IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN, Petitioner, vs. IOWA BOARD OF PHARMACY, Respondent.	**05771 CVCV051068** **PETITIONER'S BRIEF IN SUPPORT OF PETITION FOR JUDICIAL REVIEW**

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 State v. Olsen, 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 Olsen v. DEA, 878 F.2d 1458, 1461 (D.C. Cir. 1989) (Olsen is "entitled to a judicial audience")[2].

[1] Compare with State v. Bonjour, 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 Elrod v. Burns, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); and see Montana v. United States, 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 Raich v. Gonzales, 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 sources[3]. Neutrality and general applicability of the law are essential elements in free exercise of religion jurisprudence. See Employment Division v. Smith, 494 U.S. 872, 889 (1990) (citing Olsen v. DEA, 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 make[5]. The Petitioner's injury is directly

[3] 2014 Medical Cannabidiol Act, Iowa Acts Chapter 1125 § 7 (May 30, 2014), SF 2360.
[4] And see Church of Lukumi Babalu Aye v. Hialeah, 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 Fraternal Order of Police v. Newark, 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. State v. Bonjour, 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 marijuana use and the conditions, if any, it may be used to treat").

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 religion[6].

Standing is not a requirement to request the Board consider the scheduling of marijuana, but the Board says it wants to address that issue now[7]. 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 marijuana[8]. Consistency with federal scheduling of marijuana has not been the Board's past practice.

[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 1[10] 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 2008[11], 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.

[10] http://www.deadiversion.usdoj.gov/drugreg/reg_apps/225/225_form.pdf; http://www.drugcaucus.senate.gov/sites/default/files/DEA%20Rannazzisi%20CBD%20Testimony%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").

[11] 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 2015[12].

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 James v. Costa Mesa, 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 States[13]" 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. 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").

> 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

[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:

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