IN THE SUPREME COURT OF IOWA

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

APPEAL FROM THE IOWA DISTRICT COURT

FOR POLK COUNTY

HONORABLE BRAD MCCALL, JUDGE

APPELLANT'S FINAL BRIEF

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STATEMENT OF THE CASE

I. Nature of the Case:

This is an appeal from a final ruling by the Polk County District Court ("the district court" hereafter) on July 22, 2016, App. 151, dismissing a Petition for Judicial Review filed by Carl Olsen ("the petitioner" hereafter) on January 4, 2016, App. 73, reviewing actions taken by the Iowa Board of Pharmacy ("the board" hereafter) on January 5, 2015, App. 15, March 9, 2015, App. 58, November 4, 2015, Exhibit #36, App. 486, and December 29, 2015, Exhibit #41, App. 509.

The district court's ruling upheld:

1. the board's action on January 5, 2015, App. 15, denying the petitioner's Petition for Agency Action filed on July 7, 2014, App. 8;

2. the board's action on March 9, 2015, App. 58, denying the petitioner's Petition for Reconsideration of Agency Action filed on January 12, 2015, App. 53; and

3. the board's actions on November 4, 2015, Exhibit #36, App. 486, and on December 29, 2015, Exhibit #41, App. 509. See the petitioner's Request for Clarification on November 4, 2015, Exhibit #36, App. 486.

Polk County District Court Judge Brad McCall presided over all relevant proceedings.

II. Course of Proceedings:

On July 7, 2014, the petitioner filed a Petition for Agency Action, App. 8, asking the board to initiate the reclassification of marijuana consistent with the procedures set forth in the Iowa Uniform Controlled Substances Act ("the Act"). Iowa Code §§ 124.101-602, 1971 Iowa Acts 305, Chapter 148 (S.F. 1) (July 1, 1971). The petitioner referenced the following sections of the Act as the authority for the board to take action on the petition: Iowa Code § 124.201 (2014) and Iowa Code § 124.203 (2014), App. 8.

The petitioner referenced the following sections of the act where marijuana had been placed: Iowa Code § 124.204(4)(m) (2014), Iowa Code § 124.204(7) (2014), Iowa Code § 124.206(7)(a) (2014), and Iowa Code §§ 124D.1-8, 2014 Iowa Acts 369, Chapter 1125 (S.F. 2360) (May 30, 2014), App. 8.

The petitioner sought the removal of marijuana from Iowa Code § 124.204(4)(m) (2014) and Iowa Code § 124.204(7) (2014) (schedule 1), App. 8.

The petitioner did not request any action be taken in regard to the placement of marijuana in Iowa Code § 124.206(7)(a) (2014) (schedule 2), App. 8.

The board denied the Petition for Agency Action on January 5, 2015, App. 15.

The board made several recommendations:

1. that an extract from the marijuana plant, defined in Iowa Code § 124D.2(1) (2014) ("cannabidiol"), be placed in schedule 2, App. 29;

2. that Iowa Code § 124.204(4)(m) (2014) be amended by removing the phrase "except as otherwise provided by rules of the board for medicinal purposes", App. 31; and

3. that Iowa Code § 124.206(7)(a) (2014) be deleted in its entirety, App. 31, or

4. that Iowa Code § 124.206(7)(a) (2014) be amended by removing the phrase "pursuant to rules of the board", App. 31.

On January 12, 2015, the petitioner filed a Petition for Reconsideration of the board's January 5, 2015, decision, App. 53. The petitioner included position statements from the American Academy of Neurology (December 17, 2014) and the American Academy of Pediatrics (January 20, 2015) explaining why those two professional medical organizations consider schedule 1 inappropriate for marijuana. Exhibit #33, App. 452.

The board denied the Petition for Reconsideration on March 9, 2015, App. 58.

The board's proposed legislation filed with the legislature on December 29, 2015, for the next legislative session, did not include any of its recommendations, as customary, and as authorized, by Iowa Code § 2.16 (2014). Exhibits #5, App. 159; Exhibits #36 through #41, App. 486, 488, 492, 495, 497, 509.

In denying the petition, the board found marijuana has medical use in Iowa as a matter of law, explaining that the legislature has explicitly recognized the medical value of marijuana as the source of an extract from the plant ("cannabidiol") which now has medical use in Iowa, Iowa Code Chapter 124D, Exhibit #1, Addendum A, p. 3 App 29. In making this finding, the board did not

perform an analysis of the eight factors in Iowa Code § 124.201(1) (2014)[1], App. 29.

On January 4, 2016, the petitioner filed a Petition for Judicial Review with the district court pursuant to Iowa Code § 17A.19 (2014), App. 73. The district court dismissed the petition on July 22, 2016, affirming all the actions of the board, App. 151.

III. Previous Cases:

Prior cases in which petitioner has sought action related to the scheduling of marijuana include: *Olsen et al. v. State of Iowa*, 83-301-E, 1986 WL 4045 (S.D. Iowa, March 19, 1986), App. 516; *Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458 (D.C. Cir. 1989), *Olsen v. Drug Enforcement Admin.*, 495 U.S. 906 (1990); *Olsen v. Drug Enforcement Admin.*, 99 F.3d 448 (8th Cir. 1996), *Olsen v. Drug Enforcement Admin.*, 519 U.S. 1118 (1997); *Olsen v. Mukasey*, 541 F.3d 827 (8th Cir. Iowa, 2008), *Olsen v. Holder*, 556 U.S. 1221 (2009); *Olsen v. Holder*, 610 F.

[1] The district court referenced the eight factors in Iowa Code § 124.201(1) (2014) on the first page of the ruling denying the Petition for Judicial Review. The board did not perform an analysis of these eight factors. See page 1 of the district court's ruling, App. 151, and compare it with the board's ruling, App. 27. This is consistent with the ruling in *McMahon v. Iowa Board of Pharmacy*, CVCV007415 (Iowa Dist. Ct. 2009), at page 3, 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 Iowa Code section 124.203."

Supp. 2d 985 (S.D. Iowa 2009); *McMahon v. Iowa Board of Pharmacy*, CVCV007415 (Iowa Dist. Ct. 2009), App. 520, *McMahon v. Iowa Board of Pharmacy*, 09-1789 (Iowa Supreme Court, May 14, 2010), App. 525; *Olsen v. Iowa Board of Pharmacy*, CVCV008156 (Iowa Dist. Ct. 2010), App. 527; *Olsen et al. v. State of Iowa*, CVCV008682 (Iowa Dist. Ct. 2011), App. 531, *Olsen et al. v. State of Iowa*, 11-1744 (Iowa Court of Appeals, February 13, 2013), App. 537; *Americans for Safe Access v. Drug Enforcement Admin.*, 706 F.3d 438 (D.C. Cir. 2013), *Olsen v. Drug Enforcement Admin.*, 134 S. Ct. 673, 187 L. Ed. 2d 422 (2013)[2]; *Olsen v. Iowa Board of Pharmacy*, CVCV045505 (Iowa Dist. Ct. 2014), App. 541; *Olsen v. Iowa Board of Pharmacy*, CVCV047867 (Iowa Dist. Ct. 2014), App. 551, *Olsen v. Iowa Board of Pharmacy*, 14-2164 (Iowa Court of Appeals, May 11, 2016), App. 562.

IV. Facts:

The board specifically found that marijuana has medical use as a matter of law, without performing an analysis of the eight (8) factors in Iowa Code § 124.201(1) (2014)[3]. The board based this finding on the enactment of the Medical

[2] http://medicalmarijuana.procon.org/sourcefiles/carl-olsen-writ-of-certiorari-09112013.pdf

[3] While this Petition for Judicial Review was pending, and after the petitioner filed an opening brief on April 8, 2016, the Iowa Court of Appeals held on May 11, 2016, the board is not required to repeat the same action it took in 2010. The

Cannabidiol Act, Iowa Code Chapter 124D, 2014 Acts, Chapter 1125. See the board's ruling, Exhibit #1, Addendum A, p. 3, App. 29. By comparison, in 2010 the board performed an analysis of these eight (8) factors in determining that marijuana should be removed from schedule 1.[4]

In 2010, in the first of three previous actions, the board ruled that marijuana has medical use based on analysis of the eight (8) factors in Iowa Code § 124.201(1) (2010), Exhibit #10, App. 179. See *McMahon v. Iowa Board of Pharmacy*, CVCV007415 (Iowa Dist. Ct. 2009), App. 520.

In the second and third of these three previous actions, in 2012, and in 2013, the board ruled that repeating the same action it took in 2010 was not necessary or advisable. *Olsen v. Iowa Board of Pharmacy*, CVCV045505 (Iowa Dist. Ct. 2014), App. 541; *Olsen v. Iowa Board of Pharmacy*, CVCV047867 (Iowa Dist. Ct. 2014), App. 551.

Prior to the enactment of the Medical Cannabidiol Act, Iowa Code Chapter 124D, 2104 Iowa Acts 369, Chapter 1125, Iowa did not recognize any accepted medical use for marijuana. The petitioner's three previous petitions were based on state laws in other states that had accepted the medical use of marijuana ("in the

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petitioner then limited the arguments in his reply brief on May 13, 2016, to the recommendations the board made in 2015 that were different than the recommendations the board made in 2010, 2012, and 2013. See *Olsen v. Iowa Board of Pharmacy*, No. 14-2164 (Iowa Court of Appeals, May 11, 2016).

[4] See Exhibits #9 and #10, App. 176, 179.

United States") over the previous nineteen (19) years.[5] The board avoided the petitioner's argument by independently finding that marijuana has medical value in 2010 and by refusing to take any action in 2012 and 2013.[6]

In each of these three previous petitions, the board accepted that marijuana has medical use without relying on others state laws accepting the medical use of marijuana. Due to the nature of our dual system of government, known as federalism, in the absence of a federal definition for the term "medical use" in the federal drug law, state laws determine whether marijuana has "accepted" medical use within the United States. *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006).

Each of the five schedules includes the phrase "accepted medical use in treatment in the United States" in the criteria for placement in each of the five schedules. Iowa Code § 124.203(1)(b) (2014) (conditions for placement in schedule 1), Iowa Code § 124.205(1)(b) (2014) (conditions for placement in schedule 2), Iowa Code § 124.207(1)(b) (2014) (conditions for placement in schedule 3), Iowa Code § 124.209(1)(b) (2014) (conditions for placement in

[5] The Iowa Supreme Court dismissed the petitioner's appeal in 2010 reasoning that the Board's finding that marijuana has medical use based on analysis of the eight (8) factors in Iowa Code § 124.201(1) (2010) was the recommendation sought and ended any justiciable existing controversy regarding accepted medical use of marijuana in other states. The petitioner argued that marijuana had accepted medical use "in the United States" as a matter of law based on accepted medical use of marijuana in other states. *McMahon v. Iowa Board of Pharmacy*, 09-1789 (Iowa Supreme Court, May 14, 2010), App. 525.

[6] Ibid.

schedule 4), Iowa Code § 124.211(1)(b) (2014) (conditions for placement in schedule 5), all use the phrase "in the United States."

The phrase "in the United States" refers to federalism. Federalism does not limit accepted "medical use" to mean accepted only "in Iowa." Accepted medical use of marijuana in Iowa is accepted medical use "in the United States." Iowa is not the only state "in the United States," and other states that have accepted the medical use of marijuana are also "in the United States." See *Grinspoon v. DEA*, 828 F.2d 881, 886 (1st Cir. 1987). ("Congress did not intend 'accepted medical use in treatment in the United States' to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.")

The board's actions in 2015 currently under review did not include an analysis of the eight (8) factors in Iowa Code § 124.201(1) (2014), because the board found there is accepted medical use of marijuana "in Iowa" as matter of law.[7]

[7] The eight factors are formal guidelines for the administrative agency to use in the absence of a state law specifically addressing one or more of the factors. Federal law explains how the eight factors do not apply if the substance is scheduled under and international treaty, 1961 Single Convention, 18 U.S.T. 1407, 30 T.I.A.S. No. 6298, 520 U.N.T.S. 151. 21 U.S.C. § 811(d). See, 81 Fed. Reg. 53688 (August 12, 2016). The international treaty does not apply to the use of any substance specifically authorized by a domestic law. See, 1961 Single Convention, Article 36(2) ("Subject to the constitutional limitations of a Party, it's legal system and domestic law").

The petitioner cited thirty-two (32) laws in other states that had accepted the medical use of marijuana as of July 7, 2014, when the petitioner filed with the board.[8] Prior to 1996, there were no states "in the United States" that had accepted the medical use of marijuana.

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[8] States with medical marijuana laws as of July 7, 2014:

Alaska Statutes § 17.37 (1998); Arizona Revised Statutes, Title 36, Chapter 28.1, §§ 36-2801 through 36-2819 (2010); California Health & Safety Code § 11362.5 (1996); Colorado Constitution Article XVIII, Section 14 (2000); Connecticut Public Act No. 12-55, Connecticut General Statutes, Chapter 420f (2012); Delaware Code, Title 16, Chapter 49A, §§ 4901A through 4926A (2011); Hawaii Revised Statutes § 329-121 (2000); Illinois Public Act 98-0122 (2013); 22 Maine Revised Statutes § 2383-B (1999); Annotated Code of Maryland Section 13-3301 through 13-3303 and 13-3307 through 13-3311 (2014); Massachusetts Chapter 369 of the Acts of 2012 (2012); Michigan Compiled Laws, Chapter 333, §§ 333.26421 through 333.26430 (2008); Minnesota SF 2470 -- Signed into law by Gov. Mark Dayton on May 29, 2014, Approved: By Senate 46-16, by House 89-40, Effective: May 30, 2014; Montana Code Annotated § 50-46-101 (2004); Nevada Constitution Article 4 § 38 - Nevada Revised Statutes Annotated § 453A.010 (2000); New Hampshire Revised Statutes Annotated Chapter 126-W (2013); New Jersey Public Laws 2009, Chapter 307, New Jersey Statutes, Chapter 24:6I, §§ 24:61-1 through 24:6I-16 (2010); New Mexico Statutes Annotated § 30-31C-1 (2007); New York Pub. Health §§ 3360 through 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).

States with medical marijuana extract laws as of July 7, 2014:

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,

ROUTING STATEMENT

Iowa Rule of Appellate Procedure 6.1101(2) outlines the criteria for determining whether a case will be retained by the Iowa Supreme Court or transferred to the Iowa Court of Appeals. Iowa R. App. P. 6.1101(2). Petitioner-Appellant asks that this case be retained by the Iowa Supreme Court because it: ("a") presents a substantial question involving state and federal statutory language; ("b") presents a substantial issue involving published decisions of the federal courts; ("c") presents a substantial issue of first impression in the Iowa Supreme Court; ("d") presents a fundamental and urgent issue of broad public importance requiring prompt or ultimate determination by the Iowa Supreme Court; and ("f") presents a substantial question of enunciating legal principles. Iowa R. App. P. 6.1101(2)(a), (b), (c), (d), and (f).

ARGUMEMT

I. The district court erred in ruling the Board's recommendation was rational, logical, and justified.

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).

A. Error Preservation, Standard of Review, and Scope of Review.

The petitioner preserved error. On January 4, 2016, the petitioner filed a Petition for Judicial Review, App. 73, and a Memorandum in Support, App. 92. On April 8, 2016, the petitioner filed a Judicial Review Brief, App. 103. On May 13, 2016, the petitioner filed a Judicial Review Reply Brief, App. 121. In those three filings, as well as during argument at the court hearing on May 20, 2016, App. 131, petitioner generally pressed the arguments raised here.

The petitioner argued that marijuana has accepted medical use in treatment in the United States, as a matter of law, both before the enactment of the Iowa Medical Cannabidiol Act, Iowa Code Chapter 124D, in 2014, and after. Marijuana now has has accepted medical use in Iowa because an extract from the plant is defined as a medicine in Iowa.

Although the board has never accepted or rejected the argument that accepted medical use in other states is evidence that marijuana has accepted medical use in treatment in the United States, the board did find that the Iowa Medical Cannabidiol Act, Iowa Code Chapter 124D, 2014 Acts, Chapter 1125, is evidence that marijuana has accepted medical use in Iowa. See page 3 of the board's ruling, Exhibit #1, Addendum A, App. 29:

> "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)."

The error preserved for review is whether it was rational, logical, and justified for the board to reverse the recommendation it made in 2010 (and left unchanged in 2012 and 2013) by recommending in 2015 that marijuana be removed from schedule 2 and placed in schedule 1, while at the same time recommending that an extract from marijuana be placed in schedule 2. Petition for Judicial Review, p. 17, App. 89; Memorandum in Support, p. 4 (federal scheduling does not require the board to recommend marijuana be placed in state schedule 1), App. 95. Petitioner's Judicial Review Brief, p. 5 (the board was not justified), App. 107; Petitioner's Judicial Review Reply Brief. p. 2 (the board was not reasonable, e.g., not rational), App. 122; Tr., p. 6 (the board was not consistent, e.g., not logical), App. 136.

When the application of law to fact has been clearly vested in the discretion of an agency, a reviewing court may only disturb the agency's application of the law to the facts of the particular case if that application is "irrational, illogical, or wholly unjustifiable." Iowa Code § 17A.19(10)(m) (2012). *Burton v. Hilltop Care Cntr.*, 813 N.W.2d 250, 256 (Iowa 2012) (quoting *Mycogen Seeds v. Sands*, 686 N.W.2d 457, 465 (Iowa 2004)).

B. Marijuana has Accepted Medical Use in the United States

The petitioner presented thirty-three (33) state laws accepting the medical use of marijuana or extracts of marijuana prior to January 5, 2015. Petition for Judicial Review, p. 2, App. 74. The board has never contested state laws accepting the medical use of marijuana as positive proof that marijuana has accepted medical use in the United States. Iowa Code § 124.203(1)(b) (2014), on its face, would appear to the average person to preclude placement of marijuana in schedule 1.

The board has previously argued it has discretion on whether to make repeated recommendations to the Iowa legislature to remove marijuana from schedule 1[9]. Iowa Code § 124.201(1) (2014). The board now argues it has discretion to make the opposite recommendation.

The question is whether it was rational, logical, and justified for the Board to use its discretion to make a recommendation that was: (1) contrary to the conditions the Iowa legislature placed on Iowa schedule 1 in section 203(1)(b); (2) contrary to the recommendation it made in 2010; and (3) contrary to the subcommittee's recommendation on November 19, 2014, recommending the removal of marijuana from schedule 1. See the subcommittee's recommendation, Exhibit #20, App. 374.

[9] *Olsen v. Iowa Board of Pharmacy*, No. 14-2164 (Iowa Court of Appeals, May 11, 2016) (the board is not required to repeat the same recommendation it previously made).

C. Marijuana has Accepted Medical Use in Iowa

The board found that marijuana has accepted medical use in Iowa based on the Iowa Medical Cannabidiol Act of 2014, 2014 Iowa Acts, Chapter 1125, Iowa Code Chapter 124D, without deciding whether marijuana has medical use in other states or applying the eight (8) factors in Iowa Code § 124.201(1) (2014).

Iowa Code § 124.203(1)(b) (2014), on its face, would appear to the average person to preclude placement of marijuana in schedule 1. The board argues that section 203(1)(b) cannot be read out of context with sections 201(1) and 203(2), which the board believes overrides section 203(1)(b) and gives it discretion to do: (1) exactly the opposite of what section 203(1)(b) says; (2) exactly the opposite of the recommendation it made in 2010; and (3) exactly the opposite of the subcommittee's recommendation on November 19, 2014, recommending the removal of marijuana from schedule 1. Exhibit #20, App. 374.

D. The Board Previously found Marijuana has Medical Use

The Board previously found that marijuana has medical use on February 17, 2010, and recommended that marijuana be removed from schedule 1. Exhibit #10, App. 179.

Iowa Code § 124.203(1)(b) (2014), on its face, would appear to the average person to preclude placement of marijuana in schedule 1.

E. The Board's Discretion

The legislature has given the board discretion under Iowa Code § 124.201(1) (2014) and Iowa Code § 124.203(2) (2014). However, ignoring a section of law (section 203(1)(b)) that would appear to the average person to preclude the board from recommending schedule 1 raises a concern. Marijuana clearly does not belong in schedule 1. How does the board justify recommending that marijuana be placed in a schedule that it does not belong in?

Deference to agency discretion should applied cautiously when an agency ruling is contrary to a statutory requirement and the opposite of previous rulings of the same agency and a subcommittee appointed to study the petitioner's request. Iowa Code § 17A.19(11) (2014).

Iowa Code § 124.203(1)(b) (2014) was overridden and none of the eight factors listed in Iowa Code § 124.201(1) (2014) were considered in making the final decision. Why did the board ignore statutory criteria, ignore previous rulings, and ignore the subcommittee's recommendation?

The ruling from the Iowa Court of Appeals earlier this year found it reasonable for the board not to repeat annually the same recommendation it made in 2010:

> Certainly 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.

Olsen v. Iowa Board of Pharmacy, No. 14-2164 (Iowa Court of Appeals, May 11, 2016), slip op. at 3[10]. But, now, the board has completely reversed its prior recommendation and overruled the subcommittee it appointed to study the matter. This is extremely odd, considering more states, including Iowa, have accepted the medical use of marijuana over this same period of time.

In the ruling now under review, the board completely reversed the recommendation it made in 2010, and overruled its own subcommittee. What changed between November of 2014 and January of 2015?

One fact that has changed is that medical use of marijuana has significantly increased in the United States since 2010. But that fact would seem to support a finding that marijuana is incorrectly scheduled. The board is suddenly moving in the opposite direction our nation and our state are moving in.

Another fact is the odd behavior of the Office of Drug Control Policy, which has been aggressively lobbying the board arguing that marijuana has a high potential for abuse, the same argument that was rejected in *McMahon v. Iowa*

[10] The Iowa Senate voted 44-0-6 on April 15, 2015, to remove marijuana from schedule 1 and place it in schedule 2. See Senate Amendment S3123, https://www.legis.iowa.gov/legislation/BillBook?ga=86&ba=S3123. 2015 Senate Journal, p.p. 873-874. https://www.legis.iowa.gov/docs/pubs/sjweb/pdf/April%2015,%202015.pdf#page=6

Board of Pharmacy, CVCV007415 (Iowa Dist. Ct. 2009), App. 520. See Exhibits #24 through #27, App. 411, 415, 419, 423.

The abuse potential for schedule 1 is the same as the abuse potential for schedule 2, so abuse potential is not relevant to a petition to remove marijuana from schedule 1 if the action requested leaves marijuana in schedule 2 (which is exactly what would have happened if the Petition for Agency Action had been granted).

The Office of Drug Control Policy filed opposing legislation to the legislation submitted by the Iowa Board of Pharmacy in 2011 and 2012. Exhibit #13 and Exhibit #14, App. 196, 200.

Two executive branch agencies both representing the same executive representing opposing views on the same matter in their pre-filed legislation violates constitutional separation of powers. One of the agencies, the Iowa Board of Pharmacy, is specifically authorized to make recommendations on scheduling. The Office of Drug Control Policy has no expertise in scheduling. The Office of Drug Control Policy has no administrative rules, making it unaccountable to the people. The Office of Drug Control Policy has a very short enabling statute, Iowa Code Chapter 80E, Iowa Code §§ 80E.1-80E.3, defining its primary purpose to prevent the "unauthorized" use of controlled substance, not to determine which schedule they should be in. Why isn't the Office of Drug Control Policy

aggressively arguing to put morphine and cocaine in schedule 1, or a multitude of other substances far more dangerous than marijuana?[11]

F. The Board is Unreasonable

The board did not dispute any of the facts presented by the petitioner. The board did not cite any new evidence contradicting anything it looked at in 2010 or the subcommittee looked at in 2014, Exhibit #1, Addendum A, App. 27. The board did not even argue that marijuana now meets the requirements for inclusion in schedule 1.

The board's sole argument is that marijuana's placement in federal schedule 1 justifies placing marijuana in the wrong schedule here in Iowa. At the same time, the board rejected federal scheduling of a marijuana extract which is also inconsistent with federal scheduling.

The board said it should follow federal scheduling for marijuana and then recommended the legislature reject federal scheduling of the extract without explaining why federal scheduling should be followed for the plant but not for the extract.

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[11] A recent statement from the DEA acknowledges marijuana is safer than many substances in schedule 2. DEA Acting Administrator Chuck Rosenberg said: "Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger."
https://www.dea.gov/divisions/hq/2016/Letter081116.pdf

The board tried to say it was basing its decision on opium, explaining that opium is in schedule 1. Exhibit #31, App. 437. Opium has never been in schedule 1.

Opium is a perfect example of why marijuana should not be in schedule 1. Marijuana, like opium, has medical use, which rules out schedule 1.

G. Federalism

Can the board cede state authority to the federal government without the consent of our state legislature? The answer is no. Our legislature has not consented to adopt federal scheduling. The legislature has given our board positive authority to reject federal scheduling decisions. Iowa Code § 124.201(4) (2014). The board can opt out of any federal scheduling decision, explicitly when the federal government adds a new substance to federal schedule 1 that has never been previously scheduled.

There is no positive requirement in Iowa law for the board to even consider any other decisions on federal scheduling (such as adding a substance to another federal schedule, removing a substance from a federal schedule, or moving a substance from one federal schedule to another). If the board is going to skip the analysis of the eight (8) factors in Iowa Code § 124.201(1) (2014), considering the board has the power to opt out of federal scheduling decisions, the board needs to explain why it thinks federal scheduling is valid.

To demonstrate this point even further, Iowa's scheduling of marijuana has been inconsistent with federal scheduling since 1979 and the board hasn't claimed there is a positive conflict with federal scheduling for all this period of time. It is well settled that federal scheduling does not determine state scheduling. See *State v. Bonjour*, 694 N.W.2d 511, 514-515 (Iowa 2005) (Wiggins, J., dissenting):

> In 1971, the legislature repealed the Uniform Narcotic Drug Act and enacted the Uniform Controlled Substances Act. Unif. Controlled Substances Act, prefatory note, 9 U.L.A. 10 (1994). While Iowa's enactment of the Uniform Controlled Substances Act is a substantial adoption of the major provisions of the uniform act, Iowa's act contains some provisions not contained in the uniform act. Id. One such provision at variance with the uniform act occurred by amendment in 1979.
>
> Iowa's act, as originally enacted, classified marijuana as a Schedule I controlled substance without exception. Iowa Code § 204.204(4)(j) (1973). A Schedule I substance "has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision." Id. § 204.203(2). The original enactment was consistent with the uniform act. In 1979, the legislature amended Iowa's act classifying marijuana as a Schedule I substance "except as otherwise provided by the rules of the board of pharmacy examiners for medical purposes." Id. § 204.204(4)(j) (1981). In the same amendment, the legislature added a new provision to the list of Schedule I substances providing, "this section does not apply to marijuana . . . when utilized for medical purposes pursuant to rules of the state board of pharmacy examiners." Id. § 204.204(6).

The board suddenly finds there is an inconsistency with federal scheduling in Iowa's scheduling of marijuana that it hasn't found during the past 37 years. How does the board explain the sudden change in its position?

Can the board cede state scheduling decisions to the federal government without the consent of Congress? The answer again is no.

> The constitutional authority of Congress cannot be expanded by the "consent" of the governmental unit whose domain is thereby narrowed, whether that unit is the Executive Branch or the States.
>
> State officials thus cannot consent to the enlargement of the powers of Congress beyond those enumerated in the Constitution.

New York v. United States, 505 U.S. 144, 181 (1992).

> States are not mere political subdivisions of the United States. State governments are neither regional offices nor administrative agencies of the Federal Government. The positions occupied by state officials appear nowhere on the Federal Government's most detailed organizational chart. The Constitution instead "leaves to the several States a residuary and inviolable sovereignty," The Federalist No. 39, p. 245 (C. Rossiter ed. 1961), reserved explicitly to the States by the Tenth Amendment.

Id., at 188.

Did Congress intend the federal schedules to override state decisions regarding medical use of controlled substances? The answer again is no. "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).

> 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 (1985), there is no question that the Federal Government can set uniform national standards in these areas. See *Raich*, *supra*, at 9. 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.

Id., at 271-272. The federal schedules are administrative rules.[12]

There would be no reason for Iowa to have an independent scheduling procedure if federal scheduling was intended to substitute for state scheduling. Our legislature did not intend the board to follow federal scheduling unless the board actually agrees with those federal scheduling decisions.[13] A finding of medical use of marijuana is inconsistent with federal scheduling because a finding

[12] 21 C.F.R. § 1308 (2016)
[13] Iowa Code § 124.201(4) (2014)

of medical use precludes the placement of marijuana in federal schedule 1.[14] The board's explanation is that because marijuana is in federal schedule 1, the board must follow it. But, that is not an explanation.

The only time the board is specifically instructed by our legislature to even consider federal scheduling is when a new substance that has never been previously scheduled is added to federal schedule 1, and even then the board is not bound by the decision. Iowa Code § 124.201(4) (2014). The board has thirty (30) days to object to the new designation.

If the federal government were now trying to add marijuana to federal schedule 1 for the very first time, the board would have a reason to object, because it says marijuana has medical use. State law binds the board to follow state law authorizing the medical use of marijuana regardless of a federal administrative rule that conflicts with state law. *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006).

[14] *Compare* 21 U.S.C. § 812(b)(1)(B) and 21 U.S.C. § 812(b)(1)(C) *with* 21 U.S.C. § 812(b)(2)(B) and 21 U.S.C. § 812(b)(2)(C). The U.S. Drug Enforcement Administration does not consider 21 U.S.C. § 812(b)(1)(B) and 21 U.S.C. § 812(b)(1)(C) to be separate analytical factors. "The scheduling criteria of the Controlled Substances Act appear to treat the lack of medical use and lack of safety as separate considerations. Prior rulings of this Agency purported to treat safety as a distinct factor. 53 FR 5156 (February 22, 1988). In retrospect, this is inconsistent with scientific reality. Safety cannot be treated as a separate analytical question." DEA Docket No. 86-22, 57 Fed. Reg. 10499 (March 26, 1992), at page 10504. 21 U.S.C. § 812(b)(1)(A) is the same as 21 U.S.C. § 812(b)(2)(A).

The board's loyalty is to the state, not the federal government. Neither state law nor federal statute says that federal scheduling conclusively determines state scheduling. It is not reasonable for the board to follow federal scheduling when the board disagrees with federal scheduling. The board correctly finds, as a matter of law, that marijuana does not meet one of the statutory requirements necessary to place marijuana in federal schedule 1.

The federal schedule of marijuana has not been updated to reflect the national change in its accepted medical use.[15] Federal scheduling of marijuana is based on an old administrative interpretation of a phrase that Congress never defined. *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991):

> The difficulty we find in petitioners' argument is that neither the statute nor its legislative history precisely defines the term "currently accepted medical use"; therefore, we are obliged to defer to the Administrator's interpretation of that phrase if reasonable.

[15] Petitioner is not aware of any challenge to federal schedule 1 based on federalism. In 2011, the petitioner intervened in a federal scheduling petition that was filed in 2002, but the court never ruled on the petitioner's argument. See, *Americans for Safe Access v. DEA*, 700 F.3d 438 (D.C. Cir. 2013). The petitioner's Petition for Writ of Certiorari is online at: http://medicalmarijuana.procon.org/sourcefiles/carl-olsen-writ-of-certiorari-09112013.pdf

When a term defined in a state law is not defined in a federal law, the state definition stands. This is a right retained by the states under our system of federalism.

Because of the absence of a federal definition for the term "medical use," there is a record of the federal administrative agency having difficulty defining it. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1132, 1135 (D.C. Cir. 1994):

> The Final Order discards the earlier formulation and applies a new five-part test for determining whether a drug is in "currently accepted medical use"

This five-part test was eventually approved by the federal courts in 1994, but this was before there were any state laws defining the medical use of marijuana. The court said it would defer to the agency's interpretation, if reasonable. *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991). What was "reasonable" in 1994 in the absence of any state law accepting the medical use of marijuana cannot be considered reasonable now that large majority of states have accepted it.

States began accepting the medical use of marijuana in 1996. Federal scheduling (by administrative rule) has not been updated to reflect this change. The DEA's interpretation (the five-part test from 1994) of the phrase "currently accepted medical use" is no longer valid. The entire phrase reads, "currently accepted medical use in treatment in the United States," not simply "currently

accepted medical use." In 1994, there were no state laws "in the United States," so the phrase "in the United States" did not add anything significant to the administrative agency's analysis of the phrase "currently accepted medical use" at that time. See, *Grinspoon v. DEA*, 828 F.2d 881 (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.

Id., at 886.

> Unlike the CSA scheduling restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate. Compare 21 U.S.C. § 801(5) with 21 U.S.C. § 321 (b), 331, 355(a). Thus, it is possible that a substance may have both an accepted medical use and safety for use under medical supervision, even though no one has deemed it necessary to seek approval for interstate marketing.

Id., at 887.

Nothing in federal schedule 1 other than marijuana has ever been accepted for medical use by any state, which explains why the DEA is unable to find any precedent for rescheduling a plant in schedule 1. This has never happened before. This change in circumstance renders the DEA's five-part test from 1994 invalid, because the matter is no longer one that requires DEA to interpret the statute.

It was clear in 1970 when Congress wrote the law that marijuana had no currently accepted medical use in the United States. *NORML v. DEA*, 559 F.2d 735, 743 (D.C. Cir. 1977) (Letter from Dr. Theodore Cooper, Acting Assistant Secretary for Health, April 14, 1975, reproduced at 40 Fed. Reg. 44165 (1975)) ("There is currently no accepted medical use of marihuana in the United States").

Although marijuana had no currently accepted medical use in the United States in 1970 when the federal drug law was written, marijuana does have a long history of medical use in the United States. *James v. Costa Mesa*, 700 F.3d 394, 409 (9th Cir. 2012):

> First, while California in 1996 became the first of the sixteen states that currently legalize medical marijuana, the history of medical marijuana goes back much further, so that use for medical purposes was not unthinkable in 1990. At one time, "almost all States ... had exceptions making lawful, under specified conditions, possession of marihuana by ... persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person." *Leary v. United States*, 395 U.S. 6, 17 (1969).

H. Cannabidiol is Marijuana

Iowa Code §124.101(19) (2014) defines marijuana, inter alia, as the resin extracted from any part of the plant and every derivative of the plant. Iowa Code § 124D.2(1) (2015) defines "cannabidiol" as "a nonpsychoactive cannabinoid found in the plant free from plant material with a tetrahydrocannabinol level of no more than three percent." Petitioner's Brief, p. 8, n. 10, App. 110 (DEA classification of cannabidiol in federal schedule 1 because it is an extract of marijuana).

Cannabinoids are concentrated in the resin of the plant. According to the DEA, "CBD derived from the cannabis plant is controlled under Schedule I of the CSA because it is a naturally occurring constituent of marijuana."[16]

If federal scheduling was a determining factor in state scheduling, the same logic would apply to both marijuana and cannabidiol. Marijuana and cannabidiol are both in federal schedule 1. There is no difference in the definition of marijuana and cannabidiol in either state or federal law. The definition of marijuana in both state and federal law includes all of its parts, "with certain exceptions for the parts of the plant that are not the source of cannabinoids."[17]

Extracting a schedule 1 substance from a schedule 1 plant is difficult. Extracting a substance in schedule 2 from a plant in schedule 1 is equally difficult. According to the National Institute on Drug Abuse (NIDA), simply doing research on cannabidiol with the plant in schedule 1 is difficult.[18]

Proving just how difficult extracting cannabidiol is, Iowa law says cannabidiol must be obtained from an out of state source, Iowa Code §

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[16] https://www.dea.gov/pr/speeches-testimony/2015t/062415t.pdf, at page 1.
[17] Ibid.
[18] Statement from Dr. Nora Volkow, M.D., Director, National Institute on Drug Abuse (NIDA), June 24, 2015, at pages 6-7 ("it is important to try to understand the reasons for the lack of well-controlled clinical trials of CBD including: the regulatory requirements associated with doing research with Schedule I substances, including a requirement to demonstrate institutional review board approval"). http://www.drugcaucus.senate.gov/sites/default/files/Volkow.pdf

124D.6(1)(b). But, federal schedule 1 says cannabidiol can't be provided for medical use anywhere in the United States, which means it cannot be obtained from an out of state source.

Saying marijuana has medical use (for extracting its resin), but recommending that marijuana remain in schedule 1 is not logical. The availability of the marijuana to make the extract is the primary concern.

I. Comparing Plants in Schedule 1 to Plants in Schedule 2

There is no precedent for making a medicine from a plant in schedule 1. Nothing made from a plant in schedule 1 has ever been accepted for medical use by any state. Marijuana is the only plant in schedule 1 that has ever been accepted for medical use by any state.

Trying to make medicine from a plant in schedule 1 is prohibitive. Plants used for making medicine are in schedule 2 or lower. The medicines made from those plants are in schedule 2 or lower. Opium plants are in state and federal schedule 2. Iowa Code § 124.206(2)(c) (2014); 21 C.F.R. § 1308.12(b)(3) (2016). Morphine is a schedule 2 medicine that is extracted from schedule 2 opium plants. Iowa Code § 124.206(2)(a)(13) (2014); 21 C.F.R. § 1308.12(b)(1)(ix) (2016). Coca plants are in state and federal schedule 2. Iowa Code § 124.206(2)(d) (2014); 21 C.F.R. § 1308.12(b)(4) (2016). Cocaine is a schedule 2 medicine that is extracted from schedule 2 coca plants. Iowa Code § 124.206(2)(d)(1) (2014); 21

C.F.R. § 1308.12(b)(4) (2016). When the board discussed this issue, it incorrectly identified opium as a schedule 1 substance and rationalized its recommendation to place marijuana in schedule 1 on the erroneous argument that plants used to make medicine are placed in schedule 1, which has never been true. Exhibit #31, p. 3, App. 440.

When a plant is used for making medicine, the legislature does not place that plant in schedule 1 and Congress does not place that plant in schedule 1. Both the state and federal acts allow the administrative agencies to make corrections to initial scheduling decisions that are later invalidated by changes in circumstance (state laws). It was unreasonable for the board to recommend placing the medicine from the plant in schedule 2 and then recommend the plant it comes from remain in schedule 1.

Placing a plant in schedule 1 and placing the extracts from that plant in lower schedules is inconsistent with the pattern established in the state and federal controlled substances acts.

Judge McCall identified the problem when he stated, "Although legalizing the possession of the substance, the Act did not create a method by which Iowa residents can obtain cannabidiol with the state." Ruling, p. 3, n. 15, App. 153.

Since it's not legal to make anything from marijuana, the board is recommending patients use bootleg products from illegal sources. That is not a reasonable solution and it's not good for Iowans.

Nobody is testing these products to see what's in them. These products cannot be produced or manufactured legally.[19] This is a problem. Rescheduling marijuana is the right step. Rescheduling marijuana in Iowa is the place to take that step. Iowa needs to be firm with the federal government if it wants to make medicine from marijuana extracts.

J. The Board has not Filed Legislation

Through an open records request, Exhibit #40, App. 497, it was revealed the board never submitted its legislative recommendations to the legislature in 2015 or in 2016.

The only time the board shared its recommendations with any legislators was on April 15, 2015, when the Iowa Senate Republican Caucus asked the board to discuss a proposed medical marijuana program in Iowa, SF 484. At that meeting, the board presented its recommendations to the Iowa Senate Republican Caucus. Two of those Republican senators interviewed me that same day, Senator

[19] Statement from Dr. Nora Volkow, M.D., Director, National Institute on Drug Abuse (NIDA), June 24, 2015, at 7 (there is a "lack of CBD that has been produced under the guidance of Current Good Manufacturing Processes (cGMP) – required for testing in human clinical trials – available for researchers"). http://www.drugcaucus.senate.gov/sites/default/files/Volkow.pdf

Jack Whitver (my senator) and Senator Charles Schneider. Instead of adopting the 2015 recommendations, the Iowa Senate Republican Caucus asked the board for the recommendations it made in 2010. Every senator then voted to adopt the 2010 recommendation to remove marijuana from schedule 1, S-3123, by a vote of 44-0-6 on April 15, 2015. The Iowa Senate voted unanimously to remove marijuana from schedule 1 and place it in schedule 2, as the board had recommended in 2010. See Senate Amendment S-3123, https://www.legis.iowa.gov/legislation/BillBook?ga=86&ba=S3123. 2015 Senate Journal, p.p. 873-874. https://www.legis.iowa.gov/docs/pubs/sjweb/pdf/April%2015,%202015.pdf#page=6.

CONCLUSION

The board reversed its previous position from 2010, and rejected the advice of its own subcommittee in 2014, citing federal scheduling without explaining why. The board followed federal scheduling after finding that marijuana has medical use, which would make federal scheduling invalid.

In 2010, the board found marijuana has medical use after a careful examination the eight factors in Iowa Code § 124.201(1) (2010). Then in 2015, the board found that marijuana has medical use as a matter of law based on Iowa Code

Chapter 124D. Both of these findings, in 2010 and again in 2015, are inconsistent with marijuana's continued placement in federal schedule 1.

Appellant respectfully requests this Court to reverse the district court's dismissal of the petitioner's Petition for Judicial Review and to remand this case to the board to correct the inconsistencies in its decision.

REQUEST FOR ORAL ARGUMENT

Appellant respectfully requests to be heard in oral argument.

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Iowa Rule of Appellate Procedure 6.903(1)(g)(1) or (2) because this brief has 8,015 words, excluding the parts of the brief exempted by Iowa Rule of Appellate Procedure 6.903(1)(g)(1).

This brief complies with the typeface requirements and the type-style requirements of Iowa Rule of Appellate Procedure 6.903(1)(e) and (f) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2016 in 14-point, Times New Roman font.

Dated: November 27, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 27, 2016, the foregoing was served electronically on the following:

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