NOVAK**, District Judge
**Fifth Judicial District of Iowa**

Original Filed.

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# IN THE IOWA DISTRICT COURT FOR POLK COUNTY

| | |
|---|---|
| **CARL OLSEN,**<br><br>Petitioner,<br><br>vs.<br><br>**IOWA BOARD OF PHARMACY,**<br><br>Respondent. | **CASE NO. CVCV045505**<br><br>**RULING AND ORDER ON RESPONDENT'S MOTION TO DISMISS PETITION FOR JUDICIAL REVIEW** |

Now on Aug 2, 2013, this matter came before the Court upon the Respondent's Motion to Dismiss the Petition for Judicial Review. The Petitioner was personally present and represented by his counsel, Mr. Collin C. Murphy. The Iowa Board of Pharmacy was present by Iowa Assistant Attorney General Meghan Gavin. The Court, having reviewed the Respondent's Motion to Dismiss the Petition for Judicial Review, the resistance thereto, and the entire court file, makes the following findings and order:

The Petition for Judicial Review was filed by the Petitioner on April 3, 2013 seeking judicial review of the Iowa Board of Pharmacy's action take on January 16, 2013, which denied the Petitioner's Petition for Agency action. The Petitioner had requested that the Iowa Board of Pharmacy recommend to the Iowa General Assembly that the drug marijuana be reclassified. That Petition apparently included supporting documents as alluded to by the ruling on Petition for Agency action. That ruling further stated that the Iowa Board of Pharmacy considered the Petition and supporting documentation at its bimonthly meeting on November 8 and 9, 2012.

The ruling went on to state that the board voted to deny the Petition. The Board further stated in its ruling that it recognized pursuant to Section 124.201(1), the Code of Iowa, that the Board is required within 30 days after the convening of each regular session of the General Assembly to recommend to the General Assembly any deletions from or revisions in the schedules of substances, enumerated in Sections 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems necessary or advisable. The Board went on to state the following in its ruling:

> The Board recommended the reclassification of marijuana in 2010. The General Assembly took no action on the Board's recommendation at that time. On January 16, 2013, the Board concluded that the supporting documentation did not contain sufficient, new scientific information to warrant recommending the reclassification of marijuana this year.

(Ruling on Petition for Agency Action, January 16, 2013).

In the Respondent's Motion to Dismiss the Petition for Judicial Review, the Iowa Board of Pharmacy states that while it has the duty to make recommendations and such duty is mandatory, the substance of those recommendations is left to the Board's discretion. Further, the Iowa Board of Pharmacy stated in its Motion to Dismiss that even if the Board had recommended the reclassification of marijuana in January as requested, there is no evidence this action would have yielded any substantive change. The Respondent further stated in their Motion to Dismiss that two reclassification bills were already introduced in the current legislative session and that both bills failed. Further, the Respondent states that at best the only relief that the Petitioner could be entitled to under his petition, assuming he would prevail, would be an order from this Court remanding his Petition to the Board for reconsideration and a more extensive explanation of its decision. The Iowa Board of Pharmacy states that a remand at this point would be too late

as the legislative session has ended and, therefore, the petition is moot and should be dismissed.

Petitioner's resistance to the Motion to Dismiss Petition for Judicial Review states that mootness does not apply in this matter because the challenged action by the Iowa Board of Pharmacy is capable of repetition, yet evading review. The Petitioner states that the Petitioner filed a Petition with the Board on August 3, 2012, and the Board failed to consider the Petition and render a decision until January 16, 2013, two days after the start of the legislative session. The Petitioner further alleges that these delays "make it virtually impossible for Petitioner to obtain complete judicial review of the controversies before the end of the session on May 3, 2013." (Petitioner's Resistance to Motion to Dismiss Petition for Judicial Review, April 29, 2013, page 2). The Petitioner goes on to state that even assuming that the controversy here is rendered moot by the Board's delay, that the public interest exception to the mootness doctrine requires the district court to consider the Petition for Judicial Review. Further, that because Iowa law provides for annual recommendations from the Iowa Board of Pharmacy, there is a strong likelihood of future recurrence of this same problem.

Regarding motions to dismiss, the Court may grant a motion to dismiss only if the petition shows no possible right of recovery under the facts. *Trobaugh v. Sondag*, 668 N.W.2d 577, 580 (Iowa 2003). A motion to dismiss will rarely succeed. *Rees v. City of Shenandoah*, 682 N.W.2d 77, 79 (Iowa 2004). When considering a motion to dismiss, courts assess the petition "in the light most favorable to the plaintiffs, and all doubts and ambiguities are resolved in plaintiff's favor." *Robbins v. Heritage Acres*, 578 N.W.2d 262, 264 (Iowa Ct. App. 1998) (citation omitted). A petition must contain factual allegations sufficient to provide the defendant

with "fair notice" of the claim asserted. *Id*. A petition satisfies the "fair notice" standard "if it informs the defendant of the incident giving rise to the claim and of the claims general nature." *Id.* "The only issue when considering a motion to dismiss is the "petitioner's right of access to the district court, not the merits of his allegations.'" *Hawkeye Food Service Distribution, Inc. v. Iowa Educator's Corp.*, 812 N.W.2d 600, 609 (Iowa 2012) (quoting *Rieff v. Evans*, 630 N.W.2d 278, 284 (Iowa 2001); *Cutler v. Klass*, *Whicher and Mishne*, 473 N.W.2d 178, 181 (Iowa 1991) ("Both the filing and the sustaining [of motions to dismiss] are poor ideas.")

In regard to the standards for mootness, the Iowa Supreme Court has stated that:

> An appeal is moot if it no longer presents a justiciable controversy because the contested issue has become academic or nonexistent. The test is whether the court's opinion would be of force or effect in the underlying controversy. As a general rule, we will dismiss an appeal when judgment, if rendered, will have no practical legal affect upon the existing controversy.
>
> There is an exception to this general rule, however, where matters of public importance are presented and the problem is likely to recur. Under these circumstances, our court has discretion to hear the appeal. An important factor to consider is whether the challenged action is such that often the matter will be moot before it can reach an appellate court.

*In re M.T.,* 625 N.W.2d 702, 704-705 (Iowa 2001) (internal citations, quotations, and alterations omitted).

In considering the first prong of the test of whether there should be an exception to the mootness rule, the Court considers whether or not the question presented is one of public importance. The Court takes the Petition for Judicial Review filed by the Petitioner at face value as the Court must assess the Petition in the light most favorable to the Plaintiff with all doubts

and ambiguities resolved in the Plaintiff's favor. In doing this the Court does not render a decision on the merits of the Petition but rather whether or not the Petitioner has the right of access to the district court. In reviewing the Petition for Judicial Review, the Petitioner makes allegations that the usage of marijuana has an accepted medical use in the United States and that as of the date of the filing of the Petition 19 jurisdictions, 18 states and the District of Columbia, have legally recognized that marijuana has accepted medical use and treatment of various medical conditions. It would appear that on the face of the Petition, and applying the standards as set out by the Iowa Supreme Court for the review of a motion to dismiss, that the issue has one of public importance. Added to this is the Iowa Board of Pharmacy's duty under Section 124.203 of the Code of Iowa that the Board shall recommend to the General Assembly that it place in Schedule I any substance is not already included therein if the Board finds that the substance:

a. Has high potential for abuse; and

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

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

Section 124.203, the Code of Iowa.

In the Petition for Judicial Review, the Petitioner alleges that the Iowa Board of Pharmacy in its ruling went beyond the authority delegated the Agency by any provision of law;

made a decision based on the erroneous interpretation of law whose interpretation has been clearly vested by a provision of law in the discretion of the agency; took action without following the prescribed decision-making process; that the ruling was the product of a decision-making process which the agency did not consider relevant and an important matter relating to the propriety or desirability of the action in question that a rationale decision-maker in similar circumstances would have considered prior to taking that action; and the action of the agency is otherwise arbitrary, capricious or an abuse of discretion.

The Court finds that the issue presented does contains one of public importance as stated above, but also is capable of repetition but evading review. The time periods in which the Petition was filed first with the Iowa Board of Pharmacy and the final decision by the Iowa Board of Pharmacy severely constrained the time period for which the Petitioner had available to him to seek judicial review. Based upon the timing of the Iowa Board of Pharmacy's ruling and the Iowa legislative session, the Court finds that the capable of repetition but evading review element has been met.

The Court, therefore, finds that the motion to dismiss is hereby denied. The Court finds that the issue is not moot. The Petition for Judicial Review presents a justiciable controversy regarding agency action; that it further involves matters of public importance, when assessing the petition in the light most favorable to the petitioner with all doubts and ambiguities resolved in the petitioner's favor, and is capable of repetition but evading review.

Dated this 22nd day of October, 2013.

**SCOTT D. ROSENBERG**
Judge, 5th Judicial District of Iowa

Copies to:

Carl Olsen
Meghan Gavin

State of Iowa Courts

**Type:** OTHER ORDER

| **Case Number** | **Case Title** |
| --- | --- |
| CVCV045505 | CARL OLSEN V. IOWA BOARD OF PHARMACY |

So Ordered

Scott D. Rosenberg

**Scott D. Rosenberg, District Court Judge,**
**Fifth Judicial District of Iowa**

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

| | |
|---|---|
| **CARL OLSEN**,<br>Petitioner,<br><br>vs.<br><br>IOWA BOARD OF PHARMACY,<br>Respondent. | **05771 CVCV047867**<br><br>**PETITIONER'S BRIEF IN SUPPORT OF PETITION FOR JUDICIAL REVIEW** |

## I. STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

**The Board has an ongoing duty to recommend removal of marijuana from Schedule I if marijuana no longer meets the statutory conditions for placement in Schedule I.**

**Cases:**

*Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987)
*State v. Bonjour*, 694 N.W.2d 511 (Iowa 2005)

**Statutes:**

IOWA CODE § 17A.19(10)(c) (2013)
IOWA CODE § 17A.19(11) (2013)
IOWA CODE § 124.201 (2013)
IOWA CODE § 124.203 (2013)

## II. STATEMENT OF THE CASE

On July 30, 2013, Carl Olsen ("**Olsen**") filed a Petition for Agency Action with the Iowa Board of Pharmacy ("**Board**") requesting the Board to make a recommendation to the legislature that marijuana be reclassified. On November 6, 2013, the Board denied the request. The Board made no findings of fact and did not dispute the assertion that marijuana is misclassified. The Board simply denied

the petition on the grounds that no action is required by the Board as a matter of law.

On February 17, 2010, the Board did recommend that the legislature remove marijuana from Schedule I of the Iowa Uniform Controlled Substances Act after holding public hearings across the state and examining scientific and medical evidence.

The legislature has not removed marijuana from Schedule I since the Board made its recommendation in 2010, nor has the legislature removed the duty of the Board to make annual recommendations on changes needed to the classification of controlled substances.

The Board has not determined that marijuana meets the statutory conditions for placement in Schedule I since it made the recommendation to remove marijuana from Schedule I in 2010. The Board did not make any findings of fact in 2013 and there are no facts in dispute in this appeal.

The Board now refuses to recommend that marijuana be removed from Schedule I without any authorization from the legislature relieving the Board of the duty to recommend reclassification. See Ruling on Petition for Agency Action, November 6, 2013, attached as Exhibit #1 to the Amended Petition for Judicial Review, filed June 17, 2014, in this case.

## III. STANDARD OF REVIEW

On judicial review of agency action, the district court functions in an appellate capacity to apply the standards of Iowa Code section 17A.19. *Iowa Planners Network v. Iowa State Commerce Comm'n*, 373 N.W.2d 106, 108 (Iowa 1985). The Court shall reverse, modify, or grant other appropriate relief from agency action if such action was based on an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency. IOWA CODE § 17A.19(10)(c). The Court shall not give deference to the view of the agency with respect to particular matters that have not been vested by a provision of law in the discretion of the agency. IOWA CODE § 17A.19(11)(b). Appropriate deference is given to an agency's interpretation of law when the contrary is true, although "the meaning of any statute is always a matter of law to be determined by the court." *Birchansky Real Estate, L.C. v. Iowa Dept. of Public Health*, 737 N.W.2d 134, 138 (Iowa 2007); IOWA CODE § 17A.19(11)(c). The agency's findings are binding on appeal unless a contrary result is compelled as a matter of law. *Ward v. Iowa Dept. of Transp.*, 304 N.W.2d 236, 238 (Iowa 1981).

## IV. ARGUMENT

### A. Duty to recommend reclassification

The condition created by the legislature for placement in Schedule I is clear. In order for a substance to be classified in Schedule I that substance must have: "no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision." Iowa Code § 124.203(1)(b) (2013)[1]. Accepted medical use in treatment and accepted safety for use in treatment under medical supervision are synonymous.

> The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. 53 FR 5156 (February 22, 1988). In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question.

DEA Docket No. 86-22, 57 Fed. Reg. 10,499, 10,504 (March 26, 1992).

The legislature has given the Board this duty: "If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or

[1] The criteria that substances in Schedule I must have a high potential for abuse is identical to the criteria that substances in Schedule II must have a high potential for abuse, and is, therefore, not relevant to this petition. The abuse potential is the same in Iowa Code § 124.203(1)(a) as it is in Iowa Code § 124.205(1)(a). See *McMahon v. Iowa Board of Pharmacy*, No. CV 7415, Ruling on Petition for Judicial Review (Iowa District Court for Polk County, April 21, 2009) ("A finding of accepted medical use for treatment in the United States alone would be sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203"), at page 4 n.1.

remove the substance from the list of controlled substances, as appropriate." IOWA CODE § 124.203(2) (2013).

The Iowa Supreme Court has recognized the importance of the Board's role in determining proper scheduling. *State v. Bonjour*, 694 N.W.2d 511 (Iowa 2005).

> That procedure is to defer to the Board of Pharmacy Examiners, which is far better equipped than this court--and the legislature, for that matter--to make critical decisions regarding the medical effectiveness of marijuana use and the conditions, if any, it may be used to treat.

*Id*. at 514. The Board's role is not trivial.

Marijuana has now been accepted for medical use in treatment in a total of thirty-five (35) jurisdictions in the United States, in thirty-four (34) states and in the District of Columbia. No other substance in Schedule I has been accepted for medical use by any jurisdiction within the United States. This indisputable legal fact proves that marijuana has accepted medical use in treatment in the United States as a matter of law. The Board has no discretion to find otherwise. See *Grinspoon v. DEA*, 828 F.2d 881, 886 (1st Cir. 1987) ("Congress did not intend 'accepted medical use in treatment in the United States' to require a finding of recognized medical use in every state"). Twenty-three (23) states have legalized the medical use of the marijuana plant itself, and eleven (11) states, including Iowa, have legalized the medical use of a marijuana extract.

Iowa Code Chapter 17A judicial review is not limited to matters over which the agency has discretion. Review can also be based on an agency's erroneous interpretation of law.

**B. Relevance of federal law**

Because Iowa's Uniform Controlled Substances Act is modeled after the federal Controlled Substances Act, federal case law interpreting the meaning of its language is relevant. *State v. Bonjour*, 694 N.W.2d 511, 515 (Wiggins., J., dissenting) ("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)"). See Uniform Controlled Substances Act, prefatory note, 9 U.L.A. 5 (1994) ("The 1970 Uniform Act was designed to complement the federal Controlled Substances Act, which was enacted in 1970"). And see IOWA CODE § 124.601 ("This chapter shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it").

Marijuana's inclusion in Schedule I in 1970 was controversial and a Commission on Marihuana was created to make recommendations on marijuana's classification. Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, Oct. 27, 1970, 84 Stat. 1236, § 601.

> 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, 657 (D.C. Cir. 1974).

The Commission on Marihuana concluded that marihuana use entails a "relatively low social cost," and suggested that decriminalization be considered.

> New studies have indicated that the dangers of marihuana use are not as great as once believed. A recent report of a federal panel representing, inter alia, HEW, DEA, the State Department, and the White House, concluded that marihuana use entails a "relatively low social cost," and suggested that decriminalization be considered. Washington Post, Dec. 12, 1976, at A1, col. 1; Washington Star, Dec. 12, 1976, at A7, col. 1. See *United States v. Randall*, supra note 61, at 2254 (characterizing marihuana as "a drug with no demonstrably harmful effects"). Indeed, in NATIONAL COMMISSION ON MARIHUANA AND DRUG ABUSE, SECOND REPORT, DRUG USE IN AMERICA: PROBLEM IN PERSPECTIVE, Vol. I, at 235 (1973), the Commission recommended that "the United States take the necessary steps to remove cannabis from the Single Convention on Narcotic Drugs (1961), since this drug does not pose the same social and public health problems associated with the opiates and coca leaf products."

*NORML v. DEA*, 559 F.2d 735, 751 n.7 (D.C. Cir. 1977).

Marijuana also has a long history of medical use in treatment in the United States.

> First, while California in 1996 became the first of the sixteen states that currently legalize medical marijuana, the history of medical marijuana goes back much further, so that use for medical purposes was not unthinkable in 1990. At one time, "almost all States ... had exceptions making lawful, under specified conditions, possession of marihuana by ... persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person." *Leary v.*

> *United States*, 395 U.S. 6, 17, 89 S. Ct. 1532, 23 L. Ed. 2d 57 (1969). What's more, the Federal government itself conducted an experimental medical marijuana program from 1978 to 1992, and it continues to provide marijuana to the surviving participants. See *Conant v. Walters*, 309 F.3d 629, 648 (9th Cir. 2002). The existence of these programs indicates that medical marijuana was not a concept utterly foreign to Congress before 1996.

*James v. Costa Mesa*, 700 F.3d 394, 409 (9th Cir. 2012) (Berzon, J., dissenting).

So, while it may have been true that marijuana had no accepted medical use in treatment in any state in 1970 when the federal Controlled Substances Act was enacted, and in 1971 when the Iowa Uniform Controlled Substances Act was enacted, circumstances have changed.

The term "accepted medical use in treatment in the United States" is a legal question, not a question of medical efficacy. Iowa cannot "decide" whether marijuana has been accepted for medical use in treatment in a state where that state has enacted a law defining marijuana as medicine. Neither can a state executive branch agency determine whether a state had sufficient evidence of marijuana's medical utility when it enacted a law accepting the medical use of marijuana in treatment. Any discretion an administrative agency has to determine whether marijuana has medical efficacy pursuant to the eight (8) factors listed in IOWA CODE § 124.201(1)(a)-(h) or the eight (8) factors listed in U.S.C. § 811(c)(1)-(8) cannot be used to nullify the law in a state that has accepted the medical use of a controlled substance. The Board is allowed to find that marijuana has medical

efficacy pursuant to the eight factors found in state law, but the reverse is not true. If a state finds that marijuana has medical efficacy, the Board cannot claim marijuana has no accepted medical use in treatment in the United States. When a state enacts a law defining marijuana as medicine, medical efficacy is codified into law in that state. An administrative agency must accept on face value the law of each state to determine whether that state has accepted the medical use of marijuana, and cannot second guess whether that state has made the correct decision. See *Grinspoon*, at 888 ("Nowhere does Congress equate 'safety and efficacy' under the FDCA with the second and third Schedule I criteria contained in section 812(b)(1)."). Because Iowa's scheduling is modeled on federal scheduling, federal case law interpreting the statutory language is relevant.

Five years before California became the first state in the United States to accept the medical use of marijuana in treatment, the court in *Alliance for Cannabis Therapeutics v. Drug Enforcement Administration*, 930 F.2d 936 (D.C. Cir., 1991), specifically found that Congress did not define the term "currently accepted medical use":

> 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.

*Id*. at 939. And, of course, in 1991, marijuana had not yet been accepted for medical use in treatment by any state. Truncating the statutory language by

removing "in treatment in the United States" now that thirty-five (35) jurisdictions in the United States have accepted it omits a significant constitutional question of federalism. Thirty-five (35) jurisdictions in the United States now accept the medical use of marijuana in treatment and there were none in 1991. Federalism wasn't an issue in 1991. Now, it is. This is not a trivial change in circumstance.

Who has the authority to decide if a substance has currently accepted medical use? The court asked and answered this question in *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006) ("Who decides whether a particular activity is in 'the course of professional practice' or done for a 'legitimate medical purpose'?").

> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he 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.

*Id*. at 258. It is quite clear that marijuana is currently misclassified under both Iowa and federal law, since marijuana now has accepted medical use in treatment in a total of thirty-five (35) jurisdictions within the United States.

Just as the federal agency responsible for scheduling controlled substances may not interpret medical use in a manner that disregards state laws accepting the medical use of controlled substances, neither can a state administrative agency find that states have not specifically authorized the medical use of marijuana in treatment in the United States. Administrative agencies simply have no power to

interfere with state laws without explicit authorization from Congress. Congress has not authorized that interference. The Iowa legislature can not authorize a state administrative agency to interfere with state laws or not to recognize that state laws exist.

### C. Public importance

The Board has previously recommended that marijuana be removed from Schedule I as a matter of science. There is no disagreement between the parties on the question of science. Marijuana no longer belongs in Schedule I, both as a matter of science and as a matter of law. This makes this a matter of extreme importance to the health and welfare of the public.[2]

Iowa is one of eleven (11) states that have recently legalized the medical use of an extract from the marijuana plant. The Board's advice is of particular relevance and importance right now. The legislature has begun to take this matter seriously and the Board's role in that process is critically important.

The Board has two options. The Board can recommend that marijuana be placed in a different schedule, or the Board can recommend that marijuana be removed from the list of controlled substances. IOWA CODE § 124.203(2) (2013).

[2] See *Olsen v. Iowa Board of Pharmacy*, No. CVCV045505, Ruling and Order on Respondent's Motion to Dismiss Petition for Judicial Review (Iowa District Court for Polk County, October 23, 2013), at page 5 (because "19 jurisdictions, 18 states and the District of Columbia, have legally recognized that marijuana has accepted medical use and treatment of various medical conditions … the issue has one of public importance").

### D. Constitutionality and Federalism

The new law recently enacted by the Iowa legislature, 2014 Acts 1125, S.F. 2360, requires Iowa citizens to leave the state of Iowa to obtain an extract from the marijuana plant from another state. It is a federal crime to transport this extract from the marijuana plant across state lines. It is a state crime in every state that accepts the medical use of marijuana to leave that state in possession of this extract from the marijuana plant. S.F. 2360 imposes a burden on critically ill Iowans and their families of the jeopardy of federal prosecution as well as prosecution by states that do not allow the transportation of marijuana extracts through their states and/or do not allow the exportation of marijuana extracts from their state to another state. *Id*. § 7(1)(b) ("Cannabidiol . . . shall be obtained from an out-of-state source . . ."). This blatant disregard for both federal and state laws in other states demonstrates the need for professional guidance from the Board.

Removing marijuana from Schedule I resolves both state and federal conflicts because it brings state law into compliance with federal law and fulfills the constitutional separation of powers which require administrative agencies to faithfully execute the laws enacted by the legislative branches of government.

## V. CONCLUSION

Because the Board has previous found in 2010 that marijuana is incorrectly classified in Iowa, and because the Board has not found otherwise since 2010, the Board has a continuing obligation to recommend that marijuana be reclassified.

Petitioner asks this Court to order the Board to recommend the removal of marijuana from Schedule I, or, in the alternative, order the Board to explain why it no longer believes marijuana is incorrectly scheduled.

Dated this 15th day of August, 2014.

Respectfully Submitted:

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IN THE IOWA DISTRICT COURT FOR POLK COUNTY

| | |
|---|---|
| **CARL OLSEN**,<br>Petitioner,<br><br>vs.<br><br>IOWA BOARD OF PHARMACY,<br>Respondent. | **05771 CVCV047867**<br><br>**PETITIONER'S REPLY BRIEF IN SUPPORT OF PETITION FOR JUDICIAL REVIEW** |

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## STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

The Petitioner does not accept the Respondent's statement of the issue presented for review. See Respondent's Judicial Review Brief, at page 2 (filed with this Court on September 12, 2014) ("**Respondent's Brief**" hereafter). The issue presented by the Petitioner for review is:

I. WHETHER THE BOARD'S INTERPRETATION OF ITS STATUORY DUTY TO MAKE RECOMMENDATIONS ON CONTROLLED SUBSTANCES IS LAWFUL?

Authorities

IOWA CODE CHAPTER 124

IOWA CODE § 124.201

IOWA CODE § 124.203

IOWA CODE § 124.601

*Gonzales v. Oregon*, 546 U.S. 243 (2006)

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

## STATEMENT OF THE CASE

The Petitioner adopts the statement of the case presented in the Petitioner's Brief in Support of Petition for Judicial Review, at pages 1-2 (filed with this Court on August 14, 2014) ("**Petitioner's Brief**" hereafter).

## STANDARD OF REVIEW

The Petitioner adopts the standard of review presented in the Petitioner's Brief, at page 3.

## ARGUMENT

### I. THE BOARD'S DECISION NOT TO RECOMMEND RESCHEDULING WAS UNLAWFUL UNDER IOWA CODE CHAPTER 124.

#### A. FACTS

Petitioner respectfully objects to the Board's characterization of his Petition for Agency Action and his Petition for Judicial Review as attempts to force the Board to defer to the scheduling decisions of administrative agencies in other states. See Respondent's Brief, at page 8, which characterizes these state laws as, "rescheduling by another state." Petitioner relies solely on state statutes, none of which are rescheduling decisions (administrative rulings or otherwise). None of these state laws were preceded by state administrative rescheduling decisions.

The only facts presented by the Petitioner are thirty-four (34) state laws defining marijuana as medicine. Twenty-three (23) of those state laws define marijuana as medicine, and eleven (11) of those state laws define marijuana extracts as medicine. There were nineteen (19) state laws defining marijuana as medicine when the Petitioner filed his Petition for Agency Action with the Board on July 30, 2013. Because "accepted medical use in treatment in the United

States" is a question of law, the Court can judicially notice all thirty-four state laws for the purpose of this Petition for Judicial Review. Petitioner's argument is the same, whether there were nineteen (19) states when the Petition for Agency Action was filed on July 30, 2013, or thirty-four (34) states today. The Board has no authority to question the validity of state laws. State law makers make the decision whether to accept the medical use of marijuana. These state laws are indisputable legal facts that must be legally recognized. As previously noted, the rapidly increasing number of states that have accepted the medical use of marijuana makes this a matter of public importance[1].

[1] See *Olsen v. Iowa Board of Pharmacy*, No. CVCV045505, Ruling and Order on Respondent's Motion to Dismiss Petition for Judicial Review (Iowa District Court for Polk County, October 23, 2013), at page 5 (because "19 jurisdictions, 18 states and the District of Columbia, have legally recognized that marijuana has accepted medical use and treatment of various medical conditions … the issue has one of public importance").

Petitioner is only aware of two states that have rescheduled, Oregon[2] and Connecticut[3], and both of those states rescheduled legislatively without prior administrative rescheduling decisions. The Petitioner did not submit any administrative rulings from other states to the Board and submits none to the Court. In fact, there have not been any administrative rulings in other states regarding removal of marijuana from schedule 1. Iowa is unique in this regard. Iowa is the only state in which an administrative determination that marijuana has medical use and should be removed from schedule 1 has been made before the enactment of a state law accepting the medical use of marijuana[4]. This is

[2] Oregon voters accepted the medical use of marijuana in 1998. Acts 1999, ch. 4, §2, Ballot Measure 67. Oregon removed marijuana from schedule 1 in June of 2010 (4 months after the Iowa Board of Pharmacy voted unanimously on February 17, 2010, to recommend removing marijuana from schedule 1 in Iowa), but marijuana was removed from schedule 1 by the Oregon legislature, not by an administrative decision or recommendation. Acts 2009, ch. 898, §2, S.B. 728. But, see, *State v. Eells*, 72 Or. App. 492, 696 P.2d 564 (1985), review denied by 299 Ore. 313, 702 P.2d 1110 (1985). Oregon has not chosen to include medical use as a factor in its scheduling criteria, so Oregon scheduling decisions are not based on the same criteria that Iowa or the federal government uses. Oregon did move marijuana to a different schedule by administrative process in June of 2014, but statutory removal of marijuana from schedule 1 did not determine which of the other schedules, if any, marijuana actually did belong in.

[3] Connecticut's legislature removed marijuana from schedule 1 by statute, not by an administrative process. Acts 2012, ch. 55, § 18, H.B. 5389.

[4] On July 1, 2014, Iowa accepted the medical use of a marijuana extract. Acts 2014 (85th G.A.) ch. 1125, S.F. 2360.

important, because that is exactly the way the Uniform Controlled Substances Act was intended to work[5], although by no means the only way[6].

**B. LEGISLATIVE INTENT**

Respondent says the Legislature is not interested in this issue. See Respondent's Brief, at page 5, which says, "Nothing prohibits the Board from failing to make a recommendation because it does not believe that recommendation will be acted upon."

In the Board's final order under review in this case (See Exhibit #1 attached to the Amended Petition for Judicial Review filed in this case on June 17, 2010) ("**Petition for Judicial Review**" hereafter), the Board says, "The General Assembly took no action on the Board's 2010 recommendation. During the 2013 session, the legislature considered but did not act upon two bills calling for the rescheduling of marijuana."

The lack of any action by the Legislature following a recommendation from the Board is not legislative intent. The lack of any action by the Legislature cannot be interpreted as a rejection or lack of interest. The lack of any action by the Legislature must be interpreted as neutral, neither pro nor con.

[5] Uniform Controlled Substances Act (1994), at page 24, Comment on Section 201 ("flexibility allows the laws to keep in step with new trends in drug abuse and *new scientific information*") (emphasis added).
[6] *NORML v. DEA*, 559 F.2d 735, 748 (D.C. Cir. 1977) ("medical use is but one factor to be considered, and by no means the most important one").

The Iowa Legislature has given the task of advising the Legislature on the continued validity (or lack of validity) of the listing of substances in the schedules of controlled substances in the Iowa Uniform Controlled Substances Act to the Iowa Board of Pharmacy ("**Board**" hereafter). IOWA CODE §§ 124.201, 124.203, 124.205, 124.207, 124.209, and 124.211 (2013). If the Legislature no longer wishes to receive advice from the Board, the Legislature can amend the statute to relieve the board of this duty.

### C. STATUTORY INTERPRETATION

The Board refers to state laws as administrative rulings, Respondent's Brief, at page 8, but that is not accurate.

The Board interprets the phrase "accepted medical use in treatment in the United States" to entirely exclude the "states." Iowa legislators would not have accidentally included surplus language such as "in the United States." An administrative agency cannot decide whether states have accepted the medical use of marijuana.

The statutory language in question, IOWA CODE §124.203(1)(b) (2013), as well as the four other sections corresponding to it, IOWA CODE §§ 124.205(1)(b), 124.207(1)(b), 124.209(1)(b), and 124.211(1)(b), all use the same phrase, "accepted medical use in treatment in the United States." The Board is interpreting that phrase as if it mean "accepted medical use in Iowa." We don't really know for

sure what the Board thinks it means. All we know is what the Board thinks it does not mean. The Board thinks state laws accepting the medical use of marijuana in treatment are not proof that marijuana has accepted medical use in treatment in the United States.

The Board relies on the eight (8) factors in IOWA CODE § 124.201(1)(a)-(h) (2013) as excluding state laws accepting the medical use of marijuana in treatment in the United States. See Respondent's Brief at page 8. State laws are not contemplated by those eight (8) factors because administrative agencies have no constitutional authority to question the validity of statutory law.

**D. SEMANTICS**

In the Respondent's Brief, at page 5, the Board paraphrases the statute to say, "to recommend the removal of a controlled substance from Schedule I classification if the Board determines the substance no longer meets the Schedule I classification, 'as appropriate'." But that is not what the statute says.

The statute says, "If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or remove the substance from the list of controlled substances, as appropriate." IOWA CODE 124.203(2) (2013).

In the Board's final ruling on November 6, 2013, the board paraphrases the statute to say, "if the board finds that any substance does not meet the definition of

a schedule I controlled substance, the board shall recommend its rescheduling to the legislature as appropriate." But that is not what the statute says.

The board isolates the word "appropriate," without the context of the entire sentence the Legislature placed it in. If marijuana does not meet the definition of schedule 1, it must be moved or removed. Recommending the Legislature move marijuana to another schedule might be appropriate. Recommending the Legislature remove marijuana entirely from the list of schedules might be appropriate. Recommending that the Legislature leave marijuana in the wrong schedule is not appropriate.

The Board is interpreting the statute to mean the board can do whatever the Board wants to do, whenever the Board wants to do it, for any reason the board wants to give, or for no reason at all.

State administrative agencies have no power to overrule decisions of state legislatures. The Board has the duty to "consider" the eight (8) factors, but it cannot nullify state laws.

**E. PRECEDENT**

The Board claims it is not bound by previous decisions of the Board because competent professionals can reach different conclusions. Respondent's Brief at page 6. However, the board has not reached any different conclusion. What has changed that would render the prior decision invalid? If the Board wants to reach a

different conclusion it certainly has the authority to do so. If the Board had denied the Petition for Agency Action on the grounds that marijuana is properly classified, the Board would have been justified to refuse to recommend that marijuana be reclassified. But, the Board has not found that marijuana is properly classified.

In 2010 the Board found that marijuana is incorrectly classified in Iowa. The Petitioner agrees with that ruling. Absent any finding to the contrary since that time, the Board is bound by that 2010 ruling. The ruling by the Board in 2010 finding that marijuana is not correctly classified is precedent.

The Board considered absolutely no facts in 2013 which would justify reversing the ruling the Board made in 2010. The Board simply denied the Petition for Agency Action without any finding that the 2010 ruling is no longer valid. If the Board accepts the fact that marijuana is incorrectly classified, as it clearly does, then the Board has a duty to recommend the legislature remove marijuana from schedule 1.

**F. FEDERALISM**

Federal and state drug laws are intended to work in harmony[7]. See IOWA CODE § 124.601 (2013) ("This chapter shall be so construed as to effectuate its

[7] Prefatory Note for Uniform Controlled Substances Act (1990) ("The 1970 Uniform Act was designed to complement the federal Controlled Substances Act, which was enacted in 1970.") http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf

general purpose to make uniform the law of those states which enact it."). Oregon is the only state other than Iowa to make an administrative determination on what schedule marijuana should be transferred into after it is removed from schedule 1[8]. Although the question of removing marijuana from schedule 1 is a matter of law, the question of which of the other four (4) schedules, if any, to transfer marijuana into is a question that clearly requires consideration of the eight (8) factors listed in IOWA CODE § 124.201(1)(a)-(h) (2013), and the Board must consider them.

Congress never intended the federal drug law to prohibit the authorized use of controlled substances for legitimate medical purposes. See *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) (administrator "not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law").

In 1971, when the Iowa Uniform Controlled Substances Act was adopted, there were no state laws accepting marijuana as medicine. It was completely lawful to place marijuana in schedule 1 in 1971, because no constitutional violation of federalism occurred at that time. For the Board to claim now that thirty-four (34) state laws enacted since 1996 accepting the medical use of marijuana in treatment are not even relevant to the interpretation of the phrase "accepted

[8] But, see note 1, Oregon does not use the same scheduling criteria.

medical use in treatment in the United States" is a gross misunderstanding of the role of the executive branch.

### G. COCA PLANTS AND OPIUM PLANTS ARE IN SCHEDULE 2

It is worth noting that removing marijuana from schedule 1 in Iowa will not make it available for medical use without further action by the Legislature. Coca plants and opium plants are in schedule 2, but those plants are simply source material for pharmaceutical drugs. Doctors do not prescribe coca plants or opium plants in Iowa. In contrast, the principle psychoactive ingredient in marijuana, synthetic tetrahydrocannabinol, is in schedule 3, while cocaine and morphine (the drugs made from coca plants and opium plants) are in Schedule 2. One could logically assume that tetrahydrocannabinol is made synthetically solely because the marijuana plant is in schedule 1[9].

State law makers have the ultimate authority to decide whether to accept the medical use of controlled substances regardless of whether they seek the advice and consent of state administrative agencies before making laws accepting the medical use of marijuana. However, failure to address scheduling creates discord

[9] See DEA proposal to add naturally occurring THC to schedule III, Federal Register / Vol. 72, No. 184 / Monday, September 24, 2007 / Proposed Rules, 54226, at page 54230 ("natural dronabinol (derived from the cannabis plant) or synthetic dronabinol (produced from synthetic materials)") (to date, the DEA has not implemented this rule); and see, DEA proposal to establish a new drug code for marihuana extract, Federal Register / Vol. 76, No. 128 / Tuesday, July 5, 2011 / Proposed Rules (to date, the DEA has not implemented this rule).

between the states and the federal government, because federal scheduling has an impact on state law. State scheduling decisions are an important, complementary piece of the federal drug law. See the Uniform Controlled Substance Act[10].

**H. AGENCY EXPERTISE**

Senate Democrats think the law the Legislature enacted is inadequate and want to make changes to it. http://www.senate.iowa.gov/democrats/does-iowas-medical-cannabidiol-act-pose-a-legal-risk-for-families/ ("It is possible that possession of CBD would violate federal law").

A bipartisan legislative study committee thinks the law the Legislature just enacted is inadequate. https://www.legis.iowa.gov/docs/publications/BM/402702.pdf ("risking violations of other state and federal laws").

The advice of the Board is critical because it has the expertise to address these concerns. And, the biggest concern is federal scheduling. The Board possesses unique expertise on scheduling, which is the reason the Legislature gave the Board this duty in the first place.

## CONCLUSION

Contrary to the Board's assertion that the Petitioner has not cited any authority, the Petitioner has repeatedly cited federal interpretation of the statutory

[10] A link to the Uniform Controlled Substances Act is provided in Note 6.

language and intent behind the federal drug law. *Grinspoon v. DEA*, 828 F.2d 881, 886 (1st Cir. 1987) ("Congress did not intend 'accepted medical use in treatment in the United States' to require a finding of recognized medical use in every state"). *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) ("not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law").

Petitioner has shown that the language in the Iowa Uniform Controlled Substances Act comes from the federal drug law by way of the Uniform Controlled Substances Act which was created to complement the federal drug law. The Board has shown no authority explaining how these terms and phrases should be interpreted any differently in Iowa. Federal interpretation of the language is authoritative.

The Board is clearly in error and must be reversed.

Dated this 26th day of September, 2014.

Respectfully Submitted:

/s/ Carl Olsen
Carl Olsen, Pro Se
130 E. Aurora Ave.
Des Moines, IA 50313-3654
515-343-9933
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Original: filed

Copy to: Attorney General

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

| | |
|---|---|
| CARL OLSEN,<br><br>Plaintiff,<br><br>vs.<br><br>IOWA BOARD OF PHARMACY,<br><br>Defendant. | No. CV 047867<br><br>ORAL ARGUMENT ON PETITION FOR JUDICIAL REVIEW |

* * *

APPEARANCES:

Carl Olsen, P.O. Box 41381, Des Moines, Iowa 50311,

Pro se.

MEGHAN LEE GAVIN, Assistant Attorney General, Second Floor, Hoover Building, Des Moines, Iowa 50319,

-and-

ANDREW MAGNER, Law Student, University of Iowa,

For the Defendant.

The above-entitled matter came on for hearing before the Honorable Eliza Ovrom, commencing at 1:20 p.m., on October 24, 2014, at the Polk County Courthouse, Des Moines, Iowa.

Jill D. Hinders
Certified Shorthand Reporter
Room 416, Polk County Courthouse
Des Moines, Iowa 50309

P R O C E E D I N G S

THE COURT: This is the case of Carl Olsen vs. Iowa Board of Pharmacy and this is the time and place set for argument on petition for judicial review filed by Carl Olsen and you must be Mr. Olsen.

MR. OLSEN: I am.

THE COURT: And also I notice that you have filed three motions for judicial notice and the State has resisted those so I haven't yet ruled on those so if you want to offer any argument on those at this time, you may do so.

Then Meghan Gavin is here for the Board of Pharmacy.

MS. GAVIN: That's correct, your Honor, but with your Honor's permission Andrew Magner is a third year law student at Iowa. He's an extern in our office and he will be presenting our case to you this afternoon.

THE COURT: Mr. Olsen, what would you like to say here today?

MR. OLSEN: I have an opening statement. The Board is required to make annual recommendations to the legislature and I think they have a duty to make a recommendation that the legislature remove marijuana from Schedule I, and the reason is because they made

that recommendation in 2010 and they haven't backed away from it so they still stand in the position that marijuana is in the wrong classification and therefore they should just make the recommendation every year.

That's my first argument. That goes to Iowa Code Chapter 17A.19 10(h) about precedent.

THE COURT: Okay.

MR. OLSEN: Then the second argument is the argument that I started with back in 2008 and that's the existence of state medical marijuana laws proves accepted medical use and treatment in the United States as a matter of law and that when the legislature of Iowa put that condition on Schedule I marijuana no longer meets that statutory condition and that's another reason that the Board should make this recommendation. That's basically -- it's a pretty simple argument.

THE COURT: Mr. Olsen, have you filed previous judicial review actions like this?

MR. OLSEN: Yes.

THE COURT: Since when? How many years have you done this?

MR. OLSEN: I filed in 2009 as an intervenor in the ACLU's case. I filed in my own right last year and this year.

THE COURT: Okay.

MR. OLSEN: On this issue.

THE COURT: Thank you.

MR. OLSEN: Thank you.

THE COURT: And Mr. Magner.

MS. GAVIN: I'm sorry, your Honor. Just a quick follow-up information that Andrew wouldn't be aware of. In 2009 as a result of that judicial review, I believe it was Judge Novak sent the case back to the Board of Pharmacy for a more elaborate analysis of why they did not make the recommendation, and in 2013 Judge Rosenberg dismissed the judicial review for mostly air preservation purposes and did not get to the substantive statutory issue before you today.

THE COURT: Thank you. You may address the merits of the argument, Mr. Magner.

MR. MAGNER: Thank you, your Honor. So today Mr. Olsen will have you believe that this really is a case about marijuana and how it's being scheduled in the state of Iowa. However, we believe that the argument kind of blows past the true issue here which is the authority of the Iowa Board of Pharmacy to make recommendations on controlled substances to the Iowa legislature.

This is really about the duties of the Board, the discretion given to the Board and the

authority of the Board to make decisions based upon their professional expertise.

The case really comes down to two factors: Discretion and authority. The legislature has given authority to the Board to make a professional evaluation under the Iowa Code. The 2013 Board utilizing the code made a decision not to recommend rescheduling and the court should now affirm the Board's decision to not recommend rescheduling.

It is vitally important to consider the time frame in this issue. We must remember that the Board considered Mr. Olsen's petition in November of 2013. Mr. Olsen would have us evaluate the Board's decision in light of developments that have occurred since the Board has made its decision including a number of states that now permit medical marijuana.

It would be illogical to evaluate the Board's decision in light of information not available to them at the time of their decision in 2013 and it would fundamentally undermine the authority given to the Board by the legislature to evaluate the decision in that light.

While it is outside the record, the court could take notice of the fact that Mr. Olsen has filed a new petition with the Board to again recommend

rescheduling. The Board will consider Mr. Olsen's next petition in the coming weeks.

At this meeting, at this upcoming meeting the Board will be able to evaluate the increased number of states that have approved some form of medical marijuana including the Iowa Medical Cannabis Oil Act that was passed in the 2014 legislative session.

It would be inappropriate for this court to consider these facts in evaluating the Board's previous decisions before the Board has an opportunity to consider those events under the statutory scheme.

I'll turn more to the authority of the Board. The Iowa Board of Pharmacy is made up of five pharmacists licensed in Iowa and two members of the general public who are not licensed pharmacists.

Each member serves a three-year term and the members are appointed by the governor and approved by the senate. The Board is not designed to be static and the legislature has clearly designed the Board to allow it to make decisions based upon the members' experiences, viewpoints and opinions.

The 2013 Board is no more obligated to recommend rescheduling than the 2010 Board would have been to refuse a recommendation to reschedule because of prior Board decisions.

The Board has been tasked by legislature to evaluate substances and recommend their schedule. For the drug to be listed as Schedule I, the Board must find that the drug has, one, no accepted medical use in the United States and, two, a high probability of abuse.

Mr. Olsen would like the court to read Section 124.203 of the Schedule I criteria in complete isolation. Under his assessment the Board would have no guidance to evaluate these criteria. However, the Schedule I criteria section does not exist in a vacuum.

In Section 124.201, the duty to recommend rescheduling, the legislature has provided the Board with a set of eight factors to consider when evaluating the schedule.

These factors go to both medical use and include factors like scientific evidence of its pharmacological effect, the state of current scientific knowledge and the risk of public health and the probability of abuse for things like the history and current pattern of abuse or the scope, duration and significance of abuse.

These factors give the Board broad guidance on how to interpret the ambiguous criteria of the Schedule I requirement.

THE COURT: This might not be fair to ask

you. Miss Gavin can answer it if you can't. Isn't there a body of law about the authority of a public board to bind future boards? I think I have seen cases on that before. I'm not sure anybody has cited those to me.

MS. GAVIN: We didn't and there is to a certain degree. Of course, precedent is always an issue when it comes to administrative agencies but the question is how much can they bind certain boards? The point that Mr. Magner made is the Board had --

THE COURT: Is it 17A.19 10(h) for administrative agencies, is that basically --

MS. GAVIN: That's the correct standard.

THE COURT: If you deviate from prior precedent, you should explain the reasons -- you are supposed to explain why you did it? Isn't that what the statute says? I don't have it right in front of me.

MS. GAVIN: Yes. I don't think it necessarily requires that but I think --

THE COURT: Or enough explanation so you can see why they deviated.

MS. GAVIN: I think that's a fair reading, your Honor. I mean, we take precedent and of course we are all beholden to precedent to a certain extent but by that same token if the Board was always beholden to its

precedent in lockstep, in 2010 its decision to recommend the rescheduling of marijuana would have been wholly uncontrary to its 50-year precedent up and to that point in time.

So things can and do change and they are intended to and do change at certain points of time. I think post 2010 it's clear that the legislature did not act on that recommendation. I should say no account for that at all so there were intervening acts from 2010 to 2013.

THE COURT: In this case it's just about the first step which is a recommendation to the legislature then.

MS. GAVIN: Yes.

THE COURT: Am I looking at this case under an arbitrary, capricious and abuse of discretion standard under 17A?

MR. MAGNER: Your Honor, you should be considering this under 17A 10(l) which would be to review agency's action and only grant relief if the action was irrational, illogical, or wholly unjustifiable.

MS. GAVIN: We do believe, your Honor, under the standards articulated by the Supreme Court in Renda, the Board does have interpretive authority over the

Controlled Substances Act. If you look routinely throughout that act, they mention the Board shall do this, the Board shall do that, Board shall promulgate rules, and while that's not in and of itself, at the end of the day if you look at that, the legislature had clearly articulated an intention that the Board be the body of state government who moved forward and interprets Chapter 124.

THE COURT: Thank you. You can continue if you are not done with your argument.

MR. MAGNER: Thank you. As I was mentioning, the criteria under Chapter 124.201 outlines kind of the broad factors the Board should consider when considering a recommendation to reschedule.

If the Board finds after considering these factors that the substance does not meet the criteria in Schedule I, then the Board has a duty to recommend rescheduling which it deems necessary or advisable.

By including this "necessary and advisable" language, the legislature has clearly given the Board the discretion to make a recommendation if an evaluation of the factors indicates that rescheduling is necessary or advisable. In this case the Board after considering Mr. Olsen's petition did not find that recommended rescheduling necessary or advisable.

When evaluating the Board's decision, Mr. Olsen's primary contention is that the Board must find an accepted medical use in the United States when any state allows for medical marijuana use.

This argument would completely blow away the discretion granted to the Board by the legislature and indeed would render the current statutory scheme irrelevant, if not completely useless.

Under Mr. Olsen's interpretation of acceptable medical use criteria, the Board would no longer have any authority to make decisions about the scheduling of drugs in the state of Iowa. They would have to automatically recommend rescheduling when any state in the country approves a substance for potential medical use.

For example, using Mr. Olsen's interpretation of this language, if California decided to approve medical heroin tomorrow, the Board would be obligated to recommend rescheduling for heroin simply because there is potential medical use in the United States.

THE COURT: Is it wholly irrelevant what other states have done? Is it wholly irrelevant?

MR. MAGNER: It would render the current discretion of the Board wholly irrelevant because the

Board would no longer be able to evaluate criteria set out under 124.201 so the Board effectively would either have to be the first state in the nation to make a recommendation or essentially fall in line with whatever state did choose to make the first step in rescheduling any substance. Does that answer your question?

THE COURT: You don't think the Board should consider what other states have done? I understand the Board cannot consider things that haven't been done yet in other states but should the Board not consider what other states have done in this field?

MR. MAGNER: I do believe that the current statutory scheme does allow the Board to consider in general the movement of other states. It's not disputed that marijuana is having a -- it is a national relevant discussion right now as to the medical efficacy of marijuana.

However, the movements of other states are not specifically listed under those eight criteria and I do believe the criteria are broad enough to allow the Board to make a decision based upon what other states have found.

It must also be noted that Iowa is not necessarily fighting uphill against the wave of every other state. Admittedly, as I have mentioned, marijuana

has reached something of a tipping point in terms of state approval; however, marijuana is still listed as a Schedule I drug by the DEA and the only way people have been able to access marijuana in any state is because of this administration's choice not to enforce federal drug laws.

So this truly is a case about the discretion given to the Iowa Board of Pharmacy by the Iowa legislature to make recommendations about scheduling based on their evaluations using their professional expertise and judgment.

The Board appointed by the governor and approved by the senate is composed of Iowans making decisions about what is best for Iowans based upon the available evidence.

In November 2013 the Board after considering the evidence presented to it did not find it necessary or advisable to recommend rescheduling to the legislature after considering the eight factors laid out in the Iowa Code.

Mr. Olsen's argument would not only force the Iowa Board to recommend rescheduling based on the actions of any other state but would effectively destroy the authorities specifically granted to the Board by the legislature and render the Board irrelevant.

For these reasons we request this court to affirm the Board's decision not to recommend rescheduling in 2013.

THE COURT: Mr. Olsen, would you like to respond?

MR. OLSEN: Yes, I will. Thank you. The decision the Board made in 2010 was preceded by four months of public hearings and extensive evidence. They allowed anyone to give evidence for four months. There is no previous precedent of them ever looking at marijuana.

The legislature put it in Schedule I. The Board has never considered the scheduling until 2009. They did an unbelievable amount of work in 2009 and now they say they don't want to agree with that precedent because they don't feel like it. They don't give a reason.

They say it's within their discretion so that just means they can do whatever they want to do for any reason at all or no reason at all. That's my first argument.

The second one is that we are not going to do any mind reading on the legislature's failure to come to any conclusion on this recommendation that the Board made in 2010. We don't know what they are thinking or

why they are hesitating. We can guess why they are hesitating. It's a hot topic. It's a controversial issue.

The next one is that the Board makes the argument that if one state legalizes the medical use of marijuana that that makes Iowa Schedule I invalid and that is correct. That is my argument.

In conjunction with that, rescheduling marijuana doesn't make it legal for anything. So you can put it in any schedule you want or no schedule at all and it's still illegal. It doesn't make it legal for anything so there is no harm by classifying marijuana correctly that the State can identify because there is none.

Also the eight factors do not talk about state law because they all have to do with abuse potential and the abuse potential in Schedule I and Schedule II as Judge Novak said is the same so it's not relevant to abuse potential. Accepted medical use and treatment in the United States doesn't mean anything about abuse potential.

So something could have a high potential for abuse and accepted medical use and be in Schedule II and still not be legal for anything in Iowa. So there is no injury to the State from classifying substances

correctly and interpreting the law the way I am interpreting it that state law does prove accepted medical use and treatment in the United States.

Under the Board's argument state laws in other states are completely irrelevant because they are not addressed by the eight factors and so they would be looking at something else in that state but state law is just irrelevant. Doesn't have anything to do with anything, according to them.

Finally, federal law does not preempt state medical marijuana laws. We have 34 state medical marijuana laws and there is no case saying that federal law preempts state medical marijuana laws and there are quite a few that say that it doesn't preempt state law.

They are all state decisions. There is a couple California decisions, one in Montana, one in Arizona. I don't have a complete list but I can get you a list of all the cases that say it doesn't preempt state medical marijuana laws.

So if the Federal Government doesn't preempt the State from doing this, they should have to recognize it so that means that marijuana is misclassified under federal law the same way it is under state law, although that's an argument for another day.

That's why it's so important that we

schedule it right here because we are not preempted from doing that and the only way we can let the Federal Government know that we don't agree with their federal Schedule I is to put it in a different schedule here in Iowa or remove it from Schedule I so that we are on solid ground with the Federal Government.

If we do pass a medical marijuana law -- we did this year -- we need to make sure the Federal Government recognizes that state law so we are not in a position of saying we just told everybody to go violate federal law. We didn't do that.

Those are my arguments. There are no Iowa cases interpreting the language but there are federal cases that interpret the Controlled Substances Act.

Gonzalez versus Oregon says legitimate medical use is a state decision, not a federal decision. It's a U.S. Supreme Court case from 2006.

There is another case from the First Circuit from 1987 that says accepted medical use and treatment in the United States doesn't mean accepted in every state or federal marketing approval for interstate marketing.

So if it doesn't require acceptance in every state, then how many states would it be and of course my argument is one is enough. That's it.

THE COURT: Thank you. Unless you have anything else, I'll take the matter under advisement.

MS. GAVIN: Can I clear something up, your Honor? First, marijuana is the most unique controlled substance scheduled in the state of Iowa because it actually is a Schedule I and a Schedule II drug in the state.

If you look closely at the scheduling, it's a Schedule I, except as provided by rules promulgated by the Board of Pharmacy, and Schedule II as long as you use it in conformance with those rules.

The Board of Pharmacy has no current rules and has not had rules in approximately 30 years on the use of medical marijuana. That was put in there as far as I can tell because of a federal research program in the late 1970s and some evidence in the 1980s.

The other issue is on the prior precedent issue on subsection H. While Mr. Olsen did, in fact, cite that in his petition, he did not brief that issue so the Board would question whether or not that ground is properly before it today.

Third, your Honor, we would ask that the court take notice of a federal case out of the district court, District of Columbia circuit that's 706F.3d 438. Mr. Olsen intervened in that case. That case is where a

nonprofit group tried to initiate through a petition for the DEA to reschedule medical marijuana.

Admittedly the federal Substance Abuse Act has a different procedure for which recommendations are made, but I think what's important in that case is that the D.C. circuit said this is an issue for the expertise of a state agency, for the agency that's been delegated this task.

The issue with marijuana that's never addressed is the reason why it has difficulty with scheduling is unlike synthetic drugs that go through a very preset scientific examination through the DEA, through the FDA, marijuana being a naturally-occurring substance just hasn't had that same level of testing and that is why the D.C. circuit found that the DEA's decision was supported by substantial evidence and they could not compel the DEA to reschedule marijuana.

THE COURT: Okay. Do you have anything else you want to say?

MR. OLSEN: That case was argued on medical efficacy and I tried to intervene and bring in my argument about the states and I think the court said Mr. Olsen has a religious interest in the use of marijuana and they said his argument is federalism and that's it.

They didn't address my argument. They said my argument was federalism so at least they got that little sentence in there. The case was based on agency discretion. There was no argument made that the agency was in violation of the federal statute because of not being obedient to the condition that congress placed on Schedule I, no accepted medical use and treatment in the United States.

I tried to get them to argue this Gonzalez versus Oregon case saying that states make that decision and they said, No, we made our argument in 2002. We are going to stand on it. We are not going to add anything to the record. We are not going to make any new arguments and so I think that case is a different context.

THE COURT: I'll take this under advisement and issue a written ruling. I can't make any promises on when I am going to get the ruling out. I'm a little backed up on getting rulings out but I'll get to it.

Thank you.

MR. OLSEN: Take your time.

(Hearing concluded at 1:45 p.m.)

CERTIFICATE

I, Jill D. Hinders, Certified Shorthand Reporter and Notary Public of the State of Iowa, do hereby certify that I acted as the official court reporter in the foregoing matter at the time and place indicated herein; that I took in shorthand the proceedings had at said time and place; that said shorthand notes were reduced to typewriting under my direction and supervision; that the foregoing pages are a full and correct transcript of the shorthand notes so taken.

IN WITNESS WHEREOF, I have hereunto set my hand this_____ day of_____, 2014.

_____
Certified Shorthand Reporter
and Notary Public

**Iowa District Court**
**Polk County, Iowa**

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| CARL OLSEN,<br><br>Petitioner,<br><br>vs.<br><br>IOWA BOARD OF PHARMACY,<br><br>Respondent. | )<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>) | Docket No. CV 47867 |

## MOTION FOR JUDICIAL NOTICE

Carl Olsen respectfully moves the Court to take Judicial Notice, pursuant to Iowa Rules of Evidence, Rule 5.201, of a legal fact the Petitioner was unaware of when the Petitioner filed his Amended Petition for Judicial Review on June 17, 2014.

Petitioner just recently became aware that in 2008 the Iowa legislature rescheduled "natural dronabinol (derived from the cannabis plant)" to schedule 3 in Iowa. See **Exhibit #1**, 2008 Iowa Acts Chapter 1010 § 4 (March 5, 2008); Iowa Code § 124.208(9)(b) (2014). Naturally derived dronabinol is in federal schedule 1. See **Exhibit #2**, 75 Fed. Reg. 67054 (2010).

## RELEVANCE

The Respondent may argue that the Board was not given the opportunity to evaluate this evidence in making its decision to deny the Petition on November 6, 2013. This Evidence is relevant and the Court should accept it.

The question presented in my Petition of whether marijuana is misclassified in Iowa is a matter of law for this Court to determine, not a matter of agency discretion. Iowa Code § 17A.19(10)(b) (2014). The Board has no authority to find that marijuana lacks accepted medical use in treatment in the United States. Thirty-four states and two federal jurisdictions now accept the medical use of marijuana in treatment in the United States, and Iowa is just one of those states.

These are legislative decisions on controlled substances, and the Board is mandated by our law to be aware of and acknowledge them. Only this Court can ultimately decide what the law says and means in Iowa. Accepted medical use in treatment in the United States is a statutory condition created by our legislature that legally binds the Board.

The Board can determine whether marijuana has medical efficacy, and it has done so in 2010 and appears to be on the verge of doing it again. See **Exhibit #3** (November 21, 2014, proposed ruling on my 2014 petition for marijuana scheduling).

It is understandable that the Board feels obligated to look at the eight factors in Iowa Code § 124.201(1)(a)-(h) (2014). It is not wrong for the Board to look at medical evidence, even though the argument made by the Petitioner is based on law, not on medical evidence. The Petitioner believes the Board correctly looked at the medical evidence in 2009 and correctly found in 2010 that marijuana has medical efficacy, but the Petitioner is not a medical expert. Thirty-three other states and two federal jurisdictions have looked at this and reached the same conclusion that marijuana has medical efficacy.

Because the accepted medical use of marijuana created by our legislature is for the extraction of two marijuana plant based derivatives, cannabidiol and dronabinol (both of which are in federal schedule 1), the Board has no discretion to find that marijuana has no accepted medical use in Iowa (the statute says "in the United States," not "in Iowa"). See the Medical Cannabidiol Act, 2014 Iowa Acts Chapter 1125 (May 30, 2014); Iowa Admin. Code 641–154 (2014).

Accepted medical use of marijuana in treatment in the United States is determined by state laws accepting the medical use of marijuana. See Gonzales v. Oregon, 546 U.S. 243, 257 (2006) ("Who decides whether a particular activity is in 'the course of professional practice' or done for a 'legitimate medical purpose'?"); and see, Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987) (". . . Congress did

not intend 'accepted medical use in treatment in the United States' to require a finding of recognized medical use in every state . . .").

Finally, I ask the Court to notice that the proposed ruling on my 2014 marijuana scheduling petition specifically agrees with my argument that the Medical Cannabidiol Act of 2014 is inconsistent with state schedule 1:

> *While the Board believes that marijuana has a high potential for abuse, in 2014 the Iowa General Assembly passed the Medical Cannabidiol Act. That Act permits the use of cannabidiol for patients suffering from intractable epilepsy. The passage of this Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana. Continued placement of marijuana in Schedule I is not consistent with this Act. Second, marijuana is currently classified as both a Schedule I and Schedule II controlled substance in Iowa. The dual scheduling is a holdover from experimental research programs authorized more than thirty years ago. The dual scheduling has understandably lead to confusion as to this Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the legislature for the Board to unilaterally establish, design, and implement a medical marijuana program in Iowa. Removing marijuana from Schedule I and removing any reference to rules promulgated by the Iowa Board of Pharmacy will eliminate this confusion.*

## CONCLUSION

Because state laws determining the medical use of marijuana are not within administrative discretion and are judicially recognizable facts that prove marijuana has accepted medical use in treatment in the United States as a matter of law, this evidence should be accepted by this Court.

Respectfully Submitted:

/s/ Carl Olsen
Carl Olsen, Pro Se
130 E. Aurora Ave.
Des Moines, IA 50313-3654
515-343-9933

Copy to: Attorney General

State of Iowa
2008

# ACTS AND JOINT RESOLUTIONS

## (Session Laws)

Enacted at the

## 2008 REGULAR SESSION

of the

## Eighty-Second General Assembly

of the

## State of Iowa

HELD AT DES MOINES, THE CAPITAL OF THE STATE
IN THE ONE HUNDRED SIXTY-SECOND YEAR OF THE STATE

REGULAR SESSION CONVENED ON THE FOURTEENTH DAY OF JANUARY
AND ADJOURNED ON THE TWENTY-SIXTH DAY OF APRIL, A.D. 2008

Published under the authority of Iowa Code section 2B.10
by the
Legislative Services Agency
GENERAL ASSEMBLY OF IOWA
Des Moines

# CHAPTER 1009

ADVANCED PRACTICE REGISTERED NURSE
LICENSURE COMPACT

*H.F. 2151*

**AN ACT** relating to the advanced practice registered nurse licensure compact and providing an effective date.

*Be It Enacted by the General Assembly of the State of Iowa:*

Section 1. Section 147.2, unnumbered paragraph 2, Code Supplement 2007, is amended to read as follows:

For purposes of this section, a person who is licensed in another state and recognized for licensure in this state pursuant to the nurse licensure compact contained in section 152E.1 or pursuant to the advanced practice registered nurse compact contained in section 152E.3 shall be considered to have obtained a license to practice nursing ~~from the department~~.

Sec. 2. 2005 Iowa Acts, chapter 53, section 11, is repealed.

Sec. 3. 2006 Iowa Acts, chapter 1010, section 176, is repealed.

Sec. 4. 2006 Iowa Acts, chapter 1030, section 88, is repealed.

Sec. 5. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

Approved March 5, 2008

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# CHAPTER 1010

CONTROLLED SUBSTANCES —
SCHEDULES AND REPORTING REQUIREMENTS

*H.F. 2167*

**AN ACT** relating to controlled substance schedules and the reporting requirements to the board of pharmacy and making penalties applicable.

*Be It Enacted by the General Assembly of the State of Iowa:*

Section 1. Section 124.206, subsection 2, paragraph a, Code Supplement 2007, is amended by adding the following new subparagraph:

NEW SUBPARAGRAPH. (18) Oripavine.

Sec. 2. Section 124.206, subsection 4, Code Supplement 2007, is amended by adding the following new paragraph:

NEW PARAGRAPH. e. Lisdexamfetamine, its salts, isomers, and salts of its isomers.

Sec. 3. Section 124.208, subsection 3, Code Supplement 2007, is amended by adding the following new paragraph:

NEW PARAGRAPH. n. Embutramide.

Sec. 4. Section 124.208, subsection 9, Code Supplement 2007, is amended to read as follows:

9. HALLUCINOGENIC SUBSTANCES.

a. Dronabinol ~~(synthetic)~~ in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved for marketing by the United States food and drug administration ~~approved product~~.

b. Any drug product in tablet or capsule form containing natural dronabinol (derived from the cannabis plant) or synthetic dronabinol (produced from synthetic materials) for which an abbreviated new drug application (ANDA) has been approved by the United States food and drug administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act and which references as its listed drug the drug product identified in paragraph "a".

c. Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1-ol, or (-)-delta-9-(trans)-tetrahydrocannabinol.

Sec. 5. Section 124B.2, subsection 1, paragraphs j and l, Code 2007, are amended by striking the paragraphs.

Approved March 5, 2008

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# CHAPTER 1011

INTERNAL REVENUE CODE REFERENCES
AND INCOME TAX PROVISIONS

*S.F. 2123*

**AN ACT** updating the Code references to the Internal Revenue Code and including effective date and retroactive applicability date provisions.

*Be It Enacted by the General Assembly of the State of Iowa:*

Section 1. Section 15.335, subsection 4, unnumbered paragraph 2, Code Supplement 2007, is amended to read as follows:

For purposes of this section, "Internal Revenue Code" means the Internal Revenue Code in effect on January 1, ~~2007~~ 2008.

Sec. 2. Section 15A.9, subsection 8, paragraph e, unnumbered paragraph 2, Code Supplement 2007, is amended to read as follows:

For purposes of this subsection, "Internal Revenue Code" means the Internal Revenue Code in effect on January 1, ~~2007~~ 2008.

Sec. 3. Section 422.3, subsection 5, Code Supplement 2007, is amended to read as follows:

5. "Internal Revenue Code" means the Internal Revenue Code of 1954, prior to the date of its redesignation as the Internal Revenue Code of 1986 by the Tax Reform Act of 1986, or means the Internal Revenue Code of 1986 as amended to and including January 1, ~~2007~~ 2008.

this section of the preamble, we will refer to the proposed rule as a "proposed amendment." These findings are discussed below.

*The amendment to the Standard is needed to adequately protect the public against unreasonable risk of the occurrence of fire.* The current Standard specifies as the ignition source cigarettes that are no longer being produced. In order for the Standard to continue to be effective (and for labs to test mattresses and mattress pads to determine whether they comply with the Standard), it is necessary to change the ignition source specification. The proposed amendment is necessary to ensure that the testing is reliable and that results will not vary from one lab or manufacturer to another. Such variation would be likely if labs or manufacturers were able to use different ignition sources that have similar physical properties but different burning characteristics.

*The amendment to the Standard is reasonable, technologically practicable, and appropriate.* The proposed amendment is based on technical research conducted by NIST, which established that the SRM cigarette is capable of providing reliable and reproducible results in flammability testing of mattresses and mattress pads. The proposed SRM represents an equivalent, safety-neutral ignition source for use in testing to establish compliance with the Standard.

*The amendment to the Standard is limited to fabrics, related materials, and products that present an unreasonable risk.* The proposed amendment would continue to apply to the same products as the existing Standard.

*Voluntary standards.* There is no applicable voluntary standard for mattresses. The proposal would amend an existing Federal mandatory standard.

*Relationship of benefits to costs.* Amending the Standard to specify SRM cigarettes as the ignition source would allow testing to the Standard to continue without interruption, would maintain the effectiveness of the Standard, and would not significantly increase testing costs to manufacturers and importers of mattresses and mattress pads. Thus, there is a reasonable relationship between benefits and costs of the proposed amendment. Both expected benefits and costs of the proposed amendment are likely to be small. The likely effect on testing costs would be minor.

*Least burdensome requirement.* No other alternative would allow the Standard's level of safety and effectiveness to continue. Thus, the proposed amendment imposes the least burdensome requirement that would adequately address the risk of injury.

**J. Conclusion**

For the reasons discussed above, the Commission preliminarily finds that amending the mattress flammability standard (16 CFR part 1632) to specify SRM cigarettes as the ignition source is needed to adequately protect the public against the unreasonable risk of the occurrence of fire leading to death, injury, and significant property damage. The Commission also preliminarily finds that the amendment to the Standard is reasonable, technologically practicable, and appropriate. The Commission further finds that the amendment is limited to the fabrics, related materials, and products that present such unreasonable risks.

**K. References**

1. Gann, R.G., and Hnetkovsky E.J., *Modification of ASTM E 2187 for Measuring the Ignition Propensity of Conventional Cigarettes,* Technical Note 1627, National Institute of Standards and Technology, Gaithersburg, MD 20899, 2009.

2. Directorate for Economic Analysis Report, *Preliminary Regulatory Analysis: Smoldering Ignition Source Draft Proposed Technical Amendment to the Flammability Standard for Mattresses and Mattress Pads* (16 CFR part 1632).

**List of Subjects in 16 CFR Part 1632**

Consumer protection, Flammable materials, Labeling, Mattresses and mattress pads, Records, Textiles, Warranties.

For the reasons given above, the Commission proposes to amend 16 CFR part 1632 as follows:

## PART 1632—STANDARD FOR THE FLAMMABILITY OF MATTRESSES AND MATTRESS PADS (FF 4–72, AMENDED)

1. The authority citation for part 1632 continues to read as follows:

**Authority:** 15 U.S.C. 1193, 1194; 15 U.S.C. 2079(b).

2. Section 1632.4 is amended by revising paragraph (a)(2) to read as follows:

**§ 1632.4 Mattress test procedure.**

(a) * * *

(2) *Ignition source.* The ignition source shall be National Institute of Standards and Technology ("NIST") Standard Reference Material ("SRM") 1196, available for purchase from the National Institute for Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899.

* * * * *

Dated: October 26, 2010.

**Todd A. Stevenson,**

*Secretary, Consumer Product Safety Commission.*

[FR Doc. 2010–27504 Filed 10–29–10; 8:45 am]

**BILLING CODE 6355–01–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1308

**[Docket No. DEA–344P]**

### Listing of Approved Drug Products Containing Dronabinol in Schedule III

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to modify the listing of the Marinol® formulation in schedule III so that certain generic drug products are also included in that listing.

Several products are currently the subject of Abbreviated New Drug Applications (ANDAs) under review by the U.S. Food and Drug Administration (FDA). Each product is a generic formulation of Marinol® and contains dronabinol, the (-) isomer of delta-9-(trans)-tetrahydrocannabinol (THC), which is a schedule I controlled substance. Due to variations in formulation, these generic Marinol® products do not meet the specific conditions specified in the current schedule III listing.

This proposed action expands the schedule III listing to include formulations having naturally-derived dronabinol and products encapsulated in hard gelatin capsules. This would have the effect of transferring the FDA-approved versions of such generic Marinol® products from schedule I to schedule III.

**DATES:** Written comments must be postmarked and electronic comments must be submitted on or before January 3, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA–344" on all written and electronic correspondence. Written comments sent via regular or express

mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7183.

**SUPPLEMENTARY INFORMATION:**

*Posting of Public Comments:* Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

## Background

The DEA has received four petitions from companies that have products that are currently the subject of ANDAs under review by the FDA. Each product is a generic formulation of Marinol® and contains dronabinol, the (-) isomer of delta-9-(trans)-tetrahydrocannabinol (THC), which is a schedule I controlled substance. These petitions each requests amendments to Controlled Substances Act (CSA) regulations that would have the effect of transferring the proposed generic Marinol® product from schedule I to schedule III.

At present, the only formulation containing dronabinol that is in a schedule other than schedule I is the following, as set forth in 21 CFR 1308.13(g)(1) as schedule III:

"Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product."

While the petitioners cite that their generic products are bioequivalent to Marinol®, their products do not meet schedule III current definition provided above. Therefore, these firms have requested that 21 CFR 1308.13(g)(1) be expanded to include: (1) Both naturally-derived or synthetically produced dronabinol; and (2) both hard or soft gelatin capsules.

In response to these petitions, DEA prepared several scheduling review documents based upon petitioner-provided data. On June 22, 2007, and August 15, 2007, these analyses were submitted to the Department of Health and Human Services (DHHS) with requests for scientific and medical evaluation and scheduling recommendations. The submissions to DHHS also requested that they consider (1) whether dronabinol extracted from Cannabis sativa (i.e. naturally-derived), is identical to synthetically-produced dronabinol found in Marinol®; and (2) whether a formulation encapsulated in hard gelatin capsules, instead of soft gelatin capsules, changes a product's abuse potential.

On March 17, 2010, and June 1, 2010, the Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA scientific and medical evaluations and letters recommending that FDA-approved drug products containing dronabinol (both naturally-derived or synthetic) in sesame oil in a gelatin capsule (either hard or soft gelatin) be placed into schedule III of the CSA. Enclosed with the March 17, 2010, letter, was a document prepared by the FDA entitled, "Basis for the Recommendation to Control FDA-Approved Drug Products Containing Synthetic Dronabinol in Sesame Oil in a Hard Gelatin Capsule to Schedule III of the Controlled Substances Act." The June 1, 2010, letter included a document entitled, "Basis for the Recommendation to Reschedule FDA-Approved Drug Products Containing Naturally-Derived Dronabinol in Sesame Oil in a Gelatin Capsule to Schedule III of the Controlled Substances Act." These documents contained a review of the factors which the CSA requires the Secretary to consider 21 U.S.C. 811(b).

Therefore, in this rulemaking, DEA is proposing that 21 CFR 1308.13(g)(1) be modified to include generic equivalents of Marinol® which are (1) both synthetic or naturally-derived dronabinol; and/or (2) hard or soft gelatin capsules.

## Background Regarding Dronabinol

Dronabinol is a name of a particular isomer of a class of chemicals known as tetrahydrocannabinols (THC). Specifically, dronabinol is the United States Adopted Name (USAN) for the (-)-isomer of [Delta]\9\-(trans)-tetrahydrocannabinol [(-)-[Delta]\9\-(trans)-THC], which is believed to be the major psychoactive component of the cannabis plant (marijuana).

THC, as a general category, is listed in schedule I of the CSA,[1] while

[1] 21 U.S.C. 812(c), Schedule I(c)(17). Schedule I contains those controlled substances with "no currently accepted medical use in treatment in the

Continued

dronabinol contained in the product Marinol® is listed separately in schedule III. Any other formulation containing dronabinol (or any other isomer of THC), that does not meet the definition provided in 21 CFR 1308.13(g)(1), remains a schedule I controlled substance.[2]

The current wording of the Marinol® formulation in schedule III (21 CFR 1308.13(g)(1)) was added to the DEA regulations in 1986, when the substance was transferred from schedule I to schedule II after the FDA approved Marinol® for marketing.[3] The wording of this listing was not specific to Marinol® and thereby could include any generic product meeting that description that might be approved by the FDA in the future. However, at the time the regulation was promulgated, DEA did not anticipate the possibility that a generic formulation could be developed that did not fit precisely the wording of the listing that currently appears in schedule III.

Recently, firms have submitted to FDA ANDAs for their proposed generic versions of Marinol®. As these ANDAs remain pending with the FDA, the precise nature of these formulations is not available for public disclosure. However, these formulations might differ from the Marinol® formulation currently listed in schedule III. Nonetheless, the firms that have submitted the ANDAs assert that their formulations would meet the approval requirements under 21 U.S.C. 355(j), because, among other things, they have the same active ingredient, strength, dosage form, and route of administration as Marinol®, and are bioequivalent to Marinol®.

Products are bioequivalent if there is no significant difference in the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action 21 CFR 320.1. There is no requirement under 21 U.S.C. 355(j), or FDA's implementing regulations, that solid oral dosage forms such as capsules that are proposed for approval in ANDAs contain the same inactive ingredients as the listed drug referenced. The generic drug, therefore, would not fall within the scope of the current regulation. This situation, in which a generic version of a drug would not necessarily fall within the schedule for the referenced listed drug, is unique among the CSA schedules in the following respect. The Marinol® formulation listed in schedule III is the only listing in the schedules that has the effect of excluding potential generic versions of the brand name formulation.[4] As indicated above, this came about because DEA did not anticipate that other drug products could be approved by FDA that did not fit the description that was included in the schedules. Moreover, Congress structured the CSA so that there would be no distinction—for scheduling purposes—between brand name drug products and their generic equivalents. The rule being proposed here would ensure that this aspect of the CSA holds true for generic drug products approved under 21 U.S.C. 355(j) that reference Marinol® as the listed drug.

In addition, 21 U.S.C. 355(j)(2)(C) permits applicants to petition FDA for approval of an ANDA for a drug product that may differ from the listed drug in certain specified ways, if clinical studies are not necessary to establish the safety and effectiveness of the drug product. Among the types of differences permitted is a change in dosage form, or manner in which the active ingredient is produced.

This proposed rule would amend the description in schedule III [21 CFR 1308.13(g)(1)] to include products referencing Marinol® that are either (1) naturally derived or synthetic; or (2) in hard or soft gelatin capsules, as long as the formulations otherwise meet the approval requirements in 21 U.S.C. 355(j).

**The CSA Scheduling Structure**

To understand the legal justification for the rule being proposed here, the scheduling scheme established by Congress under the CSA must first be considered. One court has succinctly summarized this scheme as follows:

The [CSA] sets forth initial schedules of drugs and controlled substances in 21 U.S.C. 812(c). However, Congress established procedures for adding or removing substances from the schedules (control or decontrol), or to transfer a drug or substance between schedules (reschedule). 21 U.S.C. 811(a). This responsibility is assigned to the Attorney General in consultation with the Secretary of Health and Human Services ("HHS") Id. Sec. 811(b). The Attorney General has delegated his functions to the Administrator of the DEA 28 CFR 0.100(b). Current schedules are published at 21 CFR 1308.11–1308.15.

There are three methods by which the DEA may initiate rulemaking proceedings to revise the schedules: (1) By the DEA's own motion; (2) at the request of DHHS; (3) on the petition of any interested party. 21 U.S.C. 811(a);

21 CFR 1308.43(a). Before initiating rulemaking proceedings, the DEA must request a scientific and medical evaluation from DHHS and a scheduling recommendation. The statute requires the DEA and DHHS to consider eight factors with respect to the drug or controlled substance. 21 U.S.C. 811(b), (c).

These factors are:

(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.

Although the recommendations of DHHS are binding on the DEA as to scientific and medical considerations involved in the eight-factor test, the ultimate decision as to whether to initiate rulemaking proceedings to reschedule a controlled substance is made by the DEA.[5]

Gettman v. DEA, 290 F.3d 430, 432 (DC Cir. 2002).

The FDA plays an important role within DHHS in the development of the DHHS scientific and medical determinations that bear on eight-factor analyses referred to above (required under section 811(c) for scheduling decisions). Thus, when it comes to newly developed drug products that contain controlled substances, FDA makes scientific and medical determinations for purposes of both the Food Drug and Cosmetic Act (in connection with decisions on whether to approve drugs for marketing) and the CSA (in connection with scheduling decisions). As explained below, the eight-factor analysis can be expected to yield the same conclusions with respect to a brand name drug product and certain generic drugs referencing that product that meet the approval requirements under 21 U.S.C. 355(j).

United States" and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1).

[2] The introductory language to schedule I(c) states that any material, compound, mixture, or preparation that contains any of the substances listed in schedule I(c) (including "tetrahydrocannabinols") is a schedule I controlled substance "[u]nless specifically excepted or unless listed in another schedule." The only material, compound, mixture, or preparation that contains THC but is listed in another schedule is the Marinol® formulation, which is listed in schedule III.

[3] 51 FR 17476 (May 13, 1986). DEA subsequently transferred the FDA-approved Marinol® formulation from schedule II to schedule III. 64 FR 35928 (July 2, 1999).

[4] Generally, substances are listed in the CSA schedules based on their chemical classification, rather than any drug product formulation in which they might appear. Because of this, there have been no other situations in which a slight variation between the brand name drug formulation and the generic drug formulation was consequential for scheduling purposes.

[5] *See id.* Sec. 811(a), (b).

**The ANDA Approval Process**

The Drug Price Competition and Patent Term Restoration Act of 1984 (known as the "Hatch-Waxman Amendments"), codified at 21 U.S.C. 355, 360cc, and 35 U.S.C. 156, 271, 282, permits the submission of ANDAs for approval of generic versions of approved drug products. 21 U.S.C. 355(j). The ANDA process shortens the time and effort needed for approval by, among other things, allowing the applicant to demonstrate its product's bioequivalence to a drug already approved under a New Drug Application (NDA) (the "listed" drug) rather than having to reproduce the safety and effectiveness data for that drug. If an ANDA applicant establishes that its proposed drug product has the same active ingredient, strength, dosage form, route of administration, labeling, and conditions of use as a listed drug, and that it is bioequivalent to that drug, the applicant can rely on FDA's previous finding that the listed drug is safe and effective [*See id*].[6] Once approved, an ANDA sponsor may manufacture and market the generic drug to provide a safe, effective, and low cost alternative to the American public.

The majority of drugs approved under 21 U.S.C. 355(j) are therapeutically equivalent to the listed drug they reference. This means that the generic drug and the referenced innovator drug contain identical amounts of the active ingredient, and are bioequivalent. Therapeutic equivalents can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

The key point, for purposes of the rule being proposed here, is that the generic drug can be substituted for the innovator drug with the full expectation that the generic drug will produce the same clinical effect and safety profile as the innovator drug. Consequently, for CSA scheduling purposes, the eight-factor analysis conducted by the FDA and DEA under 21 U.S.C. 811(c) would necessarily result in the same scheduling determination for an approved generic drug product as for the innovator drug to which the generic drug is a therapeutic equivalent. This is because, in conducting the eight-factor analysis, the FDA and DEA would be examining precisely the same medical, scientific, and abuse data for the generic drug product as would be considered for the innovator drug. The same would be true of the innovator drug and a drug product approved pursuant to a petition under 21 U.S.C. 355(j)(2)(C), where the drug approved in the ANDA differs from the listed drug only because it is a hard gelatin capsule and the listed drug is a soft gelatin capsule; or the active ingredient is naturally-derived, rather than synthetically produced.

As noted earlier, these considerations never previously arose for any other controlled substance because the regulation citing the Marinol® formulation is the only scheduling regulation that is drug product formulation-specific and thereby (inadvertently) excludes certain generic versions.[7] This unintended result is not consistent with the structure and purposes of the CSA, which generally lists categories of substances in the schedules, rather than product formulations. Thus, by ensuring that generic versions of the Marinol® formulation which might be approved by the FDA in the future are in the same schedule as Marinol®, the rule being proposed here would make the DEA regulations more consistent with the structure and purposes of the CSA.

Finally, for additional clarity, the proposed rule would amend 21 CFR 1308.13(g)(1) to change the phrase "U.S. Food and Drug Administration approved product" to "drug product approved for marketing by the U.S. Food and Drug Administration."

On June 22, 2007, and August 15, 2007, DEA submitted scheduling review documents for several dronabinol generic products to the DHHS, and requested that DHHS provide scientific and medical evaluation and scheduling recommendations under the CSA. (These documents are available for review online at *http://www.deadiversion.usdoj.gov*.)

On March 17, 2010, and June 1, 2010, the Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA scientific and medical evaluations and letters recommending that FDA-approved drug products containing dronabinol (naturally-derived or synthetic) in sesame oil in a gelatin capsule (hard or soft) be placed into schedule III of the CSA. Enclosed with the March 17, 2010, letter was a document prepared by the FDA entitled, "Basis for the Recommendation to Control FDA-Approved Drug Products Containing Synthetic Dronabinol in Sesame Oil in a Hard Gelatin Capsule to Schedule III of the Controlled Substances Act." The June 1, 2010 letter included a document entitled, "Basis for the Recommendation to Reschedule FDA-Approved Drug Products Containing Naturally-Derived Dronabinol in Sesame Oil in a Gelatin Capsule to Schedule III of the Controlled Substances Act." These documents contained a review of the factors which the CSA requires the Secretary to consider. 21 U.S.C. 811(b).

**Note:** The DHHS scheduling recommendations of March 17, 2010, and June 1, 2010, are available for review online at *http://www.deadiversion.usdoj.gov*.

The factors considered by the Assistant Secretary of Health and DEA with respect to these products were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects;

(3) The state of current scientific knowledge regarding the drug;

(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; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter. 21 U.S.C. 811(c).

The DHHS scheduling recommendation of March 17, 2010, concluded that drug products containing synthetic dronabinol in sesame oil and encapsulated in a hard gelatin capsule, have a similar potential for abuse as Marinol®. "These products contain the same Active Pharmaceutical Ingredient (API), have similar chemistry and pharmacokinetics and have similar formulations in sesame oil." FDA and National Institute on Drug Abuse (NIDA), after reviewing the available information conclude "that drug products approved for marketing by FDA that contain synthetic dronabinol in sesame oil in a hard gelatin capsule be controlled in Schedule III of the CSA."

The DHHS scheduling recommendation of June 1, 2010, concluded that drug products that contain naturally-derived dronabinol in sesame oil and in a gelatin capsule, have a similar potential for abuse as Marinol®. FDA and NIDA, after reviewing the available information, concluded "that drug products approved

[6] *See* also Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), Intro. at p. vi, (27th ed.).

[7] When Congress enacted the CSA in 1970, it scheduled codeine and certain other opiates in three different schedules depending on their respective concentrations. *See* 21 U.S.C. 812(c), schedule II(a)(1), schedule III(d), and schedule V. However, this differential scheduling for opiates does not specify drug product formulation in a manner that would result in a generic version of an opiate drug product being scheduled separately from the innovator drug.

for marketing by FDA that contain naturally-derived dronabinol in sesame oil in a gelatin capsule should be rescheduled to Schedule III of the CSA."

Based on the recommendations of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act [21 U.S.C. 811(b)], and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act [21 U.S.C. 811(a) and 811(b)], finds that FDA-approved generic dronabinol products, both naturally-derived or synthetically produced, in sesame oil and encapsulated in both hard gelatin or soft gelatin capsules meet the criteria for placement in schedule III set in 21 U.S.C. 812(b), as follows:

*A. The Drug or Other Substance Has a Potential for Abuse Less Than the Drugs or Other Substances in Schedule II*

FDA-approved generic drug products that contain dronabinol (both naturally-derived or synthetically produced) in sesame oil in a gelatin capsule (both hard or soft gelatin) and reference Marinol®, have a similar potential for abuse as Marinol®, a schedule III drug product and have similar chemistry and pharmacokinetics as similar formulations in sesame oil.

*B. The Drug or Other Substance Has a Currently Accepted Medical Use in Treatment in the United States*

Marinol® was initially approved by FDA in 1985. When drug products that reference Marinol® receive FDA approval, they will have a currently accepted medical use in the United States.

*C. Abuse of the Drug or Other Substance May Lead to Moderate or Low Physical Dependence or Psychological Dependence and Such Dependence Would Be Less Than the Drugs or Other Substances in Schedule II*

The withdrawal syndrome associated with dronabinol, the API in Marinol®, produces symptoms in humans such as restlessness, irritability, mild agitation, anxiety, anger, insomnia, sleep EEG disturbances, nausea, decreased appetite, and decreased weight. Since a withdrawal syndrome is indicative of physical dependence, it is reasonable to conclude that generic dronabinol products (both naturally-derived or synthetically produced, and in hard or soft gelatin capsules) in sesame oil, will also produce physical dependence similar to those produced by Marinol®.

Therefore, in this rulemaking, DEA is proposing that 21 CFR 1308.13(g)(1) be modified to include generic equivalents of Marinol® which are (1) naturally-derived or synthetically produced dronabinol; and/or (2) hard or soft gelatin capsules. These products, once approved by FDA, shall meet the criteria for inclusion in schedule III of the CSA.

**Comments and Requests for Hearing**

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act 5 U.S.C. 556 and 557. All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may request a hearing 21 CFR 1308.42. Please note that DEA may grant a hearing only "for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable" pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

**Regulatory Certifications**

*Executive Order 12866*

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

*Regulatory Flexibility Act*

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. DEA is hereby proposing to modify the listing of the Marinol® formulation in schedule III so that certain generic drug products are also included in that listing.

*Executive Order 12988*

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

*Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

*Unfunded Mandates Reform Act of 1995*

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $126,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

*Congressional Review Act*

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices: or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Pursuant to the authority vested in the Attorney General under sections 201, 202, and 501(b) of the CSA (21 U.S.C. 811, 812, and 871(b)), delegated to the Administrator and Deputy Administrator pursuant to section 501(a) (21 U.S.C. 871(a)) and as specified in 28 CFR 0.100 and 0.104, and appendix to subpart R, sec. 12, the Deputy Administrator hereby orders that Title 21 of the Code of Federal Regulations, part 1308, is proposed to be amended as follows:

## PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

**Authority:** 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.13 is amended by revising paragraph (g) to read as follows:

**§ 1308.13 Schedule III.**

* * * * *

(g) *Hallucinogenic substances.*

(1)(i) Dronabinol in sesame oil and encapsulated in a gelatin capsule in a drug product approved for marketing by the U.S. Food and Drug Administration (FDA)—7369.

(ii) Any drug product in hard or soft gelatin capsule form containing natural dronabinol (derived from the cannabis plant) or synthetic dronabinol (produced from synthetic materials) in sesame oil, for which an abbreviated new drug application (ANDA) has been approved by the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) which references as its listed drug the drug product referred to in the preceding paragraph (g)(1)(i) of this section—7369.

**Note to paragraph (g)(1):** Some other names for dronabinol: (6a R-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6 H-dibenzo [b,d]pyran-1-ol] or (-)-delta-9-(trans)-tetrahydrocannabinol]

(2) [Reserved]

* * * * *

Dated: October 19, 2010.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. 2010–27502 Filed 10–29–10; 8:45 am]

**BILLING CODE 4410–09–P**

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Parts 85, 86, 1036, 1037, 1065, 1066, and 1068

## DEPARTMENT OF TRANSPORTATION

## National Highway Traffic Safety Administration

## 49 CFR Parts 523, 534, and 535

**[EPA–HQ–OAR–2010–0162; NHTSA–2010–0079; FRL–9219–2]**

**RIN 2060–AP61; RIN 2127–AK74**

## Public Hearings for Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles

**AGENCIES:** Environmental Protection Agency (EPA) and National Highway Traffic Safety Administration (NHTSA).

**ACTION:** Notice of public hearings.

**SUMMARY:** EPA and NHTSA are announcing public hearings to be held for the joint proposed rules "Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles," which will be published in the near future in the **Federal Register**. The agencies will also accept comment on NHTSA's Draft Environmental Impact Statement. Two hearings will be held, on November 15 and 18, 2010.

**DATES:** NHTSA and EPA will jointly hold a public hearing on Monday, November 15, 2010, beginning at 11 a.m. local time, and a second hearing on Thursday, November 18, 2010, beginning at 10 a.m. local time. EPA and NHTSA will make every effort to accommodate all speakers that arrive and register. Each hearing will continue until 5 p.m. or until everyone has had a chance to speak. If you would like to present oral testimony at one of these public hearings, please contact the person identified under **FOR FURTHER INFORMATION CONTACT**, at least ten days before the hearing.

**ADDRESSES:** The November 15 hearing will be held at the Millennium Knickerbocker Hotel Chicago, 163 East Walton Place (at N. Michigan Ave.), Chicago, Illinois 60611. The November 18, 2010 hearing will be held at the Hyatt Regency Cambridge, 575 Memorial Drive, Cambridge, Massachusetts 02139–4896. The hearings will be held at sites accessible to individuals with disabilities.

**FOR FURTHER INFORMATION CONTACT:** If you would like to present oral testimony at a public hearing, please contact Julia MacAllister at EPA by the date specified under **DATES**, at: Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4131; fax number: (734) 214–4050; e-mail address: *macallister.julia@epa.gov* (preferred method for registering), or Assessment and Standards Division Hotline; telephone number; (734) 214–4636; e-mail: *asdinfo@epa.gov.* Please provide the following information: Time you wish to speak (morning, afternoon), name, affiliation, address, e-mail address, and telephone and fax numbers, and whether you require accommodations such as a sign language interpreter.

Questions concerning the proposed rules should be addressed to NHTSA: Rebecca Yoon, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone: (202) 366–2992. EPA: Lauren Steele, Office of Transportation and Air Quality, Assessment and Standards Division (ASD), Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4788; fax number: (734) 214–4816; e-mail address: *steele.lauren@epa.gov,* or Assessment and Standards Division Hotline; telephone number; (734) 214–4636; e-mail: *asdinfo@epa.gov.* You may learn more about the proposal by visiting NHTSA's or EPA's Web pages at *http://www.nhtsa.gov/fuel-economy* or *http://www.epa.gov/otaq/climate/regulations.htm* or by searching the rulemaking dockets (NHTSA–2010–0079; EPA–HQ–OAR–2010–0162) at *http://www.regulations.gov.*

**SUPPLEMENTARY INFORMATION:** The purpose of the public hearings is to provide the public an opportunity to present oral comments regarding NHTSA and EPA's proposal for "Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles." These hearings also offer an opportunity for the public to provide oral comments regarding NHTSA's draft Environmental Impact Statement, accompanying the proposed NHTSA fuel efficiency standards. The proposed rules would establish a comprehensive Heavy-Duty National Program that will reduce greenhouse gas emissions and increase fuel efficiency for on-road heavy-duty vehicles. NHTSA's proposed fuel consumption standards and EPA's proposed carbon dioxide ($CO_2$) emissions standards would be tailored to each of three regulatory categories: (1) Combination Tractors; (2) Heavy-duty Pickup Trucks and Vans; and (3) Vocational Vehicles, as well as gasoline and diesel heavy-duty engines. EPA's proposed hydrofluorocarbon emissions standards would apply to air conditioning systems in tractors, pickup trucks, and vans, and EPA's proposed nitrous oxide ($N_2O$) and methane ($CH_4$) emissions standards would apply to all heavy-duty engines, pickup trucks, and vans. The proposal also includes a request for comment on possible alternative $CO_2$-equivalent approaches for light-duty vehicles in model years 2012–14.

The proposal for which EPA and NHTSA are holding the public hearings will be published in the near future in the **Federal Register** and is available at the Web pages listed above under **FOR FURTHER INFORMATION CONTACT** and also in the rulemaking dockets. NHTSA's draft Environmental Impact Statement is available on the NHTSA Web page and in NHTSA's rulemaking docket, both

DRAFT

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
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| PETITION FOR AGENCY ACTION | ) | BOARD'S 2015 RECOMMENDATION FOR THE SCHEDULING OF MARIJUANA |

On July 7, 2014, Carl Olsen filed a Petition for Agency Action requesting that the Iowa Board of Pharmacy recommend to the Iowa General Assembly the removal of marijuana from Schedule I. The Board first considered this Petition at its August 2014 meeting. The Board tabled consideration of the Petition in August and appointed a special committee to further study the request. The committee met on November 17, 2014 and invited public comment on the Petition. Numerous government agencies, advocacy groups, and private citizens provided both written and oral comments at the November 17th meeting. Both the committee and the Board have thoroughly reviewed the Petition and the submitted information. On November 19, 2014, the Board met in open session to deliberate and render a decision on the Petition.

It is the Board's 2015 recommendation to the Iowa General Assembly that marijuana be removed from Schedule I. The Board does not make this recommendation lightly. The Board's decision is based on two primary considerations. First, Iowa Code section 124.203 requires that this Board recommend the removal of a substance from Schedule I if the Board finds: (1) the substance does not have a high potential for abuse, or (2) the substance has *some* accepted medical use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, in 2014 the Iowa General Assembly passed the Medical Cannabidiol Act. That Act permits the use of cannabidiol for patients suffering from intractable epilepsy. The passage of this Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana. Continued placement of marijuana in Schedule I is not consistent with this Act. Second, marijuana is currently classified as both a Schedule I and

Schedule II controlled substance in Iowa. The dual scheduling is a holdover from experimental research programs authorized more than thirty years ago. The dual scheduling has understandably lead to confusion as to this Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the legislature for the Board to unilaterally establish, design, and implement a medical marijuana program in Iowa. Removing marijuana from Schedule I and removing any reference to rules promulgated by the Iowa Board of Pharmacy will eliminate this confusion.

The Petition does not request or suggest what schedule marijuana should be placed in—only that it be removed from Schedule I. The Board, however, believes it has an obligation under the Controlled Substances Act to recommend the proper schedule should marijuana be removed from Schedule I. The Board believes that marijuana is properly classified as a Schedule II. Iowa Code section 124.205 establishes three criterions for inclusion in Schedule II. Marijuana meets each of these criterion as the Board believes marijuana (1) has a high potential for abuse, (2) abuse of marijuana may lead to severe psychic or physical dependence, and (3) marijuana currently has accepted medical use with severe restrictions in the United States.

The Board wants to caution Iowans on both the limitations on this recommendation and the limitations of any rescheduling of marijuana. The Board is not recommending the legalization of marijuana or even the legalization of a medical marijuana program in Iowa. The Board is simply recommending that marijuana be reclassified as a Schedule II controlled substance. The Board is further recommending, as it did in 2010, that a coalition of stakeholders be established to further study the potential medical uses of marijuana in Iowa, including further expansion of the use of cannabidiol oil. These stakeholders should include, but not be limited to, the Office of Drug Control Policy, the Iowa Boards of Medicine and Pharmacy, law enforcement

agencies, academia, addiction treatment specialists, patients, and the alike. It is incumbent that the establishment of any medical marijuana include the perspectives of all of these groups, as no single entity can determine what conditions medical marijuana could be used to treat, what safety measures are needed to prevent the unlawful consumption of marijuana, especially by children and teens, and the myriad of other concerns raised by the potential establishment of a medical marijuana program in Iowa. This Board, in particular, has genuine concerns about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The rescheduling of marijuana will not automatically result in the legalization of medical marijuana in Iowa. Subsequent legislation will be needed, like the Medical Cannabidiol Act, to authorize the specific medical use of marijuana or marijuana derivatives. The establishment of any medical marijuana program will take sufficient time. The Board acknowledges that this may be difficult to hear for the many Iowans who sincerely believe that medical marijuana will alleviate, or even cure, their or their loved ones ailments.

Finally, the Board cautions that any state medical marijuana program may be superseded by the federal government. Marijuana remains a Schedule I controlled substances under federal law. As a matter of policy, the federal government has allowed states to serve as laboratories of democracy and experiment with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government could change that policy at any time, thereby nullifying any action taken by the State of Iowa.

_____
EDWARD MAIER
Chairperson, Iowa Board of Pharmacy

**IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY**

| | |
|---|---|
| **CARL OLSEN,**<br>**Petitioner,**<br>**vs.**<br>**IOWA BOARD OF PHARMACY,**<br>**Respondent** | **Case No.: CVCV047867**<br>**RULING ON PETITION FOR JUDICIAL REVIEW** |

Hearing in this case was held October 24, 2014. Petitioner Carl Olsen appeared personally. Megan Gavin appeared for respondent, Iowa Board of Pharmacy.

**Introduction**

This is a judicial review action from a November 6, 2013 ruling of the Iowa Board of Pharmacy. Mr. Olsen petitioned the Board to recommend to the 2014 Iowa General Assembly that it remove marijuana from Schedule I of the Uniform Controlled Substances Act, Iowa Code Chapter 124. He wishes to clear the way for medical use of marijuana in Iowa. The Board denied Mr. Olsen's petition.

Olsen timely filed this judicial review action in Polk County District Court. He asserts that the Board erred because it has a duty under Iowa Code Chapter 124 to recommend reclassification of marijuana. He filed an amended petition June 17, 2014. Mr. Olsen asks that the court set aside the Board's November 6, 2013 ruling, enter a declaratory judgment that marijuana has accepted medical use in treatment in the United States, and issue a writ of mandamus requiring the Board to recommend removal of marijuana from Schedule I of the Iowa Controlled Substances Act. The Board resists.

The record consists of attachments filed with the Petition for Judicial Review, and the Proposed Agency Record filed by respondent on July 25, 2014.

**Statement of Facts**

In 2010, at the request of Mr. Olsen, the Iowa Board of Pharmacy recommended to the legislature that it reclassify marijuana from a Schedule I controlled substance to a Schedule II controlled substance, under Iowa Code Chapter 124. The legislature has never adopted this recommendation.

In general, Schedule I controlled substances are illegal to sell or possess in the State of Iowa, and include such substances as opium derivatives and hallucinogens. *See* Iowa Code § 124.204(2013).[1] The Board of Pharmacy may recommend to the legislature that it remove a controlled substance from Schedule I, or reclassify a substance to Schedule II, which would allow for its use for medicinal purposes. *See* Iowa Code § § 124.203, 124.205.

In August 2012 Olsen again petitioned the Board of Pharmacy to recommend removal of marijuana from Schedule I. In November 2012, the Board denied that request, stating "that the supporting documentation did not contain sufficient, new scientific information to warrant recommending the reclassification of marijuana this year." (Cited in Ruling and Order on Petition for Judicial Review, Polk County Case No. CVCV045505). Olsen sought judicial review of that ruling. In February 2014, the Polk County District Court denied Mr. Olsen's petition for judicial review, holding that the Board's ruling was not irrational or illogical on its face, and that the record before the District Court was insufficient to determine whether the Board's decision was in error. (Case No. CVCV045505, February 18, 2014 Ruling and Order on Petition for Judicial Review.)

In July 2013, Olsen again petitioned the Pharmacy Board to recommend that the legislature remove marijuana from Schedule I. He cited a number of scientific studies, as well as statutes from other states which allow medical use of marijuana. In November 2014, the Board denied Olsen's request. This ruling is attached to plaintiff's petition. It states:

[1] References in this ruling are to the 2013 Code of Iowa in effect at the time the Board ruled on Olsen's petition, unless otherwise noted.

> The Board recommended the rescheduling of marijuana in 2010. The Board recognized at that time and continues to recognize that the scheduling of controlled substances is ultimately a decision for the Iowa Legislature. The General Assembly took no action on the Board's 2010 recommendation. During the 2013 session, the legislature considered but did not act upon two bills calling for the rescheduling of marijuana. On November 6, 2013, the Board concluded that it was not advisable or appropriate to recommend the rescheduling of marijuana in 2014.

Ex. 1.

**Motions for Judicial Notice**

Olsen asks the court to take judicial notice of: 1) a law enacted in North Carolina in July 2014, 2) a law enacted in New York in July 2014, and 3) a law enacted in Missouri in July 2014. The Board resists.

The court may consider such evidence as it deems appropriate in judicial review of "other agency action", i.e. actions other than evidentiary hearings. Iowa Code § 17A.19(7). However, the court's discretion to hear additional evidence "is for the limited purpose of 'highlighting what actually occurred in the agency in order to facilitate the court's search for errors of law or unreasonable, arbitrary, or capricious action.'" *Office of Consumer Advocate v. Iowa Utilities Board,* 770 N.W.2d 334, 343 (Iowa 2009) (internal citations omitted). The additional evidence is not to be used to retry the factual issues in district court. *Id.*

Because the laws that petitioner asks the court to consider were enacted after the Board's ruling was issued in November 2013, they have no relevance to what actually happened before the Board. Therefore, the three motions to take judicial notice are overruled.

Petitioner also cites legislation that was passed by the Iowa legislature in 2014 allowing use of cannabinoid oil for treatment of epilepsy. 2014 Iowa Acts, SF 2360. This legislation was also enacted after the agency action at issue here, and is not directly relevant to the Board's 2013 decision.

On December 6, 2014, Mr. Olsen filed a motion asking the court to consider a section of the statute that he had not cited previously – Section 124.208(9)(b). This code section was in effect when the Board issued its decision in November 2013. The court will consider this statute in ruling on this matter.

**Standard of Review**

This is a proceeding for judicial review of administrative agency action under Iowa Code Chapter 17A. Petitioner may obtain relief from agency action if his substantial rights are prejudiced, and the agency has violated any of the subsections of Code Section 17A.19(10). Olsen asserts that the Board's decision is based upon an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency, in violation of Iowa Code Section 17A.19(10)(c).[2]

The Board argues that the decision to recommend rescheduling of marijuana is a decision that is vested by a provision of law in the Board's discretion, and thus its decision should be reversed only if it is irrational, illogical, or wholly unjustifiable, pursuant to Section 17A.19(10)(*l*). The court must not give any deference to the agency's view of whether it is vested with discretion to interpret the law. Iowa Code § 17A.19(11)(a).

The Iowa Supreme Court has stated:

> Our review of authorities on this subject has confirmed our belief that each case requires a careful look at the specific language the agency has interpreted as well as the specific duties and authority given to the agency with respect to enforcing particular statutes. It is generally inappropriate, in the absence of any explicit guidance from the legislature, to determine whether an agency has the authority to interpret an entire statutory scheme. As we have seen, it is possible that an agency has the authority to interpret some portions of or certain specialized language in a statute, but does not have the authority to interpret other statutory provisions. Accordingly, broad articulations of an agency's authority, or lack of authority,

[2] Olsen's petition for judicial review alleges violations of additional provisions of Section 17A.19(10). *See Id.*, ¶ 31. However, he did not brief or argue these additional alleged violations. Therefore the court deems them waived.

> should be avoided in the absence of an express grant of broad interpretive authority.

*Renda v. Iowa Civil Rights Com'n*, 784 N.W.2d 8, 13 -14 (Iowa 2010). The Court in *Renda* set forth guidelines for courts to follow, including 1) whether the statutory provision being interpreted is a substantive term within the special expertise of the agency; 2) whether the provisions to be interpreted are found in a statute other than the statute the agency has been tasked with enforcing; and 3) whether the term has an independent legal definition that is not uniquely within the subject matter expertise of the agency. *Renda,* 784 N.W.2d at 14.

The court has reviewed the specific authority granted to the Board to make annual recommendations for reclassification of controlled substances to the legislature (Sections 124.201(1) and (2)); the statutes listing marijuana as controlled substances (Iowa Code § 124.204(4)(m), 124.206(7)(a), and 124. 208(9)(b)); and the statutes dealing with reclassification or deletions of controlled substances (Code Sections 124.203 and 124.205). In addition, Iowa Code Section 135.31 gives the Board of Pharmacy policymaking authority. Five of the seven members of the board must be licensed pharmacists. Iowa Code § 147.(1)(e). The statutory scheme for classification of controlled substances is highly technical and relies heavily on the expertise of the Board. Based upon these statutes, the court concludes the Board is given discretion to make recommendations for rescheduling controlled substances, and the decision of the Board is entitled to appropriate deference under Section 17A.19(10) and (11).

Therefore, the court will reverse the agency's decision only if it is irrational, illogical, or wholly unjustifiable. Iowa Code § 17A.19(10)(*l*). Review of agency action under the irrational, illogical, or wholly unjustifiable standard is highly deferential. *Iowa Dental Ass'n v. Iowa Ins. Div.*, 831 N.W.2d 138, 142-43 (Iowa 2013).

**Discussion and Analysis**

This case turns on interpretation of several provisions of Iowa Code Chapter 124, the Uniform Controlled Substances Act. *See* Iowa Code Section 124.601.

Chapter 124 creates five schedules for controlled substances. Schedule I substances are listed in Section 124.204, and are the most highly regulated substances. Schedule I substances include opiates and hallucinogenic substances. Marijuana is listed under Schedule I as follows: "Marijuana, except as otherwise provided by rules of the board [of pharmacy] for medicinal purposes." Iowa Code § 124.204(4)(m). The Code section also states, "Exclusions. This section does not apply to marijuana, tetrahydrocannabinols or chemical derivatives tetrahydrocannabinol when utilized for medicinal purposes pursuant to rules of the board." Iowa Code § 124.204(7).

Schedule II controlled substances are listed in Section 124.206, and include substances which are addictive, but frequently used for medical purposes such as opiates, codeine, hydrocodone, and morphine. *See* Iowa Code § 124.206(2). Marijuana is also listed in Schedule II as follows: "Marijuana when used for medicinal purposes pursuant to rules of the board." Iowa Code § 124.206(7)(a).

Schedule III controlled substances are listed in Code Section 124.208. They include stimulants, depressants, and narcotic drugs. *See* Iowa Code § 124.208(2). Dronabinol, a derivative of the cannabis plant, is listed in Schedule III. Iowa Code § 124.208(9)(b). This Code section states that the referenced drug – ANDA – has been approved the U.S. Food and Drug Administration. *Id.*

Thus the legislature has recognized that the Board may enact rules for medical use of marijuana under both Schedule I and Schedule II. To date the Board of Pharmacy has not enacted rules relating to the medical use of marijuana. The history of these enactments

concerning marijuana's listing in Schedule I and Schedule II of Chapter 124 is set forth in a dissenting opinion in *State v. Bonjour,* 694 N.W.2d 511, 516-17 (Iowa 2005) (Wiggins, J. and Lavorato, C.J. dissenting). In that case the court considered a different issue than is presented here, but the discussion of the statutory history concerning inclusion of marijuana under Schedules I and II is instructive. This is an issue which has been raised, studied, and considered in the past in Iowa. *See Id.*

The Board is given the duty to make recommendations to the legislature for deletions and revisions to the schedules of controlled substances "which it deems necessary or advisable." Iowa Code Section 124.201(1). That section states:

> 1. The board shall administer the regulatory provisions of this chapter. Annually, within thirty days after the convening of each regular session of the general assembly, the board ***shall recommend to the general assembly any deletions from, or revisions in the schedules of substances***, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, ***which it deems necessary or advisable***. In making a recommendation to the general assembly regarding a substance, the board shall consider the following:
>
> . . . . . .
>
> 2. After considering the above factors, the board shall make a recommendation to the general assembly, specifying the change which should be made in existing schedules, if it finds that the potential for abuse or lack thereof of the substance is not properly reflected by the existing schedules.

Iowa Code § 124.201(1)(emphasis added).

In addition, Iowa Code Section 124.203 states that the Board shall recommend to the legislature that it place a substance in Schedule I if it has a high potential for abuse, and has no accepted medical use in treatment in the United States, or lacks accepted safety for use in treatment under medical supervision. Iowa Code § 124.203(1) (2013). The statute also states: "If the board finds that any substance included in schedule I does not meet these criteria, the board shall recommend that the general assembly place the substance in a different schedule or

remove the substance from the list of controlled substances, as appropriate." Iowa Code § 124.203(2).

Iowa Code Section 124.205 states that the Board shall recommend to the legislature that is place a substance in Schedule II if it has 1) a high potential for abuse, 2) 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. Iowa Code § 124.205(1).

Petitioner argues that, based on the record presented to the Board with his petition, the Board is required to conclude that marijuana has "currently accepted medical use in treatment in the United States," within the meaning of Iowa Code Section 124.203(1). His petition to the Board includes citations to the record made before the Board in 2010 when it voted to recommend rescheduling marijuana from Schedule I to Schedule II. He also cited 19 states which accepted medical use of marijuana in treatment and a CD of scientific literature on this topic. (Petition for Agency Action, pp. 7-8.) He then argues that, under subsection (2) of Section 124.205, the Board must recommend removal of marijuana from the list of Schedule I controlled substances.

In construing statutes, the court must ascertain legislative intent. *Mall Real Estate, L.L.C. v. City of Hamburg,* 818 N.W.2d 190, 194 (Iowa 2012). In doing so, the court is to consider the language used in the statute, the object the legislature sought to accomplish, and the wrong the general assembly sought to remedy. *Id.* The court searches for legislative intent as shown by what the legislature said, rather than what it should or might have said. *Auen V. Alcoholic Beverages Div., Iowa Dept. of Commerce.* 679 N.W.2d 586, 590 (Iowa 2004). If a term is not defined in a statute, the term is given its ordinary and common meaning by considering the

context within which it is used. *Id.* If possible, a statute must be construed so as to give effect to all its provisions. *State v. Harrison,* 325 N.W.2d 770, (Iowa Ct. App. 1982); *see also State v. Netzer,* 579 S.W.2d 170 (Mo. Ct. App. S.D. 1979) (stating provisions of Uniform Controlled Substances Act must be construed together).

Chapter 124 is based on the Uniform Controlled Substances Act, and is to be construed to carry out its general purpose of making uniform the law of those states which enact it. Iowa Code § § 124.601, 124.602. "The Uniform Controlled Substances Act was drafted to maintain uniformity between the laws of the several states and those of the federal government and is designed to complement the federal law and provide an interlocking trellis of federal and state law to enable government at all levels to control more effectively the drug abuse problem." Prefatory Note to Uniform Controlled Substances Act (1990). One of the major purposes of the federal Controlled Substances Act is to prevent illegal manufacture, distribution, and possession of controlled substances that have a substantial and detrimental effect on the health and welfare of the American people. 21 U.S.C. § 801.

Petitioner focuses on the language of Section 124.203(2), which states that the legislature "shall" recommend deletion of a controlled substance from Schedule I if it does not meet the criteria concerning medical use in treatment in the United States. However, this narrow reading of the statute ignores the broad language of Section 124.201, which states that the Board shall annually recommend revisions to the schedules of substances "which it deems necessary or advisable." Sections 124.201, .203, and .205 must be read to give effect to all of them. In doing so, the court concludes the legislature intended that the Board have discretion to recommend whether a controlled substance should be removed from Schedule I, or reclassified from Schedule I to Schedule II. This authority is clearly stated in subsection (201). The criteria for

reclassification or deletion are set forth in subsections (203) and (205). Petitioner's interpretation would nullify the language in Section 124.201.

Because the Board has discretion, petitioner must show that the Board abused its discretion in denying his petition for agency action. The Board made a finding that it did not deem it "advisable or appropriate to recommend the rescheduling of marijuana in 2014." This is within the discretion of the Board, and petitioner has not shown that this decision is irrational, illogical, or wholly unjustifiable. While a previous iteration of the Board did make such a recommendation to the legislature in 2010, in subsequent years the Board has declined to do so. This is within its discretion.

The court has also considered Section 124.208(9) and its listing of dronabinol, derived from the cannabis plant, as a Schedule III controlled substance. However, this does not cause the court to change its opinion that it is within the discretion of the Board whether to recommend marijuana be removed from Schedule I, for the reasons set forth above.

For the reasons stated above, the petition for judicial review should be dismissed.

IT IS ORDERED that the petition for judicial review is dismissed, with costs taxed to petitioner.

Dated this 10th day of December, 2014.

State of Iowa Courts

**Type:** OTHER ORDER

| **Case Number** | **Case Title** |
| --- | --- |
| CVCV047867 | CARL OLSEN VS IOWA BOARD OF PHARMACY |

So Ordered

Eliza Ovrom, District Court Judge,
Fifth Judicial District of Iowa

Electronically signed on 2014-12-10 10:43:29 page 11 of 11