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IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN, Petitioner, vs. IOWA BOARD OF PHARMACY, Respondent.	**05771 CVCV051068** **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 use[1], 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 use[2]. The Board's ruling that marijuana should be placed in schedule 1 and removed from schedule 2 is contrary to Iowa law[3].

In 2010, the Board found that marijuana had accepted medical use and recommended its reclassification[4].

[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, McMahon v. Iowa Board of Pharmacy, 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 reclassification[5].

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. Gonzales v. Oregon, 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 2008[6] while those same products remain in federal schedule 1 today[7]. 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 2014[8], but remain in Iowa schedule 3[9]. 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

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> 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 1[10]); 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:

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[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.