IN THE SUPREME COURT OF IOWA

CARL OLSEN,)
Petitioner-Appellant,)) SUPREME COURT NO. 16-1381
v.)
IOWA BOARD OF PHARMACY,))
Respondent-Appellee.)

APPEAL FROM THE IOWA DISTRICT COURT

FOR POLK COUNTY

HONORABLE BRAD MCCALL, JUDGE

APPENDIX

CARL OLSEN 130 E. Aurora Ave. Des Moines, IA 50313-3654 515-343-9933 carl-olsen@mchsi.com Appellant, Pro Se

CERTIFICATE OF FILING

On November 24, 2016, 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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> 0 ANAN C Description ANSWER

Comment(s) AFFIDAVIT OF SERVICE TO IOWA BOARD OF PHARMACY ON 1/13/16

C Description OTHER AFFIDAVIT

Filed By AT0008949 GAVIN, MEGHAN LEE

Filed By PK2768917 OLSEN, CARL ERIC

13-JAN-16 11:43 AM 0 FOOT

01-FEB-16 11:40 AM

Comment(s) BY RESPONDENT, THE IOWA BOARD OF PHARMACY

C Description COURT REPORTER MEMORANDUM AND CERTIFICATE

Rpt ID : CPW200 Iowa Court Information System Page: 2 Rpt Date: 17-AUG-16 POLK Rpt Time: 04:10 PM Clerk of Court - POLK COUNTY CLERK OF COURT, Rpt Beg : 01-JAN-16 Combined General Docket Rpt End : 17-AUG-16 ----- Case Name -----Case 05-77-1- -CV-CV051068 Title CARL OLSEN VS IA BOARD OF PHARMACY ----- Papers Filed -----Filed Date / Time Seq Event Reference St C Description ORDER SETTING HEARING 18-MAR-16 01:39 PM 0 ODHR Filed By PK4372288 PORTER, DAVID MATTHEW Comment(s) HEARING 05/20/2016 08:15 AM ROOM 305 08-APR-16 06:48 PM 0 BRIF C Description BRIEF Filed By PK2768917 OLSEN, CARL ERIC Comment(s) OPENING TRIAL BRIEF OF PETITIONER 08-APR-16 06:48 PM 1 NOOT C Description NOTICE Filed By PK2768917 OLSEN, CARL ERIC Comment(s) NOTICE OF COMPLIANCE WITH I.R.CIV.P.1.442(4) C Description BRIEF Filed By PK2768917 OLSEN, CARL ERIC Comment(s) AMENDED OPENING TRIAL BRIEF OF PETITIONER 29-APR-16 01:11 PM 0 NOOT C Description NOTICE Filed By AT0008949 GAVIN, MEGHAN LEE Comment(s) OF SERVING RESPONDENT'S JUDICIAL REVIEW BRIEF 29-APR-16 01:11 PM 1 BRIF C Description BRIEF Filed By AT0008949 GAVIN, MEGHAN LEE Comment(s) - RESPONDENT'S JUDICIAL REVIEW BRIEF 13-MAY-16 03:23 PM 0 BRIF Filed By PK2768917 OLSEN, CARL ERIC Comment(s) PETITIONER'S JUDICIAL REVIEW REPLY BRIEF 13-MAY-16 03:23 PM 1 NOOT C Description NOTICE Filed By PK2768917 OLSEN, CARL ERIC Comment(s) NOTICE OF COMPLIANCE WITH I.R.CIV.P.1.442(4) 0 EXLT 19-MAY-16 02:25 PM C Description EXHIBIT LIST Filed By PK2768917 OLSEN, CARL ERIC Comment(s) TABLE OF CONTENTS FOR EXHIBITS

20-MAY-16 03:27 PM

Filed By PK3238617 MOON, JULIE A

0 CRMC

Comment(s) \$40.00 APPLICATION FOR JUDICIAL REVIEW ON 5/20/16 WITH JUDGE

E-FILED 2016 AUG 17 4:16 PM POLK - CLERK OF DISTRICT COURT Rpt ID : CPW200 Iowa Court Information System Page: 3 Rpt Date: 17-AUG-16 POLK Rpt Time: 04:10 PM Clerk of Court - POLK COUNTY CLERK OF COURT, Rpt Beg : 01-JAN-16 Combined General Docket Rpt End : 17-AUG-16 ----- Case Name -----Case 05-77-1- -CV-CV051068 Title CARL OLSEN VS IA BOARD OF PHARMACY ----- Papers Filed -----Filed Date / Time Seq Event Reference St 20-MAY-16 03:27 PM 0 CRMC C Description COURT REPORTER MEMORANDUM AND CERTIFICATE Filed By PK3238617 MOON, JULIE A Comment(s) MCCALL 12-JUN-16 09:14 AM 0 MOOT C Description MOTION Filed By PK2768917 OLSEN, CARL ERIC Comment(s) FOR LEAVE TO FILE TRANSCRIPT OF PROCEEDINGS ON MAY 20, 2016 05-JUL-16 08:14 AM 0 OROT C Description OTHER ORDER Filed By PK3847639 MCCALL, BRADLEY M Comment(s) ORDER DENYING PETITIONER'S REQ TO FILE A TRANSCRIPT OF PROCEEDINGS HELD ON 5/20/16 22-JUL-16 08:47 AM 0 ORDI C Description ORDER REGARDING DISMISSAL Filed By PK3847639 MCCALL, BRADLEY M Comment(s) ACTION OF THE BOARD OF PHARMACY IS DENYING THE PETITION. THIS MATTER IS DISMISSED. CC ASSESSED AGAINST PETITIONER 22-JUL-16 11:28 AM 0 NOOT C Description NOTICE Comment(s) STATEMENT OF COSTS FOR CARL (MAILED COPY TO CARL OLSEN ON 7/22/16) 09-AUG-16 07:00 PM 0 MOOT C Description MOTION Filed By PK2768917 OLSEN, CARL ERIC Comment(s) FOR ORDER DIRECTIN CLERK OF COURT TO ACCEPT PAYMENT FOR COSTS 09-AUG-16 07:13 PM 0 MOOT C Description MOTION Filed By PK2768917 OLSEN, CARL ERIC

Comment(s) AMENDED, FOR ORDER DIRECTING CLERK OF COURT TO ACCEPT

PAYMENT FOR COURT COSTS

0 MOOT 09-AUG-16 08:22 PM C Description MOTION

Filed By PK2768917 OLSEN, CARL ERIC

Comment(s) FOR LEAVE TO W/DRAW MOTION TO COMPEL CLERK TO ACCEPT PAYMENT

13-AUG-16 12:42 PM 0 NOAP C Description NOTICE OF APPEAL

Filed By PK2768917 OLSEN, CARL ERIC

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Rpt Time: 04:10 PM Clerk of Court - POLK COUNTY CLERK OF COURT,

Port Rea: 01-JAN-16 Combined General Docket

Rpt End : 17-AUG-16

----- Case Name -----

Case 05-77-1- -CV-CV051068

Title CARL OLSEN VS IA BOARD OF PHARMACY

----- Judgment/Lien Detail -----

Date Time Sq 04/24/15 01:47 PM 0 St Date St Judgment Status

07/22/16 N NONE

Create Dt Judgment/Lien Entry

22-JUL-16 CARL OLSEN- CC(OWED TO THE STATE)

Against Sat Status Sta Date Code Sat Date

PK2768917 OLSEN, CARL, ERIC NONE

07/22/16 SATS 07/22/16

For

STATEIOWA STATE OF IOWA

Rpt ID : FM8070 Page: 1 Iowa Court Information System

Rpt ID : FM80/0

Rpt Date: 17-AUG-16

Rpt Time: 04:10 PM

Clerk of Court - POLK COUNTY CLERK OF COURT

Rpt Beg : 01-JAN-16

Rpt End : 17-AUG-16

Financial Summary

Case ID : 05-77-1- -CV-CV051068 Title: CARL OLSEN VS IA BOARD OF PHARMACY

Name :

Obligor PIN: Name : Obligee PIN: Name : Payor PIN :

Payee PIN :

Filed Dt Filed Tm Sq F-Cd C Description Owed Amount Paid Amount Due Amount

-------20-MAY-16 03:27 PM 1 CF01 C COURT REPORTER SERVICES \$40.00 \$40.00 \$.00 01-JAN-16 04:49 PM 1 CP31 C FILING AND DOCKETING PET \$185.00 \$185.00 \$.00

	- Financial Totals				
Description	Owed Amount	Paid Amount	Due Amount		
Court Costs	\$225.00	\$225.00	\$.00		
All Other	\$.00	\$.00	\$.00		
** Grand Totals	\$225.00	\$225.00	\$.00		

Rpt ID : FM8080 Iowa Court Information Systems Page: 1

Rpt Date: 17-AuG-16 POLK

Rpt Time: 04:10 PM Clerk of Court - POLK COUNTY CLERK OF COURT,

Rpt Beg : 01-JAN-16 Case Financial Management

Rpt End : 17-AuG-16 Financial Detail

Case Id : 05-77-1- -CV-CV051068 Title: CARL OLSEN VS IA BOARD OF PHARMACY

Receipt Nbr: 404533

Fin			Rece	eipt				Disbur	rsement	
AR-F C Fin Cd Desc	Date	No	Oblgr PIN	Oblgr Name	Amount	Date	No	Oblge PIN	Oblge Name	Amount
AP-F C Fin Cd Desc	F-T T-C	Batch	Payor PIN	Payor Name		F-T T-C	Batch	Payee PIN	Payee Name	
CP31 C FILING AND DOCKET	04-JAN-16	404533	PK2768917	OLSEN, CARL	\$185.00	01-FEB-16	601876	STATEIOWA	STATE OF I	-\$185.00
CP32 C FILING AND DOCKET	EDM EDM	EDMS	PK2768917	OLSEN, CARL		CHK EDM	EDMS	STATEIOWA	STATE OF I	
	04-JAN-16	404533	PK2768917	OLSEN, CARL	\$185.00	01-FEB-16	601876	STATEIOWA	STATE OF I	\$185.00
	EDM EDM	EDMS	PK2768917	OLSEN, CARL		CHK EDM	EDMS	STATEIOWA	STATE OF I	

** Receipt Totals \$370.00 \$.00

Receipt Nbr: 566400

Fin		Receipt		Disbursement	
AR-F C Fin Cd Desc	Date No	Oblgr PIN Oblgr Name	Amount Date	No Oblge PIN Oblge Name	e Amount
AP-F C Fin Cd Desc	F-T T-C Batch	Payor PIN Payor Name	F-T T-C	Batch Payee PIN Payee Name	2
CF01 C COURT REPORTER SE	22-JUL-16 566400	PK2768917 OLSEN, CARL	\$40.00 01-AUG-16	616105 STATEIOWA STATE OF 1	\$40.00
CF02 C COURT REPORTER SE	CRC STD MILL77	PK2768917 OLSEN, CARL	CHK STD	MILL77 STATEIOWA STATE OF I	Ī
** Re	ceipt Totals		\$40.00		\$40.00

** Grand Total \$410.00 \$40.00



State of Iowa Courts

Type: COMBINED GENERAL DOCKET REPORT

Case Number Case Title

CVCV051068 CARL OLSEN VS IA BOARD OF PHARMACY

So Ordered

Jennifer Tietjen, Clerk of Court Designee,

Polk County Iowa

Electronically signed on 2016-08-17 16:22:52 page 7 of 7

Exhibit #2

RECEIVED-FILED 2016 JAN 01 4:49 PM POLK - CLERK OF DISTRICT COURT

JUL 07 2014

IOWA BOARD OF PHARMACY IOWA BOARD OF PHARMACY

MARIJUANA SCHEDULING) PETITION FOR
) AGENCY ACTION

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) (2014).

- 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 (2014).

Since the year 1996, twenty-two (22) states have enacted laws accepting the medical use of marijuana in treatment¹. In the year 2014, ten

¹ 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–

(10) additional states, including the state of Iowa, enacted laws accepting the medical use of marijuana extracts². Marijuana has been accepted for medical use in treatment in the United States since 1996. No state has repealed a law accepting the medical use of marijuana in treatment. As the U.S. Drug Enforcement Administration's Chief Administrative Law Judge, Francis L. Young, held in 1988, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF ADMINISTRATIVE LAW JUDGE, DEA Docket No. 86-22, Sept. 6, 1988, pp. 58-59.

In the year 2010, this board conducted a thorough analysis of the eight (8) factors listed in Iowa Code § 124.201(1)(a)-(h), and found that marijuana should be removed from Schedule I, Iowa Code § 124.204(4)(m), and made a recommendation to the Iowa legislature that marijuana should be removed from Schedule I.

In the year 2011, the lowa legislature did not remove marijuana from Schedule I; neither did the legislature remove the duty this board has to recommend changes to the schedules of controlled substances.

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). ² 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); North Carolina, House Bill 1220, Signed by Gov. Pat McCrory (July 3, 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).

In the year 2012, the lowa legislature did not remove marijuana from Schedule I; neither did the legislature remove the duty this board has to recommend changes to the schedules of controlled substances.

In the year 2013, the lowa legislature did not remove marijuana from Schedule I; neither did the legislature remove the duty this board has to recommend changes to the schedules of controlled substances.

In the year 2014, the lowa legislature did not remove marijuana from Schedule I; neither did the legislature remove the duty this board has to recommend changes to the schedules of controlled substances.

In sum, this board still has a statutory duty to recommend that marijuana be removed from Schedule I until such time as: (1) this board finds that marijuana has no accepted medical use in treatment in the United States and is unsafe for use in treatment under medical supervision; or (2) the lowa legislature removes the duty this board has to recommend changes to the schedules of controlled substances.

The board has not conducted any analysis of the eight (8) factors listed in Iowa Code § 124.201(1)(a)-(h) as they relate to the medical use of marijuana since 2010. Therefore, the board has no basis on which to reverse its previous finding that marijuana should be removed from Schedule I. It is unreasonable, as well as unlawful, for this board to now refuse to recommend the removal of marijuana from Schedule I. 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 sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203").

This board has a continuing duty to notify the legislature that the condition for including marijuana in Schedule I is no longer true for marijuana. Marijuana no longer meets that statutory condition of having no accepted medical use in treatment in the United States, by any analysis, legal or scientific.

The board is not constrained to considering only the eight (8) factors in lowa Code 124.201(1)(a)-(h). lowa law says the board must "consider"

the eight (8) factors, but these are by no means the only factors the board must consider. None of the eight (8) factors are determinative, either individually, or in combination, as to whether a substance has or does not have accepted medical use in treatment in the United States.

The lowa legislature did not say marijuana must have accepted medical use in treatment in the state of lowa. The lowa legislature's choice of the term "in the United States" was not just some mere accident. This board cannot interpret the language of lowa Code §§ 124.203(1)(b), 124.205(1)(b), 124.207(1)(b), 124.209(1)(b), and 124.211(1)(b), to mean "accepted medical use in treatment in the state of lowa" when it was clearly not the intent of the lowa legislature in enacting the lowa Uniform Controlled Substances Act to determine whether the state of lowa accepts marijuana's medical use in treatment. The intent of the act is to make lowa's law uniform with the other states that have enacted the uniform act. lowa Code § 124.601 (2014). And, the intent of the Uniform Controlled Substances Act is to make it uniform with the federal Controlled Substances Act. Uniform Controlled Substances Act (1994), Prefatory Note

(http://www.uniformlaws.org/shared/docs/controlled%20substances/UCSA_final%20_94%20with%2095amends.pdf).

A federal court has interpreted the meaning of "accepted medical use in treatment in the United States" in <u>Grinspoon v. DEA</u>, 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.

If the board thinks marijuana has "medical efficacy," then so be it. However, marijuana clearly had no legally accepted medical use in treatment in Iowa in 2010 when the board recommended removing marijuana from Schedule I, Iowa Code § 124.204(4)(m), so marijuana

clearly must have had some accepted medical use in treatment somewhere else in the United States when the board made that recommendation.

This board must accept its statutory duty to notify the lowa legislature that marijuana can no longer be legally classified as a Schedule I controlled substance here in lowa, either as a matter of law or as a matter of science. The current classification of marijuana in lowa is unlawful, regardless of any scientific analysis simply because of the statutory condition that marijuana must have no accepted medical use in treatment anywhere in the United States to remain lawfully classified in lowa Schedule I. If the lowa legislature no longer wants to hear the advice of the board, it can amend the statute to remove that duty from the board.

Because this matter is of great importance to the public, the board cannot withhold its advice from the lowa legislature and must recommend that marijuana be removed from Iowa Schedule I. 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:

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.

lowa law does not give the board the option of doing nothing unless the facts have changed. The board has not found any evidence that marijuana should be included in lowa Schedule I. lowa Code § 124.203(2) (2014), clearly states the board must either: (1) "recommend that the general assembly place the substance in a different schedule" or, (2) recommend that the general assembly "remove the substance from the list of controlled substances."

Compliance with the law here in Iowa is not optional. Where the legislature has specifically required the advice of the board on the question of marijuana's accepted medical use in treatment in the United States, the board cannot withhold that advice. The executive branch has a clear duty to faithfully execute the laws the legislature enacts.

Respectfully Submitted:

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

Exhibit #1

State of Johna

Board of Pharmacy

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

BOARD MEMBERS

SHARON K. MEYER, Pharm. D. Urbandale

EDWARD L. MAIER, R. Ph., Mapleton Chairperson

LADONNA GRATIAS

LLOYD K. JESSEN, R. Ph., JD., West Des Moines Executive Director

EDWARD J. McKENNA, R. Ph. Storm Lake

MINUTES

January 5-6, 2015

The Iowa Board of Pharmacy met on January 5-6, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa. Vice-Chair Miller called the meeting to order at 1:00 p.m.

MEMBERS PRESENT

BOARD MEMBERS

SUSAN M. FREY, R. Ph.

JAMES MILLER, R. Ph.

JUDITH M. TRUMPY

Villisca

Dubuque

Ames

Edward L. Maier, Chairperson (joined at 2:15 p.m. on January 5) James Miller, Vice-Chair Susan M. Frey LaDonna Gratias Edward J. McKenna Sharon K. Meyer

MEMBERS ABSENT

Judith M. Trumpy

SPEAKERS

Heather Rickertsen, Mercy Family Pharmacy Josh Feldman, Mercy Family Pharmacy Megan Myers, Iowa Pharmacy Association Carl Olsen, Des Moines

STAFF PRESENT

Lloyd Jessen, Executive Director Meghan Gavin, Esq., Assistant Attorney General Laura Steffensmeier, Esq., Assistant Attorney General Therese Witkowski, Executive Officer Debbie Jorgenson, Administrative Assistant Becky Hall, Secretary

Compliance Officers Present:

Andrew Funk Curt Gerhold Mark Mather Sue Mears Jean Rhodes Jennifer Tiffany Jennifer O'Toole Jim Wolfe

I. Minutes.

The Minutes of the November 14, 2014, teleconference meeting; the November 18-19, 2014, meeting; and the December 10, 2014, teleconference meeting were read.

Page 2 of 10

January 5-6, 2015

Motion (Gratias/Meyer) to approve the minutes of the November 14, 2014, teleconference meeting. Passed: 5-0-0-2. Absent: Maier, Trumpy.

Motion (Gratias/McKenna) to approve the minutes of the November 18-19, 2014, meeting. Passed: 5-0-0-2. Absent: Maier; Trumpy.

Motion (McKenna/Meyer) to approve the minutes of the December 10, 2014, teleconference meeting. Passed: 4-1-0-2. Abstain: Frey; Absent: Maier, Trumpy.

II. Requests.

A. Request for Termination of Probation – Bill Poulos, Pharmacist License No. 20076, Dodge City, Kansas.

Motion (Frey/McKenna) to table request. Passed: 5-0-0-2. Absent: Maier, Trumpy.

Motion (Miller/Frey) to approve request for termination of probation. Passed: 6-0-0-1. Absent: Trumpy.

B. Request for Waiver – 657 I.A.C. 8.34 Collaborative Drug Therapy Management – Heather Rickertsen, Pharmacist License No. 20196, Delmar.

Motion (Frey/Meyer) to table the request for waiver pending additional information and follow-up with the Board of Medicine and Board of Nursing. Passed: 4-0-1-2. Abstain: Miller; Absent: Maier, Trumpy.

C. 2015 Pharmacy Summit Invitation – University of Iowa College of Pharmacy.

The University of Iowa College of Pharmacy will be hosting an Iowa Pharmacy Technician Education Summit on February 5, 2015, in Des Moines.

D. Recommendations Regarding Licensure Preferences for Military Spouses.

Motion (Frey/McKenna) to send recommendation to the Legislature to include Military Spouses. Passed: 5-0-0-2. Absent: Maier, Trumpy.

E. Petition to Request Reclassification of Marijuana – Carl Olsen, Des Moines.

Motion (Miller/Frey) to deny the petition. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order Denying Petition is attached as Addendum A.

Motion (Frey/Gratias) to recommend to the Legislature that Cannabidiol be classified as a Schedule II substance in the Controlled Substances Act (CSA). Passed: 6-0-0-1. Absent: Trumpy. A copy is attached as Addendum B.

Motion (Frey/Gratias) to recommend to the Legislature that they remove the phrase "pursuant to rules of the Board," from Schedule I exemption for medical marijuana because the Board does not have the authority to establish such a program and I further recommend that the same

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phrase be removed from Schedule II regarding medical marijuana for the same reason. Passed: 6-0-0-1. Absent: Trumpy. Addendum B addresses this motion.

III. Reports.

Executive Director's Report.

A. Financial.

FY15 as of 11/30/14 ((41.67% of FY completed)

Revenue Anticipated: \$3,833,933

Revenue Y-T-D \$ 1,586,494 (59%)

Carry-over from FY14 \$ 1,504,637

FY15 Fee Receipts \$ 771,538

Budget Allocation \$ 3,833,933

Obligations Y-T-D \$ 1,275,116 (33.3%)

Cash Fund Balance \$1,365,568

(\$ 850,000 reserved for database)

Fines/Civil Penalties Collected \$ 32,250

B. Meetings and Travel.

- 1. A public hearing on proposed administrative rules will be held on January, 15, 2015, at the Board office in Des Moines.
- 2. The next Rules Committee Meeting is scheduled for January 27, 2015, at the Board office in Des Moines.
- 3. An Administrative Hearing for PCM Venture, LLC, Sandy, Utah, is scheduled for January 28-29, 2015, at the Board office in Des Moines.
- 4. The IPA Legislative Day will be held on January 29, 2015, in Des Moines.
- 5. An Iowa Pharmacy Technician Education Summit will be held on February 5, 2015, at the Pappajohn Education Center in Des Moines. The summit is being hosted by the University of Iowa College of Pharmacy. The Iowa Board of Pharmacy will present information on pharmacy technician demographics in Iowa.
- 6. An Iowa Prescription Monitoring Program (PMP) Conference will be held on February 10, 2015, at Camp Dodge in Johnston. The conference is being hosted by the Iowa Board of Pharmacy, the Iowa PMP Advisory Council, and the Governor's Office of Drug Control Policy.
- 7. The 2015 Midwest Pharmacy Expo will be held in Des Moines, on February 13-15, 2015. The Iowa Board of Pharmacy will provide a pharmacy law presentation on February 15, 2015.

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- 8. The March Board Meeting is scheduled for March 9-11, 2015, at the Board office in Des Moines. The meeting will begin at 1:00 p.m. on March 9.
- 9. The April Board Meeting is scheduled for April 28-29, 2015, at the Board office in Des Moines. A retirement dinner for Susan Frey will be held on the evening of April 28.
- C. Prescription Drug Abuse: 2013- Strategies to Stop the Epidemic Trust for America's Health. Informational item.
- D. Iowa Electronic Pseudoephedrine Tracking System Annual Report (National Precursor Log Exchange NPLEx) Office of Drug Control Policy.

The Iowa Electronic Pseudoephedrine Tracking System Annual Report was provided for review.

E. Carl Olsen vs. Iowa Board of Pharmacy – Ruling on Petition for Judicial Review.

Meghan Gavin advised the Board that this matter has now been appealed to the Iowa Supreme Court. She further indicated that a decision may be issued by the Iowa Court of Appeals as early as sometime in the Fall of 2015. A copy of Ruling on Petition for Judicial Review is attached as Addendum C.

F. Surescripts Second Update Regarding Industry Progress in Implementing Electronic Prescribing for Controlled Substances (EPCS).

Discussion was held regarding prescribers and pharmacies being in full compliance with the Drug Enforcement Administration's (DEA) interim final rule (IFR) allowing electronic prescribing for controlled substances (EPCS) and that all application vendors connecting to the Surescripts network have met all the applicable DEA EPCS IFR requirements, ensuring that EPCS communications on Surescripts' network are legal.

G. Pharmacy Opening and Closing Statistics.

Opening and closing statistics for Iowa Pharmacies were provided for review. In future reports, the Board requested geographical information regarding as to where the changes are occurring.

$$2012 \text{ New} = 43 / \text{Closed} = 44$$

$$2013 \text{ New} = 43 / \text{Closed} = 45$$

$$2014 \text{ New} = 24 / \text{Closed} = 40$$

H. Patient Safety & Medication Error Prevention for Pharmacy.

The Oregon State University College of Pharmacy recently released their Patient Safety & Medication Error Prevention for Pharmacy Course. The course provides pharmacists the tools

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to identify problems, reduce risks, and improve communications, resulting in improved patient safety within the pharmacy environment.

- List of Those Indicted in NECC Case John R. Ellement, Boston Globe.
 Informational item.
- J. New Practice Model Interim Report Megan Myers, Iowa Pharmacy Association.
 The Iowa Pharmacy Association and Drake University College of Pharmacy provided their Quarterly New Practice Model Report for review.

IV. Legislation.

A. Non-Resident Pharmacy Legislation Language: Karen Sisson, Walgreen Co., and Jeff Lindoo, Thrifty White Pharmacies.

Informational item.

B. Public Comment on Proposed Legislation.

Informational item.

- V. Licensure/Registration.
 - A. Iowa Wholesale Drug License Application.

Motion (Frey/Miller) to approve renewal application and have compliance officer follow-up with the parent company in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

- 1. AR Scientific Inc., Wholesale Drug License No. 6310 of Philadelphia, Pennsylvania.
- Mutual Pharmaceutical Company Inc., Wholesale Drug License No. 7480 of Philadelphia, Pennsylvania.
- 3. Mutual Pharmaceutical Company Inc., Wholesale Drug License No 7479 of Philadelphia, Pennsylvania.
- B. Preliminary Notice of Intent to Deny License Sun Pharmaceutical Industries, Inc., Cranbury, New Jersey.

Motion (Miller/Gratias) to approve Preliminary Notice of Intent to Deny License. Passed: 6-0-0-1. Absent: Trumpy. A copy is attached as Addendum D.

C. Preliminary Notice of Intent to Deny Registration.

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Motion (Miller/McKenna) to approve Preliminary Notice of Intent to Deny Registration in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

- 1. Michelle Heidebrink, of Oskaloosa. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum E.
- 2. Rhonda Macy of Des Moines. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum F.
- 3. Stephanie Wadell of Orange City. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum G.
- D. Pharmacy Support Person Application Shaunetta L. McNeil, Iowa City.
 Motion (Miller/McKenna) to approve Pharmacy Support Person Application. Passed: 4-1-0-1. No: Frey; Absent: Trumpy.
- E. Zachary Monono Licensure Transfer Candidate, Omaha, Nebraska.

 Motion (Miller/McKenna) to approve Application for Transfer of Pharmacist License to the state of Iowa. Passed: 6-0-0-1. Absent: Trumpy.
- VI. Complaints Against Non-Licensees.
 - A. 2014-193 Wellmark Blue Cross Blue Shield of Iowa.

 Motion (Frey/Miller) to close with no action. Passed: 6-0-0-1. Absent: Trumpy.

VII. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; and 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Frey) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

VIII. Administrative Hearing.

A. Robert Osborn, Pharmacist License No. 19079 of Rock Island, Illinois.

On November 19, 2014, the Iowa Board of Pharmacy found probable cause to file Notice of Hearing and Statement of Charges against the above-named individual.

Margaret LaMarche, Administrative Law Judge for the State, presided. Assistant Attorney General Meghan Gavin represented the Board. Robert Osborn appeared without counsel.

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The hearing was conducted in the presence of the Board. The hearing was closed to the public.

The Board heard testimony of witnesses and examined exhibits.

VIX. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Miller) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (Gratias/Frey) to direct Administrative Law Judge LaMarche to draft the decision of the Board in the Osborn case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

X. Closed Session.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential; and 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (Frey/McKenna) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

In open session the following actions were taken.

A. Settlement Agreement and Final Order.

Motion (Miller/Frey) to approve the Settlement Agreement and Final Order in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

- 1. Matthew Sherrow, Pharmacist License No. 18612 of Springfield, Illinois. A copy of the Settlement Agreement and Final Order is attached as Addendum H.
- 2. James Kaufman, Pharmacist License No. 18228 of Sioux City. A copy of the Settlement Agreement and Final Order is attached as Addendum I.
- 3. OK Compounding LLC, Nonresident Pharmacy License No. 4204 of Skiatook, Oklahoma. A copy of the Settlement Agreement and Final Order is attached as Addendum J.

B. Combined Statement of Charges, Settlement Agreement, and Final Order.

Motion (Miller/McKenna) to approve the Combined Statement of Charges, Settlement Agreement, and Final Order in the case of Richard Upton, Pharmacist License No. 19779 of

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Sidney. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum K.

C. Combined Notice of Hearing and Statement of Charges.

Motion (Frey/McKenna) to approve Notice of Hearing and Statement of Charges in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

- 1. Amanda Knouse, Pharmacy Technician Registration No. 20304 of Des Moines. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum L.
- 2. Stacy Jahlas, Pharmacy Technician Registration No. 14928 of Belle Plaine. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum M.
- 3. Stephen Scott, Pharmacist License No. 18067 of Tipton. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum N.

D. Order to Show Cause.

Motion (Miller/Frey) to approve Order to Show Cause in the following cases. Passed: 6-0-0-1. Absent: Trumpy.

- 1. Paula Curran, CSA Registration No. 5201077 of Burlington. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order to Show Cause is attached as Addendum O.
- 2. Timothy Smith, CSA Registration No. 1709957 of Marshalltown. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Order to Show Cause is attached as Addendum P.

E. Confidential Order for Evaluation.

Motion (Miller/Meyer) to approve Confidential Order for Evaluation for C.S. and D.H. Passed: 6-0-0-1. Absent: Trumpy.

F. Draft Statement of Charges.

Motion (Miller/McKenna) to draft Statement of Charges against the stated individuals in the following complaints: pharmacy and pharmacist in charge in 2014-50; pharmacy in 2014-100; technician in 2014-137; technician in 2014-169; technician in 2014-173; pharmacy in 2014-182; technician in 2014-189; and pharmacy and pharmacist in charge in 2014-204. Passed: 6-0-0-1. Absent: Trumpy.

G. Administrative Warning.

Motion (Miller/McKenna) to send an Administrative Warning to the pharmacy in 2014-186. Passed: 6-0-0-1. Absent: Trumpy.

H. Letter of Education.

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Motion (Miller/McKenna) to send a Letter of Education to the CSA Registrant in 2014-191. Passed: 6-0-0-1. Absent: Trumpy.

I. Close With No Action.

Motion (Miller/McKenna) to close with no further action the investigative file in complaint numbers: 2013-146, 2013-3435, 2013-3591, 2013-4095, 2013-9992, 2014-144, 2014-166, 2014-167, 2014-170, 2014-174, 2014-178, 2014-179, 2014-183, 2014-184, 2014-185, 2014-187, 2014-190, 2014-192, 2014-194, 2014-195, 2014-196, 2014-197, 2014-199, and 2014-206. Passed: 6-0-0-1. Absent: Trumpy.

J. Close and Refer to Another Agency.

Motion (Frey/Miller) to close 2014-16 and refer to another agency. Passed: 6-0-0-1. Absent: Trumpy.

K. Release Request from Consultant Requirement.

Motion (Miller/McKenna) to release Randy Moad from consultant requirement. Passed: 6-0-0-1. Absent: Trumpy.

L. Draft Order to Show Cause.

Motion (Miller/McKenna) to draft Order to Show Cause against the CSA registrant in 2014-171. Passed: 6-0-0-1. Absent: Trumpy.

XI. Closed Session.

Assistant Attorney Generals Meghan Gavin and Laura Steffensmeier left the room.

Motion (Frey/McKenna) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

Motion (McKenna/Gratias) to go into open session. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Miller; No: None; Abstain: None; Absent: Trumpy. Passed: 6-0-0-1.

In open session the following actions were taken.

A. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Miller/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of James Nielcen, Pharmacist License No. 14579 of Waterloo. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Q.

B. Findings of Fact, Conclusions of Law, Decision and Order.

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Motion (Frey/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of Matthew Biggerstaff, CSA Registration No. 1306092 of Ankeny. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum R.

C. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Miller/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of Medicap Pharmacy, CSA Registration No. 1106533 of Oskaloosa. Passed: 6-0-0-1. Absent: Trumpy. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum S.

Meeting adjourned at 1:15 p.m. on January 6, 2015.

Becky Hall

Recording Secretary

Lloyd K. Jessen

Executive Director

Edward L. Maigr

Board Chair

APPROVED THIS 10 DAY OF March, 2015

ADDENDUM A

ORDER DENYING PETITION FOR AGENCY ACTION TO RESCHEDULE MARIJUANA

JANUARY 5, 2015

BEFORE THE IOWA BOARD OF PHARMACY

PETITION FOR AGENCY ACTION) OR TO RESCHEDULE MARIJUANA)	RDER DENYING PETITION
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PROCEDURAL BACKGROUND

On July 7, 2014, Carl Olsen filed a Petition for Agency Action requesting that the Iowa Board of Pharmacy ("Board") recommend to the Iowa General Assembly the removal of marijuana from Schedule I. The Petition does not request or suggest what schedule marijuana should be placed in, only that it be removed from Schedule I.

The Board first considered the Petition at its August 2014 meeting. The Board tabled consideration of the Petition at that time and appointed a committee to further study the request. The committee met on November 17, 2014, and invited public comment on the Petition. Several government agencies, advocacy groups, and private citizens provided both written and oral comments at the November meeting.

On November 19, 2014, the Board met in open session to deliberate the Petition. At that time, the Board voted to table the Petition until the January 2015 meeting. On January 5, 2015, the Board met in open session to deliberate and render a decision on the Petition. The Board voted to deny the Petition.

FACTUAL AND LEGAL BACKGROUND

Marijuana is currently listed in Schedule I under state law. See Iowa Code section 124.204(4)"m" (stating "Marijuana, except as otherwise provided by rules of the board for medicinal purposes."). Marijuana is also currently listed in Schedule II under state law. See Iowa Code section 124.206(7)"a" (stating "Marijuana when used for medicinal purposes pursuant to rules of the board."). In Iowa, marijuana is defined by Iowa law to include

all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

Iowa Code section 124.101(19). Marijuana is currently listed in Schedule I under federal law. See 21 CFR § 1308.11(d)"23".

The Controlled Substances Act places some responsibilities on the Board as it relates to the scheduling of substances. In particular, Iowa Code section 124.203(2) provides:

- 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 medicinal 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.

In 2014, the Iowa General Assembly passed the Medical Cannabidiol Act. See Iowa Code chapter 124D. The Act permits the use of cannabidiol by patients suffering from intractable epilepsy. The Iowa General Assembly granted the authority to administer the provisions of the Act to the Iowa Department of Public Health.

ANALYSIS

Typically, the Board makes recommendations regarding the scheduling of substances to the Iowa General Assembly when the federal Drug Enforcement Agency (1) adds a new substance to a schedule, (2) moves a scheduled substance to a different schedule, or (3) removes a substance from scheduling. Essentially, the Board notifies the Iowa General Assembly of changes in the federal scheduling of controlled substances and recommends changes in the schedules under state law to be in accordance with federal scheduling.

Despite the passage of laws regarding marijuana in several states, it remains a Schedule I controlled substance under federal law. As a matter of policy, the federal government has allowed states, through non-enforcement of federal law, to serve as laboratories of democracy by experimenting with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government may change its policy at any time, thereby nullifying any laws or programs related to marijuana enacted by any state. The Board is hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law.

Regardless of federal law, Iowa Code section 124.203 requires that the Board recommend the removal of a substance from Schedule I if the Board finds that either (1) the substance does not have a high potential for abuse, or (2) the substance has some accepted medicinal use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, it also believes that the passage of the Medical Cannabidiol Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana, as it is defined by Iowa Code section 124.101(19). As a result of the Medical Cannabidiol Act, Schedule I is inappropriate for cannabidiol.

The Board is not inclined to make the broader recommendation requested by the Petition that marijuana be removed from Schedule I. Many substances can be derived from marijuana—some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to schedule each derivate after an individualized analysis. The Board points out that separately scheduling a substance that is a derivative of marijuana, such as cannabidiol, should be accompanied by an amendment to the definition of marijuana in Iowa Code section

124.101(19), explicitly excluding the derivative from the definition of marijuana, in order to avoid conflict.

The Board believes it has an obligation under the Controlled Substances Act to recommend the proper schedule for cannabidiol. Iowa Code section 124.205 establishes the criteria for including a substance in Schedule II. The criteria are: (1) the substance has a high potential for abuse, (2) the substance currently has accepted medical use with severe restrictions in the United States, and (3) abuse of the substance may lead to severe psychic or physical dependence. The Board feels that cannabidiol meets the criteria for Schedule II, and thus recommends to the Iowa General Assembly that cannabidiol, as defined by Iowa Code section 124D.2(1), be placed in Schedule II.

The Board believes that, if the Iowa General Assembly chooses to expand the Medical Cannabidiol Act or implement a medical marijuana program, a coalition of stakeholders should be established to further study the potential medicinal uses of marijuana or its derivatives in Iowa. 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, and patients. It is incumbent that the establishment of a program involving marijuana or its derivatives for medicinal use includes the perspectives of all of these groups. No single entity can determine what conditions marijuana or its derivatives could be used to treat, what safety measures are needed to prevent unlawful use, and the myriad of other concerns raised by a program involving marijuana or its derivatives for medicinal use in Iowa. The Board is particularly concerned about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The dual scheduling of marijuana under state law is a holdover from experimental marijuana research programs authorized more than thirty years ago. The dual scheduling has understandably led to confusion as to the Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the Iowa General Assembly for the Board to unilaterally establish and implement a medical marijuana program in Iowa. This is evidenced by the fact that the Department of Public Health was vested with the authority to implement the Medical Cannabidiol Act. To avoid confusion, the Board recommends that the phrase "except as otherwise provided by rules of the board for medicinal purposes" be deleted from Iowa Code section 124.204(4)"m". In addition, the Board recommends that either the entirety of Iowa Code section 124.206(7)"a" be deleted, or, at a minimum, the phrase "pursuant to rules of the board" be deleted from Iowa Code section 124.206(7)"a".

ORDER

For the reasons stated herein, the Petition for Agency Action to Reschedule Marijuana is **DENIED**.

EDWARD MAIER

Chairperson, Iowa Board of Pharmacy

ADDENDUM B

RECOMMENDATION TO THE IOWA GENERAL ASSEMBLY RE: CANNABIDIOL AND MARIJUANA

JANUARY 5, 2015

BEFORE THE IOWA BOARD OF PHARMACY

)	
RECOMMENDATION TO THE)	RE: CANNABIDIOL AND
IOWA GENERAL ASSEMBLY)	MARIJUANA
)	

FACTUAL AND LEGAL BACKGROUND

Marijuana is currently listed in Schedule I under state law. *See* Iowa Code section 124.204(4)"m" (stating "Marijuana, except as otherwise provided by rules of the board for medicinal purposes."). Marijuana is also currently listed in Schedule II under state law. *See* Iowa Code section 124.206(7)"a" (stating "Marijuana when used for medicinal purposes pursuant to rules of the board."). In Iowa, marijuana is defined by Iowa law to include

all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

Iowa Code section 124.101(19). Marijuana is currently listed in Schedule I under federal law. See 21 CFR § 1308.11(d)"23".

The Controlled Substances Act places some responsibilities on the Board as it relates to the scheduling of substances. Iowa Code section 124.201 states, in part, "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 addition, Iowa Code section 124.203(2) provides:

- 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 medicinal 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.

In 2014, the Iowa General Assembly passed the Medical Cannabidiol Act. *See* Iowa Code chapter 124D. The Act permits the use of cannabidiol by patients suffering from intractable epilepsy. The Iowa General Assembly granted the authority to administer the provisions of the Act to the Iowa Department of Public Health.

RECOMMENDATION

Typically, the Board makes recommendations regarding the scheduling of substances to the Iowa General Assembly when the federal Drug Enforcement Agency (1) adds a new substance to a schedule, (2) moves a scheduled substance to a different schedule, or (3) removes a substance from scheduling. Essentially, the Board notifies the Iowa General Assembly of changes in the federal scheduling of controlled substances and recommends changes in the schedules under state law to be in accordance with federal scheduling.

Despite the passage of laws regarding marijuana in several states, it remains a Schedule I controlled substance under federal law. As a matter of policy, the federal government has allowed states, through non-enforcement of federal law, to serve as laboratories of democracy by experimenting with medical marijuana programs. This, however, is a matter of policy and not of law. The federal government may change its policy at any time, thereby nullifying any laws or programs related to marijuana enacted by any state. The Board is hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law.

Regardless of federal law, Iowa Code section 124.203 requires that the Board recommend the removal of a substance from Schedule I if the Board finds that either (1) the substance does

not have a high potential for abuse, or (2) the substance has some accepted medicinal use in treatment in the United States. While the Board believes that marijuana has a high potential for abuse, it also believes that the passage of the Medical Cannabidiol Act is an affirmative recognition by the Iowa General Assembly that there is some medical use for marijuana, as it is defined by Iowa Code section 124.101(19). As a result of the Medical Cannabidiol Act, Schedule I is inappropriate for cannabidiol.

The Board is not inclined to make the broader recommendation that marijuana be removed from Schedule I. Many substances can be derived from marijuana—some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to schedule each derivate after an individualized analysis. The Board points out that separately scheduling a substance that is a derivative of marijuana, such as cannabidiol, should be accompanied by an amendment to the definition of marijuana in Iowa Code section 124.101(19), explicitly excluding the derivative from the definition of marijuana, in order to avoid conflict.

The Board believes it has an obligation under the Controlled Substances Act to recommend the proper schedule for cannabidiol. Iowa Code section 124.205 establishes the criteria for including a substance in Schedule II. The criteria are: (1) the substance has a high potential for abuse, (2) the substance currently has accepted medical use with severe restrictions in the United States, and (3) abuse of the substance may lead to severe psychic or physical dependence. The Board feels that cannabidiol meets the criteria for Schedule II, and thus recommends to the Iowa General Assembly that cannabidiol, as defined by Iowa Code section 124D.2(1), be placed in Schedule II.

The Board believes that, if the Iowa General Assembly chooses to expand the Medical Cannabidiol Act or implement a medical marijuana program, a coalition of stakeholders should

be established to further study the potential medicinal uses of marijuana or its derivatives in Iowa. 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, and patients. It is incumbent that the establishment of a program involving marijuana or its derivatives for medicinal use includes the perspectives of all of these groups. No single entity can determine what conditions marijuana or its derivatives could be used to treat, what safety measures are needed to prevent unlawful use, and the myriad of other concerns raised by a program involving marijuana or its derivatives for medicinal use in Iowa. The Board is particularly concerned about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment.

The dual scheduling of marijuana under state law is a holdover from experimental marijuana research programs authorized more than thirty years ago. The dual scheduling has understandably led to confusion as to the Board's authority to promulgate rules authorizing the legal use of medical marijuana. The Board does not believe it was the intention of the Iowa General Assembly for the Board to unilaterally establish and implement a medical marijuana program in Iowa. This is evidenced by the fact that the Department of Public Health was vested with the authority to implement the Medical Cannabidiol Act. To avoid confusion, the Board recommends that the phrase "except as otherwise provided by rules of the board for medicinal purposes" be deleted from Iowa Code section 124.204(4)"m". In addition, the Board recommends that either the entirety of Iowa Code section 124.206(7)"a" be deleted, or, at a minimum, the phrase "pursuant to rules of the board" be deleted from Iowa Code section 124.204(4)"u" and 124.207 should also be deleted to ensure consistency.

Attached are proposed legislative changes reflecting the Board's recommendations described herein.

EDWARD MAIER

Chairperson, Iowa Board of Pharmacy

Proposed Legislative Changes relating to Controlled Substances January 14, 2015

An Act making changes to controlled substances schedules and making penalties applicable.

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

Section 1. Section 124.101, subsection 19, Iowa Code 2015, is amended to read as follows:

19. "Marijuana" means all parts of the plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination. It does not include cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 2. Section 124.204, subsection 4, paragraph "m," Iowa Code 2015, is amended to read as follows:

m. Marijuana, except as otherwise provided by rules of the board for medicinal purposes.

Section 3. Section 124.204, subsection 4, paragraph "u," Iowa Code 2015, is amended to read as follows:

- u. Tetrahydrocannabinols, except as otherwise provided by rules of the board for medicinal purposes, meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (Cannabis plant) as well as synthetic equivalents of the substances contained in the Cannabis plant, or in the resinous extractives of such plant, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
- (1) 1 cis or trans tetrahydrocannabinol, and their optical isomers.
- (2) 6 cis or trans tetrahydrocannabinol, and their optical isomers.
- (3) 3,4 cis or trans tetrahydrocannabinol, and their optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)
- **Section 4.** Section 124.204, subsection 7, Iowa Code 2015, is deleted in its entirety as follows:
 - 7. Exclusions. This section does not apply to marijuana, tetrahydrocannabinols or chemical derivatives of tetrahydrocannabinol when utilized for medicinal purposes pursuant to rules of the board.
- **Section 5.** Section 124.206, subsection 7, Iowa Code 2015, is amended by adding the following new paragraph:
 - NEW PARAGRAPH: xx. Cannabidiol, as defined in Iowa Code section 124D.2, subsection 1.

Section 6. Section 124.206, subsection 7, paragraph "a," Iowa Code 2015, is deleted in its entirety as follows:

a. Marijuana when used for medicinal purposes pursuant to rules of the board.

ADDENDUM C

RULING ON PETITION FOR JUDICIAL REVIEW

CARL OLSEN DES MOINES, IOWA

E-FILED 2014 DEC 10 10:43 AM POLK - CLERK OF DISTRICT COURT

IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

CARL OLSEN,

Petitioner,

VS.

IOWA BOARD OF PHARMACY,

Respondent

Case No.: CVCV047867

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.

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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.

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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.

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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.

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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).

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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

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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

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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

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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

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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.

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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

Exhibit #4

IOWA BOARD OF PHARMACY

MARIJUANA SCHEDULING) PE	TITION FOR
) RE	CONSIDERATION

INTRODUCTION

I would like to thank the board for its discussion on January 5, 2015, at the third hearing on my petition for marijuana scheduling. I also want to thank the subcommittee for the report it prepared for the second hearing on my petition on November 19, 2014. And, I would like to thank the committee for its decision to form the subcommittee to take a closer look during the first hearing on my petition on August 27, 2014.

In particular, I would also like to thank the board for the 4 public hearings it held on this issue in 2009.

I acknowledge this is an unusual request, and I appreciate the time the board has spent on it.

THE SCHEDULING PROCESS

The scheduling of controlled substances in Iowa is not a formal rule making process. See Iowa Code § 124.201 (2014). I would like the board to pay particular attention to the fact that, unlike federal scheduling which is a formal rule making procedure, Iowa law makes scheduling an informal procedure. Please compare the process in 21 U.S.C. § 811 (2014) with the Iowa version. Also, you will find that same difference between the uniform act and Iowa's version of it. Compare § 201 of the uniform act with Iowa's version in Iowa Code § 124.201 (2014).

http://www.uniformlawcommission.com/ http://www.uniformlaws.org/Act.aspx?title=Controlled Substances Act

This should explain why you are "struggling" and "wrestling" with this issue. See Iowa Code § 124.601 (2014) ("This chapter shall be so construed as to effectuate its general purpose to make uniform the law of

those states which enact it"); Iowa Code §124.602 (2014) ("This chapter may be cited as the 'Uniform Controlled Substances Act"). The Uniform Controlled Substances Act says scheduling should be a formal rule making process. Iowa's scheduling process is not uniform in this regard.

While I acknowledge this difference in Iowa law, the board still has a statutory duty to advise the legislature on the scheduling of controlled substances in Iowa. The eight factor analysis in Iowa Code § 124.201(1)(a)-(h), and the recommendation requirements in sections 201, 203, 205, 207, 209, and 211, make it clear that the legislature intended the board to give its expert advice to the legislature.

Finally, there is no requirement in Iowa that requires Iowa to adopt federal scheduling. See Iowa Code, § 124.201(4). A reasonable interpretation of this section is that Iowa will typically adopt federal scheduling, but there is no requirement that Iowa must do so. The section clearly gives the board the option not to follow federal scheduling. This is consistent with federalism. See *Gonzales v. Oregon*, 546 U.S. 243, 271 (2006) ("health and safety is 'primarily, and historically, a matter of local concern"").

Federal licensing requires compliance with state laws, and state licensing requires compliance with federal laws. So, any appearance of conflict between state and federal scheduling is resolved by the more restrictive of the two.

The question this board must face is, "When is it appropriate not to adopt federal scheduling?" The fact that thirty-four states and two federal jurisdictions (DC and Guam) have enacted medical marijuana laws over the past two decades is the evidence that state scheduling can and must be adjusted to reflect this change in circumstance. Marijuana is also the only substance in schedule 1 that had extensive medical use in the United States before the state and federal controlled substances acts were enacted. *James v. Costa Mesa*, 700 F.3d 394, 409 (9th Cir. 2012) (Berzon, J., dissenting). Marijuana does not belong in schedule 1.

And, finally, less than 30 days ago federal law was amended to prevent the enforcement of federal marijuana laws that conflict with state medical marijuana laws. Federal law now recognizes state medical marijuana laws. And, this new federal law specifically references lowa.

Consolidated and Further Continuing Appropriations Act, 2015 (H.R. 83, Congressional Session 2014-2015), signed into law by the President on December 16, 2014, Section 538.

I know this summary of the scheduling process does not address all of your concerns, but lowa law does allow you to recommend scheduling of marijuana that differs from federal scheduling. The next question, then, is whether you should recommend the rescheduling marijuana in lowa.

COMPOUNDS OR CHEMICALS

At the hearing on January 5, 2015, several members of the board brought up the issue of derivatives of marijuana, compounds of marijuana derivatives, and chemicals in the marijuana plant.

The point was made at the hearing that derivative products made from marijuana, Sativex (dronabinol and cannabidiol) and Epidiolex (cannabidiol), are in clinical trials intended to have them approved by the FDA as products in the United States. The point was also made at the hearing that we currently have Marinol (dronabinol) scheduled as a drug product in both the Iowa and federal schedules.

Also, the point was made at the hearing that cannabidiol is in federal schedule 1, and the board has now voted to recommend that lowa reclassify cannabidiol to schedule 2, in spite of the fact there are no federally approved products that contain cannabidiol. The board has affirmatively recognized that lowa is not required to adopt federal scheduling (see the section above).

However, at the hearing the board made a critical error in logic when comparing marijuana to opium. The argument was made by a member of the board that opium is in schedule 1 and the derivative made from it, morphine, is in schedule 2. The argument was then made that marijuana should be in the same schedule as opium. Opium is actually in schedule 2 and has always been in schedule 2. I am requesting that this board recommend the removal of marijuana from schedule 1 because marijuana has at least as much medical value as opium. The board said it wanted these two plants to be in the same schedule, but actually voted to put them in different schedules.

lowa law currently classifies naturally derived dronabinol in state schedule 3. Because we have naturally derived dronabinol in state schedule 3 and because the board just voted to recommend that lowa place naturally derived cannabidiol in state schedule 2 (because state law says it is medicine), marijuana currently has at least as much, if not more, medical value than opium here in the state of lowa. There are no currently approved drug products that contain either naturally derived dronabinol or naturally derived cannabidiol. Both of these substances are in federal schedule 1. Iowa is leading the way on these two substances which are not approved drug products and Iowa should be consistent by leading the way on the plant these two substances are made from.

CONCLUSION

The board should not reject the reclassification of marijuana because marijuana hasn't been approved by the FDA for use as a drug product. Plants in state and federal schedule 2 are not FDA approved drug products. Opium is not an FDA approved drug product. Plants such as opium only have medical use as source material for the products that are made from them. Under that same rationale, marijuana belongs in schedule 2 or lower here in Iowa. The principle drug made from opium, morphine, is in Iowa schedule 2, while the principle drug made from marijuana, dronabinol, is in Iowa schedule 3. Opium is in schedule 2 and morphine is in schedule 2, but only morphine is an FDA approved drug product. Marijuana should be reclassified, not for approval as a drug product, but solely because it is the source material for drug products in schedule 2 and 3 in Iowa. I submitted a statement from the American Academy of Neurology from December 17, 2014, explaining their rationale for recommending the rescheduling marijuana and I ask that you adopt their reasoning as your own. Please reconsider your decision not to recommend rescheduling of marijuana this year.

Respectfully Submitted:

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

Exhibit #3

State of Jowa

Board of Pharmacy

RiverPoint Business Park 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688 http://www.iowa.gov/ibpe

Telephone: (515) 281-5944 Facsimile: (515) 281-4609

BOARD MEMBERS SHARON K. MEYER, Pharm. D. Urbandale

LADONNA GRATIAS

EDWARD J. McKENNA, R. Ph. Storm Lake

BOARD MEMBERS SUSAN M. FREY, R. Ph. Villisca

JAMES MILLER, R. Ph. Dubuque

JUDITH M. TRUMPY

EDWARD L. MAIER, R. Ph., Mapleton Chairperson

LLOYD K. JESSEN, R. Ph., JD., West Des Moines Executive Director

MINUTES

March 9-11, 2015

The Iowa Board of Pharmacy met on March 9-11, 2015, in the conference room at 400 SW Eighth Street, Des Moines, Iowa.

MEMBERS PRESENT

Edward L. Maier, Chairperson James Miller, Vice-Chair Susan M. Frey LaDonna Gratias Edward J. McKenna Sharon K. Meyer

MEMBERS ABSENT

Judith M. Trumpy

SPEAKERS

Carl Olsen, Des Moines Connie Nogart, West Des Moines Sally Gaer, West Des Moines Kari Sckerl, Waterloo Ned Milenkovich, FLAVORx Chad Baker, FLAVORx Megan Myers, IPA Cheri Schmit, Medicap/GRX Holdings Anthony Pudlo, IPA Katy Brown, Telligen

STAFF PRESENT

Lloyd Jessen, Executive Director Meghan Gavin, Esq., Assistant Attorney General Laura Steffensmeier, Esq., Assistant Attorney General Therese Witkowski, Executive Officer Debbie Jorgenson, Administrative Assistant Becky Hall, Secretary Andrew Funk, Compliance Officer Curt Gerhold, Compliance Officer Mark Mather, Compliance Officer Sue Mears, Compliance Officer Jean Rhodes, Compliance Officer Jennifer Tiffany, Compliance Officer Jennifer O'Toole, Compliance Officer Jim Wolfe, Compliance Officer

At 1:00 p.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order on Monday, March 9, 2015.

March 9-11, 2015

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Approval of Open Session Minutes

The minutes of the January 5-6, 2015, meeting; the January 16, 2015, teleconference meeting; and the February 12, 2015, teleconference meeting were reviewed.

Motion by Susan Frey, seconded by LaDonna Gratias, to approve the open session minutes of the January 5-6, 2015, meeting as presented. Motion approved unanimously.

Motion by James Miller seconded by Edward McKenna, to approve the open session minutes of the January 16, 2015, teleconference meeting as presented. Motion approved unanimously.

Motion by Edward McKenna, seconded by LaDonna Gratias, to approve the open session minutes of the February 12, 2015, teleconference meeting as presented. Motion approved unanimously.

Requests

- Marijuana Scheduling Petition for Reconsideration Carl Olsen, Des Moines.
 Motion by James Miller, seconded by Susan Frey, to deny the Petition for Reconsideration. Motion approved unanimously.
- 2. Approval to Continue Participation in Amicare Pharmacy Anticoagulation Clinic as an Authorized Pharmacist Kari A. Sckerl, Iowa Pharmacist License No. 18670, Waterloo. Motion by James Miller, seconded by Sharon Meyer, to approve Kari Sckerl as a qualified pharmacist to participate in the collaborative practice agreement. Motion approved unanimously.
- 3. Authorization to Participate in Unity Point at Home Infusion Pharmacy's Vancomycin Collaborative Practice Agreement Patrick J. Walter.
 - Motion by Susan Frey, seconded by Edward McKenna, to approve the request. Motion approved unanimously.
- 4. Authorization to Participate in Unity Point at Home Infusion Pharmacy's Vancomycin Collaborative Practice Agreement Jill Swallow.
 - Motion by James Miller, seconded by Edward McKenna, to approve the request. Motion approved unanimously.
- 5. Authorization to Participate in Unity Point at Home Infusion Pharmacy's Vancomycin Collaborative Practice Agreement Melissa Wessels.
 - Motion by James Miller, seconded by Susan Frey, to approve the request. Motion approved unanimously.
- 6. Authorization to Participate in Unity Point at Home Infusion Pharmacy's Vancomycin Collaborative Practice Agreement Tracy McVey.
 - Motion by Susan Frey, seconded by James Miller, to approve the request. Motion approved unanimously.
- 7. Request for Waiver 657 I.A.C. Records HyVee Pharmacy Clinic #1504, Bloomfield.

 Motion by James Miller, seconded by Susan Frey to approve the request for two years with the condition Bloomfield Hy-Vee Pharmacy Clinic keep their records separate from the

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Ottumwa Pharmacy and the records are secured in a location that only the Bloomfield employees have access to. Motion approved unanimously.

- 8. Request for Waiver 657 I.A.C. 6.16 Records Hy-Vee Drugstore # 7057, Mount Pleasant. Motion by Susan Frey, seconded by James Miller, to deny the request for waiver due to the storage facility not meeting board criteria. Motion approved unanimously.
- 9. Request for Internship Credit Rania Abdelwahed, Cedar Rapids.

Motion by Susan Frey, seconded by LaDonna Gratias, to approve the request granting credit for 1,200 hours of internship in lieu of life experience requiring Ms. Abdelwahed to complete an additional 300 hours of internship. Motion approved unanimously.

Rules/Legislation

- Bill to Help Pharmacists Provide Medical Services to Older Americans in Under-served Areas The Honorable Charles Grassley Press Release.
 - Informational item.
- 2. Iowa Board of Medicine Seeks Legislation to Expedite Multiple-State Licensure. Informational item.
- 3. Comments on Pharmacy Compounding Rules Ned Milenkovich, Much Shelist, P.C., Illinois.
 - Ned Milenkovich and Chad Baker addressed the Board regarding the proposed changes to Chapter 20, "Pharmacy Compounding Practices," which would define compounding as including the flavoring of prescriptions, believing the proposed change would impact patient care and supports removing flavoring from the definition of compounding.
- 4. Adopted and Filed: Amends Chapter 3, "Pharmacy Technicians," Chapter 6, "General Pharmacy Practice," and Chapter 7, "Hospital Pharmacy Practice"; to rescind Chapter 13, "Sterile Compounding Practices"; and to rescind Chapter 20, "Pharmacy Compounding Practices," and adopt a new Chapter 20, "Compounding Practices," Iowa Administrative Code.
 - Motion by James Miller, seconded by Edward McKenna, to terminate current Notice of Intended Action based on comments and suggestions from the public and file a new proposed Notice of Intended Action. Motion approved unanimously. Copies are attached as Addendum A (Notice of Termination) and Addendum B (Notice of Intended Action.)
- 5. Adopted and Filed: Amends Chapter 8, "Universal Practice Standards."
 - Motion by Susan Frey, seconded by LaDonna Gratias, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum C.

Closed Session

At 2:22 p.m., motion by Susan Frey, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section § 21.5(1)(a) to review records required by state or federal law to be kept confidential.

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At 2:30 p.m., while still in closed session, Edward McKenna moved that the Board go into open session, seconded by James Miller. Motion approved unanimously.

In open session, the following action was taken:

Motion by Susan Frey, seconded by James Miller, to grant request modifying October 10, 2013, Board Order by extending the time requirement for an additional 18 months starting March 9, 2015, for Janet Rote McEvoy. Motion approved unanimously.

Rules/Legislation

- 1. Adopted and Filed: Amends Chapter 36, "Discipline."
 - Motion by Susan Frey, seconded by LaDonna Gratias, to approve for Adoption and Filing as amended. Motion passed by roll call vote. James Miller and Edward McKenna voted nay. A copy is attached as Addendum D.
- 2. Adopted and Filed: Amends Chapter 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 9, "Automated Medication Distribution Systems and Telepharmacy Services," Chapter 15, "Correctional Pharmacy Practice," Chapter 18, "Centralized Prescription Filling and Processing," Chapter 19, "Nonresident Pharmacy Practice, Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," and Chapter 23, "Long Term Care Pharmacy Practice."
 - Motion by Susan Frey, seconded by James Miller, to approve for Adoption and Filing. Motion approved unanimously. A copy is attached as Addendum E.
- 3. A Bill For an Act Creating the Medical Cannabis Act and Providing for Civil and Criminal Penalties and Fees.

Informational item.

Reports

Executive Director's Report.

- 1. Edward McKenna has been reappointed to a second term on the Board. Mr. McKenna's new term will be May 1, 2015, to April 30, 2018.
- 2. Jason Hansel of Bettendorf has been appointed to the Board effective May 1, 2015. Mr. Hansel will replace Susan Frey when Ms. Frey retires from the Board on April 30, 2015.
- 3. 50-Year Pharmacist List Iowa Pharmacists Licensed in 1965.

A list of 26 pharmacists was provided for review.

4. Financial.

FY15 as of 02/28/15 (66.67% of FY completed)

Revenue Anticipated:

\$ 3,833,933

Revenue Y-T-D

\$ 2,945,063 (77%)

Carry-over from FY14

\$ 1,504,637

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FY15 Fee Receipts \$ 1,440,426

Budget Allocation \$ 3,833,933

Obligations Y-T-D \$ 1,996,524 (52%)

Cash Fund Balance \$ 1,445,069

\$850,000 reserved for database

Fines/Civil Penalties Collected \$ 43,250

5. Meetings and Travel.

- A. The Rules Committee has a meeting with a committee from the Iowa Board of Podiatry on March 10, 2015, to continue discussion relating to the sale of diabetic shoes and related items by pharmacies.
- B. The Iowa Pharmacy Recovery Network (IPRN) will hold its Spring Meeting on April 20, 2015, from 3:00 to 5:00 pm in Iowa City.
- C. The April Board Meeting is scheduled for April 28-29, 2015, at the Board office in Des Moines.
- D. A retirement dinner for Susan Frey will be held on Tuesday evening, April 28, 2015, in Des Moines.
- E. The 111th Annual Meeting of the National Association of Boards of Pharmacy (NABP) will be held in New Orleans, Louisiana on May 16-19, 2015.
- F. The Iowa Pharmacy Association (IPA) Annual Meeting will be held in Coralville on June 11-13, 2015.
- G. The June Board Meeting is scheduled for June 23-24, 2015, at the Board office in Des Moines.
- H. The 78th Annual Meeting of District Five NABP/AACP will be held in Fargo, North Dakota on August 6-8, 2015.
- I. The September Board Meeting is scheduled for September 1-2, 2015, at the Board office in Des Moines.
- 6. Iowa Pharmacist Recovery Network (IPRN) Report.

The IPRN Report was submitted for review.

- NuCara Pharmacy #29, License No. 1450, Telepharmacy Quarterly Report.
 NuCara Pharmacy submitted their Telepharmacy Quarterly Report for review.
- Allen Hospital Tech-Check-Tech Program Quarterly Report.
 Allen Hospital submitted their Tech-Check-Tech Quarterly Report for review.
- Baum Harmon Mercy Hospital Quarterly Waiver Report.
 Baum Harmon Mercy Hospital submitted their Quarterly Waiver Report for review.
- 10. Hy-Vee Pharmacy Fulfillment Center's 2014 Fourth Quarterly Error Report.

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Hy-Vee Pharmacy Fulfillment Center submitted their Fourth Quarterly Error Report for review.

- 11. Phase One Third Quarterly Report- New Practice Model Megan Myers, Iowa Pharmacy Association.
 - Megan Myers provided the third Quarterly New Practice Model Report.
- 12. Job Licenses in Spotlight as Uber Rises New York Times (January 27, 2015 online.) Informational item.
- 13. Job Licensing Laws Need Thorough Review Des Moines Register (February 20, 2015 online.)
 - Informational item.
- 14. Iowa Prescription Monitoring Program (PMP) Conference February 10, 2015.
 - A list of findings and recommendations from PMP conference attendees was provided for review. Changes to the PMP may be accomplished in three ways: (1) internal or administrative program changes; (2) rule revision to 657 Iowa Administrative Code Chapter 37; or (3) legislative changes to Iowa Code §124.551. A majority of attendees supported providing access to the PMP via "auto registration" for prescribers and pharmacists administratively by the Board and encouraged the Board to explore the possibility of providing that service. Discussion was held regarding auto registration; adding personnel to the board staff for the purpose of providing more services to providers and pharmacists; and the future funding needs of the PMP. Recommendations will be referred to the Rules Committee for further discussion. The Rules Committee will plan to meet with the PMP Advisory Council to discuss the recommendations. The Board will continue with the current system they are using and send a letter to registrants reminding them the PMP is available as an important clinical tool.
- 15. The Expanding Role of Pharmacists in a Transformed Health Care System National Governors Association Center for Best Practices.
 - Board staff and Anthony Pudlo will meet with the Health Department to have dialogue about collaborative practice between pharmacists and non-physician prescribing practitioners.
- 16. State Board of Pharmacy Update.
 - The Pharmacy Technician Certification Board (PTCB) administers an accredited certification program for pharmacy technicians. This year marks the twentieth anniversary of the founding of PTCB.

Medication Safety and Adverse Drug Event Prevention Presentation - Katy Brown, Telligen

Katie Brown provided a presentation on Medication Safety and Adverse Drug Event Prevention. Telligen is a Quality Improvement Organization (QIO) for the states of Iowa, Colorado, and Illinois, contracted by the Centers for Medicare and Medicaid Services. QIO activities include direct technical assistance to physicians, clinical pharmacists, hospitals, nursing homes, and home health agencies to improve the outcomes of health care services. QIO's mission is better care for individuals; better health for populations; and lower cost through improvement (affordable care.)

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Licensure/Registration

- Premier Kids Care Inc., Hollywood, Florida, and Premier Kids Care Inc., Monroe, Georgia.
 Motion by James Miller, seconded by Susan Frey, to approve the applications for Nonresident Iowa Pharmacy License. Motion approved unanimously.
- 2. Ashley Steele, West Burlington.

Motion by James Miller, seconded by Edward McKenna, to approve the Application for Pharmacy Technician Trainee Registration without restrictions. Motion approved unanimously.

Closed Session

At 4:40 p.m., motion by Susan Frey, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code Section § 21.5(1)(a) to review records required by state or federal law to be kept confidential.

At 5:02 p.m., while still in closed session, James Miller moved that the Board go into open session, seconded by Susan Frey. Motion approved unanimously.

In open session, the following actions were taken:

Motion by Susan Frey, seconded by Sharon Meyer, to approve request for license transfer for Benjamin Grote. Motion approved unanimously.

Motion by LaDonna Gratias, seconded by James Miller, to approve request to extend validation of internship hours until May 31, 2015, for Veronica Montefusco. Motion approved unanimously.

Motion by James Miller, seconded by LaDonna Gratias, to approve request to extend validation of internship hours until May 31, 2015, for Sharon Rosal. Motion approved unanimously.

Motion by James Miller, seconded by Susan Frey, to approve request to extend validation of internship hours and to retake the NAPLEX and MPJE examinations with a deadline of September 9, 2015, for B.M. Motion approved unanimously.

Complaints Against Non-Licensees

2015-05 Aetna Inc.

Motion by Susan Frey, seconded by Ed McKenna, to close with a referral to the Insurance Commissioner. Motion approved unanimously.

Executive Director's Retirement

Lloyd Jessen announced his retirement from the Executive Director's position at the Iowa Board of Pharmacy. Meghan Gavin provided the Board with information on how to proceed with filling the position. The Board may hire a National Search Firm or select a three board member committee to serve as the Board's Search Committee. The Board discussed the options of hiring a National Search Firm or selecting a three board member committee to serve as the Board's Search Committee to fill the Executive Director's position. Discussion was held regarding salary, position description, timeline, Request for Proposal, posting the position, transition, and an

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Interim Director. Edward Maier, Sharon Meyer, and James Miller will serve on the Board's Search Committee. The Search Committee and board staff will meet with a representative from the Department of Administrative Services on Wednesday afternoon, March 11, 2015, to discuss the Board's options for hiring a new Executive Director.

Closed Session

At 6:15 p.m., motion by Susan Frey, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session for the following reasons:

For review of Closed Session Minutes pursuant to Iowa Code § 21.5(1)(a) because closed session minutes are confidential under Iowa Code § 21.5(4).

For Follow-Up Investigative Information pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigation or proceedings and § 21.5(1)(a) because complaints and investigative reports are confidential under Iowa Code § 272C.6(4).

For Settlement Agreement and Final Orders pursuant to Iowa Code § 21.5(1)(f) to discuss the decision to be rendered in a contested case.

For Combined Statement of Charges, Settlement Agreement, and Final Orders pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and § 21.5(1)(f) to discuss the decision to be rendered in a contested case.

For Notice of Hearings and Statement of Charges pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings.

For Orders to Show Cause pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings.

For Complaints and Investigative Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and § 21.5(1)(a) because complaints and investigative reports are confidential under Iowa Code § 272C.6(4).

At 7:58 p.m., while still in closed session, Edward McKenna moved that the Board go into open session, seconded by James Miller. Motion approved unanimously.

At 8:00 p.m., the Board went to recess.

The meeting reconvened in open session on Tuesday, March 10, 2015, at 9:00 a.m.

TUESDAY, MARCH 10, 2015

MEMBERS PRESENT

Edward L. Maier, Chairperson James Miller, Vice-Chair Susan M. Frey LaDonna Gratias Edward J. McKenna Sharon K. Meyer

STAFF PRESENT

Lloyd Jessen, Executive Director Laura Steffensmeier, Esq., Assistant Therese Witkowski, Executive Officer Debbie Jorgenson, Administrative Assistant Becky Hall, Secretary Andrew Funk, Compliance Officer Curt Gerhold, Compliance Officer

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MEMBERS ABSENT Judith M. Trumpy

Mark Mather Compliance Officer Sue Mears, Compliance Officer Jean Rhodes, Compliance Officer Jennifer Tiffany, Compliance Officer Jennifer O'Toole, Compliance Officer Jim Wolfe, Compliance Officer

At 9:10 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

Administrative Hearing

Case 2013-167 John Doe II

At 9:10 a.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Laura Steffensmeier represented the State. Mr. Doe appeared without counsel. The hearing was conducted in the presence of the Board. The hearing was closed to the public.

The Board heard testimony of witnesses and examined exhibits.

At 9:52 a.m., the record was closed.

At 9:53 a.m., motion by Susan Frey, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 10:05 a.m., James Miller moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

Motion by Susan Frey, seconded by LaDonna Gratias, to direct Administrative Law Judge Margaret LaMarche to draft the Order consistent with the Board's deliberations for case 2014-167 John Doe II. Motion approve unanimously.

Closed Session

At 10:20 a.m., motion by Susan Frey, seconded by LaDonna Gratias, the Board voted unanimously by roll call vote to move into closed session for Complaints and Investigative Reports pursuant to Iowa Code § 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or proceedings and § 21.5(1)(a) because complaints and investigative reports are confidential under Iowa Code § 272C.6(4).

At 11:02 a.m., Edward McKenna moved that the Board go into open session, seconded by Sharon Meyer. Motion approved unanimously.

In open session, the following actions were taken:

1. Settlement Agreement and Final Order.

Motion by James Miller, seconded by Edward McKenna, to approve the Settlement Agreement and Final Order in the following cases. Motion approved unanimously.

- A. Daniel Ashton, Jr., Pharmacist License No. 13182 of Effingham, Illinois. A copy of the Settlement Agreement and Final Order is attached as Addendum F.
- B. Olufemi Omodara, Pharmacist License No. 17817 of Goodyear, Arizona. A copy of the

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- Settlement Agreement and Final Order is attached as Addendum G.
- C. Mary McMillian, Pharmacist License No. 19740 of Elgin. A copy of the Settlement Agreement and Final Order is attached as Addendum H.
- D. Rashid LTC Pharmacy, Pharmacy License No. 1129 of Fort Madison. A copy of the Settlement Agreement and Final Order is attached as Addendum I.
- E. David Tracey King, Pharmacist License No. 19586 of Burlington. A copy of the Settlement Agreement and Final Order is attached as Addendum J.
- F. Gwen Rugger, Pharmacy Support Person Registration No. 2675 of Coralville. A copy of the Settlement and Final Order is attached as Addendum K.
- G. Brady Rolfes, Pharmacy Technician Registration No. 18729 of Iowa City. A copy of the Settlement Agreement and Final Order is attached as Addendum L.
- H. Amanda Knouse, Pharmacy Technician Registration No. 20304 of Des Moines. A copy of the Settlement Agreement and Final Order is attached as Addendum M.
- I. Stacy Jahlas, Pharmacy Technician Registration No. 14928 of Belle Plaine. A copy of The Settlement Agreement and Final Order is attached as Addendum N.
- J. John E. Guck, Pharmacist License No. 18556 of Libertyville. A copy of the Settlement Agreement and Final Order is attached as Addendum O.
- K. Stephen Scott, Pharmacist License No. 18067 of Tipton. A copy of the Settlement Agreement and Final Order is attached as Addendum P.
- 2. Combined Statement of Charges, Settlement Agreement, and Final Order.

Motion by Susan Frey, seconded by James Miller, to approve the Combined Statement of Charges Settlement Agreement and Final Order in the case of Village Fertility Pharmacy, Nonresident Pharmacy License No. 4230 of Waltham, Massachusetts. Motion approved unanimously. A copy of the Combined Statement of Charges, Settlement Agreement, and Final Order is attached as Addendum Q.

3. Combined Notice of Hearing and Statement of Charges.

Motion by James Miller, seconded by LaDonna Gratias, to approve Notice of Hearing and Statement of Charges in the following cases. Motion approved unanimously.

- A. Weatherford Compounding Pharmacy, Nonresident Pharmacy License No. 4075 of Weatherford, Texas. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum R.
- B. Donald Versluys, Pharmacist License No. 15600 of Pella. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum S.
- C. Marquaisha Haygood, Pharmacy Technician Registration No. 19605 of Des Moines. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum T.
- D. Sherri Marshall, Pharmacy Technician Registration No. 18129 of Des Moines. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum U.
- E. Mark Frahm, Pharmacist License No. 15271 of Ottumwa. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum V.
- F. Mary Mosher, Pharmacist License No. 20661 of Cedar Rapids. A copy of the Notice of Hearing and Statement of Charges is attached as Addendum W.
- 4. Close With No Action.

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Motion by James Miller, seconded by Edward McKenna, to close with no further action the investigative file in complaint numbers: 2013-3579, 2013-4048, 2014-158, 2014-173, 2014-200, 2015-28, 2015-30, 2015-33, 2014-211, 2014-209, 2014-210, 2015-1, 2015-16, 2014-188, 2014-198, 2015-7, 2014-159, 2014-207, 2015-11, 2014-124, 2014-180, 2015-9, 2015-18, 2015-21, 2014-203, 2014-212, 2015-2, 2015-3, and 2015-4. Motion approved unanimously.

5. Letter of Education.

Motion by Susan Frey, seconded by Edward McKenna, to issue a Letter of Education to the pharmacy in 2014-204; pharmacist in 2014-119; and pharmacist in charge in 2014-2013. Motion approved unanimously.

6. Administrative Warning.

Motion by James Miller, seconded by Sharon Meyer, to issue an Administrative Warning to the pharmacist in 2015-29; pharmacy in 2014-214; and Controlled Substance Registrant in 2015-8. Motion approved unanimously.

7. Draft Statement of Charges.

Motion by James Miller, seconded by Edward McKenna, to draft Statement of Charges against the pharmacy in 2015-31; pharmacy in 2015-34; pharmacy and pharmacist in charge in 2015-10; technician in 2014-205; and technician in 2014-208. Motion approved unanimously.

8. Intent to Deny.

Motion by Edward McKenna, seconded by Ladonna Gratias, to issue Preliminary Notice of Intent to Deny License in case 2015-34. Motion approved unanimously. A copy of the Preliminary Notice of Intent to Deny License is attached as Addendum X.

9. Closed Minutes.

Motion by Susan Frey, seconded by James Miller, to approve the Closed Minutes of the February 12, 2015, teleconference meeting. Motion approved unanimously.

Assistant Attorney General Laura Steffensmeier left the room.

Closed Session

At 11:12 a.m., motion by Susan Frey, seconded by Sharon Meyer, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code § 21.5(1)(a) because ongoing investigations are confidential under Iowa Code § 272C.6(4).

At 11:14 a.m., James Miller moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

In open session, the following action was taken:

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Motion by James Miller, seconded by LaDonna Gratias, to approve Order Denying Motion to Quash Subpoena for Walgreens Pharmacy 05721, Pharmacy License No. 355. Motion approved unanimously. A copy of the Order Denying Motion to Quash Subpoena is attached as Addendum Y.

Closed Session

At 11:15 a.m., motion by Susan Frey, seconded by James Miller, the Board voted unanimously by roll call vote to move into closed session pursuant to Iowa Code § 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 11:23 a.m., James Miller moved that the Board go into open session, seconded by LaDonna Gratias. Motion approved unanimously.

In open session, the following action was taken:

Motion by James Miller, seconded by Susan Frey, to approve the Findings of Fact, Conclusions of Law, Decision and Order for Robert Osborn, Pharmacist License No. 19079 of Rock Island, Illinois. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum Z.

<u>Legislation – Senate File 453</u>

The Board reviewed Senate File 453 a bill for an Act relating to the Board of Pharmacy, including nonresident pharmacy and outsourcing facility licensure, pharmacist supervision of pharmacy technicians, alternate board members, and enforcement authority has passed the Committee and is now in the Senate.

Administrative Hearing

Matthew Biggerstaff, D.O., CSA Registration No. 1306092 of Ankeny.

At 1:00 p.m. Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Laura Steffensmeier represented the State. Mr. Biggerstaff was represented by Michael Sellers. The hearing was conducted in the presence of the Board. The hearing was closed to the public.

At 1:10 p.m., the record was closed.

At 1:11 p.m., motion by Susan Frey, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 2:00 p.m., Susan Frey moved that the Board go into open session, seconded by Edward McKenna. Motion approved unanimously.

Motion by Susan Frey, seconded by Sharon Meyer, to deny Request for Stay and direct Administrative Law Judge Margaret LaMarche to draft the Order consistent with the Board's deliberations for the Chair's signature in the Matthew Biggerstaff case. Motion passed by roll call vote. James Miller and Edward McKenna voted nay. A copy of Order Denying Motion for Stay is attached as Addendum AA.

Motion to Dismiss - Ameridose, LLC., License Nos. 3828, 3829, 6859, 6569

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Motion by James Miller, seconded by Susan Frey to dismiss. Motion approved unanimously. A copy of the Order is attached as Addendum BB.

At 3:00 p.m., the Board went to recess.

The meeting reconvened in open session on Wednesday, March 11, 2015, at 9:00 a.m.

WEDNESDAY, MARCH 11, 2015

MEMBERS PRESENT

Edward L. Maier, Chairperson James Miller, Vice-Chair LaDonna Gratias Edward J. McKenna Sharon K. Meyer

STAFF PRESENT

Meghan Gavin, Esq., Assistant Attorney General Laura Steffensmeier, Esq., Assistant Attorney General Becky Hall, Secretary

MEMBERS ABSENT

Susan M. Frey Judith M. Trumpy

At 9:00 a.m., Edward Maier, Chairperson, called the meeting of the Iowa Board of Pharmacy to order.

Administrative Hearing

Bauder Pharmacy, Inc., Pharmacy License No. 222, Des Moines.

At 9:00 a.m., Margaret LaMarche, Administrative Law Judge, Department of Inspections and Appeals opened the record. Assistant Attorney General Meghan Gavin represented the State. Bauder Pharmacy was represented by Guy Cook and Adam Zenor. The hearing was conducted in the presence of the Board. The hearing was open to the public.

The Board heard testimony of witnesses and examined exhibits.

At 11:24 a.m., the record was closed.

At 11:25 a.m., motion by LaDonna Gratias, seconded by Edward McKenna, the Board voted unanimously by roll call vote to move into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case.

At 11:55 a.m., Edward McKenna moved that the Board go into open session, seconded by James Miller. Motion approved unanimously.

Motion by James Miller, seconded by Edward McKenna, to direct Administrative Law Judge Margaret LaMarche to draft the Order consistent with the Board's deliberations in the Bauder case. Motion approved unanimously.

Motion by James Miller, seconded by Sharon Meyer, to adjourn at 11:58 a.m. on March 11, 2015.

Becky Hall

Recording Secretary

E-FILED 2016 JAN 01 4:49 PM POLK - CLERK OF DISTRICT COURT

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Therese Witkowski

Executive Officer

Edward L/Maier Board Chair

APPROVED THIS 28th DAY OF

. 20 (5

Iowa District Court Polk County, Iowa

CARL OLSEN,)	
Petitioner,)	
)	
vs.)	D - 14 N - CV 51000
IOWA BOARD OF PHARMACY)	Docket No. CV 51068
)	
Respondent.)	

PETITION FOR JUDICIAL REVIEW

Carl Olsen ("Petitioner" hereafter) respectfully petitions for judicial review of the following actions of the Iowa Board of Pharmacy ("Board" hereafter):

- (1) the Board's January 5, 2015, decision (attached hereto as Exhibit #1, at Addendum A) denying Petitioner's July 7, 2014, Marijuana Scheduling Petition (attached hereto as Exhibit #2);
- (2) the Board's March 9, 2015, decision (attached hereto as Exhibit #3, at p.2) denying Petitioner's January 12, 2015, Marijuana Scheduling Petition for Reconsideration (attached hereto as Exhibit #4); and
- (3) the Board's November 3, 2015, decision (attached hereto as Exhibit #5) not to recommend the change it approved on January 5, 2015 (attached hereto as Exhibit #1, at Addendum B) for the reclassification of cannabidiol.

Introduction

Marijuana is listed in Schedule 1 of the Iowa Uniform Controlled Substances Act (Iowa Code Chapter 124). Iowa Code § 124.204(4)(m). Schedule 1 of the Act is restricted to 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 sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203") (attached hereto as Exhibit #6, at p. 4, n. 1).

At the time the Petitioner filed his request asking the Board to recommend the reclassification of marijuana, there were thirty-four (34) jurisdictions, twentythree (23) states¹ and the District of Columbia² that had legally recognized the medical use of marijuana in the United States, and another ten (10) states³ that had accepted extracts of marijuana. Iowa is one of those ten (10) states that recognized extracts of marijuana.⁴

Between July 7, 2014, the time the Petitioner filed his request asking the Board to recommend the reclassification of marijuana, and the Board's November

^{...}

¹ 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), 410 Ill. Comp. Stat. Ann. 130/1-130/199 (2014); 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); New York Pub. Health §§ 3360–3369-e (2014); 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 D.C. Law 18-210; D.C. Official Code, Title 7, Chapter 16B, §§ 7-1671.01 through 7-1671.13 (2010).

³Alabama, 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); North Carolina, House Bill 1220, Signed by Gov. Pat McCrory (July 3, 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).

3, 2015, scheduling recommendations to the legislature for 2016,⁵ an additional nine (9) jurisdictions had accepted some form of medical marijuana,⁶ bringing the total to forty-two (42) jurisdictions in the United States that had accepted some form of medical marijuana as of November 3, 2015.

Background

On July 21, 2009, the Board issued a proposal to hold public hearings on the question of marijuana's accepted medical use in the United States (attached as Exhibit #7). The proposal was reported in an editorial in the Des Moines Register on July 27, 2009 (attached as Exhibit #8). Hearings were held at the following times and locations (attached as Exhibit #9):

Wednesday, August 19, 2009 – 10:00 a.m. to 7:00 p.m. Iowa State Historical Building (Auditorium) 600 East Locust Street Des Moines, Iowa

Wednesday, September 2, 2009 – 10:00 a.m. to 7:00 p.m. The Music Man Square (Reunion Hall) 308 South Pennsylvania Avenue Mason City, Iowa

⁵ "Departments and agencies of state government shall, at least forty-five days prior to the convening of each session of the general assembly, submit copies to the legislative services agency of proposed legislative bills and joint resolutions which such departments desire to be considered by the general assembly." Iowa Code § 2.16 (2015).

⁶ Louisiana, SB143, June 29, 2015 (medical marijuana); Georgia, HB1, April 16, 2015 (marijuana extract); Missouri, HB2238, July 14, 2014 (marijuana extract); Oklahoma, HB2154, April 30, 2015 (marijuana extract); Texas, SB339, June 1, 2015 (marijuana extract); Virginia, HB1445, February 26, 2015 (marijuana extract); Wyoming, HB32, March 2, 2015 (marijuana extract); Guam, Proposal 14A, November 4, 2014 (medical marijuana); Puerto Rico, EO 2015-10, May 3, 2015 (medical marijuana).

Wednesday, October 7, 2009 – Noon to 7:00 p.m. University of Iowa Bowen Science Building (3rd Floor Auditorium) 51 Newton Road Iowa City, Iowa

Wednesday, November 4, 2009 – 10:00 a.m. to 7:00 p.m. Harrah's Casino & Hotel (Ballroom I) One Harrah's Boulevard Council Bluffs, Iowa

Both written and oral testimony was received during the four months of hearings.

Each of the four hearings was transcribed by a certified court reporter, SueAnn

Jones, CSR, RPR, Johnson Reporting Services, Ltd., Certified Shorthand

Reporters, 913 27th Street, West Des Moines, Iowa 50265, (515) 224-1166.

On February 17, 2010, the Board reached the unanimous conclusion that marijuana should be removed from Schedule 1 (attached as Exhibit #10).

On November 24, 2010, the Board approved legislation recommending that marijuana be removed from Schedule 1 (attached as Exhibit #11).

The Board's November 24, 2010, legislative proposal was prepared by the Legislative Services Agency and submitted as a pre-filed agency bill⁷ (attached as Exhibit #12).

Prior to the start of the 2011 session, the Legislative Services Agency also submitted the Office of Drug Control Policy ("ODCP" hereafter) scheduling

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⁷ See footnote 5.

recommendation to maintain marijuana in Schedule 1 as a pre-filed agency bill⁸ (attached as Exhibit #13).

And, prior to the start of the 2012 session, the Legislative Services Agency again submitted a pre-filed agency bill⁹ by ODCP opposing the Board's bill and recommending that marijuana remain classified in Schedule 1 (attached as Exhibit #14).

Procedural History

- The Petitioner's Marijuana Scheduling Petition was filed with the 1. Board on July 7, 2014 (see Exhibit #2).
- 2. The Board considered the Marijuana Scheduling Petition on August 27, 2014, and voted to form a subcommittee to make a report to the full Board at its next meeting on November 19, 2014 (attached as Exhibit #15, at p. 4). Petitioner made an audio recording of the August 27, 2014 meeting (attached as Exhibit #16; the audio recording is available upon request). The Board distributed a newspaper article from the August 26, 2014, Des Moines Register, "Cannabis oil 'light years away' for Iowa families," at the meeting (attached as Exhibit #17).

⁸ See footnote 5.

⁹ See footnote 5.

- 3. The subcommittee held a public hearing on November 17, 2014, and took written and oral statements (the written statements are attached as Exhibits #18 and #19).
- 4. On November 19, 2014, the subcommittee recommended granting the Marijuana Scheduling Petition (attached as Exhibit #20), but the recommendation was tabled indefinitely (see Exhibit #21, at p. 6) at the Board meeting. Petitioner made an audio recording of the November 19, 2014 meeting (attached as Exhibit #22; the audio recording is available upon request).
- 5. On December 1, 2014, the Petitioner submitted a written response to some of the arguments that were made at the Board meeting on November 19, 2014 (attached as Exhibit #23).
- 6. On December 8, 2014, the Petitioner submitted a Correction to Erroneous Interpretation of Law Petition to the Office of Drug Control Policy (attached as Exhibit #24) for erroneous statements it submitted to the Board on November 17, 2014, citing the Iowa District Court (see Exhibit #6) ruling that abuse potential is not a factor that requires marijuana to be maintained in Schedule 1 (Schedule 2 has the same abuse potential as Schedule 1).
- 7. On December 21, 2014, the Petitioner submitted a request to the Office of the State Ombudsman asking if the Office of Drug Control Policy is subject to the Iowa Administrative Procedures Act. On December 22, 2014, the

Office of the State Ombudsman said it could not answer the question (attached as Exhibit #25).

- 8. On December 26, 2014, the Petitioner submitted a Correction to Erroneous Interpretation of Law Petition for Reconsideration to the Office of Drug Control Policy after the Petitioner's Correction to Erroneous Interpretation of Law Petition was denied (attached as Exhibit #26).
- 9. On December 26, 2014, the Petitioner requested clarification from the Monitoring the Future Principle Investigator asking if the Office of Drug Control Policy had correctly interpreted his position on the scheduling of marijuana. On December 26, 2014, the Principle Investigator of the Monitoring the Future study replied that many of the state medical marijuana laws, but not the rescheduling of marijuana, promote drug abuse (attached as Exhibit #27).
- 10. On December 29, 2014, the Board notified the Petitioner that the recommendation of the subcommittee would be removed from the table and considered at the January 5, 2015, Board meeting (attached as Exhibit #28).
- 11. On January 1, 2015, the Petitioner notified the Board that Congress had temporarily suspended for one year the enforcement of federal Schedule 1

when state law provides for the medical use of marijuana (attached as Exhibit #29). 10

- 12. On January 2, 2015, the Board's proposed changes to the schedules of controlled substances for 2015 was pre-filed¹¹ with the Iowa legislature (attached as Exhibit #30).
- 13. On January 5, 2015, the Board rejected the subcommittee's recommendation and denied the Marijuana Scheduling Petition (see Exhibit #1, at Addendum A). Petitioner made an audio recording of the January 5, 2015 meeting (attached as Exhibit #31; the audio recording is available upon request).
- 14. On January 12, 2015, the Petitioner filed a Marijuana Scheduling Petition for Reconsideration of the Board's ruling from January 5, 2015 (attached as Exhibit #32).
- 15. On March 2, 2015, the Petitioner submitted additional items for consideration by the Board for the Petitioner's Marijuana Scheduling Petition for Reconsideration of the Board's ruling from January 5, 2015 (attached as Exhibit #33).

¹⁰ There is a recent federal court ruling on Section 538 of the Consolidated and Further Continuing Appropriations Act of 2015, Pub. L. 113-235, 128 Stat. 2130 (2014) ("2015 Appropriations Act"), which has now been extended for another year. *United States v. Marin Alliance*, Case 3:98-cv-00086-CRB (Northern District of California, Document 277, Filed 10/19/15).

¹¹ See footnote 5.

- 16. At the March 9, 2015, meeting of the Board, the Petitioner submitted a written statement addressing the concerns the board had raised at the November 19, 2014, and January 5, 2015, meetings (attached as Exhibit #34).
- 17. At the March 9, 2015, meeting of the Board, the Board denied the Petitioner's Marijuana Scheduling Petition for Reconsideration without any discussion or written explanation (attached as Exhibit #35, at p. 2).
- 18. At the November 4, 2015, meeting of the Board, the Petitioner submitted a Request for Clarification of the Board's proposed changes to the schedules of controlled substances for 2016 because the recommendation the Board made to reschedule cannabidiol was not included in the proposed changes (attached as Exhibit #36).
- 19. On November 5, 2015, the Petitioner received an email from the Assistant Attorney General characterizing the Petitioner's November 4, 2015, Request for Clarification as a request for some kind of administrative action by the Board and said it was submitted too late (attached as Exhibit #37).
- 20. On November 15, 2015, the Petitioner filed an Open Records Request with the Board asking what was done to promote the Board's January 5, 2015, recommendation for the rescheduling of cannabidiol (attached as Exhibit #38)

- 21. On November 17, 2015, the Petitioner received a second email from the Assistant Attorney General saying she was confused about the nature of the Request for Clarification (attached as Exhibit #39).
- 22. On November 25, 2015, the Board responded to the Open Records Request with the documents requested by the Petitioner (attached as Exhibit #40). There are only two emails that were exchanged between the Board and legislators, so I've attached those as Exhibits #40-1 and #40-3. Neither of those emails were initiated by the Board. Exhibit #40-1 is an invitation dated January 16, 2015, to the Board from the chair of the Senate Judiciary Committee to attend a subcommittee meeting on SSB 1005 on January 20, 2015. Exhibit #40-2 is a cancellation notice of the January 20, 2015, Senate Judiciary Committee subcommittee meeting on SSB 1005. Exhibit #40-3 is a response from the Board dated April 7, 2015, responding to a request from the Republican Senate Caucus.
- 23. On December 29, 2015, the Board's proposed changes to the schedules of controlled substances for 2016 was pre-filed¹² with the Iowa legislature (attached as Exhibit #41).

Jurisdiction, Parties & Venue

¹² See footnote 5.

- 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.
- 3. Petitioner resides at 130 E. Aurora Ave., Des Moines, Iowa 50313-3654.
- 4. The Iowa Board of Pharmacy 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 final actions by the Board dated January 5, 2015 (see Exhibit #1), denying the Petition, March 9, 2015 (see Exhibit #3), denying the Petition for Reconsideration, and December 29, 2015 (see Exhibit #41), recommending changes to the schedules of controlled substances that do not include those requested by the Petitioner.
- 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. Petitioner has exhausted administrative remedies and this is an appeal from final action 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 1 of the Iowa Uniform Controlled Substances Act (see Exhibits #7 through #12), supported by four months of research, written documentation, and oral testimony in 2009.
- 11. Since the Board's unanimous ruling on February 17, 2010, the Board has not found any evidence that would contradict the ruling it made in 2010.
- 12. In 2008, there were 12 states that had accepted the medical use of marijuana. Now, there are 40 states¹³ and three federal jurisdictions that have accepted the medical use of marijuana. More than three times as many states have accepted marijuana's medical use as of 2015 than there were in 2008. Professional medical organizations have recently recommended that marijuana be removed from Schedule 1 (particularly, the American Academy of Neurology in December of 2014, and the American Academy of Pediatrics in January of 2015). The Board found absolutely zero evidence to the contrary.

¹³ Louisiana accepted the medical use of marijuana on June 29, 2015, HB 143.

- 13. The facts have not changed since the Board made its recommendation in 2010 and there are no facts in dispute in this case. The evidence has only gotten stronger.
- 14. There is no disagreement between the Petitioner and the Board that medical evidence warranting removal of marijuana from Schedule 1 has only gotten stronger.
- 15. The Petitioner agrees with the Board's decision in 2010 to recommend removing marijuana from Schedule 1.
- 16. There is nothing for this court to decide regarding the sufficiency of the evidence.
- 17. 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."
- 18. Because the Board has not found any evidence to suggesting that marijuana should not be reclassified, the Board must recommend removal of marijuana from Schedule 1.
- 19. Doing nothing is not an option for the Board, unless material facts have changed that would prove its previous decision was in error.

- 20. Because material facts have not shown the Board was in error when it recommended removing marijuana from Schedule 1 in 2010, the Board must recommend the general assembly remove marijuana from Schedule 1.
- 21. Because marijuana no longer meets the criteria required by Schedule 1 of the Act the Board has a legal duty to recommend the general assembly remove marijuana from Schedule 1. Iowa Code § 124.203(2).
- 22. Because another executive branch agency, the Office of Drug Control Policy, which has no authority to recommend scheduling, has continually attempted to subvert the clear authority the legislature has given the Board of Pharmacy to recommend scheduling changes, the Board has a duty to defend its position against an unconstitutional attack from the same branch of government to which it belongs, the executive branch.
 - 23. The ruling of the Board is:

Iowa Code § 17A.19(10)(a).

The decision of the Board is unconstitutional because it violates due process for the Board to ignore the statutory provisions of Iowa Code § 124.203(2) when a citizen brings it to their attention. The legislature has not given the Board the option of ignoring the scheduling criteria. The scheduling criteria exist to protect the public health.

Iowa Code § 17A.19(10)(b).

The decision of the Board exceeds the discretion given to the Board as a matter of law, because the Board has no authority to ignore the provisions of Iowa Code § 124.203(2).

Iowa Code § 17A.19(10)(c).

The decision of the Board is based upon an erroneous interpretation of the law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency. The Board must recognize accepted medical use of marijuana in the United States when state laws show it has been accepted for medical use.

Iowa Code § 17A.19(10)(d).

The decision of the Board is based on faulty logic and errors in fact. The Board did not find that any facts that had changed that would have cast doubt on the validity of the unanimous decision it made in 2010 to recommend reclassification of marijuana. The Board's finding that opium plants are in Schedule 1 was a critical error and a finding that marijuana should be in the same schedule as opium plants should have resulted in a finding that marijuana should be removed from Schedule 1.

Iowa Code § 17A.19(10)(e).

The decision of the Board was based on improper interference from another executive branch agency, the Office of Drug Control Policy, in flagrant disregard for a district court order making it clear that abuse potential is not a relevant fact in moving a substance from Schedule 1 to Schedule 2. The Office of Drug Control Policy filed legislation opposing the Board in 2011 and 2012, and it incorrectly stated the positions of the Monitoring the Future study and the National Institute on Drug Abuse in 2014, neither of which as ever taken any position on scheduling. It is an unconstitutional violation of separation of powers for two executive branch agencies to oppose each other when one has been authorized by the legislature to make a specific decision (scheduling) and the other has not.

Iowa Code § 17A.19(10)(f).

The decision of the Board was based on an erroneous finding that opium plants are in Schedule 1. Opium plants are in Schedule 2 and always have been. Opium plants have never been in Schedule 1.

Iowa Code § 17A.19(10)(h).

The decision of the Board not to recommend the removal of marijuana from Schedule 1 is inconsistent with the Board's prior finding that marijuana should be removed from Schedule 1. The Board has not justified the inconsistency by stating credible reasons sufficient to indicate a fair and rational basis for the inconsistency.

Iowa Code § 17A.19(10)(i)

The decision of the Board is so illogical as to render it wholly irrational because opium plants are not in Schedule 1 and the Board said marijuana should be in the same schedule as opium plants which are in fact in Schedule 2 and not in Schedule 1. Other arguments that only products can be moved to lower schedules are also illogical as there are many substances in the lower schedules that are not products.

Iowa Code § 17A.19(10)(j).

The decision of the Board is a result of a decision-making process in which the agency did not accurately identify 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. The Board incorrectly stated that opium plants are in Schedule 1 and marijuana belongs in the same classification as opium plants. Opium plants have always been in both state and federal Schedule 2 and marijuana is in Schedule 1. If marijuana belongs in the same classification as opium plants, then marijuana is clearly in the wrong schedule.

Iowa Code § 17A.19(10)(k).

The decision of the Board was not required by law and has a negative impact on public health so grossly disproportionate to the benefits accruing to the public interest that it must necessarily be deemed to lack any foundation in rational agency policy. 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. The Board's arguments that the legislature must reclassify a substance before the Board can reclassify it is completely backward from the plain meaning of the statute. The Board's role is to advise the legislature, not to wait for advice from the legislature.

Iowa Code § 17A.19(10)(m).

The decision of the Board was based on an irrational, illogical, and wholly unjustifiable application of law to fact because the Board said it can only reclassify products and then recommended the reclassification of cannabidiol which is not a product. The Board said it had no idea what was in the various products covered by the Iowa Medical Cannabidiol Act and then recommended that cannabidiol be reclassified. Cannabidiol is not a product.

Iowa Code § 17A.19(10)(n).

The decision of the Board was an abuse of discretion because the Board made up its mind to deny the petition and then tried to come up with reasons for it. The reasons given were just opinions of various Board members that were not based in fact or law.

Prayer for Relief

WHEREFORE, the Petitioner prays for:

- A. A judgment setting aside the January 5, 2015, ruling of the Iowa Board of Pharmacy denying the Marijuana Scheduling Petition; and
- B. A declaratory ruling from the 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 January 4, 2016, 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

> <u>/s/ Carl Olsen</u> Carl Olsen, Pro Se Petitioner

Iowa District Court Polk County, Iowa

CARL OLSEN,)	
Petitioner,)	
vs.)	
IOWA BOARD OF PHARMACY) Docket No. CV 510)68
Respondent.)	

MEMORANDUM IN SUPPORT OF PETITION FOR JUDICIAL REVIEW

Federal Preemption

Federal preemption is an issue that is frequently brought up in any discussion of state medical marijuana laws.

California enacted a medical marijuana law in 1996. Since that time, the federal government has never made the argument that California did not have a constitutional right to enact such a law. Since that time, forty states, the District of Columbia, the Territory of Guam, and the Commonwealth of Puerto Rico, have enacted medical marijuana laws, and the federal government has never made the argument that any of these laws are unconstitutional. The issue has been litigated. This is by no means an exhaustive list, but here are two judicial rulings that were submitted to the Board on December 1, 2014 (see Exhibit #23, at p. 10): *Garden*

Grove v. Superior Court, 157 Cal.App.4th 355, 385, 68 Cal.Rptr.3d 656, 677 (2007), cert. denied, 555 U.S. 1044, 129 S. Ct. 623, 172 L. Ed. 2d 607 (2008); San Diego County v. San Diego NORML, 165 Cal.App.4th 798, 809, 81 Cal.Rptr.3d 461, 468 (2008), cert. denied, 556 U.S. 1235, 129 S. Ct. 2380, 173 L. Ed. 2d 1293 (2009).

The United States Supreme Court has found that the anti-preemption clause, 21 U.S.C. § 903, in the federal Controlled Substances Act, 21 U.S.C. §§ 801-971, coupled with the explicit enumeration of national standard for medical treatment in the United States, show that Congress did not intend to determine what states can define as accepted medical use of controlled substances and that the federal act simply targets abuse (unauthorized use) (see Exhibit #23, at p. 7). *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) ("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."). *Gonzales v. Oregon*, 546 U.S. 243, 271-272 (2006):

Even though regulation of health and safety is "primarily, and historically, a matter of local concern," *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 719, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985), there is no question that the Federal Government can set uniform national standards in these areas. See *Raich, supra*, at 9, 125 S. Ct. 2195, 162 L. Ed. 2d 1. In connection to

the CSA, however, we find only one area in which Congress set general, uniform standards of medical practice. Title I of the Comprehensive Drug Abuse Prevention and Control Act of 1970, of which the CSA was Title II, provides that:

"[The Secretary], after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress." § 4, 84 Stat. 1241, codified at 42 U.S.C. § 290bb-2a.

This provision strengthens the understanding of the CSA as a statute combating recreational drug abuse, and also indicates that when Congress wants to regulate medical practice in the given scheme, it does so by explicit language in the statute.

The federal controlled substance schedules are administrative rules and not statutes (unlike here in Iowa where the schedules are statutory). The schedules in 21 U.S.C. §§ 812(b)(1)-(5) are the "initial schedules" and the official schedules are the ones listed in 21 C.F.R. §§ 1308(11)-(15). Therefore, federal Schedule 1 is just an ordinary administrative rule. The Attorney General has the authority to remove marijuana from federal Schedule 1 by administrative rule without any action from Congress. 21 U.S.C. § 811(a)(2). So, essentially, the Attorney General is unlawfully maintaining a rule that declares illegitimate the medical use of marijuana in forty states and three federal jurisdictions that have accepted it.

If this were a situation where the Attorney General was trying to make a rule placing marijuana in Schedule 1, it would be an impossible task. However, maintaining marijuana in Schedule 1 is simple for the Attorney General; just do nothing and wait for someone else to say something about it. I'm here to say something about it.

What the Iowa Code says about Federal Scheduling

At the hearing on November 19, 2014, James Miller said the Iowa Board of Pharmacy is bound by the scheduling decisions of the federal government (see Exhibit #22, at p. 1). While federal scheduling decisions might be rubber stamped by the Board more often than not, there is no requirement that they be accepted. Mr. Miller's statement is not a legally valid interpretation of Iowa law. If a federal scheduling decision makes sense, there is no reason why Iowa should not adopt it.

The Iowa Code only mentions federal scheduling once in the scheduling requirements (see Exhibit #23, at p. 6). The only instance where the Iowa legislature requires the board to consider federal scheduling is when the federal government adds a new substance to the federal schedules that has never been previously scheduled. Iowa Code § 124.201(4) (2014). And, when the federal government does add a new substance to the federal schedules, the board is not

legally bound to make that same recommendation to the Iowa legislature. Iowa Code § 124.201(4) (2014); 657 IAC 10.37(3).

Because marijuana is not a new substance being added to Schedule 1 by the federal government, the Board is not bound in any way by federal scheduling. Iowa's scheduling of marijuana has been inconsistent with federal scheduling since 1979. Iowa Code § 124.204(4)(m) (2014); Iowa Code § 124.204(4)(u) (2014); Iowa Code § 124.204(7); Iowa Code § 124.206(7)(a) (2014). Another inconsistency is the scheduling of naturally extracted THC, which is in Iowa Schedule 3 since 2008, but has always been in federal Schedule 1. Iowa Code § 124.208(9)(b).

Mr. Miller gave the example of hydrocodone products (see Exhibit #22, at p. 1). Mr. Miller stated that when the federal government transferred hydrocodone products from federal Schedule 3 to federal Schedule 2, the state was legally bound to do the same. Mr. Miller's statement is not a legally valid interpretation of law. Iowa Code § 124.201(4) (2014); 657 IAC 10.37(3) ("The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law.").

Iowa could, in theory, leave hydrocodone products in state Schedule 3 after the federal government moves them to federal Schedule 2. Federal Schedule 2

would prevail, because every doctor and every pharmacist that handles hydrocodone has to have both a state and a federal license and agree to comply with both state and federal law. There is no state law that allows the sale of hydrocodone products outside of a pharmacy, so it would be impossible to obtain it legally without getting it from a pharmacy with a prescription from a doctor. It might make sense to move hydrocodone products to state Schedule 2, but it's certainly not required by any federal law. States are unlikely to pass laws allowing the use of hydrocodone as a non-prescription medicine sold in state dispensaries, but forty states have allowed the use of marijuana or marijuana extracts that are not being sold in pharmacies.

At that same hearing on November 19, Mr. Miller identified marijuana as a "drug product" which is not technically accurate in the sense that opium plants and coca plants are not technically "drug products." Plants in Schedule 2 that are used to make "drug products," like opium plants and coca plants are certainly commercial products (like fruits and vegetables) in their raw form, but they are not sold to end users as "drug products." Both opium plants and coca plants are in state and federal Schedule 2 and always have been (see Exhibit #23, at p. 13). Marijuana does not have to be a "drug product" to be removed from Schedule 1. Marijuana can be used to make "drug products," like cannabidiol, the same as opium plants (used to make morphine) and coca plants (used to make cocaine).

It's also worth noting that morphine and cocaine are not approved for end users unless they are in an FDA-approved "drug product." In theory, there could be a state law that allows them to be sold without being approved for marketing by the FDA, but there are no such state laws. Since morphine and cocaine prescriptions can be obtained legally, there's no reason to sell them in a state dispensary. With legal access, there is no reason for state to allow the use of these products outside the doctor/pharmacy model. States that have legalized marijuana or marijuana extracts allow people to dispense it in a separate facility (because they are in violation of federal law due to the inaccurate federal scheduling of marijuana) or they don't even allow it to be dispensed at all (in states like Iowa, you can have it in Iowa but you can't obtain it in Iowa). Manufactures of medical marijuana and marijuana extracts, dispensers, and end users, are all in violation of federal law because marijuana is being unlawfully maintained in federal Schedule 1 by the federal administration despite the fact it has accepted medical use in forty states and three federal jurisdictions. It's a total mess, because of the illegal federal classification.

Duty to Recommend

At that the hearing on January 5, 2015, Mr. Miller suggested that the Board should recommend rescheduling cannabidiol because the legislature had

recognized its medical use (see Exhibit #31, at p. 1). But, the statute governing the operation of the Board says the Board must make recommendations to the legislature. Is this an admission by the Board that state laws do require the removal of marijuana from Schedule 1? Is the Board admitting that state laws prove that marijuana has accepted medical use in the United States? The Board thinks a state law here in Iowa proves that cannabidiol has medical use in the United States because it must have accepted medical use in the United States to be in Schedule 2.

The Iowa statute does not say "in Iowa," it says "in the United States." The only reference to state laws in the statue is Iowa Code § 124.203(1)(b) (2014), Iowa Code § 124.205(1)(b) (2014), Iowa Code § 124.207(1)(b) (2014), Iowa Code § 124.293(1)(b) (2014), and Iowa Code § 124.211(1)(b) (2014). There is federal case law directly on this point. *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 or, as the Administrator contends, approval for interstate marketing of the substance.").

If you take away the reference in Iowa Code Chapter 124 to state laws, the Board would have to make recommendations to the legislature based solely on the 8 factors in Iowa Code §§ 124.201(1)(a)-(h) (2014), none of which references any state law. There is inconsistency in the Board's logic.

Mr. Miller also says that recommending scheduling of controlled substances is not within the Board's "purview," and that the Board's sole purview is the regulation of pharmacists and pharmacies in Iowa, but that is another incorrect interpretation of law (see Exhibit #31, at p. 3). There is an entire section on scheduling. Iowa Code §124.201 (2014). And the title of that section is "Duty to Recommend Changes in Schedules."

Scheduling does not make a substance legal

Placing a substance in Schedule 2 does not make it legal for anything. It takes a separate law to make it legal to actually use it. In the case of an FDA approved product, an FDA approved product is legal for an end user who has a valid prescription from a doctor who is licensed to prescribe scheduled substances and obtained from a pharmacy licensed to dispense scheduled substances.

In the case of marijuana and marijuana extracts, some states have laws explaining how those substances can be produced and distributed without a prescription and without obtaining it from a pharmacy.

Most states that have legalized marijuana or marijuana extracts for medical use have not even changed their state schedules. Colorado, for example, has never had marijuana in any schedule. Colorado made marijuana illegal in 1917 and

probably saw no reason to include it in Schedule 1. Schedule 1 would not make marijuana any more illegal than it already was.

During discussion on January 5, 2014, the Board made references to a medical marijuana program, but a medical marijuana program was not requested in the Marijuana Scheduling Petition (see Exhibit #31, at pp. 3 & 4). Moving marijuana to another schedule, or even removing it from all of the schedules, would not create any obligation on the Board to recommend a medical marijuana program in Iowa. It might make sense to make such a recommendation, but such a recommendation is not required.

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 January 4, 2016, 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

IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN,

Petitioner,

05771 CVCV051068

VS.

PETITIONER'S BRIEF IN SUPPORT OF PETITION FOR JUDICIAL REVIEW

IOWA BOARD OF PHARMACY, Respondent.

I. STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

The Board has a duty to recommend removal of marijuana from schedule 1 if marijuana no longer meets a condition required for inclusion in schedule 1.

Cases:

Grinspoon v. DEA, 828 F.2d 881 (1st Cir. 1987)
Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991)
State v. Bonjour, 694 N.W.2d 511 (Iowa 2005)
Gonzales v. Oregon, 546 U.S. 243 (2006)

Statutes:

IOWA CODE § 17A.19(10) (2015)

IOWA CODE § 17A.19(11) (2015)

IOWA CODE § 124.201 (2015)

IOWA CODE § 124.203 (2015)

II. STATEMENT OF THE CASE

On July 7, 2014, Carl Olsen ("**Petitioner**") filed a Petition for Agency Action with the Iowa Board of Pharmacy ("**Board**") requesting the Board to recommend reclassifying marijuana. On August 27, 2014, the Board formed a subcommittee to consider the Petitioner's request. On November 19, 2014, after a

public hearing, the subcommittee recommended reclassifying marijuana. On January 5, 2015, the Board denied the request based solely on erroneous legal arguments.

The Board also rejected precedent from February 17, 2010, in which the Board had previously recommended reclassifying marijuana.

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. STANDING

The Board's Answer, filed on February 1, 2016, p. 3, says the Petitioner is not aggrieved or adversely affected.

Petitioner is not "aggrieved or adversely affected" by the final agency decisions cited in the Petition, as required by Iowa Code section 17A.19(1).

In 1982, the Iowa Supreme Court held the Iowa Board of Pharmacy had shown there was a compelling interest in overriding the Petitioner's free exercise of religion. See <u>State v. Olsen</u>, 315 N.W.2d 1, 8 (Iowa 1982) (Olsen's belief in the marijuana sacrament is "sincere and central" to the religion)¹. And see <u>Olsen v. DEA</u>, 878 F.2d 1458, 1461 (D.C. Cir. 1989) (Olsen is "entitled to a judicial audience")².

¹ Compare with <u>State v. Bonjour</u>, 694 N.W.2d 511, 513 (Iowa 2005) ("our legislature has foreseen the potential medical uses for marijuana but has deferred on the issue until the Board of Pharmacy Examiners has acted").

² See <u>Elrod v. Burns</u>, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); and see <u>Montana v. United States</u>, 440 U.S. 147, 163 (1979) ("Unreflective invocation of collateral estoppel against parties with an ongoing interest in constitutional issues could freeze doctrine in areas of the law where responsiveness to changing patterns of conduct or social mores is critical"); and see <u>Raich v. Gonzales</u>, 500 F.3d 850, 866 (9th Cir. 2007) (on the question of whether a federal fundamental right exists to use marijuana for health, the court stated, "Although that day has not yet dawned, considering that during the last ten years eleven states have legalized the use of medical marijuana, that day may be upon us sooner than expected").

In 2014, Iowa legalized the possession and use of a marijuana extract obtained from illegal sources³. Neutrality and general applicability of the law are essential elements in free exercise of religion jurisprudence. See <u>Employment</u> <u>Division v. Smith</u>, 494 U.S. 872, 889 (1990) (citing <u>Olsen v. DEA</u>, supra)⁴.

The Board's recommendation to reclassify marijuana in 2010 and the Board's recent recommendation in 2015 to reclassify cannabidiol, are also indications that the compelling interest overriding the Petitioner's free exercise of religion is eroding. The Board is the sole authority authorized by Iowa Code Chapter 124 to address these changes.

The Board determines the strength of the state's compelling interest in denying the Petitioner's free exercise of religion. The interest is now less compelling than it was then (accepted medical use of marijuana by state laws began in 1996 with the state of California, and reached Iowa in 2014). The determination of the state's interest in denying the Petitioner's free exercise of religion is a decision the Board must make⁵. The Petitioner's injury is directly

³ 2014 Medical Cannabidiol Act, Iowa Acts Chapter 1125 § 7 (May 30, 2014), SF 2360.

marijuana use and the conditions, if any, it may be used to treat").

⁴ And see <u>Church of Lukumi Babalu Aye v. Hialeah</u>, 508 U.S. 520, 546 (1993) ("A law that targets religious conduct for distinctive treatment or advances legitimate governmental interests only against conduct with a religious motivation will survive strict scrutiny only in rare cases"); and see <u>Fraternal Order of Police v. Newark</u>, 170 F.3d 359, 363 (3rd Cir. 1999) ("plaintiffs are entitled to a religious exemption since the Department already makes secular exemptions").

⁵ See footnote 1. <u>State v. Bonjour</u>, 694 N.W.2d 511, 514 (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

caused by the Board. The Board is the only authorized authority named in the statute with the authority to advise the legislators and the courts on the strength of the state's interest.

The religious use of schedule 1 controlled substances requires the Board's evaluation of the substance, which is why the Iowa Supreme Court deferred to the Board in 1982 when denying the Petitioner's free exercise of religion⁶.

Standing is not a requirement to request the Board consider the scheduling of marijuana, but the Board says it wants to address that issue now⁷. The Petitioner has standing to seek judicial review.

V. **ARGUMENT**

A. The Board rejected precedent without justification Iowa Code §17A.19(10)(h) (2015)

While the Petitioner acknowledges the Board is not strictly bound by precedent, the Board must cite new or additional facts justifying an inconsistency.

⁶ Iowa Code Chapter 124 includes a religious exemption for the use of a schedule 1 substance, peyote. Iowa Code §124.203(8) ("Nothing in this chapter shall apply to peyote when used in bona fide religious ceremonies of the Native American Church").

⁷ See Americans for Safe Access v. DEA, 706 F.3d 438 (D.C. Cir. 2013). "On September 1, 2011, Carl Olsen intervened on behalf of Petitioners. He asserts a religious interest in the use of marijuana." Id., at 441. "Petitioners were under no obligation to establish ... standing." Id., at 443. "However, when a federal court of appeals reviews an agency action, ... standing must be demonstrated 'as it would be if such review were conducted in the first instance by the district court." Id., at 443.

The Board held four public hearings in 2009, eight to nine hours each, transcribed by a certified court reporter, and accepted expert testimony for a period of four months (Exhibit #7, Exhibit #8, Exhibit #9). Based on that evidence, on February 17, 2010, the Board reached the unanimous conclusion that marijuana should be reclassified (Exhibit #10).

The Board formed a subcommittee on August 27, 2014, to consider the reclassification of marijuana (Exhibit #15, Exhibit #16). The subcommittee held a three-hour public hearing on November 17, 2014 (Exhibit #18, Exhibit #19). On November 19, 2014, the subcommittee unanimously recommended the reclassification of marijuana (Exhibit #20, Exhibit #21, Exhibit #22).

On January 5, 2015, the Board rejected both the 2010 recommendation and the 2014 subcommittee recommendation without citing any new evidence which would justify the inconsistency with the unanimous ruling on February 17, 2010, or the unanimous subcommittee recommendation on November 19, 2014.

Additionally, on March 2, 2015, before the March 9, 2015, hearing on the Petitioner's Petition for Reconsideration of the Board's ruling (Exhibit #32), the Petitioner submitted position statements from two major professional medical organizations, the American Academy of Neurology on December 17, 2014, and the American Academy of Pediatrics on January 20, 2015, recommending the

reclassification of marijuana (Exhibit #33). The Board denied the Petition for Reconsideration without any further explanation (Exhibit #35).

The Board's action is inconsistent with the agency's prior practice or precedents, and the Board has not stated any credible reasons sufficient to indicate a fair and rational basis for the inconsistency. Iowa Code §17A.19(10)(h) (2015).

B. Federal scheduling example

Iowa Code §17A.19(10)(k) (2015)

Iowa's scheduling process only mentions federal scheduling once. Iowa
Code §124.201(4) (2015). When the federal government places a new substance in
federal schedule 1, the Iowa Board of Pharmacy has the option to place it
temporarily in Iowa schedule 1. There is no requirement the Board follow federal
scheduling. In the single instance where federal scheduling is mentioned, the
Board has the option not to follow it.

The Board's January 5, 2015, order says that it's past practice has been to follow federal scheduling, while at the same time complaining the Petitioner is unnecessarily detailing the Board's history on scheduling of marijuana⁸.

Consistency with federal scheduling of marijuana has not been the Board's past practice.

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⁸ See the Board's Answer, February 1, 2016, at p. 1.

There are three examples where the Board has not followed federal scheduling of marijuana or federal scheduling of substances extracted from marijuana. These three are:

- (1) marijuana has been listed in both schedule 1 and schedule 2 in Iowa since 1979, Iowa Code §124.204(4)(m) (2015), Iowa Code §124.206(7) (2015)⁹, and marijuana has only been listed in one schedule (schedule 1) of the federal schedules since 1970, 21 C.F.R. §1308.11(d)(23) (2015);
- (2) cannabidiol (CBD) is in federal schedule 1¹⁰ and the board has now recommended cannabidiol be placed in Iowa schedule 2; and
- (3) natural delta-9-tetrahydrocannabinol (THC) (derived from the cannabis plant) is in federal schedule 1 while the same substance was placed in Iowa schedule 3 in 2008¹¹, Iowa Code §124.208(9)(b) (2015) (Exhibit #23, at p. 3), whereas only *synthetic* delta-9-tetrahydrocannabinol (THC) is in federal schedule 3, 21 C.F.R. §1308.13(g) (2015) (emphasis added).

⁹ The first time the Board addressed this inconsistency in state law was in 2010 when it recommended that marijuana be removed from schedule 1 rather than maintained in schedule 1. See Exhibit #11.

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf;
 http://www.drugcaucus.senate.gov/sites/default/files/DEA%20Rannazzisi%20CBD%20Testimo ny%20%2824June15%29.pdf at page 1 ("CBD derived from the cannabis plant is controlled under Schedule I of the CSA because it is a naturally occurring constituent of marijuana").
 2008 Iowa Acts Chapter 1010 § 4 (March 5, 2008), HF 2167.

The Board has not recommended consistency with federal scheduling of marijuana for a long time (25 years) and the Board has never suggested that Iowa follow federal scheduling of marijuana when it has made recommendations.

The Board recommended removing marijuana from Iowa schedule 1 in 2010, which was neither required nor prohibited by federal scheduling.

Denying the petition because of federal scheduling was 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. Iowa Code §17A.19(10)(k) (2015).

C. Hydrocodone combination products scheduling example. Iowa Code §17A.19(10)(i) (2015)

At the hearing on November 19, 2014, the Board gave an example of hydrocodone combinations products which were rescheduled by the U.S. Drug Enforcement Administration from federal schedule 3 to federal schedule 2 on August 8, 2014, effective October 6, 2014. 79 FR 49661.

On December 19, 2014, the Iowa Board of Pharmacy recommended the removal of hydrocodone combination products from Iowa schedule 3, Controlled

Substances Scheduling (1218DP). The legislature took no action on the Board's recommendation to reschedule hydrocodone products in 2015¹².

The Board's ruling of January 5, 2015 (Exhibit #1, at p. 3), states:

The Board is hesitant to recommend a change in state scheduling of a substance that directly conflicts with federal law.

But there is no direct conflict with federal law. Maintaining hydrocodone combinations products in Iowa schedule 3 while the federal government has them in federal schedule 2 is not a direct conflict. The legislature would have acted on it by now if it was a direct conflict. The reason there is no direct conflict is because doctors and pharmacists who prescribe and dispense controlled substances in Iowa have to maintain both state and federal licenses and must abide by the stricter of the two schedules. If the situation were reversed and Iowa had hydrocodone combinations products in Iowa schedule 2 while the federal government maintained them in federal schedule 3, they would still be schedule 2 in Iowa regardless of federal scheduling. These state and federal laws were designed to provide flexibility between the two without causing any direct conflict between them. Iowa could maintain hydrocodone combination products in schedule 3 if it

¹² The Board resubmitted the recommendation to reclassify hydrocodone combination products again on December 29, 2015 (Exhibit #41), currently pending as SSB3004 (LSB 5151DP) 86th General Assembly 2nd Session.

considered federal scheduling to be incorrect and wanted to challenge the federal scheduling.

It's critical to note that no one is asking the Board to keep hydrocodone combination products in schedule 3 in Iowa, most likely because federal scheduling effectively makes them schedule 2 in Iowa without any change in state scheduling. It's even more critical to note that our legislature is not passing laws allowing people to obtain hydrocodone combination products from illegal sources to avoid federal scheduling. Our legislature did enact a law allowing people to obtain cannabidiol from illegal sources to avoid federal scheduling, so that's the critical difference here. There is a good reason Iowa should not follow federal scheduling, because Iowa obviously does not agree with federal scheduling in this instance.

The Board's assertion that state rescheduling of hydrocodone was required because of federal scheduling was based upon an irrational, illogical, or wholly unjustifiable interpretation of a provision of law whose interpretation has clearly been vested by a provision of law in the discretion of the agency. Iowa Code \$17A.19(10)(i) (2015).

D. Opium scheduling example

Iowa Code §17A.19(10)(j) (2015)

At the hearing on January 5, 2015, the Board said opium is in schedule 1 and pharmaceutical drugs are made from it. The Board said the plants we make medicines from are in schedule 1 and the medicines we make from them are in the lower schedules. That is absolutely false.

The Petitioner pointed out the error before the Board voted on whether to grant or deny the petition. When the Board said opium was in schedule 1, the Petitioner was recognized and stated opium was in schedule 2. In response to the Petitioner pointing out this error, Board member James Miller said, "Duly noted. I move we deny the petition." Board member Susan Frey, who said opium was in schedule 1, seconded the motion and the vote was taken immediately and the petition was denied.

The Board did not know what schedule opium was in. They could have taken a moment and looked it up. There are no plants in schedule 1 from which accepted medicines are made. Marijuana is the only plant in schedule 1 that has had a long history of medical use in the United States. See <u>James v. Costa Mesa</u>, 700 F.3d 394, 409 (9th Cir. 2012) (Berzon, J., dissenting):

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).

Opium plants are in schedule 2 and always have been. Iowa Code §124.206(c) (2015). It was plain error to cite opium as the reason for keeping marijuana in schedule 1. The Board said marijuana should be in the same schedule as opium and then erroneously stated that opium was in schedule 1. The Board could have simply looked it up in the Iowa Code.

The Board's ruling was a 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. Iowa Code \$17A.19(10)(j) (2015).

E. Petitioner's legal argument and supporting evidence were uncontested.

Iowa Code §17A.19(10)(c) (2015)

The Petitioner presented state medical marijuana laws as evidence of currently accepted medical use in the United States (see Exhibit #2). The term "currently accepted medical use" is not defined anywhere in the state or federal controlled substances acts. Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991) ("neither the statute nor its legislative history precisely defines the term 'currently accepted medical use"").

Because the phrase "accepted medical use in treatment in the United States¹³" is language borrowed from the federal statute and because Iowa Code Chapter 124 does not define what it means, "accepted medical use in Iowa" is not a valid interpretation and federal courts have interpreted the federal language for us.

The Board cannot interpret the laws of other states. Therefore, the best evidence of accepted medical use of marijuana in the United States are state laws accepting it for medical use. This is an issue of federalism.

The Board never addresses this legal argument and never disputed that marijuana has accepted medical use in the United States. The Board previously ruled in 2010 that marijuana does have accepted medical use, but never actually addressed the legal argument the Petitioner made in 2008 when that petition was filed with the Board.

There is federal case law showing that intrastate medical use is "accepted medical use in the United States" as that phrase is used in the federal controlled substances act. <u>Grinspoon v. DEA</u>, 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").

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

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¹³ Iowa Code §124.203(1)(b) (2015).

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.

Id., at 887.

Moreover, federal regulations (which is what the federal schedules are ¹⁴) cannot be used to interfere with accepted intrastate medical use of controlled substances. Gonzales v. Oregon, 546 U.S. 243, 258 (2006):

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.

The Board's interpretation of "accepted medical use in treatment in the United States" must be consistent with constitutional principles of federalism.

Where a phrase is not defined in the federal statute, and that phrase is defined in state laws, the Tenth Amendment to the U.S. Constitution says it is a power reserved to the states. And, where a term is used in Iowa law that refers to accepted medical use in the United States, other state laws are relevant and cannot be contested for their validity or authenticity. The Full Faith and Credit Clause of the U.S. Constitution requires that Iowa recognize other state's law as proof another state has made a final decision.

¹⁴ See 21 C.F.R. §1308

The Board's failure to recognize fundamental principles of federalism is 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) (2015).

VI. CONCLUSION

The single instance where Iowa law references federal scheduling is when a new substance is added to federal schedule 1, and when a new substance is added to federal schedule 1 the Board has the option not to schedule the substance at all. Federal scheduling is not determinative of Iowa scheduling. There is harmony and balance between the two, but no rigid requirement they be exact duplicates.

In discussing its conclusion not to recommend rescheduling of marijuana, the Board stated, "there is some medical use for marijuana." See the Board's January 5, 2015, order at page 3 (Exhibit #1). A finding of medical use alone is sufficient to recommend reclassification of marijuana. 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 sufficient to warrant recommendation for reclassification or removal pursuant to the language of Iowa Code section 124.203") (See Exhibit #6). Medical use is a statutory condition that prohibits the Board from recommending schedule 1, so the

Board illegally ignored a statutory duty by recommending that marijuana remain in schedule 1. Iowa Code §17A.19(10)(b) (2015).

The Board also violated the principles of federalism embodied in the U.S. Constitution. Iowa is a state in the United States, and it has accepted the U.S. Constitution as the supreme law of the land. Iowa Code §17A.19(10)(a) (2015).

The Board's final ruling on January 5, 2015, suggests that "the phrase 'pursuant to rules of the board' be deleted from Iowa Code §124.206(7)(a) (2015)," which would leave marijuana unconditionally in schedule 2 (Exhibit #1, at p. 5). That part of the ruling is inconsistent with the denial of the petition. Iowa Code §17A.19(10)(i) (2015).

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 an obligation to recommend that marijuana be reclassified.

Petitioner asks this Court to remand to the Board to address the legal arguments made by the Petitioner and explain why it no longer believes marijuana is incorrectly scheduled. If the Board still believes the petition should be denied after it corrects the errors it made, it should give valid reasons for doing so.

Dated this 8th day of April, 2016.

Respectfully Submitted:

/s/ Carl Olsen Carl Olsen, Pro Se

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IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN,

Petitioner,

05771 CVCV051068

VS.

IOWA BOARD OF PHARMACY, Respondent.

PETITIONER'S REPLY BRIEF IN SUPPORT OF PETITION FOR JUDICIAL REVIEW

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ARGUMENT

I. THE BOARD'S RECOMMENDATION TO PLACE MARIJUANA IN SCHEDULE I WAS UNREASONABLE UNDER IOWA CODE CHAPTER 124.

A. Accepted medical use

The Board argues that despite the Board's finding that marijuana has accepted medical use¹, it now has the duty to recommend that marijuana placed in schedule 1 and removed from schedule 2. Iowa law says that substances in schedule 1 must have no accepted medical use². The Board's ruling that marijuana should be placed in schedule 1 and removed from schedule 2 is contrary to Iowa law³.

In 2010, the Board found that marijuana had accepted medical use and recommended its reclassification⁴.

¹ On Page 3 of the Board's Final Ruling, the Board says, "there is some medical use for marijuana." See Exhibit #1, at page 15.

² On Page 3 of the Board's Final Ruling, the Board says schedule 1 prohibits the inclusion of a substance that, "has some accepted medicinal use." See Exhibit #1, at page 15

³ In 2009, Iowa District Court Judge Joel D. Novak said, "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". Ruling on Petition for Judicial Review, <u>McMahon v. Iowa Board of Pharmacy</u>, No. CV 7415, Polk County District Court (April 21, 2009), at page 4, footnote 1. See Exhibit #6, at p. 4, n. 1.

⁴ See Exhibit #10.

After forming a subcommittee on August 27, 2014, and holding a public hearing on November 17, 2014, the subcommittee found that marijuana had accepted medical use and recommended its reclassification⁵.

On January 5, 2015, the Board rejected the recommendation of the subcommittee, making erroneous legal arguments to justify reversing its prior recommendation to reclassify marijuana in 2010 and the subcommittee's recommendation to reclassify marijuana on November 19, 2014.

B. Conflict with federal law

The U.S. Supreme Court has considered whether the federal Controlled Substances Act can nullify state decisions on the accepted medical use of controlled substances. <u>Gonzales v. Oregon</u>, 546 U.S. 243, 251 (2006) ("The CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its pre-emption provision").

"No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together." § 903.

The Board argues that rescheduling would cause a conflict with federal scheduling, and then proceeds to recommend the rescheduling of cannabidiol

⁵ See Exhibit #20, Exhibit #21, and Exhibit #22.

(CBD) which would cause a conflict with federal scheduling if such a conflict actually existed. Because state scheduling does not legalize the actual use of cannabidiol or marijuana, state scheduling that differs from federal scheduling does not cause any conflict with federal scheduling. The Board's argument that state schedules can cause a conflict with federal schedules is erroneous.

The Board's finding that marijuana has accepted medical use is "contrary" to federal scheduling, but not in "conflict" with federal scheduling. The Board is not authorized to recommend changes in federal scheduling. Federal scheduling of cannabidiol and marijuana is invalid for the same reason the Board's finding of medical use makes Iowa's scheduling of cannabidiol and marijuana invalid, but the Board's authority is limited to making recommendations to the state legislature.

Another reason that state scheduling cannot create a conflict with federal scheduling is that doctors and pharmacists have to be licensed under both state and federal law and must follow the more restrictive of the two schedules, thereby eliminating any difference between the two schedules from being in conflict with each other.

The statute and our case law amply support the conclusion that Congress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally.

Gonzales v. Oregon, 546 U.S. 243, 269-70 (2006).

The Iowa legislature placed delta-9-tetrahydrocannabinol (THC) products derived from the cannabis plant in Iowa schedule 3 in 2008⁶ while those same products remain in federal schedule 1 today⁷. This does not create any conflict with federal scheduling because there are no federally approved products containing natural THC derived from cannabis plants. Federal law prohibits marijuana from being used to make such products, regardless of what schedule Iowa puts them in. Federal law only allows products containing synthetic THC to be sold and marketed, and those products are not made from marijuana.

Another example is hydrocodone combination products which were federally rescheduled from schedule 3 to schedule 2 in 2014⁸, but remain in Iowa schedule 3⁹. Again, there is no conflict between state and federal scheduling, because federal scheduling prohibits the sale or marketing of a schedule 2 substance as a schedule 3 substance in the state of Iowa. Just because these products are in Iowa schedule 3 does not mean it's legal to sell or market them as

 6 Iowa Code 124.208(9)(b) (2015); 2008 Iowa Acts Chapter 1010 $\$ 4 (March 5, 2008), HF 2167.

⁷ 21 C.F.R. §1308.13(g) (2015). The federal government proposed making these products federal schedule 3 in 2010, but never finalized the rule. 75 FR 67054. These products still remain in federal schedule 1, similar to Epidiolex and Sativex manufactured by GW Pharmaceuticals in Great Britain because the marijuana used to make them can't be grown in the United States.

⁸ The U.S. Drug Enforcement Administration rescheduled hydrocodone combination products from federal schedule 3 to federal schedule 2 on August 8, 2014, effective October 6, 2014. 79 FR 49661.

⁹ Iowa Code 124.208(5)(a)(3) (2015); Iowa Code 124.208(5)(a)(4) (2015).

schedule 3 products in the state of Iowa. The more restrictive of the two schedules prevails, thus eliminating any potential conflict. And, it's worth noting here that Iowa does not allow the possession of hydrocodone combinations products in Iowa without a prescription. Iowa does allow the possession of cannabidiol in Iowa without a prescription, and that is a positive conflict with federal law for those possessing the cannabidiol. Making cannabidiol and the plant it comes from schedule 2 substances in Iowa would at least give people some assurance that Iowa considers their federal scheduling invalid. It has to start somewhere, and that is usually locally.

If Iowa were to reschedule cannabidiol (CBD) to Iowa schedule 2, as the Board recommended in its final ruling, CBD would still be in federal schedule 1. And, again, placing CBD in state schedule 2 is not a conflict between state and federal scheduling. Iowa would simply be saying, in the most direct way possible, that it does not agree with federal scheduling. This is entirely appropriate under these two acts. That is the way these two acts were intended to work. There would be no reason to have two acts, one state and one federal, if they were intended to be identical carbon copies of each other without any exception. This is called federalism. The federal government is simply respecting the rights of the states, as it should.

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.

Gonzales v. Oregon, 546 U.S. 243, 258 (2006)

If the Board agrees with federal scheduling, then it would be entirely appropriate for the Board to follow federal scheduling. However, the Board has clearly stated it does not agree with federal scheduling by stating that marijuana has accepted medical use. Federal scheduling says that marijuana has no medical use. Lack of accepted medical use is a pre-requisite for placement in both state and federal schedule 1. The Board cannot follow federal scheduling if it does not agree with it. That is the only reason we have our own schedules in the state of Iowa. If both sets of schedules were intended to be identical carbon copies of each other, there would be no reason to have two sets.

The Petitioner admits that differences between state and federal schedules are not frequent, but in this particular case, with marijuana, Iowa law demonstrates three instances where the state has or could make a different scheduling determination than the federal government has made.

1. Iowa has THC products derived from cannabis plants in a different schedule than the federal government (Iowa has them in schedule 3 and the federal government has them in schedule 1);

- 2. The Board is now recommending that CBD be placed in a different schedule than the federal government (the Board recommends schedule 2 and the federal government has CBD in schedule 1¹⁰); and
- 3. Marijuana is in two schedules in Iowa (schedule 1 and schedule 2) and the federal government only has marijuana in one schedule (schedule 1). It is beyond question that Iowa does not follow federal scheduling (particularly in the case of marijuana and marijuana derivatives), and it is also beyond question that there is no conflict with federal scheduling when this occurs.
- II. THE BOARD'S RECOMMENDATION TO PLACE MARIJUANA IN SCHEDULE I WAS UNLAWFUL UNDER IOWA CODE CHAPTER 124.

Petitioner repeats the arguments under Section I, because Iowa law prohibits the Board from recommending the inclusion of substances with accepted medical use in the United States in schedule 1. If the Board does choose to make a recommendation to the legislature, it cannot make a recommendation that marijuana be placed in schedule 1. Marijuana now has accepted medical use in forty-one (41) states, the District of Columbia, Guam, and Puerto Rico (a total of 44 federal jurisdictions). At the time the petition was filed in July of 2014, there were a total of thirty-two (32) states that had accepted the medical use of marijuana. The Board has never disputed the Petitioner's characterization of these

¹⁰ http://www.dea.gov/divisions/hq/2015/hq122315.shtml

laws as "accepted" medical use of marijuana in the United States, nor could it.

Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991)

(neither the statute nor its legislative history precisely defines the term "currently accepted medical use"); 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"). Therefore, it is an undisputed fact in this case that marijuana has accepted medical use in the United States, and not just in Iowa.

CONCLUSION

The Board's recommendation that marijuana be placed in schedule 1 and removed from schedule 2 is prohibited by law because the Board found that marijuana has accepted medical use. And, it was unreasonable even if it had not been unlawful.

The Board's ruling was not supported by any new evidence casting doubt on the validity of the Board's 2010 recommendation to place marijuana in schedule 2, or the validity of the subcommittee's recommendation on November 19, 2014, to place marijuana in schedule 2.

The Board cannot cede state scheduling decisions to the federal government without the consent of Congress. The Board is required to make an independent

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decision. There would be no need for a state controlled substances act if it were

otherwise.

The Court should remand the petition to the Board to correct its errors. The

Board can either make a recommendation based on valid legal arguments and the

evidentiary record or decline to make any recommendation at all (leaving its

previous recommendation from 2010 as the last word on this question from the

Board as the Iowa Court of Appeals noted two days ago)¹¹.

Dated this 13th day of May, 2016.

Respectfully Submitted:

/s/ Carl Olsen

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Original: filed

Copy to: Attorney General

¹¹ See, Olsen v. Iowa Board of Pharmacy, No. 14-2164 (Slip Opinion, Iowa Court of Appeals, decided May 11, 2016), 2016 Iowa App. LEXIS 455.

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1
            IN THE IOWA DISTRICT COURT FOR POLK COUNTY
2
    CARL E. OLSEN,
                               * File No. CVCV051068
3
           Petitioner,
4
                               * TRANSCRIPT OF PROCEEDINGS-
    VS.
5
                               * Application for
    IOWA BOARD OF PHARMACY,
                              * Judicial Review
 6
           Respondent.
                               * May 20, 2016
7
8
           The above-entitled matter came on for hearing
    regarding Petitioner's Application for Judicial Review
9
10
    before the Honorable Brad McCall, Judge of the
11
    Fifth Judicial District of Iowa, commencing at 8:24 a.m.
12
    on the 20th day of May, 2016, at the Polk County
13
    Courthouse, 500 Mulberry Street, Room 313, Des Moines,
14
    Iowa.
15
16
                       A P P E A R A N C E S
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1 PROCEEDINGS 2 (The hearing commenced at 8:24 a.m. on the 20th day of May, 2016, with the Court and parties 3 4 present.) THE COURT: This is the case of Carl Olsen, 5 6 plaintiff, versus Iowa Board of Pharmacy, defendant, 7 Polk County No. CVCV051068. 8 This is the time and place set for hearing on the plaintiff's application for judicial review. 9 10 plaintiff appears in person, pro se. The Iowa Board of 11 Pharmacy appears by Meghan Gavin, assistant attorney 12 general. 1.3 Mr. Olsen. And I will tell you, sir, I have had an opportunity to read your brief. I have not 14 15 looked in detail at the exhibits attached to your brief 16 in your petition, but I have a general understanding of the issues that are before me. 17 18 MR. OLSEN: Good. Thank you, Your Honor. 19 Good morning. 2.0 THE COURT: Good morning. 21 MR. OLSEN: My name is Carl Olsen, 22 And Carl with a "C." 0-1-s-e-n. 23 And the -- I have -- This is, like, about my 24 third case with the Iowa Board of Pharmacy. And the 2.5 Iowa Court of Appeals issued an opinion last week that

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is relevant to this case. So in that case the Board had declined to take any action, and the Iowa Court of Appeals ruled that they were not obligated to take any action.

And so in this case they actually did take some action, and so that's what distinguishes this case from that one. So in this one I'm complaining about the action that they did take.

The Board is basically saying that they think they should follow federal scheduling of marijuana. Marijuana is a federal Schedule I. In Iowa marijuana has been in both Schedule I and Schedule II since 1979.

And the Board, in this action, has recommended that marijuana be removed from Schedule II and placed in Schedule I, which is the exact opposite of what they ruled in 2010. They ruled that it should be removed from Schedule I and placed in Schedule II. So that's what the case is about.

The inconsistency in Iowa's scheduling was addressed by the Iowa Supreme Court in the year 2005.

And the case was *State vs. Bonjour*, 694 N.W.2d 511. And in that case the ruling was that if marijuana had medical use and there was a medical necessity defense available as an affirmative defense that the Board would

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have acknowledged that marijuana has medical use by creating some kind of something to allow it. I'm not sure. And that they hadn't done that, so there was no medical necessity defense.

The dissenting opinion, Chief Justice

Lavorato and Justice Wiggins said that the Board had an obligation to resolve this inconsistency in the scheduling.

And so the next year the U.S. Supreme Court ruled in a case called *Gonzales vs. Oregon*, 546 U.S. 243 (2006), that states have the final say on accepting medical use under the Federal Drug Act.

So I began to develop a strategy to get the Board to address this issue. I contacted medical experts and legal experts, and I got the ACLU to help me. And in 2008 I petitioned the Board.

And my argument was that marijuana had accepted medical use in 12 states in the United States and that that was accepted medical use in treatment in the United States by definition, that that is the meaning of the language in the statute.

The Board denied the petition saying I failed to address abuse potential. So we appealed to the Iowa District Court, and Judge Novak ruled that abuse potential is not relevant and that the Board did

1 not address my argument and that abuse potential was not 2 relevant to the argument that I was making and that they 3 needed to address the actual argument that I was making. So they denied the petition again. 4 I went 5 to the Iowa Supreme Court. While my case was pending, 6 the Board decided independently to look at the 7 scientific evidence. And I had prepared for that, so I 8 had notified everybody that they were going to do that. And after they did that for four months at 9 10 public hearings, they said that marijuana does have 11 accepted medical use and recommended that it be removed from Schedule I. 12 1.3 So that brings us up to the ruling I got last week that said the Board doesn't have to take any 14 action, that that ruling from 2010 still stands as long 15 16 as they haven't made a different decision. In this case 17 they did make a different decision. So that's what this 18 case is about. 19 So the Board is saying that -- And in the 20 ruling, in the final ruling that I got January 5, 2015, 21 the Board says marijuana does have medical use and then 22 recommended that it be placed in Schedule I. 23 And my argument in my reply brief -- I wrote 24 my reply brief after I got the Iowa Court of Appeals

decision, so in the reply brief, I'm not covering stuff

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1
    that's not really relevant anymore. I made a lot of
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    arguments in my opening brief that were disposed of by
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    that case last week.
                So the only argument that I have left is
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    that the Board made a recommendation that's contrary to
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 6
    the statute. The statute says if marijuana has medical
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    use, it can't be in Schedule I. They recommended that
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    it be in Schedule I. And they made inconsistent
    arguments saying that a component of marijuana should be
9
10
    placed in Schedule II which is in federal Schedule I.
11
    That would be inconsistent with federal scheduling if
12
    there was such an inconsistency. There is not.
13
                But they claimed that if they recommended
14
    marijuana be in Schedule II, it would create an
15
    inconsistency with federal scheduling and then turned
16
    around and recommended that a component of marijuana be
17
    rescheduled, which would create the same conflict with
18
    federal scheduling.
19
                So -- But, basically, my argument is that if
20
    they say marijuana has medical use, that rules out
21
    Schedule I and they cannot recommend Schedule I.
22
    that's my argument.
23
                THE COURT: You know, I presided over a case
24
    that you were involved in several years ago.
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                MR. OLSEN:
                            Yeah.
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1
                THE COURT: And in that particular case,
2
    basically analyzing the statute, I concluded that
3
    marijuana is ordinarily a Schedule I controlled
    substance except as otherwise provided by rules of the
4
    Board for medicinal purposes.
5
                MR. OLSEN: Right.
 6
7
                THE COURT: And then it is considered to be
8
    a Schedule II controlled substance but only if it's used
9
    for medicinal purposes pursuant to the rules of the
10
    Board.
11
                MR. OLSEN: Correct.
12
                THE COURT: Do you agree with all that?
                MR. OLSEN: I absolutely do, yeah.
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14
                THE COURT: All right. Why then can't it
15
    remain a Schedule I controlled substance except for
16
    those specific uses that are allowed by the Board?
                            Well, I'm not sure the answer to
17
                MR. OLSEN:
18
    that is no. The answer is that the Board says they
19
    can't make rules like that. They consistently say it's
20
    impossible for them to make such rules. But they
21
    haven't cured the problem by saying marijuana should be
22
    removed from Schedule II until now.
23
                This order that they just made would cure
24
    that problem. If marijuana were removed from
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    Schedule II and that language about rules of the Board
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1
    of Pharmacy was removed from the Code, then it would
2
    clarify the situation.
 3
                And just the opposite, if they recommended
    Schedule II without that extra verbiage about rules of
4
    the Board, that would also cure the problem which is
5
 6
    what -- And so they've addressed that twice.
7
                In 2010 they said the answer is to put it in
8
    Schedule II. And now they say the answer is to put it
    in Schedule I. But the answer that they're giving now
9
10
    is inconsistent with the statute because they say in the
11
    order that marijuana does have medical use.
12
                THE COURT: Okay. All right. Thank you,
13
    sir.
14
                MR. OLSEN: Thank you.
15
                THE COURT: Ms. Gavin.
16
                MS. GAVIN: Thank you, Your Honor.
17
                First, Your Honor is correct. Marijuana is
18
    confusingly scheduled. It's uniquely scheduled under
19
    the Controlled Substances Act, Chapter 124.
20
                And Mr. Olsen is correct, that dual
21
    scheduling in Schedule I and Schedule II dates back to
22
    the late '70s when the federal government authorized a
23
    limited number of medical testing with marijuana.
24
    then the federal government has prohibited all medical
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    testing related to marijuana.
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And the state's particular program that was authorized in the late '70s never really went to fruition. And the Board currently does not have any rules regarding the medical use of marijuana.

I think a couple things are of note,

Your Honor. And I agree with Mr. Olsen that the Court

of Appeals decision that was issued on May 11th is very

relevant to the outcome of this case.

This is actually the fourth time Mr. Olsen has challenged the Board's recommendation or lack thereof. And while he focuses exclusively on the 2010 recommendation, he does not focus on the Board's 2012, '13, or '14 recommendations.

And what's most important about the Court of Appeals decision that was issued last week is that the Court of Appeals applied the heightened deferential standard from the *Renda* decision in evaluating the Board's interpretation of its duty under the Controlled Substances Act. So they didn't apply the correction of errors of law under 17A.19(10)(c). They applied the more deferential standard under 11.

So the question, I believe, again, for this Court when it looks at the 2015 decision, is whether the Board's decision is based upon an irrational, illogical or wholly unjustifiable interpretation of its obligation

under the Controlled Substances Act.

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And I don't believe that that -- any review of that with that heightened standard you can come to that conclusion that it is wholly irrational, unjustifiable.

Mr. Olsen focuses exclusively on how the Code defines a Schedule I substance versus Schedule II.

And a Schedule I substance is a highly-addictive substance with no accepted medical use. And he ends his analysis there.

But if you look more closely at the Board's duty to make scheduling decisions, there's language in the Code that the Court of Appeals focused on, and that's -- If you look in 124.201, it says, The board shall -- Annually the board shall recommend to the General Assembly any scheduling decisions which it deems necessary and advisable.

So the Board's position consistently for the last four years has been, regardless of whether marijuana has an accepted medical use in the United States, or even in Iowa, the Board, nevertheless, has discretion over which individual recommendations it makes to the legislature about what substances should be rescheduled.

THE COURT: Hasn't the legislature, in at

1 least a limited sense, recognized that marijuana does 2 have some medicinal purpose? 3 MS. GAVIN: Yes, Your Honor. And the Board recognized that. 4 5 THE COURT: Well, how then is it logical or rational or justifiable for the Board to recommend that 6 7 marijuana be classified solely as a Schedule I substance 8 that by definition, by statutory definition has no medicinal purpose? 9 10 MS. GAVIN: Well, for two reasons, Your Honor. First, I would say I don't believe that 11 12 that is an accurate reflection of what the Board did in 13 2015. I don't think it was recommending that marijuana 14 exclusively remain in Schedule I. 15 I mean, the Board talked at length about the 16 intervening acts between 2014 and '15, which was the 17 passage of the cannabidiol bill. And it talked about 18 how, you know, marijuana, sometimes we look at it as 19 this universal thing, but marijuana exists in many 2.0 derivative forms. 21 Cannabidiol, for instance, has little to no 22 THC in it, and it is substantively different than what 23 we consider recreational marijuana or what people would 24 know as marijuana. So the Board in 2015 took a more 2.5 nuance view.

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And I think this has been part of the difficulty of regulating medical marijuana, is that marijuana in general has never gone through any FDA testing, and so it's unlike a synthetic drug where if you take a Lipitor pill every day, it's the same pill, it's the same dosage, it's the same thing. Marijuana doesn't have that kind of regulatory standard to ensure that the active ingredients are the same dosage-wise every day.

And the Board has discussed that issue at length, and it's difficult to recommend a medical use for something that can't be put into the formula that we use for medicinal purposes. It's kind of fitting a square peg into a round hole.

So the Board took a more nuance view and said, We should look at these derivatives individually where there has been testing, where there is consistency in dosage and there have been some proven results.

So in addition to that evidence, it recognized what the legislature did with cannabidiol, and it kept its recommendation consistent with that.

THE COURT: So you're suggesting that cannabidiol is a separate and distinct substance from marijuana generically.

MS. GAVIN: Yes. I think that it most

1 certainly is, and I think that people that produce it 2 believe that too. Many people don't believe it even 3 falls under the rubric of marijuana. And so where it falls in the scheduling --4 There's an argument that it's not scheduled at all 5 6 either under Iowa or federal law based upon its THC 7 content, which is usually less than .3 percent. So it's 8 something that's functionally different than marijuana globally. 9 10 THE COURT: Okay. 11 MS. GAVIN: And so I think the Board was 12 kind of recognizing some of that reality. And 13 cannabidiol is an exception generally because we do have some medical evidence for it. 14 15 You know, it's interesting that when the 16 legislature decriminalized the possession of cannabidiol 17 for a very select group of Iowans, it didn't change the 18 scheduling for marijuana. They kept marijuana the same. 19 THE COURT: Did it specifically list 20 cannabidiol on a schedule? 21 MS. GAVIN: It did not. And so the Board 22 recognizes that as a hole; and part of the 2015 23 recommendation was to fill that hole, which is its obligation, I believe, under the Controlled Substances 24 2.5 Act, to do so.

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I also don't think that the 2015 decision is inconsistent with the Board's prior decisions based upon the intervening act between 2014 and 2015, which is the passage of the cannabidiol bill.

And since Mr. Olsen has conceded that it is the interpretation of the Board's duty under

Chapter 124, which is the sole issue in this case, the Board would rest on its brief and note the distinctions made by the Court of Appeals, unless this Court has any further questions.

THE COURT: I don't believe I do.

Mr. Olsen, anything further?

MR. OLSEN: Yes. Meghan is correct on the four appeals that I have filed. The first one was a 2010 ruling, which I won. And the 2012 one, the Board refused to take any action, and I lost. And the 2013 one, which was last week, I lost because they didn't take any action.

The 2015 ruling is different because they did take action. So the rulings that the Board has -- can rationally refuse to take any action are based on them not doing anything, but this case they actually did something. And I'm complaining about how they went about doing it. So that's the distinction between this case and the other three.

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Ms. Gavin talks about recreational marijuana. Well, there's recreational opium. There's recreational coca plants. They're in Schedule II, not Schedule I. We don't prescribe opium plants, and we don't prescribe coca plants, but we do make medicines from them, which brings me to CBD. Cannabidiol is an extract from the marijuana plant. It doesn't come out of thin air. It's not made synthetically. It's made from a marijuana plant. So it has the same quality that morphine has or the same quality that cocaine has. It's made from a plant. Those plants are not in Schedule I. Schedule I is prohibitive. And that's a problem when you're going to start extracting substances from a plant material. And CBD is Schedule I according to the DEA. Repetitively the DEA has made statements that CBD, cannabidiol, is in federal Schedule I. And my argument is that Iowa can put it in Schedule II. There's no inconsistency because putting a substance in Schedule II, III, IV or V in Iowa doesn't make it legal to use that substance if the federal schedule says it's Schedule I. It's still illegal under federal law. The scheduling doesn't create a conflict,

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    but it doesn't make it legal to do the activity.
2
    would require change in federal classification to make
3
    it legal to actually possess or use.
 4
                The law that we passed here in Iowa requires
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    people to leave Iowa to get this cannabidiol.
6
    cannot acquire it here in Iowa. And it's illegal to
7
    possess in Iowa. It's illegal to possess -- to cross
8
    state lines. It is Schedule I.
9
                So those are my rebuttal arguments.
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                THE COURT: Okay. Thank you very much.
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                MR. OLSEN: Yes. Thank you.
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                THE COURT: I will take a look at things.
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    I'll look at the exhibits in detail, and I'll get a
14
    ruling done as quickly as I can. Thank you.
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                MR. OLSEN: All right. Thank you.
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                MS. GAVIN: Thank you, Your Honor.
17
                 (Hearing concluded at 8:45 a.m., on the
18
    20th day of May, 2016.)
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20
21
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1 CERTIFICATE OF REPORTER 2 I, Julie A. Moon, Certified Shorthand Reporter 3 and Official Court Reporter for the Fifth Judicial 4 District of Iowa, do hereby certify that I was present 5 during the foregoing proceedings and took down in 6 shorthand the testimony and other proceedings held, that 7 said shorthand notes were transcribed by me by way of 8 computer-aided transcription, and that the foregoing 9 pages of transcript contain a true, complete, and 10 correct transcript of said shorthand notes so taken. 11 DATED this 2nd day of June, 2016. 12 13 /s/ Julie A. Moon Julie A. Moon 14 Certified Shorthand Reporter 15 16 Transcript ordered: 5-22-16 Transcript completed: 6-2-16 17 18 Ordered by: Carl Olsen 19 20 21 22 23 24

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•	accepted [5] - 4:18,	available [1] - 3:25	classification [1] -	D
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IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

CARL OLSEN, :

Petitioner. : CVCV051068

v. : RULING

IOWA BOARD OF PHARMACY, :

Respondent. __: __

The above matter came before the Court on a Petition for judicial review of agency action taken by the Iowa Board of Pharmacy. Hearing was held on May 20, 2016. Petitioner appeared in person, pro se. Respondent, Iowa Board of Pharmacy, appeared by Assistant Attorney General Meghan Gavin.

The Petition before the Court is the most recent in a series of efforts by Petitioner to have marijuana reclassified under Iowa's Controlled Substances Act.¹ Pursuant to the provisions of Chapter 124, drugs are classified in five different schedules. Placement of a substance on a particular schedule depends upon a variety of factors:

- a. The actual or relative potential for abuse;
- b. The scientific evidence of its pharmacological effect, if known;
- c. State of current scientific knowledge regarding the substance;
- d. The history and current pattern of abuse;
- e. The scope, duration, and significance of abuse;
- f. The risk to the public health;
- g. The potential of the substance to produce psychic or physiological dependence liability; and
- h. Whether the substance is an immediate precursor of a substance already controlled under this division.²

Substances with a high potential for abuse and with no accepted medical use in treatment or lacking in accepted safety for use in treatment are listed on schedule I.³

Substances having a high potential for abuse which may lead to psychological or

¹ Iowa Code Chapter 124. Prior cases in which Petitioner has sought action related to the scheduling of marijuana include *Olsen et al. v. State of Iowa*, CVCV008682 (Iowa Dist. Ct. 2011), *Olsen v. Iowa Bd. of Pharmacy*, CVCV045505 (Iowa Dist. Ct. 2014) and *Olsen v. Iowa Bd. of Pharmacy*, CVCV047867 (Iowa Dist. Ct. 2014)

² Iowa Code §124.201(1)

³ Iowa Code §124.203

physical dependence, but with a currently accepted medical use are listed on schedule II. Substances with currently accepted medical use but a lower potential for abuse than schedule II substances are listed on schedule III.⁵ Substances with currently accepted medical use but a limited potential for abuse are listed on schedule IV.6 Finally, substances with currently accepted medical use and a low potential for abuse or dependence are listed on schedule V.7

In Iowa marijuana is listed on both schedule I and schedule II. It appears as a schedule I "hallucinogenic substance . . . except as otherwise provided by rules of the board for medicinal purposes."8 It also appears on schedule II, as a "hallucinogenic substance . . . when used for medicinal purposes pursuant to rules of the board."9

By statute, the Iowa Board of Pharmacy Examiners makes "recommendations" to the general assembly as to the placement of substances on particular schedules. The Code directs the Board to make recommendations for placement on a particular schedule if it is not already on that schedule, and also directs the Board to recommend removal or reclassification of a substance if the Board does not believe a substance fits the criteria for the schedule it is on. 10 lowa's statutory scheme vests the ultimate decision making determination as to schedule assignment to the general assembly. The Board of Pharmacy Examiners is limited to making recommendations, which the general assembly may then choose to accept or reject.

As noted by the Iowa Supreme Court in State v. Bonjour, "the legislature has recognized that marijuana may have medical value. . . These statutes¹¹ show that our

⁴ Iowa Code §124.205

⁵ Iowa Code §124.207

⁶ Iowa Code §124.209

⁷ Iowa Code §124.211

⁸ Iowa Code §124.204(4)(m)

⁹ Iowa Code §124.206(7)(a)

¹⁰ *Compare* Iowa Code §124.203(1) *with* Iowa Code §124.203(2). ¹¹ Iowa Code §124.204(4)(m) and §124.206(7)(a)

legislature has foreseen the potential medical uses for marijuana but has deferred on the issue until the Board of Pharmacy Examiners has acted."¹²

In 2010 the Iowa Board of Pharmacy voted unanimously to recommend that the legislature reclassify marijuana from Schedule I to Schedule II. The Board action included a recommendation that the legislature convene a task force/study committee "for the purpose of making recommendations back to the legislature regarding the administration of a medical marijuana program".¹³

While the legislature did not take action on the Board's 2010 recommendation to reclassify marijuana, in 2014 the Iowa legislature did enact the Medical Cannabidiol Act. ¹⁴ Pursuant to the provisions of this Act, permanent residents of Iowa may possess cannabidiol for purposes of treating intractable epilepsy. ¹⁵

On July 7, 2014 Petitioner filed a Petition for Agency Action with the Iowa Board of Pharmacy, requesting the Board again recommend legislative removal of marijuana from Schedule I. After appointing a committee to study the request, the Board ultimately voted unanimously, at a meeting held on January 5, 2015, to deny the Petition.¹⁶

In deciding to deny the request to reschedule marijuana the Board noted it was "hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law". The Board recognized the lowa legislature had taken action to legalize possession of cannabidiol for certain individuals, but observed "[m]any substances can be derived from marijuana – some may have a medical use, while others may not. Therefore, in the Board's opinion, it would be more accurate to

¹² 694 N.W.2d 511, 513 (Iowa 2005).

¹³ Iowa Board of Pharmacy, Board Minutes, February 10, 2010 (Petitioner's Exh. 10).

¹⁴ Iowa Code Chpt. 124D; 2014 Acts, ch. 1125.

¹⁵ Although legalizing the possession of the substance, the Act did not create a method by which Iowa residents can obtain cannabidiol within the state.

¹⁶ Order Denying Petition, appended as Exh. A to Iowa Board of Pharmacy, Board Minutes, January 5-6, 2015 (Petitioner's Exh. 1). A request by Petitioner to reconsider the decision was denied, without written decision, at the Board's March 9, 2015 meeting.

¹⁷ *Id.* at 3.

schedule each derivate after an individualized analysis."18 The instant proceeding is for review of the Board's decision to deny the Petition.

Judicial review of agency action is governed by the provisions of Iowa Code §17A.19, which sets forth "the exclusive means by which a person or party who is aggrieved or adversely affected by agency action may seek judicial review of such agency action". "The burden of demonstrating the required prejudice and the invalidity of agency action is on the party asserting invalidity."¹⁹

The Court "may grant relief if the agency action has prejudiced the substantial rights of the petitioner, and the agency action meets one of the enumerated criteria contained in section 17A.19(10)(a) through (n)."20 Where an agency has been "clearly vested" with a fact-finding function, the appropriate "standard of review [on appeal] depends on the aspect of the agency's decision that forms the basis of the petition for judicial review"—that is, whether it involves an issue of 1) findings of fact, 2) interpretation of law, or 3) application of law to fact.²¹

In the case now before the Court, Petitioner asserts the Board incorrectly interpreted its statutory duty in connection with making scheduling recommendations to the legislature. The scope of this Court's administrative review depends on the level of statutory interpretation vested in the agency. If statutory interpretation has been vested in the discretion of the agency, the court is obligated to defer to the agency's actions unless the agency interpretation is "irrational, illogical, or wholly unjustififed]". 22 If

¹⁸ Id. While the Board refused to recommend the rescheduling of marijuana, consistent with the quoted language the Board did recommend the rescheduling of cannabidiol as a Schedule II controlled substance. ¹⁹ Iowa Code §17A.19(8)

²⁰ Burton v. Hilltop Care Cntr., 813 N.W.2d 250, 256 (Iowa 2012) (quoting Evercom Sys., Inc. v. Iowa Utilities Bd., 805 N.W.2d 758, 762 (Iowa 2011))

²¹ *Id.* at 256 ²² Iowa Code §17A.19(10)(1)

statutory interpretation has not been vested in the discretion of the agency the inquiry is whether the agency has erroneously interpreted the statute."²³

Unless the legislature has explicitly authorized an agency to interpret a statute, it is necessary to evaluate "the phrases or statutory provisions to be interpreted, their context, the purpose of the statute, and other practical considerations to determine whether the legislature intended to give interpretive authority to an agency". This determination "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." Where the provision is a "substantive term within the special expertise of the agency" it is more likely the agency has been granted authority to interpret the provision. 26

Based on the broad authority delegated to the Board in terms of making recommendations regarding the scheduling of controlled substances, the specialized expertise of the Board itself²⁷, and the fact the Board is not enacting rules or regulations but simply making "recommendations" for legislative action, the Court finds the Board has been granted broad interpretive authority regarding its scheduling recommendations. This conclusion is reinforced by legislative language directing the Board to make recommendations "as appropriate"²⁸, which the Board deems "necessary or advisable"²⁹. Thus, determinations made by the Board should be affirmed unless irrational, illogical or wholly unjustified.

Insight into the powers and responsibilities of the Board comes from a recent lowa Court of Appeals decision involving a prior attempt by this Petitioner to challenge

²³ Iowa Code §17A.19(10)(c)

²⁴ Renda v. Iowa Civil Rights Com'n., 784 N.W.2d 8, 11-12 (Iowa 2010)

²⁵ Renda, 784 N.W.2d at 13

²⁶ Renda, 784 N.W.2d at 14

²⁷ Five of the seven Board members are required to be licensed pharmacists. Iowa Admin. Code r. 657-12

²⁸ Iowa Code §124.203

²⁹ Iowa Code §124.201

the action of the Board. In that case Petitioner challenged a 2013 ruling of the Board rejecting his petition seeking a recommendation to the legislature for marijuana to be removed from inclusion on Schedule I. The Court of Appeals noted "the Board could reasonably conclude it was unnecessary to repeat its recommendation for reclassification that it provided in 2010 in light of the fact that the legislature gave consideration to reclassification in the 2013 legislative session."³¹ The Court affirmed the Board's conclusion "it has discretion to recommend or to choose not to continually recommend reclassification under section 124.401(1). . . Although the Board must make annual recommendations, section 124.401 does not require a running list of its past recommendations on an annual basis."32

This decision, that the Board "has discretion to recommend or to choose not to continually recommend reclassification", is dispositive of Petitioner's arguments in the case at bar that "lowa law prohibits the Board from recommending the inclusion of substances with accepted medical use in the United States in schedule I."33

It is apparent from the Boards decision the Board clearly understands its legislative direction to make recommendations as to scheduling changes to the legislature. In the Order under review the Board recognizes that while marijuana, or derivatives thereof, has some accepted medicinal use in treatment in the United States, it also has high potential for abuse.³⁴ Insightfully, the Board suggests the rescheduling of marijuana derivatives on a case by case basis, after individualized analysis of each

³⁰ Olsen v. Iowa Bd. of Pharmacy, No. 14-2164, 2016 WL 2745845 (Iowa App. May 11, 2016).

³³ Petitioner's Reply Brief, p. 8 ³⁴ Petitioner's Exh. 1 at 3.

derivate reveals its unique medicinal value. In keeping with that philosophy the Board affirmatively recommended to the legislature rescheduling cannabidiol to Schedule II.³⁵

In denying Petitioner's request to remove marijuana from inclusion in schedule I the Board noted marijuana's continued inclusion as a Federal schedule I controlled substance and observed it was "hesitant to recommend a change in the state scheduling of a substance that directly conflicts with federal law". Although it recommended ongoing study to ascertain potential medical uses for marijuana, the Board observed a particular concern "about the ability of any program to establish the standardization of dosage and potency necessary to ensure patient safety and effective treatment."

Contrary to Petitioner's arguments, the Board action in denying Petitioner's request was not irrational, illogical or wholly unjustified. This Court concludes the Board action was learned, reflective and insightful.

IT IS THEREFORE ORDERED the action of the Board of Pharmacy in denying the Petition to recommend to the legislature the removal of marijuana from Schedule I is affirmed. This matter is hereby dismissed. Costs are assessed against the Petitioner.

³⁵ Again evidencing their clear understanding of the statute and their legislative directive, the Board also recommends exclusion of rescheduled marijuana derivatives from the broad definition for marijuana contained Iowa Code §124.101(19).



State of Iowa Courts

Type: OTHER ORDER

Case Number Case Title

CVCV051068 CARL OLSEN VS IA BOARD OF PHARMACY

So Ordered

Brad McCall, District Court Judge, Fifth Judicial District of Iowa

Electronically signed on 2016-07-22 08:47:37 page 8 of 8

Exhibit #5

An Act making changes to the controlled substance schedules and providing penalties.

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

Section 1. Section 124.204, subsection 4, Code 2015, is amended by adding the following new paragraphs:

<u>NEW PARAGRAPH:</u> al. 4-methyl-N-ethylcathinone. Other names: 4-MEC, 2-(ethylamino)-1-(4-methylphenyl)propan-1-one.

NEW PARAGRAPH: am. 4-methyl-alpha-pyrrolidinopropiophenone. Other names: 4-MePPP, MePPP, 4-methyl-[alpha]-pyrrolidinopropiophenone, 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one.

NEW PARAGRAPH: an. Alpha-pyrrolidinopentiophenone. Other names: [alpha]-PVP, [alpha]-pyrrolidinovalerophenone, 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one.

NEW PARAGRAPH: ao. Butylone. Other names: bk-MBDB, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one.

<u>NEW PARAGRAPH:</u> ap. Pentedrone. Other names: [alpha]-methylaminovalerophenone, 2-(methylamino)-1-phenylpentan-1-one.

<u>NEW PARAGRAPH:</u> aq. Pentylone. Other names: bk-MBDP, 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one.

<u>NEW PARAGRAPH:</u> ar. 4-fluoro-N-methylcathinone. Other names: 4-FMC, flephedrone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one.

<u>NEW PARAGRAPH:</u> as. 3-fluoro-N-methylcathinone. Other names: 3-FMC, 1-(3-fluorophenyl)-2-(methylamino)propan-1-one.

NEW PARAGRAPH: at. Naphyrone. Other names: naphthylpyrovalerone, 1-

(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one.

NEW PARAGRAPH: au. Alpha-pyrrolidinobutiophenone. Other names: [alpha]-PBP, 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one.

Sec. 2. Section 124.204, subsection 9, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: g. Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate. Other names: PB-22, QUPIC.

NEW PARAGRAPH: h. Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate.

Other names: 5-fluoro-PB-22, 5F-PB-22.

<u>NEW PARAGRAPH:</u> i. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide. Other name: AB-FUBINACA.

<u>NEW PARAGRAPH:</u> j. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Other name: ADB-PINACA.

NEW PARAGRAPH: k. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1+indazole-3-carboxamide. Other name: AB-CHMINACA.

<u>NEW PARAGRAPH:</u> I. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide. Other name: AB-PINACA.

<u>NEW PARAGRAPH:</u> m. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone. Other name: THJ-2201.

<u>NEW PARAGRAPH:</u> n. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide. Other name: acetyl fentanyl.

<u>NEW PARAGRAPH:</u> o. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1- (cyclohexylmethyl)-1H-indazole-3-carboxamide. Other names: MAB-CHMINACA; ADB-

CHMINACA.

- **Sec. 3.** Section 124.206, subsection 2, paragraph (a), is amended as follows:
- a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, <u>naloxegol</u>, naloxone, and naltrexone, and their respective salts, but including the following:
 - **Sec. 4.** Section 124.206, subsection 2, paragraph (d), is amended as follows:
- d. Coca leaves and any salt, compound, derivative, or preparation of coca leaves including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), . Decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine, are excluded from this paragraph. The following substances and their salts, optical and geometric isomers, derivatives, and salts of derivatives and optical and geometric isomers, and any salt, compound, derivative, or preparation thereof that is chemically equivalent or identical to any of such substances, are included in this paragraph except that the substances shall not include:
- (1) Cocaine Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
 - (2) Ecgonine [\123\I]ioflupane.
- **Sec. 5.** Section 124.208, subsection 5, paragraph (a), subparagraphs (3) and (4), Code 2015, are amended by striking the subparagraphs.
 - Sec. 6. Section 124.210, subsection 2, Code 2015, is amended by adding the

following new paragraph:

NEW PARAGRAPH: c. 2-[(dimethylamino)methyl]-1-(3-

methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol).

Sec. 7. Section 124.210, subsection 3, Code 2015, is amended by adding the following new paragraphs:

NEW PARAGRAPH: bb. Alfaxalone.

NEW PARAGRAPH: bc. Suvorexant.

EXPLANATION

The bill modifies the controlled substance schedules and provides penalties.

The bill adds 10 synthetic cathinones, eight synthetic cannabinoids, and acetyl fentanyl to the list of substances classified as schedule I controlled substances. The board of pharmacy has determined that these substances should be classified as schedule I controlled substances because each substance has a high potential for abuse and no accepted medical use in the United States.

The bill removes hydrocodone-combination products from the list of substances classified as schedule III controlled substances. Hydrocodone, as a single-entity substance, is currently classified as a schedule II controlled substance. The change under the bill effectively makes all hydrocodone-containing products subject to the controls, security, reporting, and penalty provisions for schedule II controlled substances.

The bill removes naloxegol, a new molecular entity and derivative of naloxone, from control as a schedule III controlled substance. The federal Food and Drug

Administration (FDA) recently approved naloxegol for the treatment of opioid-induced constipation in adults with chronic non-cancer pain. The bill also removes [\123I]ioflupane from control as a schedule II controlled substance. This substance is a new molecular entity and is the active pharmaceutical ingredient in the drug DaTscan, recently approved by the federal Food and Drug Administration for use in diagnosis of patients suspected of Parkinson's disease. Evidence supports the removal of [123\]ioflupane from control as a controlled substance.

The bill also classifies the substance commonly known as tramadol, a centrally acting opioid analgesic, as a schedule IV controlled substance. This substance was previously marketed and distributed as a noncontrolled prescription drug. Effective August 18, 2014, the federal Drug Enforcement Administration classified tramadol as a schedule IV controlled substance under federal law.

The bill also classifies alfaxalone, a neurosteroid with central nervous system depressant properties, as a schedule IV controlled substance. The federal Food and Drug Administration (FDA) recently approved this intravenous injectable anestheticfor use by or on the order of a licensed veterinarian. Alfaxalone is not available by prescription and is approved for use in veterinary practice.

The bill classifies suvorexant, a new insomnia treatment approved by the federal Food and Drug Administration, as a schedule IV controlled substance. This is a novel, first in class, chemical substance and information on actual abuse data is not available. However, data from clinical studies support the classification in schedule IV.

It is a class "C" felony pursuant to Code section 124.401(1)(c)(8) for any unauthorized person to violate a provision of Code section 124.401, involving a

classified substance placed in schedule I, II, or III pursuant to the bill. A class "C" felony for this particular offense is punishable by confinement for no more than 10 years and a fine of at least \$1,000 but not more than \$50,000.

It is an aggravated misdemeanor pursuant to Code section 124.401(1)(d) for any unauthorized person to violate a provision of Code section 124.401 involving a classified substance placed in schedule IV pursuant to the bill. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least \$625 but not more than \$6,250.

If a person possesses a controlled substance in violation of Code section 124.401(5) as a first offense, the person commits a serious misdemeanor. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least \$315 but not more than \$1,875.

Exhibit #6

IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

GEORGE McMAHON, BRYAN SCOTT and BARBARA DOUGLASS,	Case No. CV7415		
Petitioners,			
CARL OLSEN,	RULING ON PETITION FOR JUDICIAL REVIEW		
Intervenor,	2 009		
V.	2009 APR		
IOWA BOARD OF PHARMACY,	DISTRIC		
Respondent.	PH COURT		
	poster.		

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

¹¹ 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'

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, District Judge Fifth Judicial District of Iowa

Original Filed.

Copies mailed to:

Randall Wilson 901 Insurance Exchange Bldg. Des Moines, IA 50309 ATTORNEY FOR PETITIONERS

Scott Galenbeck 1305 E. Walnut Street Des Moines, IA 50319 ATTORNEY FOR RESPONDENT

Carl Olsen 130 E. Aurora Ave. Des Moines, IA 50313 INTERVENOR

Exhibit #7

Iowa Board of Pharmacy Controlled Substance Scheduling Review— Medical Marijuana July 21, 2009

The following plan is presented for Board review and consideration:

- 1. A series of public hearings would be held around the State to receive evidence and testimony regarding the pros and cons of medical marijuana from the scientific, medical, and legal communities.
- 2. Input would be sought from medical practitioners, patients, care-givers, law enforcement personnel, regulatory agencies, legislators, educators and members of the general public.
- 3. Oral testimony would be allowed but the submission of written information would be encouraged. Each interested party would be allowed a maximum of ten minutes to present information. Requests for additional time would be considered by the chair of the hearing.
- 4. Each hearing would be a half-day in length, from approximately 1:00 to 5:00 p.m. One hearing would be held in August, September, October and November. Hearings would be held in Des Moines, Iowa City, Council Bluffs, and Mason City. Dates and locations of the hearings would be coordinated by board staff.
- 5. The Des Moines hearing would be chaired by ______; the Iowa City hearing would be chaired by ______; the Council Bluffs hearing would be chaired by ______; and the Mason City hearing would be chaired by
- 6. The review would include current federal law and regulations and the laws and rules of all U.S. states and jurisidictions relating to medical marijuana.
- 7. The review will include information previously gathered by board staff.
- 8. All material considered during the review process would be received and discussed in open session. The public would be invited to attend and observe the review process.
- 9. All information gathered would be reviewed by the Board at a public meeting to be held in Des Moines in November or December 2009.
- 10. The Board may make a recommendation to the 2010 legislature based upon the evidence received as a result of the review process.

Exhibit #8

whether the drug is properly classified — which ultimately raised questions the

poard considered serious enough to explore through public meetings.

n April, a Polk County judge ordered the lowa Board of Pharmacy to examine

United States."

among the most tightly regulated drugs under state law. That categorization

owa law considers marijuana a Schedule I controlled substance, putting it

🖁 The judge's order

was challenged in a recent lawsuit, which argued the drug did not meet the statutory requirement of having "no accepted medical use treatment in the The lowa Board of Pharmacy plans to hold public meetings in Des Moines, Iowa

Dates to come

City, Council Bluffs and Mason City. Dates and details will be posted soon at

Opinion

The Des Moines Register

Laura L. Hollingsworth, Publisher and President Carolyn Washburn, Editor and Vice President .inda Lantor Fandel, Editorial Page Editor

Andie Dominick, Editorial Writer Rox Laird, Editorial Writer

Time for conversation about medical marijuana **Register Editorial**

Weigh in on whether to legalize drug for sick people

whether sick residents should drugs, has voted unanimously to Board of Pharmacy, which reguto treat health problems, includhold public hearings around the L be allowed to use marijuana ing pain and nausea. The Iowa the distribution of prescription lates pharmacy practices and wa is about to explore

changes to the law regarding the pharmacy board deserves credit for initiating a statewide conver-Though the Iowa Legislature medical use of marijuana, the would have to approve any

amine the scientific research and are this state's opportunity to ex Amarijuana for medical purposes disn't about being "soft on drugs" or catering to those who think and get involved. The meetings at the end of the day, the use of opinions. This matters because Iowans should pay attention

Lit's their "right" to smoke mari-It's a medical issue

The federal government treated marijuana use as a medical issue certain medical conditions to use it. In 1992 it closed the program George McMahon is one of the program to allow people with ew remaining Americans still in 1978 when it established a o new applicants, but Iowan participating.

daily to control pain, spasms and prescription drug worked as well Patella Syndrome, a rare genetic ties of joints, kidneys and bones. McMahon is afflicted with Nail disorder that causes abnormalinausea. He told the Register no for nearly 20 years, McMahon nas been using marijuana as marijuana.

and others who use the drug as owans should hear from him

when 13 other states have legalreinvent the wheel on this issue zed marijuana for medical use. also invite people from outside The pharmacy board should he state to add to the conversation. Iowa doesn't have to

ing what medical conditions the about their experiences, includ-This state should find out more decriminalization increased ildrug is used for and whether

also come forward. Opponents to the legalization of marijuana say People with objections should it could open the door for more recreational use of the drug.

World Health Organization — on And the board should examine cluding information from the institute of Medicine and the the plethora of studies — inmedical use of the drug.

ww.iowa.gov/ibpe.

listen to their constituents. In the be a popularity contest. It should be based on whether the medical problems with making marijuana the law regarding the drug, they available as a prescription drug. Responsible for any changes in end, though, the decision can't benefit outweighs the potential should become educated, and Lawmakers should attend.

of support, but several Iowans

nittee hearing. Bolkcom said

Now a broader conversadown in the politics of the legalization could lead.

drug that may alleviate pain and Statehouse. Not dominated by treatment and science and the societal impact of legalizing a versation focused on medical narrow constituency. A condiscomfort for sick lowans patients. The bill died due to lack shared their stories in a subcom-

That's a conversation worth

expressed concerns about where

Sen. Joe Bolkcom (D-Iowa City)

of getting in trouble. Others

for pain relief, but were afraid

some wanted to try the drug

ion can ensue in communities around the state. Not mired distribute the drug to approved proposed legislation calling for nizations would cultivate and centers." The nonprofit organeard from Iowans when he the creation of "compassion

Medical Marijuana Hearings Dates, Locations, Purpose and Procedure

Iowa Board of Pharmacy (515) 281-5944

Wednesday, August 19, 2009 – 10:00 a.m. to 7:00 p.m. **Iowa State Historical Building** (Auditorium) 600 East Locust Street Des Moines, Iowa

Wednesday, September 2, 2009 – 10:00 a.m. to 7:00 p.m. **The Music Man Square** (Reunion Hall) 308 South Pennsylvania Avenue Mason City, Iowa

Wednesday, October 7, 2009 – Noon to 7:00 p.m. University of Iowa **Bowen Science Building** (3rd Floor Auditorium)
51 Newton Road
Iowa City, Iowa

Wednesday, November 4, 2009 – 10:00 a.m. to 7:00 p.m. **Harrah's Casino & Hotel** (Ballroom I) One Harrah's Boulevard Council Bluffs, Iowa

Purpose and Procedure:

- 1. These hearings are being held to receive evidence and testimony regarding the pros and cons of medical marijuana from a scientific, medical and legal perspective.
- 2. The Board is interested in hearing from medical practitioners including physicians, mid-level practitioners, nurses, pharmacists, and hospice workers; patients; care-givers; law-enforcement personnel; regulatory agencies; legislators; educators; scientists; researchers; other interested parties; and members of the general public.
- 3. Specifically, the Board is seeking information including, but not limited to, the following:
- a) Marijuana's actual or relative potential for abuse,
- b) Marijuana's pharmacological effect,
- c) Current scientific knowledge regarding marijuana,
- d) The history and current pattern of abuse of marijuana,
- e) The scope, duration, and significance of abuse of marijuana,
- f) The risk to the public health from moving marijuana to a different controlled substance schedule,
- g) The potential of marijuana to produce psychic or physiological dependence liability, and

- h) Whether marijuana is an immediate precursor of a substance on some other controlled substance schedule.
- 4. Oral testimony will be received but will be limited to approximately 5 to 10 minutes per person, based on the number of speakers attending each hearing. Additional time may be allowed if circumstances permit.
- 5. An appointment to make oral comments at a specified time on August 19, September 2, October 7, or November 4 may be pre-arranged by contacting Debbie Jorgenson at the Iowa Board of Pharmacy at 515/281-6674 or by sending a written request via e-mail to: Debbie.Jorgenson@ibpe.state.ia.us
- 6. All oral comments will be recorded by a certified shorthand reporter.
- 7. The submission of written comments is encouraged.
- 8. The deadline for submitting written comments is Wednesday, November 4, 2009. Written comments may be sent via e-mail to Debbie.Jorgenson@ibpe.state.ia.us or via regular mail to: Iowa Board of Pharmacy, RiverPoint Business Park, 400 SW 8th Street, Suite E, Des Moines, Iowa 50309-4688.
- 9. All oral testimony and written comments received by the Board will be public information.
- 10. The public is invited to attend and observe the hearings.

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State of Jowa

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

BOARD MEMBERS

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ANN DIEHL Osceola

MARK M. ANLIKER, R. Ph.

VERNON H. BENJAMIN, R. Ph., Argyle
Chairperson

LLOYD K. JESSEN, R. Ph., JD., West Des Moines

Executive Director

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

BOARD MEMBERS

Mapleton

Villisca

Cedar Rapids

EDWARD L. MA!ER, R. Ph.

SUSAN M. FREY, R. Ph.

MARGARET WHITWORTH

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.

Recording Secretary

Becky Hall

Executive Director

APPROVED THIS 9th DAY OF March 2010

E-FILED 2016 JAN 01 4:49 PM POLK - CLERK OF DISTRICT COURT

State of Iowa

Board of Pharmacy

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MARGARET WHITWORTH Cedar Rapids

VERNON H. BENJAMIN, R. Ph., Argyle
Chairperson

LLOYD K. JESSEN, R. Ph., JD., West Des Moines

Executive Director

TELECONFERENCE MINUTES November 24, 2010

The special meeting of the Iowa Board of Pharmacy was held on Wednesday, November 24, 2010, at 2:00 p.m., via teleconference pursuant to the provisions of Iowa Code section 21.8. An in-person meeting was impractical due to the travel distances of members of the Board, the limited agenda, and the need for immediate action. Chairperson Benjamin called the meeting to order at 2:03 p.m.

MEMBERS PRESENT

Vernon H. Benjamin, Chairperson Susan M. Frey, Vice-Chair Annabelle Diehl Edward L. Maier DeeAnn Wedemeyer Oleson Peggy M. Whitworth

MEMBERS ABSENT Mark M. Anliker

<u>SPEAKERS</u> Alan Koslow, Des Moines

STAFF PRESENT

Lloyd Jessen, Executive Director Scott Galenbeck, Esq., Assistant Attorney General Therese Witkowski, Executive Officer Becky Hall, Secretary

COMPLIANCE OFFICERS PRESENT

Bernie Berntsen Jean Rhodes Jennifer Tiffany Jim Wolfe

I. Open Session.

A. NABP Developing System to Link Prescription Monitoring Programs Across States Facilitate Data Exchange.

NABP will be moving forward and developing an interconnected communications hub for state Prescription Monitoring Programs that will link all the Prescription Monitoring Programs across the states. The program will be made accessible to the states to help further the protection of the public health.

II. Requests.

A. Pre-file legislation for the 84th Iowa General Assembly Removing Marijuana from Schedule I of the Iowa Uniform Controlled Substances Act – Carl Olsen, Des Moines.

This item was addressed under Legislation.

B. Board Position Regarding Proposed Legislation Restricting Substitution of Epilepsy Drugs.

The Iowa Public Health Association's Advocacy Committee has been asked to support a bill that requires a pharmacist to notify the prescribing physician whenever a change in brand of epilepsy medication is made by the pharmacist. The group has asked for the Board's official opinion regarding this issue.

Dr. Alan Koslow addressed generic substitution and therapeutic interchange and discussion was held regarding the difference between the two.

The Board is in support of generic substitution but does not support therapeutic interchange outside of a collaborative drug therapy management agreement.

III. Legislation.

A. Proposed Amendments to Iowa Code Chapter 124 Iowa Uniform Controlled Substances Act Regarding Marijuana.

Motion (Diehl/Frey) to approve for filing. Passed: 6-0-0-1. Absent: Anliker. A copy is attached as Addendum A.

IV. Rules.

A. Notice of Termination of Rulemaking ARC 8891B and Proposed Notice of Intended Action to Amend Chapter 3, "Pharmacy Technicians," 3.22(155A).

Motion (Maier/Oleson) to approve for filing Notice of Termination and Notice of Intended Action. Passed: 6-0-0-1. Absent: Anliker. A copy of the Notice of Intended Action is attached as Addendum B.

B. Notice of Intended Action to Amend Chapter 8, "Universal Practice Standards."

Motion (Oleson/Frey) to approve for filing Notice of Intended Action. Passed: 6-0-0-1.

Absent: Anliker. A copy is attached as Addendum C.

V. Closed Session.

Motion (Frey/Maier) to go into closed session in accordance with Iowa Code Section 21.5(1)(a) to review complaint or investigative information required by Section 272C.6(4) to be kept confidential, 21.5(1)(d) to discuss whether to initiate licensee disciplinary investigations or formal charges, and 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Benjamin, Diehl, Frey, Maier, Oleson, Whitworth; No: None; Abstain: None; Absent: Anliker. Passed: 6-0-0-1.

Motion (Oleson/Diehl) to go into open session. Roll call vote. Yes: Benjamin, Diehl, Frey, Maier, Oleson, Whitworth; No: None; Abstain: None; Absent: Anliker. Passed: 6-0-0-1.

In open session, the following actions were taken:

A. Draft Statement of Charges.

Motion (Maier/Frey) to draft Statement of Charges against the pharmacist in charge in case 2010-143. Passed: 6-0-0-1. Absent: Anliker.

B. Statement of Charges.

Motion (Frey/Maier) to file Statement of Charges in the following cases. Passed: 6-0-0-1. Absent: Anliker.

- 1. Heather Briney, Pharmacist License No. 19981 of Winterset. A copy of the Statement of Charges is attached as Addendum D.
- 2. Walgreens Pharmacy, Pharmacy License No 1257 of Clive. A copy of the Statement of Charges is attached as Addendum E.
- 3. Karla J. Fiori, Pharmacist License No. 18081 of Grimes. A copy of the Statement of Charges is attached as Addendum F.

C. Stipulation and Consent Order.

Motion (Diehl/Frey) to approve the Stipulation and Consent Order in the following cases. Passed: 6-0-0-1. Absent: Anliker.

- 1. Food Bonanza, Pharmacy License No. 634 of Ottumwa. A copy of the Stipulation and Consent Order is attached as Addendum G.
- 2. Marvin A. Elliot, DVM, Controlled Substance Registration No. 1502390 of Eldridge. A copy of the Stipulation and Consent Order is attached as Addendum H.

D. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Frey/Oleson) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the following cases. Passed: 6-0-0-1. Absent: Anliker.

- 1. Joseph J. Campanelli of Iowa City. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum I.
- 2. Winthrop S. Risk II, M.D., Controlled Substance Registration No. 1241656 of Cedar Rapids. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum J.
- 3. Hillary Reich, Pharmacy Technician Registration No. 4915 of Mason City. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum K.
- 4. Julie Johnson, Pharmacy Technician Registration No. 11931 of Manchester. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum L.
- E. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Maier/Diehl) to approve the Findings of Fact, Conclusions of Law, Decision and Order in the case of Gabriel L. Weefar of Surprise, Arizona. Passed: 5-1-0-1. No: Benjamin; Absent: Anliker. A copy of the Findings of Fact, Conclusions of Law, Decision and Order is attached as Addendum M.

Meeting adjourned at 3:30 p.m. on November 24, 2010.

Becky Hall

Recording Secretary

Lloyd K. Jessen

Executive Director

Vernon H. Benjamin

Board Chair

APPROVED THIS

DAY OF

ADDENDUM A

IOWA CODE CHAPTER 124 IOWA UNIFORM CONTROLLED SUBSTANCES ACT REGARDING MARIJUANA

NOVEMBER 29, 2010

Proposed amendments to Iowa Code Chapter 124, Iowa Uniform Controlled Substances Act.

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

- **Section 1.** Section 124.204, subsection 4, paragraph "m," Code 2009, is amended by striking the paragraph and renumbering the remaining paragraphs.
- **Section 2.** Section 124.204, subsection 4, renumbered paragraph "t," Code 2009, is amended to read as follows:
- u. t. Tetrahydrocannabinols, except as otherwise provided by rules of the board for medicinal purposes, meaning tretrahydrocannabinols naturally contained in a plant of the genus Cannabis (Cannabis plant) as well as synthetic equivalents of the substances contained in the Cannabis plant, or in the resinous extractives of such plant, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
 - (1) 1 cis or trans tetrahydrocannabinol, and their optical isomers.
 - (2) 6 cis or trans tetrahydrocannabinol, and their optical isomers.
- (3) 3,4 cis or trans tetrahydrocannabinol, and their optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)
- **Section 3.** Section 124.204, subsection 7, Code 2009, is amended by striking the subsection and renumbering the remaining subsections.
- **Section 4.** Section 124.204, renumbered subsection 8, Code 2009, is amended to read as follows:
 - 9. 8. Other materials. Any material, compound, mixture, or preparation which

contains any quantity of the following substances:

- a. N-[I-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers. 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297. Other names: CP-47,497.
- b. N-[I-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers. 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298. Other names: cannabicyclohexanol and CP-47,497 C8 homologue.
 - c. 1-Butyl-3-(1-naphthoyl)indole-7173. Other names: JWH-073.
 - d. 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200. Other names: JWH-200.
 - e. 1-Pentyl-3-(1-naphthoyl)indole-7118. Other names: JWH-018 and AM678.
- **Section 5.** Section 124.206, subsection 6, Code 2009, is amended by adding the following new paragraph:

<u>NEW PARAGRAPH</u>: c. Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP).

- **Section 6.** Section 124.206, subsection 7, paragraph "a," Code 2009, is amended to read as follows:
- a. Marijuana when used for medicinal purposes pursuant to rules of the board of pharmacy examiners.
- **Section 7.** Section 124.208, subsection 6, Code 2009, is amended by adding the following new paragraphs:

NEW PARAGRAPH: bh. Boldione (androsta-1,4-diene-3,17-dione).

NEW PARAGRAPH: bi. Desoxymethyltestosterone (17[alpha]-methyl-

5[alpha]-androst-2-en-17[beta]-ol); also known as madol.

NEW PARAGRAPH: bj. 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione).

EXPLANATION

This bill identifies and places into appropriate drug schedules substances that meet the criteria for control and classification as controlled substances in Iowa.

The bill removes marijuana from Schedule I, eliminates all references to the use of marijuana and tetrahydrocannabinols for medical purposes pursuant to the rules of the board of pharmacy, and classifies marijuana as a Schedule II controlled substance.

The bill classifies five synthetic cannabinoids as Schedule I controlled substance in conformance with recent action by the federal Drug Enforcement Administration. Four of these substances were designated, by rule of the Board of Pharmacy, as imitation controlled substances subject to the provisions of Iowa Code chapter 124A. As Schedule I controlled substances, the distribution of these substances is more closely controlled and the penalties for illicit distribution and possession are more stringent. The bill also removes benzylfentanyl and thenylfentanyl from classification as Schedule I controlled substances in conformance with recent action by the federal Drug Enforcement Administration.

The bill classifies the precursor chemical substance, ANPP, as an immediate precursor for the Schedule II controlled substance fentanyl, in conformance with action by the federal Drug Enforcement Administration. ANPP is used in the illicit manufacture of fentanyl. The bill also identifies and classifies as Schedule III controlled substances three anabolic steroids, in conformance with recent action by the federal Drug Enforcement Administration.

SENATE/HOUSE FILE _____

BY (PROPOSED DEPARTMENT OF
PUBLIC HEALTH/BOARD OF
PHARMACY BILL)

A BILL FOR

- 1 An Act revising the controlled substances schedules, and
- providing penalties.
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 124.204, subsection 4, paragraph m, Code
- 2 2011, is amended by striking the paragraph.
- 3 Sec. 2. Section 124.204, subsection 4, paragraph u,
- 4 unnumbered paragraph 1, Code 2011, is amended to read as
- 5 follows:
- 6 Tetrahydrocannabinols, except as otherwise provided
- 7 by rules of the board for medicinal purposes, meaning
- 8 tetrahydrocannabinols naturally contained in a plant of
- 9 the genus Cannabis (Cannabis plant) as well as synthetic
- 10 equivalents of the substances contained in the Cannabis plant,
- ll or in the resinous extractives of such plant, and synthetic
- 12 substances, derivatives, and their isomers with similar
- 13 chemical structure and pharmacological activity to those
- 14 substances contained in the plant, such as the following:
- 15 Sec. 3. Section 124.204, subsection 4, Code 2011, is amended
- 16 by adding the following new paragraph:
- 17 NEW PARAGRAPH. ai. 5-methoxy-N, N-dimethyltryptamine.
- 18 Some trade or other names:
- 19 5-methoxy-3-[2-(dimethylamino)ethyl]indole;5-MeO-DMT.
- Sec. 4. Section 124.204, subsection 7, Code 2011, is amended
- 21 by striking the subsection.
- Sec. 5. Section 124.204, subsection 9, Code 2011, is amended
- 23 to read as follows:
- Other materials. Any material, compound, mixture,
- 25 or preparation which contains any quantity of the following
- 26 substances:
- 27 a. N-[1-benzyl-4-piperidyl]-N-phenylpropanamide
- 28 (benzylfentanyl), its optical isomers, salts and salts of
- 29 isomers.
- 30 b. N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide
- 31 (thenylfentanyl), its optical isomers, salts and salts of
- 32 isomers.
- 33 a. 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-
- 34 phenol. Other names: CP-47,497.
- 35 b. 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-

- 1 phenol. Other names: cannabicyclohexanol and
- 2 CP-47,497 C8 homologue.
- 3 c. 1-Butyl-3-(1-naphthoyl) indole. Other names: JWH-073.
- 4 d. 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole. Other
- 5 names: JWH-200.
- 6 e. 1-Pentyl-3-(1-naphthoyl)indole. Other names: JWH-018
- 7 and AM678.
- 8 Sec. 6. Section 124.206, subsection 6, Code 2011, is amended
- 9 by adding the following new paragraph:
- 10 NEW PARAGRAPH. c. Immediate precursor to fentanyl:
- 11 4-anilino-N-phenethyl-4-piperidine (ANPP).
- 12 Sec. 7. Section 124.206, subsection 7, paragraph a, Code
- 13 2011, is amended to read as follows:
- 14 a. Marijuana when used for medicinal purposes pursuant to
- 15 rules of the board.
- 16 Sec. 8. Section 124.208, subsection 6, Code 2011, is amended
- 17 by adding the following new paragraphs:
- 18 NEW PARAGRAPH. bh. Boldione
- 19 (androsta-1, 4-diene-3, 17-dione).
- 20 NEW PARAGRAPH. bi. Desoxymethyltestosterone
- 21 (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol);
- 22 also known as madol.
- 23 NEW PARAGRAPH. bj. 19-nor-4,9(10)-androstadienedione
- 24 (estra-4,9(10)-diene-3,17-dione).
- 25 EXPLANATION
- 26 This bill revises the lists of drugs on the controlled
- 27 substances schedules, and provides penalties.
- 28 The bill removes marijuana from schedule I and reclassifies
- 29 it as a schedule II controlled substance. The bill also
- 30 strikes references to the authority of the board of pharmacy to
- 31 adopt rules for the use of marijuana or tetrahydrocannabinols
- 32 for medicinal purposes. A schedule I controlled substance is a
- 33 highly addictive substance that has no accepted medical use in
- 34 the United States and a scheduled II controlled substance is a
- 35 highly addictive substance that has an accepted medical use in

- 1 the United States.
- 2 The reclassification of marijuana from a schedule I
- 3 controlled substance to a schedule II controlled substance
- 4 permits a physician to issue a prescription for marijuana.
- 5 The bill also revises the lists of drugs in the controlled
- 6 substance schedules to conform with action undertaken by
- 7 the federal drug enforcement administration. The bill
- 8 classifies five synthetic cannabinoids, more commonly known
- 9 as "K2", as schedule I controlled substances. The bill
- 10 adds a drug commonly referred to as 5-MeO-DMT to the list
- 11 of schedule I controlled substances as well. The bill also
- 12 removes benzylfentanyl and thenylfentanyl from the schedule
- 13 I classification. The bill classifies the substance ANPP, a
- 14 precursor substance to the controlled substance fentanyl, as a
- 15 schedule II controlled substance. The bill classifies three
- 16 anabolic steroids as schedule III controlled substances. A
- 17 controlled substance classified as a schedule III substance is
- 18 a substance that has potential for abuse which is less than
- 19 schedule I and II substances but has an accepted medical use in
- 20 the United States.
- 21 It is a class "C" felony pursuant to Code section 124.401,
- 22 subsection 1, paragraph "c", subparagraph (8), for any
- 23 unauthorized person to violate a provision of Code section
- 24 124.401 involving a classified substance placed on schedule
- 25 I, II, or III pursuant to the bill. The penalties remain
- 26 unchanged for marijuana under the bill. The penalties under
- 27 Code section 124.401 range from a class "B" felony punishable
- 28 by up to 50 years of confinement to a serious misdemeanor
- 29 punishable by up to six months of confinement depending on the
- 30 amount of marijuana involved in the offense.

SENATE/HOUSE FILE BY (PROPOSED GOVERNOR'S OFFICE OF DRUG CONTROL POLICY BILL)

A BILL FOR

- 1 An Act relating to the control of marijuana, providing
- penalties, and including an effective date provision. 2
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

E 0001-01-01

E 0001-01-01

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E 0001-01-01

- 1 Section 1. Section 124.204, subsection 4, paragraph m, Code
- 2 2011, is amended to read as follows:
- 3 m. Marijuana, except as otherwise provided by rules of the
- 4 board for medicinal purposes.
- 5 Sec. 2. Section 124.204, subsection 4, paragraph u,
- 6 unnumbered paragraph 1, Code 2011, is amended to read as
- 7 follows:
- 8 Tetrahydrocannabinols, except as otherwise provided
- 9 by rules of the board for medicinal purposes, meaning
- 10 tetrahydrocannabinols naturally contained in a plant of
- 11 the genus Cannabis (Cannabis plant) as well as synthetic
- 12 equivalents of the substances contained in the Cannabis plant,
- 13 or in the resinous extractives of such plant, and synthetic
- 14 substances, derivatives, and their isomers with similar
- 15 chemical structure and pharmacological activity to those
- 16 substances contained in the plant, such as the following:
- 17 Sec. 3. Section 124.204, subsection 7, Code 2011, is amended
- 18 by striking the subsection.
- 19 Sec. 4. Section 124.206, subsection 7, Code 2011, is amended
- 20 to read as follows:
- 21 7. Hallucinogenic substances. Unless specifically excepted
- 22 or unless listed in another schedule, any material, compound,
- 23 mixture, or preparation which contains any quantity of the
- 24 following substances:
- 25 a. Marijuana when used for medicinal purposes pursuant to
- 26 rules of the board.
- 27 b. Nabilone nabilone [another name for nabilone:
- 28 (+-) trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-
- 29 hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one].
- 30 Sec. 5. EFFECTIVE UPON ENACTMENT. This Act, being deemed of
- 31 immediate importance, takes effect upon enactment.
- 32 EXPLANATION
- 33 This bill relates to the control of marijuana.
- 34 Under the bill, all types of marijuana and
- 35 tetrahydrocannabinols are classified as schedule I controlled

- 1 substances. The bill eliminates a provision classifying
- 2 marijuana used for medicinal purposes, pursuant to rules of the
- 3 board of pharmacy, as a schedule II controlled substance.
- 4 The bill strikes references to the authority of the board
- 5 to establish rules relating to the medicinal use of marijuana
- 6 including tetrahydrocannabinols naturally contained in a
- 7 cannabis plant.
- 8 A schedule I controlled substance is a highly addictive
- 9 substance that has no accepted medical use in the United States
- 10 and a schedule II controlled substance is a highly addictive
- 11 substance that has an accepted medical use in the United
- 12 States.
- 13 The penalties for possessing, manufacturing, delivering,
- 14 or possessing with intent to deliver marijuana including
- 15 tetrahydrocannabinols range from a serious misdemeanor to a
- 16 50-year class "B" felony depending on the amount of marijuana
- 17 or tetrahydrocannabinols involved in the offense.
- 18 A serious misdemeanor is punishable by confinement for no
- 19 more than one year and a fine of at least \$315 but not more than
- 20 \$1,875. An aggravated misdemeanor is punishable by confinement
- 21 for no more than two years and a fine of at least \$625 but
- 22 not more than \$6,250. A class "D" felony is punishable by
- 23 confinement for no more than five years and a fine of at
- 24 least \$750 but not more than \$7,500. A class "C" felony is
- 25 punishable by confinement for no more than 10 years and a fine
- 26 of at least \$1,000 but not more than \$10,000. A class "B"
- 27 felony is normally punishable by confinement for no more than
- 28 25 years. A 50-year class "B" felony or sometimes referred to
- 29 as a "super B" felony is punishable by confinement for no more
- 30 than 50 years.
- 31 The bill takes effect upon enactment.

SENATE/HOUSE FILE ______

BY (PROPOSED GOVERNOR'S OFFICE OF DRUG CONTROL POLICY BILL)

A BILL FOR

- 1 An Act relating to the controlled substance of marijuana,
- 2 including an effective date provision, and providing a
- 3 penalty.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

E 0001-01-01

E 0001-01-01

E 0001-01-01

E 0001-01-01

1 Section 1. Section 124.204, subsection 4, paragraph m, Code

- 2 Supplement 2011, is amended to read as follows:
- 3 m. Marijuana, except as otherwise provided by rules of the
- 4 board for medicinal purposes.
- 5 Sec. 2. Section 124.204, subsection 4, paragraph u,
- 6 unnumbered paragraph 1, Code Supplement 2011, is amended to
- 7 read as follows:
- 8 Tetrahydrocannabinols, except as otherwise provided
- 9 by rules of the board for medicinal purposes, meaning
- 10 tetrahydrocannabinols naturally contained in a plant of
- 11 the genus Cannabis (Cannabis plant) as well as synthetic
- 12 equivalents of the substances contained in the Cannabis plant,
- 13 or in the resinous extractives of such plant, and synthetic
- 14 substances, derivatives, and their isomers with similar
- 15 chemical structure and pharmacological activity to those
- 16 substances contained in the plant, such as the following:
- 17 Sec. 3. Section 124.204, subsection 7, Code Supplement
- 18 2011, is amended by striking the subsection.
- 19 Sec. 4. Section 124.206, subsection 7, Code 2011, is amended
- 20 to read as follows:
- 21 7. Hallucinogenic substances. Unless specifically excepted
- 22 or unless listed in another schedule, any material, compound,
- 23 mixture, or preparation which contains any quantity of the
- 24 following substances:
- 25 a. Marijuana when used for medicinal purposes pursuant to
- 26 rules of the board.
- 27 b. Nabilone nabilone [another name for nabilone:
- 28 (+-) trans-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-
- 29 hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one].
- 30 Sec. 5. EFFECTIVE UPON ENACTMENT. This Act, being deemed of
- 31 immediate importance, takes effect upon enactment.
- 32 EXPLANATION
- 33 This bill relates to the control of marijuana.
- 34 Under the bill, all types of marijuana and
- 35 tetrahydrocannabinols are classified as schedule I controlled

- 1 substances. The bill eliminates a provision classifying
- 2 marijuana used for medicinal purposes, pursuant to rules of the
- 3 board of pharmacy, as a schedule II controlled substance.
- 4 The bill strikes references to the authority of the board
- 5 to establish rules relating to the medicinal use of marijuana
- 6 including tetrahydrocannabinols naturally contained in a
- 7 cannabis plant.
- 8 A schedule I controlled substance is a highly addictive
- 9 substance that has no accepted medical use in the United States
- 10 and a schedule II controlled substance is a highly addictive
- 11 substance that has an accepted medical use in the United
- 12 States.
- 13 The penalties for possessing, manufacturing, delivering,
- 14 or possessing with intent to deliver marijuana including
- 15 tetrahydrocannabinols range from a serious misdemeanor to a
- 16 50-year class "B" felony depending on the amount of marijuana
- 17 or tetrahydrocannabinols involved in the offense.
- 18 A serious misdemeanor is punishable by confinement for no
- 19 more than one year and a fine of at least \$315 but not more than
- 20 \$1,875. An aggravated misdemeanor is punishable by confinement
- 21 for no more than two years and a fine of at least \$625 but
- 22 not more than \$6,250. A class "D" felony is punishable by
- 23 confinement for no more than five years and a fine of at
- 24 least \$750 but not more than \$7,500. A class "C" felony is
- 25 punishable by confinement for no more than 10 years and a fine
- 26 of at least \$1,000 but not more than \$10,000. A class "B"
- 27 felony is normally punishable by confinement for no more than
- 28 25 years. A 50-year class "B" felony or sometimes referred to
- 29 as a "super B" felony is punishable by confinement for no more
- 30 than 50 years.
- 31 The bill takes effect upon enactment.

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State of Jowa

Board of Pharmacy

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

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LLOYD K. JESSEN, R. Ph., JD., West Des Moines Executive Director

MINUTES

August 27, 2014

The Iowa Board of Pharmacy met on August 27, 2014, in the conference room at 400 SW Eighth Street, Des Moines, Iowa. Acting Chairperson Frey called the meeting to order at 9:02 a.m.

MEMBERS PRESENT

Edward L. Maier, Chairperson (participated by telephone) Susan M. Frey LaDonna Gratias Edward J. McKenna

Sharon K. Meyer Judith M. Trumpy

MEMBERS ABSENT James Miller, Vice-Chair

SPEAKERS

Anthony Pudlo, IPA Brett Barker, NuCara Kristin Williams, Hy-Vee Megan Myers, IPA Ned Looney, Des Moines Jennifer Goings, Mercy Medical Center Jamie Sinclair, Mercy Medical Center Carl Olsen, Des Moines

STAFF PRESENT

Lloyd Jessen, Executive Director Meghan Gavin, Esq., Assistant Attorney General Laura Steffensmeier, Esq., Assistant Attorney General Therese Witkowski, Executive Officer Debbie Jorgenson, Administrative Assistant Becky Hall, Secretary

Compliance Officers Present:

Andrew Funk Curt Gerhold Mark Mather Sue Mears Jean Rhodes Jennifer Tiffany Jennifer O'Toole Jim Wolfe

Page 2 of 8

I. Approval of Minutes.

The Minutes of the June 30 – July 2, 2014, meeting were read.

Motion (Gratias/McKenna) to approve the minutes of the June 30 – July 2, 2014, meeting. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

II. Reports.

Executive Director's Report.

A. Financial.

1. FY14 as of 7/31/14 (100% of FY completed)

Revenue Anticipated:	\$ 4,058,926	
Revenue Actual	\$ 4,228,428	(104%)
Carry-over from FY13	\$ 1,904,222	
FY14 Fee Receipts	\$ 2,324,206	
Budget Allocation	\$ 3,953,101	
Obligations Actual	\$ 2,518,565	(64%)
Fines/Civil Penalties Collected	\$ 70,750	

2. FY15 as of 7/31/14 (8.3% of FY completed)

Revenue Anticipated:	\$ 3	3,776,461	
Revenue Y-T-D	\$ 1	,586,494	(42%)
Carry-over from FY14	\$ 1	,447,165	
FY15 Fee Receipts	\$	139,329	
Budget Allocation	\$ 3	3,776,461	
Obligations Y-T-D	\$	332,122	(8.8%)
Cash Fund Balance	\$ 1	,501,152	
(\$ 850,000 reserved for database)		
Fines/Civil Penalties Collected	\$	6,500	

B. Meetings and Travel.

- 1. The PIC Task Force will hold its third meeting on September 8, 2014, at the Board office in Des Moines.
- 2. The Iowa Pharmacy Compounding Task Force will hold its third meeting on September 9, 2014, at the Board office in Des Moines.

- 3. IPRN will hold its Fall Meeting at the Board office in Des Moines on September 25, 2014.
- 4. The November Board Meeting will be held on November 18-19, 2014, at the Board office in Des Moines. A committee of the Board will meet with the Iowa Pharmacy Association Board of Trustees for an annual dinner meeting on the evening of November 18, 2014, at the Iowa Pharmacy Association's office in Urbandale.
- 5. The 2015 Midwest Pharmacy Expo will be held in Des Moines, on February 13-15, 2015. The Board will provide a pharmacy law presentation on Sunday, February 15, 2015.
- C. Investigation of Simulated Pharmacist Decision Making Involving Prescriptions With a High Probability of Causing Patient Harm – Journal of Pharmacy Technology.
 Information item.
- D. Iowa Man Seeks Court Help in Getting Marijuana Reclassified Quad City Times (online, July 15, 2014.)
 Information item.
- E. Iowa Pharmacy Recovery Network Statement of Financial Position- June 30, 2014.

 Motion (Trumpy/McKenna) to approve the Statement of Financial Position. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.
- F. Allen Hospital Tech-Check-Tech Quarterly Report June 2014.

 Allen Memorial Hospital provided their quarterly progress report for their Tech-Check-Tech Program for review.
- G. Zearing Telepharmacy's 2014 Second Quarter Telepharmacy Report.

 NuCara Telepharmacy in Zearing provided their Quarterly Telepharmacy Report for review.
- H. Hy-Vee Pharmacy Fulfillment Center's 2014 Second Quarter Error Report.
 Hy-Vee Pharmacy Fulfillment Center provided their Quarterly Error Report for review.
- I. New Practice Model Quarter One Report Megan Meyers, Iowa Pharmacy Association.
 The Iowa Pharmacy Association provided their first Quarter New Practice Model Report for review.
- IX. Requests.

Page 4 of 8

A. Application for Limited Use Pharmacy – The Naturopathic Pharmacist, Harbor View Medical, Des Moines and Request for Waiver – 657 I.A. C. Chapter 6, General Pharmacy Requirements – Ned J. Looney, The Naturopathic Pharmacist.

Motion (Meyer/McKenna) to approve the Limited Use Pharmacy Application and waiver request. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

B. Request for Variance – 657 I.A.C. 8.34(2), Collaborative Drug Therapy Management – Jennifer Goings, Mercy Medical Center, Cedar Rapids.

Motion (Maier/Trumpy) to deny the waiver request on the basis the waiver is not necessary. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

C. Petition for Agency Action - Marijuana Scheduling - Carl Olsen.

Motion (Trumpy/McKenna) to form a special committee to review the Petition for Agency Action for Marijuana Scheduling and bring back for discussion at the November 19, 2014, board meeting. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

D. Request for Internship Credit - Inae Oh, Reno, Nevada.

Motion (Trumpy/Gratias) to approve the request granting credit for 250 hours of internship for life experience requiring Ms. Oh to complete an additional 1250 hours of internship. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

E. Request for Internship Credit - Mohamed A. Zeinelabdin, Overland Park, Kansas.

Motion (Meyer/McKenna) to approve the request granting credit for 250 hours of internship for life experience requiring Mr. Zeinelabdin to complete an additional 1250 hours of internship. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

F. Request for Pharmacist Reciprocity with California and Extension of Internship Hours – Olga Zadorozhnyaya, La Quinta, California.

Motion (McKenna/Gratias) to accept reciprocity from California licensees provided the candidates have taken and passed the North American Pharmacist Licensure Examination (NAPLEX) after January 1, 2004. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

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G. Hy-Vee Pharmacies – Request for Clarification Regarding Delegation of the Administration of Vaccines.

This item was referred to the Rules Committee.

H. Request for Waiver – 657 I.A.C. 9.3(2) Telepharmacy – NuCara Pharmacy – Brett Barker. Motion (Gratias/McKenna) to approve the request extending the Telepharmacy Pilot Project for 18 months beginning December 1, 2014. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

X. Licensure/Registration.

- A. Preliminary Notice of Intent to Deny License Medical Supply Liquidators, West Des Moines. Motion (Gratias/McKenna) to approve Preliminary Notice of Intent to Deny License. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1. A copy of the Preliminary Notice of Intent to Deny License is attached as Addendum A.
- B. Preliminary Notice of Intent to Deny Registration Susan M. Terry, Omaha, Nebraska.

 Motion (Maier/Trumpy) to approve Preliminary Notice of Intent to Deny Registration.

 Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain:

 None; Absent: Miller. Passed: 6-0-0-1. A copy of the Preliminary Notice of Intent to Deny Registration is attached as Addendum B.

XI. Rules.

A. Notice of Intended Action - Amend Chapter 3, "Pharmacy Technicians."

Motion (Trumpy/McKenna) to approve for filing Notice of Intended Action. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1. A copy is attached as Addendum C.

B. Notice of Intended Action – Amend Chapter 4, "Pharmacist-Interns," and Chapter 8, "Universal Practice Standards."

Motion (Trumpy/McKenna) to approve for filing Notice of Intended Action. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1. A copy is attached as Addendum D.

C. Notice of Intended Action - Amend Chapter 10, "Controlled Substances."

Motion (Gratias/McKenna) to approve for filing Notice of Intended Action. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent:

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Miller. Passed: 6-0-0-1. (Prior to filing, Notice of Intended Action was amended and approved at the September 11, 2014, meeting.)

D. Notice of Intended Action – Amend Chapter 19, "Nonresident Pharmacy Practice."

Motion (Trumpy/McKenna) to approve for filing Notice of Intended Action. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent:

Miller. Passed: 6-0-0-1. A copy is attached as Addendum E.

E. Notice of Intended Action to Adopt New Chapter 33, "Military Service and Veteran Reciprocity."

Motion (Gratias/Trumpy) to approve for filing Notice of Intended Action to adopt <u>new</u> Chapter 33, "Military Service and Veteran Reciprocity." Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1. A copy is attached as Addendum F.

XII. Legislation.

A. Proposed 2015 Legislative Changes.

The amendments being considered to Iowa Code Chapter 155A, Iowa Pharmacy Practice Act by the Iowa Board of Pharmacy relate to supervision of pharmacy technicians in telepharmacy practice; the licensure and discipline of nonresident pharmacies and outsourcing facilities; various definitions relating to pharmacy practice; the appointment of a pool of alternative Board Members; Board Investigator enforcement authority; and the sharing of inspection reports with other state boards of pharmacy through the National Association of Boards of Pharmacy's inspection network.

XIII. Complaints Against Non-Licensees.

A. 2014-42 - PharmaCo Ventures, L.P., Philadelphia, Pennsylvania.

Motion (Trumpy/McKenna) to close with no action. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

B. 2014-77 - KVP Pharmacy, Glendale, California.

Motion (Maier/Meyer) to issue a Cease and Desist Order. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

C. 2014-79 - MedEx Direct, Warren, Michigan.

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Motion (Meyer/Trumpy) to issue a Cease and Desist Order. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

D. 2014-88 – Hopkington Drug, Hopkington, Massachusetts.

Motion (Trumpy/Meyer) to draft Licensure by Consent Agreement. Roll call vote. Yes: Frey, Gratias, Maier, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Miller. Passed: 6-0-0-1.

E. 2014-108 – Medical Supply Liquidators, Clive.

This item was tabled.

XIV. Closed Session.

Motion (McKenna/Gratias) to go into closed session in accordance with Iowa Code Section 21.5(1)(f) to discuss the decision to be rendered in a contested case. Roll call vote. Yes: Frey, Gratias, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Maier, Miller. Passed: 5-0-0-2.

Motion (Meyer/McKenna) to go into open session. Roll call vote. Yes: Frey, Gratias, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Maier, Miller. Passed: 5-0-0-2.

In open session, the following actions were taken.

A. Dismissal Order.

Motion (Meyer/Trumpy) to approve the Dismissal Order for Amy Moet, Pharmacist License No. 19502 of North Liberty. Roll call vote. Yes: Frey, Gratias, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Maier, Miller. Passed: 5-0-0-2. A copy of the Dismissal Order is attached as Addendum G.

B. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Meyer/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision, and Order in the case of Chuck Long, Pharmacy Support Person Registration No. 1054 of Cedar Rapids. Roll call vote. Yes: Frey, Gratias, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Maier, Miller. Passed: 5-0-0-2. A copy of the Findings of Fact, Conclusions of Law, Decision, and Order is attached as Addendum H.

C. Findings of Fact, Conclusions of Law, Decision and Order.

Motion (Trumpy/McKenna) to approve the Findings of Fact, Conclusions of Law, Decision, and Order in the case of Christopher Tuetken, Pharmacist License No. 19681 of Robins, and Downtown Drug, Pharmacy License No. 1281 of Cedar Rapids. Yes:

August 27, 2014

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Frey, Gratias, McKenna, Meyer, Trumpy; No: None; Abstain: None; Absent: Maier, Miller. Passed: 5-0-0-2. A copy of the Findings of Fact, Conclusions of Law, Decision, and Order is attached as Addendum I.

Meeting adjourned at 3:08 p.m. on August 27, 2014.

Becky Hall

Recording Secretary

Lloyd K. Jessen

Executive Director

Edward L. Maier

Board Chair

APPROVED THIS /9 DAY OF \cancel{Nov} ., 20/4.

Exhibit #16

Board members present: Susan Frey (temporary chair, licensed pharmacist), LaDonna Gratias (public member), Edward Maier (chair, licensed pharmacist), Edward McKenna (licensed pharmacist), Sharon Meyer (licensed pharmacist), Judith M. Trumpy (public member). Board member absent: James Miller (licensed pharmacist).

Susan Frey: Next up we have 4.4 and that is a petition for agency action for marijuana scheduling from Carl Olsen.

Carl Olsen: Yes.

Susan Frey: You're here.

Carl Olsen: Are you ready?

Susan Frey: I'm ready.

Carl Olsen: Alright. My name is Carl Olsen. I would like the board to recommend the Iowa legislature remove marijuana from Schedule 1. The code sections are Iowa Code Chapter 124 Section 201 and 124.203. Under those sections the board has the authority to recommend the legislature remove marijuana from Schedule 1. I made this recommendation last year. I made this recommendation several times, this request. But, particularly last year I made this same request. At that time there were nine-teen (19) states that had legalized the medical use of marijuana. As of today there are twenty-three (23). And as of this year another eleven (11) have enacted cannabis oil bills, like Iowa enacted this year, that require people to leave the state of Iowa, go to another state where they can obtain this oil, one of the states where it is authorized to produce the cannabis, and then bring it back to Iowa, which violates state and federal laws all the way through.

Removing marijuana from Schedule 1 would be an important step in a big obstacle, federal Schedule 1. The board has the authority to recommend that marijuana be removed from state Schedule 1. That would be an important first step in sending an important message to the federal government that there's a big problem with Schedule 1 and the implementation of these state laws. We've got thirty-four (34) states now and last year when I was here it was only nineteen (19). So, you can see how rapidly this is moving forward. I don't think the board can say

this is not a valid concern, or that the board should not be saying, be participating in the legislative process as required by the Iowa Code.

Thank you.

Susan Frey: Any comments from board members? Thoughts?

And, we're handing out an article from the Des Moines Register today, or yesterday August 26th, on the cannabis oil.

Carl Olsen: Yeah, there was a hearing held yesterday in the Iowa Department of Public Health on that.

Sharon Meyer: You would like a recommendation from the board to the schedule. Here, it's saying the family could find an out of state supplier. It would be implemented, ... Sorry, got on the wrong paragraph. It says people are frustrated by the pace of the implementation and the oil is not available. Are you saying that we need to make a statement to the legislature?

Carl Olsen: I don't think the legislature understands the technical nature of the five (5) schedules, and I think the board does. And I think they need the assistance of the board with that particular issue. It's obvious they want to do something. And, it's obvious that they've started to move forward. But, I don't think they understand how important the scheduling is. Schedule 1 says no accepted medical use in treatment in the United States, and that is just not the case. It has accepted medical use in thirty-four (34) states. Why the federal government hasn't moved it out of Schedule 1 I can't say. But this board recommended it be removed from state Schedule 1 in 2010. And, I think the board should continue to stand behind that and not let the legislature think that you've changed your mind, or that you're not interested anymore, or ... I've heard that comment from legislators, like, "What's happened with the board of pharmacy? Why are they backing out on this?" So, I think there's real damage there.

Ed Maier: Madam chair, this is Ed. I think a couple of us that looked through this in 2010, I think this is important enough, if we can, I think we should maybe somehow discuss, whether we appoint a committee, or send it to rules committee to talk about, or whatever, for some recommendations, and talk. I think it's

important, whatever we do, that we have a solid cut message that the people understand. Last time, we were totally misunderstood, exactly what was happening. I don't know that, I guess I might recommend that we somehow study this and that we take it up at the next meeting if that's possible.

Susan Frey: Well, you've been... I was not aware of the recent hearing. I guess I would like to, you know, look at some of that information and incorporate that. I think, you know, I would certainly be willing to establish a study group.

Carl Olsen: I participated in that hearing yesterday and they said they would give me all, everything that was submitted, and a recording of the hearing and all of that.

Terry Witkowski: Just to clarify, that hearing was their proposed rules.

Carl Olsen: Yeah.

Terry Witkowski: for the cannabidiol program, correct?

Carl Olsen: Right. And there were a lot of comments that weren't... didn't stay confined to that and they kept saying you'll have to talk to the legislators about. But, anyway, it was all...

Susan Frey: And, I mean... If they're talking about rules, that will set a precedent also, so I think that's probably something that we need to, you know, look into a little deeper, further. So, I would entertain a motion to form a...

Terry Witkowski: You want to refer it to a committee? Or, form a separate committee?

Susan Frey: Well, Ed suggested... Ed, do you want to go to rules committee with that or do you want a separate committee?

Ed Maier: You know, I'm not sure. I don't know where the rules committee is now. I know that they have a considerable amount of work that they're doing on legislation and other things, so I might defer to somebody on the rules committee as to whether they would prefer that. Or, do we prefer a separate committee that

would take a look at all of the new things that have happened and try to make some sort of recommendation?

Terry Witkowski: Do you anticipate having something ready to present a legislative proposal this year? Because the deadline for that is the end of November.

Ed Maier: The end of November?

Terry Witkowski: Yes. Really by Thanksgiving we have to have it submitted. It would have to go to, you'd have to have a legislator to present it.

Ed Maier: So, Terry, if we were to defer it and take action one way or the other at our next meeting, would that be too late? Or, is that pushing it?

Terry Witkowski: You could, if we had a proposal ready for the next board meeting, that would be timely.

Ed Maier: Okay. I think that's probably what we need to do. Either rules,... Rules is really, really busy, and I know they have been, but, you know, maybe a separate committee, a small committee that could take a look at this stuff and then get together and just decide on a recommendation.

Ed McKenna: Being on the rules committee I would probably agree with Ed that we should have a separate committee and get more input from other people.

Susan Frey: I would agree.

Ed McKenna: I know we have a lot of separate committees, but...

Susan Frey: Okay, well...

Terry Witkowski: Ed, did you want to be on that committee? Or, chair that committee?

Ed Maier: Let me...

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Terry Witkowski: You have the history, so I'm thinking that that might be, you know, it would be a good thing to have somebody with that...

Ed Maier: Yes, Yeah, I would do that.

Terry Witkowski: You can read all the cases you want this weekend.

(LAUGHTER)

Ed Maier: You got it Terry.

Lloyd Jessen: Why don't we have a motion then to form a committee with Ed as chair and then I'll work with Ed so,...

Ed Maier: There you go. We'll work together to put a committee together here and get it taken care of.

Terry Witkowski: Ask the board members to see if anybody's interested, too.

Lloyd Jessen: Yeah, we can do that.

Sharon Meyer: So moved.

Susan Frey: Okay, it's been moved. Do I have a second?

Ed McKenna: Second.

Susan Frey: Okay, it's been moved and seconded to form a committee to review the petition on agency action for marijuana scheduling with a, to bring it back at our November meeting. All of those in favor say aye. Want a role call vote?

Ed Maier: Maier, aye.

LaDonna Gratias: Gratias, aye.

Ed McKenna: Aye.

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Sharon Meyer: Meyer, aye.

Judith M. Trumpy: Trumpy, aye.

Susan Frey: Frey, aye. All those opposed? Motion carries.

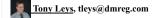
Carl Olsen: Well, I have to get back to work, but thank you all. You guys are

awesome. I'll see you later.

Exhibit #17

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Cannabis oil 'light years away' for lowa families



11:28 p.m. CDT August 26, 2014



(Photo: Tony Leys/The Register)

The lowa parents who persuaded lawmakers last spring to approve the use of marijuana oil to treat epilepsy say they're nowhere close to obtaining the medicine for their children.

"I feel like it's still light years away," Sally Gaer said today. "We have a lot more work to do."

The West Des Moines mother helped persuade legislators to decriminalize possession of a marijuana extract for patients, like her daughter, who suffer seizures from epilepsy. But the law included no legal method for growing or selling the product. State administrators are still working out the details of how to issue ID cards allowing residents to possess marijuana extract bought in other states.

Gaer and other parents believe their children's seizures could be significantly dampened with a form of marijuana oil that has low levels of THC, the chemical that makes marijuana users high. But they remain unable to legally obtain the oil, which is said to have worked well in other states.

Gaer and another mother of epileptic children, Kim Novy of Altoona, spoke of their frustrations Tuesday in an interview after a hearing before state administrators.

The mothers noted that most publicity about the marijuana extract has focused on producers in Colorado. But Colorado law only allows sales of the medication to Colorado residents, they said. They've heard that once they have their lowa-issued cards, they might be allowed to purchase the extract in Oregon. "What are we all going to do, get in a wagon train and go over the mountains?" Gaer said with a wry laugh.

The women said they were disappointed by how long it's taking lowa officials to implement the law, which technically took effect July 1. "Everybody keeps coming up to me and saying, 'How's that oil working for your daughters?" Novy said. She explains that her family is at least several months away being able to take advantage of the new law.

The women said they have found lowa-licensed neurologists willing to sign a form recommending the marijuana extract for their children, as the lowa law requires. However, the form has not been created yet by state officials. If the families can find an out-of-state supplier willing to sell the oil to them, they would face a cost of several hundred to more than a thousand dollars per month – plus the cost of travel. They also could risk arrest for carrying the oil through states that don't allow it.

lowa Department of Public Health administrator Deborah Thompson said during the hearing that state officials hope to start issuing registration cards by the end of the year. She said she understood that people were frustrated by the pace of implementation. But, she added, "there are a lot of moving parts for any new program."

A few dozen lowans participated in the hearing, either in Des Moines or via video linkups to other cities.

Several people raised concerns that lowa's medical-marijuana law was limited to people who want to use the medication to control seizures from epilepsy.

"There's many other people that suffer that should not have to suffer like they do," said Linda Gale of Sioux City, who said she has Crohn's disease, an intestinal disorder that can cause chronic pain and nausea. She said she's been given heavy-duty pain pills for her condition.

"I'm not quite sure what the fear of cannabis oil is, when I take all these narcotics that make me sick and make me not be able to function," she said.

Boris Shcharansky of Des Moines wants the state to let his company obtain marijuana oil in other states and deliver it to families with medical needs in lowa. He said any lowa families who tried to use the current law to obtain marijuana for a child in Colorado would be committing a state crime there and a federal crime when they carried the medication across the border. "It is unacceptable to force families to break state and federal laws in order to obtain an oil that can, without exaggeration, save lives," he said. "The families dealing with the tragedy of epilepsy have gone through enough."

Thompson, the health-department administrator, responded to such points by urging people to contact their legislators.

Gov. Terry Branstad, a Republican, initially opposed efforts to legalize marijuana for any purpose, but he praised the limited bill during a public signing ceremony in June. His spokesman, Jimmy Centers, said Tuesday that health-department administrators are working as fast as they can, given that the Legislature declined to give them emergency rulemaking powers for this measure. "Gov. Branstad is committed to working, within the bounds of the law,

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to help lowa families and their lowed lorde Docation to help lowa families and their lowed lorde Docation to help lowa families and their lowed lorde Docation to help lowa families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help loward families and their lowed lorde Docation to help lorde

Sen. Joe Bolkcom, an lowa City Democrat who has spearheaded the effort to legalize medical marijuana, said Tuesday that he sympathizes with the families' frustrations.

Bolkcom praised Gaer, Novy and other parents who persevered last spring to get the Legislature's approval for the bill. He expressed optimism that legislators would listen to them again if they return to the Statehouse in January to explain problems with the new law. "I think these moms are 10 paces ahead of us on understanding what's going on," he said. "Our work ahead is identifying the barriers and moving them out of the way."

However, any effort to expand the law could face serious opposition. Rep. Clel Baudler, a Greenfield Republican known for his law-and-order views, was a key supporter of the limited medical marijuana bill last spring. Baudler, a retired state trooper, expressed skepticism Tuesday about the chances that lawmakers would approve major revisions next year. "I think most people want to see the results of this law before they jump in" to broaden it, he said.

Gaer and Novy said Tuesday that they will keep pushing. Gaer said she's rooting for a Congressional bill that would legalize interstate shipment of the marijuana oil for patients who need it. Both women said they remain optimistic. "You have to be," Novy said. "When you're in our situation, you can't give up hope. We live on hope."

Earlier: Sally Gaer makes marijuana plea for disabled daughter



Sally Gaer, of West Des Moines, is rallying support for legalizing medical marijuana in Iowa to treat her daughter Margaret, who suffers from violent seizures.

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