IN THE SUPREME COURT OF IOWA

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

APPEAL FROM THE IOWA DISTRICT COURT

FOR POLK COUNTY

HONORABLE ELIZA OVROM, JUDGE

APPELLANT'S FINAL REPLY BRIEF

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CERTIFICATE OF FILING

On August 24, 2015, I certify that I did electronically file through the Iowa Court System Appellant's Reply Brief

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I. WHETHER THE DISTRICT COURT ERRED IN FINDING THE IOWA BOARD OF PHARMACY HAD NO DUTY TO RECOMMEND RECLASSIFICATION OF MARIJUANA.

AUTHORITIES

Iowa Code Chapter 124

State v. Bonjour, 694 N.W.2d 511 (Iowa 2005)

Controlled Substances Act, 21 U.S.C. §§ 801-971

Uniform Controlled Substances Act, 9 U.L.A. Part 2

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

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

ARGUMEMT

I. The District Court Erred in Ruling the Board had no Duty to Recommend Reclassification of Marijuana.

A. Uniformity of interpretation

Our legislature's intent is that Iowa's version of the Uniform Controlled Substances Act, 9 U.L.A. Part 2 (UCSA), be interpreted consistently with the other states that have adopted it. Iowa Code § 124.601 (2013):

> This chapter shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it.

Under both the UCSA and the federal Controlled Substances Act, 21 U.S.C. §§ 801-971 (CSA), scheduling of controlled substances is an administrative function, not a legislative one. *See* UCSA, § 201; 21 U.S.C. § 811. The administrative body is usually a public health agency or public safety authority. At the federal level, this duty is shared between the U.S. Department of Justice and the U.S. Department of Health and Human Services. In Iowa, the administrative agency is the Iowa Board of Pharmacy, a division of the Iowa Department of Public Health.

Iowa's version of the UCSA is inconsistent with both the UCSA and the CSA because, in Iowa, scheduling is a legislative branch function. The Board, however, argues that point to the extreme. The Board argues that under Iowa's version of the UCSA scheduling is purely legislative with no role at all for the administrative agency.

The Board's argument is wrong. Our legislature has defined a substantial role for the Iowa Board of Pharmacy in scheduling decisions that is just as extensive as the role the administrative agencies perform under the UCSA and the CSA. Under Iowa Code § 124.201(1) (2013), which sets out the same 8 factors the administrative agencies must consider under the UCSA and the CSA, the Board acts in an advisory role to the Iowa legislature. Iowa Code §§ 124.203, 205, 207, 208, and 209 (2013), set out the same criteria the administrative agencies must

consider under the UCSA and the CSA, and the Iowa Board of Pharmacy must evaluate them and give its advice to the legislature.

The Board argues that its advice is not required to initiate scheduling. Respondent-Appellee's Brief at page 4 footnote 1. But, the law is clear. The General Assembly has defined a substantial role for the Iowa Board of Pharmacy in Iowa Code Chapter 124. As this Court has previously noted in State v. Bonjour, 694 N.W.2d 511, 514 (Iowa 2005) ("the legislature has deferred the initial decision on the matter to the Board of Pharmacy Examiners"). The Board argues the chapter must be read as a whole and not piecemeal. And, yet the Board is reading its role completely out of the statute by selectively quoting pieces of the statute.

The Board has expertise that the legislature does not. 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.").

Therefore, it was unreasonable for the Board to conclude that its opinion on marijuana's scheduling was unneeded, unwanted, or unnecessary in 2014.

B. Marijuana no longer meets the condition for schedule 1

It was unreasonable for the board to refuse to recommend the reclassification of marijuana to the legislature in 2014, because the Board was aware the limitation the legislature placed on schedule 1 in 1971 was met in 2014 in two ways.

First, in 2010, the Board found that marijuana was misclassified by carefully analyzing the 8 factors in Iowa Code § 124.201(1) (2009). The Board has not suggested that any new evidence has cast any doubt on its previous decision in 2010.

Second, in 2008, when the first petition was filed alerting the Board that marijuana had accepted medical use in the United States, there were 8 states in the United States that had accepted it.

At the time the Board rejected the petition in 2013 there were 19 states in the United States that had accepted the medical use of marijuana, more than double the number in 2008. The Board has not suggested that any of these 19 states has mistakenly concluded that marijuana has accepted medical use. The Board agrees with them.

The Board's own independent analysis of the medical evidence in 2009 and 2010 affirms the validity of these 19 state decisions accepting the medical use of marijuana in 2013, although an Iowa administrative agency has no authority to consider whether the laws in other states are valid. A state law accepting the

medical use of marijuana is sufficient to establish beyond question that marijuana has accepted medical use in the United States. *See* Gonzales v. Oregon, 546 U.S. 243, 264 (2006):

> As for the federal law factor, though it does require the Attorney General to decide "[c]ompliance" with the law, it does not suggest that he may decide what the law says. Were it otherwise, the Attorney General could authoritatively interpret "State" and "local laws," which are also included in 21 U.S.C. § 823(f), despite the obvious constitutional problems in his doing so.

The Board must recognize states in the United States have accepted the medical use of marijuana as a matter of constitutional law. The Board can and did determine that marijuana has accepted medical use under the 8 factors in Iowa Code § 124.201(1)(a)-(h) (2009), but the Board's opinion on whether other states' laws are valid is not entitled to any deference whatsoever. Those states had the authority to make the decision to accept the medical use of marijuana, and they made it.

Although there were 8 states in the United States that had accepted the medical use of marijuana when the petitioner petitioned the Board in 2008, it was reasonable for the board to make its own independent analysis of the 8 factors in Iowa Code § 124.201(1)(a)-(h) (2009). The board made its own independent analysis, and agreed, by its unanimous ruling, that those 8 states had correctly recognized marijuana's medical use. In November of 2013, when the Board denied the petition, there were 19 states in the United States that had accepted the

medical use of marijuana. The Board has no authority to question the validity of those states' laws from a legal perspective and has not disagreed with those states' laws from a medical perspective.

In denying the petition in November of 2013, the Board did not dispute any of facts presented by the petitioner. The Board accepted the fact that marijuana is incorrectly classified in Iowa, but found it had no duty to take any action based on that fact.

The Board asks this court to give deference to inaction by citing Houck v. Iowa Bd. of Pharmacy Examiners, 752 N.W.2d 14, 16 (Iowa 2008). *See* Respondent-Appellee's Brief at p. 6. The decision in Houck is distinguished, however, because the Board in that case accepted facts and then took action. In Houck, the Board found that compounding prescription drugs does not transform them into non-prescription ("over-the-counter") medications. Contrast Houck with the Board's decision not to take any action after accepting that marijuana is incorrectly classified.

C. The meaning of words used in the statute

The Board cites Renda v. Iowa Civil Rights Comm'n, 784 N.W.2d 8, 13 (Iowa 2010) (all the words in a statute must be considered, not just some of the words). *See* Respondent-Appellee's Brief at p. 7. The Board relies heavily on the words "necessary or advisable" in Iowa Code § 124.201(1) (2013), but not on the

word “or” in Iowa Code § 124.203(2) (2013). Instead, the Board relies heavily on the word “appropriate” in Iowa Code § 124.203(2) (2013). As the Court cautioned in Renda, “It is conceivable that the legislature intends an agency to interpret certain phrases or provisions of a statute, but not others.” Id. at 12. Did the legislature intend for the Board to leave out the word “or” and an entire sentence containing the word “or” before the last comma in that sentence where the words “as appropriate” appear? Not likely.

The Board also cites State v. Pickett, 671 N.W.2d 866, 870 (Iowa 2003) (examining other laws that use the same or similar language to determine legislative intent). *See* Respondent-Appellee’s Brief at p. 11. In Pickett, this Court said, “Similarly, we interpret a statute consistently with other statutes concerning the same or a related subject.” Id. at 870. As previously mentioned, the language at issue here is also found in the UCSA and the CSA. Those acts do not provide administrative agencies with the option of doing nothing when the statutory condition for schedule 1 is no longer met. The UCSA and the CSA require action by the administrative agency.

The Board does not quote Iowa Code § 124.203(2) (2013) precisely as it was written. The Board does not include all the words. The words “as appropriate” do not stand alone in that sentence. The entire sentence reads:

> 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*.

(emphasis added).

The Board has the authority to recommend another schedule, if that is appropriate. The Board has the authority to recommend none of the schedules, if none are appropriate. Reading the entire sentence, there are two choices and the Board must pick one, *as appropriate*. Instead, the Board reads into that sentence a third choice, "do nothing at all." Petitioner urges the Court to reject this third choice as inconsistent with language, the intent, and the purpose, of the chapter as a whole.

D. Our legislature's intent

The Board says it can refuse to act if it thinks the legislature does not want the Board's advice. *See* Respondent-Appellee's Brief at p. 11. How can the Board determine that its advice is not wanted or needed? This is not a reasonable interpretation of the act. The act lays out the Board's duty to make recommendations, not refuse to make recommendations. The Board says the legislature is considering marijuana's scheduling as justification for withholding its advice. There could not be a timelier occasion for the Board's advice than when the legislature is considering this matter.

E. The Board confuses scheduling with medical use

Iowa Code 124.203(1)(b) (2013) does not say marijuana must have accepted medical use "in Iowa" as a condition for removing it from schedule 1. Our law says it must have accepted medical use "in the United States." *See* Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987):

> We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "in the United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.

The Board confuses scheduling with medical use. Scheduling is a classification. Medical use is an action. Scheduling recognizes medical use, it does not cause it. A substance can have accepted medical use in the United States and still have no accepted medical use in Iowa.

For one example, if the substance has not yet been removed from federal schedule 1, then no doctor in Iowa can prescribe it and no pharmacy in Iowa can dispense it. To use marijuana as medicine in Iowa without federal reclassification would require a separate state law setting forth the details on how marijuana can be used medically in Iowa without a prescription and without dispensing it from a pharmacy, just as it has been set forth in the 19 states aforementioned. Unless there is a state law that provides details on access (manufacture, distribution,

qualifications on who can possess, qualifications on conditions of use, etc.) then removing it from Iowa schedule 1 does not automatically allow medical use of that substance in Iowa.

There is another good example in Iowa Code § 124.208(9)(b) (2013) where naturally extracted dronabinol is listed. Naturally extracted dronabinol is in federal Schedule 1. No doctor in Iowa can prescribe a product with naturally extracted dronabinol and no pharmacy in Iowa can dispense it. There is no actual use of naturally extracted dronabinol in Iowa because there is no separate law in Iowa explaining how it can be produced or distributed. The federal government has considered rescheduling naturally extracted dronabinol, but has never completed the rescheduling process. *See* Motion for Judicial Notice on December 6, 2013, Exhibit #2 (App. 123-128). Judge Ovrom granted the motion on December 10, 2013, at p. 4 (App. 136). *See* 2008 Iowa Acts Chapter 1010 § 4 (March 5, 2008); 75 Fed. Reg. 67054 (2010).

Indeed, there is no requirement in Iowa Code Chapter 124 that Iowa schedules be consistent with federal schedules. In most states that have accepted the medical use of marijuana, there is no direct involvement of state officials in the production or use of marijuana. Private individuals or groups in those states are licensed to produce the marijuana and the patients obtain it with a "recommendation" from a doctor as defined in a state law enacted for this purpose.

The difference between a "recommendation" and a "prescription" is discussed in detail in Conant v. Walters, 309 F.3d 629 (9th Cir. 2002), *rehearing denied by*, *rehearing*, *en banc*, *denied by* Conant v. McCaffrey (9th Cir., Feb. 6, 2003) (unpublished), *certiorari denied by* Walters v. Conant, 540 U.S. 946; 124 S. Ct. 387; 157 L. Ed. 2d 276 (2003). Whether it's good public policy to enact state medical marijuana laws without insisting on federal rescheduling is a question outside the scope of this appeal. It is troublesome and puzzling.

The Board says scheduling decisions in other states do not require rescheduling in Iowa, but the petitioner did not present any scheduling decisions from other states. Only two states have rescheduled marijuana and those decisions have no relevance to scheduling here in Iowa. Iowa law does not say marijuana must have been rescheduled in other states. Iowa law says marijuana must have accepted medical use in other states in the United States.

Oregon rescheduled marijuana in 2010, but its scheduling criteria are not the same as Iowa's or the federal government's. Chapter 898 Oregon Laws 2009. *See* State v. Eells, 72 Or. App. 492, 497, 696 P.2d 564, 567 (1985) ("Oregon has not chosen to include medical use as a factor"). The petitioner did not ask the Board to consider Oregon's scheduling. Oregon accepted the medical use of marijuana in 1998. Oregon Ballot Measure 67 (1998). Petition cited the 1998 state law, not the state scheduling in 2010.

Connecticut rescheduled marijuana in 2013, but the petitioner never cited it as evidence either. On May 31, 2012, the state of Connecticut enacted Connecticut Public Act No. 12-55, Section 18(e) (2012), directing the Connecticut Commissioner of Consumer Protection to remove marijuana from Schedule I by January 1, 2013. Petitioner cited the state law, not the state scheduling.

The petitioner specifically cited 19 state laws defining marijuana as "medicine" and defining marijuana's "medical use" as evidence that marijuana has accepted medical use in the United States. The petitioner's argument had nothing to do with scheduling in other states. The petitioner's argument had nothing to do with federal scheduling. Federal scheduling includes the same limitation that schedule 1 substances must have no currently accepted medical use in the United States in order to lawfully remain in schedule. Again, while this is troublesome and problematic, it is outside the scope of this appeal. *See* Grinspoon v. DEA, 828 F.2d 881, 887 (1st Cir. 1987):

> 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.

The Board presents what seems to be a troubling question. The Board asks what would happen in Iowa if heroin was accepted for medical use in Wyoming.

First, let's be clear that heroin was not being considered for medical use by any state in 2013. Not one state had accepted the medical use of heroin in 2013. At the same time there was no accepted medical use of heroin in the United States there were 19 states in the United States that had accepted the medical use of marijuana. The Iowa Board of Pharmacy did not find heroin had any accepted medical use in the United States in 2010 when it found that marijuana did have accepted medical use.

So, following along with this hypothetical question, if Wyoming had accepted the medical use of heroin in 2013 and heroin was then removed from Iowa schedule 1 as it must, and federal schedule 1 as well for the same reason, would that make heroin legal as a prescription drug in Iowa? Would that make heroin legal as a prescription drug in any state that hasn't accepted it for medical use? No, it would not. Would the federal government be forced to accept it? The federal government does not decide what the legitimate use of controlled substances is, Gonzales v. Oregon, 546 U.S. 243 (2006), so the answer, again, is no.

Some states, like Colorado for example, did not place marijuana in any of the schedules. Colorado criminalized the possession of marijuana in 1917, but never included marijuana in schedule 1 of its state controlled substances act. The criminalization of marijuana in Colorado barred its medical use in Colorado until

2000 when the voters amended the Colorado constitution. Colorado Ballot Amendment 20 (2000). Scheduling was not necessary to bar its medical use in Colorado. Neither is scheduling necessary to bar medical use of heroin in Iowa. Iowa could easily remove heroin from Iowa schedule 1 and then simply criminalize it without including it in any of the other schedules. Acceptance of heroin for medical use in Wyoming would not force Iowa to accept heroin for medical use here. The Board is really grasping for straws here.

Suggesting that other states can determine medical use in Iowa shows the Board does not understand the difference between scheduling and laws accepting medical use. Scheduling recognizes medical use, it does not create it. The statute says accepted medical use "in the United States," not just "in Iowa." Scheduling does not make a substance accepted for medical use. Medical use requires a change in scheduling if the substance is in schedule 1.

Two more examples are plants in Iowa schedule 2, opium and coca plants. Iowa Code § 124.206(c) (2013); Iowa Code § 124.206(d) (2013). Opium and coca are source materials for prescription drugs, but they are not prescribed or dispensed in their raw plant form in Iowa. Placing them in schedule 2 acknowledges they have some medical use. We make drugs from these plants, and that is a medical use. Doctors are not using these plants directly to treat patients in Iowa, even

though these plants are in schedule 2. Pharmacies in Iowa are not dispensing these plants.

The Board also cites an outdated federal regulation, 21 C.F.R. § 1308.11(d)(23) (2012), that incorrectly classifies marijuana as having no accepted medical use in the United States. *See* Respondent-Appellee's Brief at p. 14. Failure of a federal administrative agency to reclassify marijuana does not justify the failure of Iowa to reclassify it. We have our own law here. The federal government seems to have the same problem Iowa has, since schedule 1 is off limits for a substance with accepted medical use in the United States. The Board cannot blindly accept an erroneous federal classification. Marijuana does not meet the conditions for placement in federal schedule 1, but that is outside the scope of this appeal.

And, Iowa law clearly does not require blind obedience to federal scheduling. If the federal government adds a new substance to schedule 1 that has never been previously scheduled, Iowa may accept that. See Iowa Code § 124.201(4) (2013). But, under Iowa Code § 124.201(4) (2013), the Board still has the option of refusing to follow the federal decision adding the new substance to federal schedule 1. Nothing else in the chapter even suggests that Iowa must follow federal scheduling decisions. It might be wise or prudent to follow them, or not.

F. Brevity of the Board's ruling

The Board says the petitioner is complaining about the short length of the Board's ruling. *See* Respondent-Appellee's Brief at p. 14 footnote 2. The Board confuses brevity with lack of substance. The board did not articulate any valid reason for denying the petition. The Petitioner is complaining about lack of substance, not the short length of the ruling.

CONCLUSION

This Court should reverse the District Court's dismissal of the Petitioner's Petition for Judicial Review and order the Iowa Board of Pharmacy to recommend the reclassification of marijuana.

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 3,543 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 2013 in 14-point, Times New Roman font.

Dated: August 24, 2015

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