

IN THE IOWA DISTRICT COURT IN AND FOR POLK COUNTY

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<p>CARL OLSEN,  Petitioner,  vs.  IOWA BOARD OF PHARMACY,  Respondent.</p>	<p>CASE NO. CVCV056841  <b>RESPONDENT'S BRIEF</b></p>
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**A. STATEMENT OF THE ISSUES PRESENTED FOR REVIEW**

1. Whether the Board's responsive letter explained a fair and rational basis for its handling of Mr. Olsen's request.

Iowa Code § 17A.19(10)(h)

*Olsen v. Iowa Bd. Of Pharmacy*, No. 16-1381, 2017 WL 3283296 (Iowa Ct. App. August 2, 2017)

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

Iowa Code § 124.204(8)

Iowa Code § 124.201(1)(a)-(h)

Iowa Code § 124.201

Iowa Code § 124.201(1)

Iowa Code § 124.101(20)

2. Whether the Board's refusal to make a recommendation that would have contravened Iowa Code section 124.201 was irrational, illogical, or wholly unjustifiable.

Iowa Code § 124.201

*Olsen v. Iowa Bd. Of Pharmacy*, No. 16-1381, 2017 WL 3283296 (Iowa Ct. App. August 2, 2017)

Iowa Code § 17A.19(10)(m)

*Greenwood Manor v. Iowa Dep't. of Pub. Health*, 641 N.W.2d 823, 834 (Iowa 2002)

Iowa Code chapter 124

1971 Iowa Acts ch. 148, § 201 (codified at Iowa Code § 204.201 (1973))

1967 Iowa Acts ch. 189, § 2 (codified at Iowa Code § 204A.2(12) (1971))

*State Religious Freedom Restoration Acts*, NATIONAL CONFERENCE OF STATE LEGISLATURES, [www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx](http://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx) (last updated May 4, 2017)

3. Whether the Board abused its discretion when it declined to exceed its legal obligations.

Iowa Code § 17A.19(10)(n)

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

*Olsen v. Iowa Bd. Of Pharmacy*, No. 16-1381, 2017 WL 3283296 (Iowa Ct. App. August 2, 2017)

Iowa Code chapter 124

Iowa Code chapter 124E

Iowa Code § 124.201

## **B. STATEMENT OF THE CASE**

The Petition for Judicial Review seeks review of the Iowa Board of Pharmacy's ("Board") response to a request filed with the Board by Mr. Olsen, which is considered "other agency action." Only July 5, 2018, Petitioner emailed the Board's executive director with a request for the Board to make a recommendation to the General Assembly regarding the bona fide religious use of cannabis by Rastafari. Agency Record (A.R.) at 1. The

request was captioned as a “Petition for Scheduling Recommendation” and was accompanied by an “Argument and Memorandum in Support of Petition.”<sup>1</sup> *Id.* at 2–26, 28–45. Specifically, the request asked the Board to recommend to the legislature that a new paragraph be added immediately after Iowa Code section 124.204(8) stating:

Nothing in this chapter shall apply to the bona fide religious use of cannabis by Rastafari; however, persons supplying the product to the church shall register, maintain appropriate records of receipts and disbursements of cannabis, and otherwise comply with all applicable requirements of this chapter and rules adopted pursuant thereto.

*Id.* at 28. Petitioner indicated the request was being made pursuant to the Board’s authority in Iowa Code section 124.201 (2018). *Id.* Iowa Code section 124.201(1) states:

The board shall administer the regulatory provisions of this chapter. Annually, within thirty days after the convening of each regular session of the general assembly, the board shall recommend to the general assembly any deletions from, or revisions in the schedules of substances, enumerated in section 124.204, 124.206, 124.208, 124.210, or 124.212, which it deems necessary or advisable. In making a recommendation to the general assembly regarding a substance, the board shall consider the following:

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

On July 16, 2018, the Board’s executive director emailed a responsive letter to Mr. Olsen and his counsel, which stated the Board was declining to take any action in response to his request and included an explanation for the decision. A.R. at 48–50. This meant

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<sup>1</sup> Petitioner actually emailed the documentation twice on July 5, 2018, because the page numbering on Exhibit #4 was incorrect on the first transmission. A.R. at 27.

that the Board (1) would not be having any proceedings regarding the request and (2) would not be making the recommendation to the General Assembly that Mr. Olsen had requested. The Board's responsive letter dated July 16, 2018, is the subject of this judicial review proceeding.

The Board was created pursuant to Iowa Code sections 147.12 and 147.13 to regulate the practice of pharmacy in Iowa. The Iowa Pharmacy Practice Act is intended to

promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and other engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized.

Iowa Code § 155A.2(1). In addition, the Board has attendant responsibilities pursuant to the Uniform Controlled Substances Act, which is codified in Iowa Code chapter 124. Specifically, the Board has responsibilities as it pertains to the "regulatory provisions" of chapter 124. *Id.* § 124.201(1). This responsibility largely consists of regulating the lawful distribution of prescription drugs that are listed in schedules II through V of the Uniform Controlled Substances Act. By contrast, substances placed in schedule I, by definition, have no accepted medical use in treatment or a lack of accepted safety for use in treatment under medical supervision. *Id.* § 124.203. Schedule I substances cannot be lawfully prescribed; marijuana and its psychoactive component, tetrahydrocannabinols (THC), are schedule I substances. *Id.* § 124.204(4)(m), (u). Criminal law enforcement agencies are primarily responsible for regulating the unlawful manufacture and possession of schedule I substances.<sup>2</sup>

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<sup>2</sup> The Board's role in regulating schedule I substances is essentially limited to issuing Controlled Substances Act registrations to individuals engaged in the lawful research of schedule I substances. *See* Iowa Code § 124.302.

The Board appoints its own executive director to oversee the administrative staff, which assists the Board by managing daily operations. *Id.* § 147.80; Iowa Admin. Code r. 657—1.2 (2018). The executive director is responsible for ensuring that any request received by the Board that is required by law to be considered by the Board<sup>3</sup> is placed on the Board’s agenda. The executive director may use discretion to decline to include other types of requests on the Board’s agenda, particularly if the request is not germane to the Board’s purpose. In this case, the executive director declined to add Mr. Olsen’s request on the Board’s agenda, and instead sent a responsive letter. Petitioner is seeking to reverse this action and have the matter remanded to the Board for “further proceedings.” Petitioner has failed to cite any statute or rule that would govern the “proceeding” he is seeking on remand.

### C. SCOPE OF REVIEW

Judicial review under Iowa Code section 17A.19 is for correction of errors at law, not *de novo*, and the reviewing court functions solely in an appellate capacity to correct errors of law on the part of the agency. *Garcia v. Naylor Concrete Co.*, 650 N.W.2d 87, 89 (Iowa 2002). A reviewing court is not empowered to substitute its own judgment for that of the Board. *McClure v. Iowa Real Estate Comm’n*, 356 N.W.2d 594, 597 (Iowa Ct. App. 1984). The scope of judicial review is limited to the grounds for relief set forth in subsection 17A.19(10) that have been briefed by Petitioner. *See Kopecky v. Iowa Racing & Gaming Comm’n*, 891 N.W.2d 439, 442 (Iowa 2017). Under section 17A.19, “[t]he

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<sup>3</sup> Examples of requests that are required by law to be heard by the Board include petitions for rulemaking made pursuant to Iowa Code section 17A.7 and Iowa Admin. Code r. 657—26 (2018), petitions for declaratory orders made pursuant to Iowa Code section 17A.9 and Iowa Admin. Code r. 657—27 (2018), and petitions for waivers and variances made pursuant to Iowa Code section 17A.9A and Iowa Admin. Code r. 657—34 (2018).

burden of demonstrating the required prejudice and invalidity of [challenged] agency action is on the party asserting the invalidity.” Iowa Code § 17A.19(8)(a). This Court must conduct its review of the issues raised by Petitioner within the narrow framework of these standards.

#### D. ARGUMENT

1. The Board’s responsive letter explained a fair and rational basis for its handling of Mr. Olsen’s request.

Petitioner asserts the Board’s action was “inconsistent with the agency’s prior practice or precedents” without “justif[ying] that inconsistency by stating credible reasons sufficient to indicate a fair and rational basis for the inconsistency.” Iowa Code § 17A.19(10)(h). It is true that Petitioner has repeatedly filed requests with the Board regarding the rescheduling of marijuana based on assertions of its purported accepted medical use. *See Olsen v. Iowa Bd. of Pharmacy*, No. 16-1381, 2017 WL 3283296 at \*1 (Iowa Ct. App. August 2, 2017); *Olsen v. Iowa Bd. of Pharmacy*, No. 14-2164, 2016 WL 2745845 at \*1 (Iowa Ct. App. May 11, 2016). This particular request, however, was the first instance in which Mr. Olsen directly asked the Board to make a recommendation to the legislature pertaining to the religious use of cannabis. The Board’s handling of this request may have been inconsistent with its prior practice<sup>4</sup> because Petitioner’s request was inconsistent with his prior requests.

The Board’s responsive letter stated credible reasons sufficient to explain why it

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<sup>4</sup> Notably, the Board did respond to a “Petition for Agency Action” filed by Mr. Olsen on May 12, 2017, in a similar fashion. On May 31, 2017, the Board’s executive director sent a responsive letter to Mr. Olsen detailing the Board’s rationale for declining to act in response to that particular request. *See Respondent’s Proposed Exhibit A.*

was handling the request differently than it may have handled prior requests. As described in the Board's responsive letter, the Board did not take any action in response to this request because the legislature did not authorize the Board to consider religious use when making scheduling recommendations.<sup>5</sup> All of the statutory factors the Board must consider when making a scheduling recommendations to the legislature are grounded in the Board's pharmacological expertise. *See* Iowa Code § 124.201(1)(a)–(h). The Board has no experience or knowledge from which to decide that it would be necessary or advisable for marijuana to be permitted in certain bona fide religious circumstances.

Additionally, the Board's authority in Iowa Code section 124.201 is limited to recommending “any deletions from, or revisions in the schedules of substances . . . which it deems necessary or advisable.” Iowa Code § 124.201(1). The scheduled *substance* in Petitioner's request is marijuana.<sup>6</sup> Petitioner's request did not ask the Board to recommend a deletion of marijuana from the schedules or to otherwise revise how marijuana, as a substance, was scheduled. Therefore, Petitioner's request was outside of the scope of the Board's authority under Iowa Code section 124.201. It would be wholly improper for the Board to act outside its designated scope and recommend an exemption based on a religious practice.

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<sup>5</sup> In fact, the only instance in which the term “religion” or “religious” is used in chapter 124 is in the statutory exemption for peyote when used in bona fide religious ceremonies of the Native American Church. Iowa Code § 124.204(8).

<sup>6</sup> *See* Iowa Code § 124.101(20) (defining marijuana as “all parts of the plants of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination”).

Petitioner's brief incorrectly states the Board is claiming the Board's administrative rules do not *allow* a private request relating to the rescheduling of controlled substances.<sup>7</sup> This is not what the Board is asserting. Rather, the Board is asserting that neither the Iowa Code nor the Board's administrative rules *require* the Board to hear a private request of this nature. As established in Iowa Code section 124.201, the Board is authorized to make recommendations that *the Board* deems necessary or advisable. Iowa Code section 124.201 does not require that the Board consider making a recommendation that a private individual deems necessary or advisable.

2. The Board's refusal to make a recommendation that would have contravened Iowa Code section 124.201 was not irrational, illogical, or wholly unjustifiable.

The Iowa Court of Appeals has previously stated that “[Iowa Code section 124.201] vests the Board with discretion to interpret the schedules. Accordingly, we will reverse the Board's legal interpretation only if it is ‘irrational, illogical, or wholly unjustifiable.’” *Olsen*, 2017 WL 3283296 at \*1 (quoting Iowa Code § 17A.19(10)(l)). This Court should reverse the Board's action only if it is “[b]ased upon an irrational, illogical, or wholly unjustifiable application of law to fact that has clearly been vested by a provision of law in the discretion of the agency.” Iowa Code § 17A.19(10)(m).

It is undisputed that Iowa Code chapter 124 does not explicitly establish a right or a procedure for a private individual to petition the Board regarding which scheduling recommendations the Board should make to the General Assembly. When agency action does not constitute a contested case or a rulemaking procedure, it is considered “other

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<sup>7</sup> Page 4 of Petitioner's Brief states “However, for the first time, Respondent now asserts that the administrative rules do not allow private request for agency action to reschedule a controlled substance.”

agency action,” as is the case here. For other agency action, “[p]arties are only entitled to those procedures voluntarily promulgated by the agency, and to the general requirement that the agency act reasonably.” *Greenwood Manor v. Iowa Dep’t. of Pub. Health*, 641 N.W.2d 823, 834 (Iowa 2002). The Board has not promulgated, either by rule or otherwise, an official procedure for handling a request of this nature. Because a procedure does not exist, it is unclear exactly what type of proceeding would need to occur if this matter were remanded to the Board for further proceedings.

Petitioner asserts that it would be reasonable for the Board to consider recommending a religious exemption because there is already a religious exemption for the use of peyote by the Native American Church in Iowa Code chapter 124. Notably, this statutory exemption was *not* the result of a recommendation from the Board.<sup>8</sup> The General Assembly must have enacted the statutory exemption for peyote without a recommendation from the Board; the legislature could choose to do the same with any legislative amendment proposed by Mr. Olsen.

Petitioner’s brief mentions the federal Religious Freedom Restoration Act and the DEA’s process for allowing a private individual to petition the DEA for a religious exemption. To clarify, the DEA’s process cited in Petitioner’s brief provides a mechanism for an individual to secure an *individual* religious exemption—it is not a mechanism for an individual to request a universal change to the schedules.<sup>9</sup> While twenty-one state

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<sup>8</sup> As mentioned by Petitioner, the peyote exemption was codified in 1971. 1967 Iowa Acts ch. 189, § 2 (codified at Iowa Code § 204A.2(12) (1971)). The language in section 124.201 authorizing the Board to make recommendations was not codified until 1973. 1971 Iowa Acts ch. 148, § 201 (codified at Iowa Code § 204.201 (1973)).

<sup>9</sup> Because federal scheduling is done through regulation, rather than statute, a petition for rulemaking would presumably be the procedure an individual could utilize to request an amendment to the DEA’s regulations.

legislatures have enacted versions of the Religious Freedom Restoration Act, the Iowa General Assembly has not. *See State Religious Freedom Restoration Acts*, NATIONAL CONFERENCE OF STATE LEGISLATURES, [www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx](http://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx) (last updated May 4, 2017). Nor has the Iowa legislature enacted any laws authorizing the Board to grant individual religious exemption requests. Petitioner's reference to the DEA's process is perhaps relevant only to the extent it provides an example of a procedure that an agency has promulgated to handle requests. If the Board had published a process for private individuals to request a scheduling recommendation, then it could be problematic if the Board did not follow its published process. Given the nature of the request at hand and the language of Iowa Code section 124.201, the Board's responsive letter certainly meets the general requirement to act reasonably.

3. The Board did not abuse its discretion when it declined to exceed its legal obligations.

Petitioner asserts the Board's action was "an abuse of discretion." Iowa Code § 17A.19(10)(n). Petitioner states that the Board abused its discretion because if Petitioner lobbies the General Assembly, they will "undoubtedly inquire whether its advisory board first recommends a second religious exemption in Chapter 124." Petitioner's Brief at 8. The Iowa General Assembly has not enacted recommendations from the Board pertaining to the scheduling of marijuana. For example, in 2010, the Board recommended the rescheduling of marijuana and the legislature took no action on that recommendation. *See Olsen*, 2016 WL 2745845 at 1. In 2015, the Board recommended that cannabidiol, a derivative of marijuana, be carved out from the definition of marijuana and removed from schedule I. *See Olsen*, 2017 WL 3283296 at 2. To date, this change has not been made to

Iowa Code chapter 124. In fact, when the legislature enacted the Medical Cannabidiol Act, it vested regulatory oversight of the medical cannabidiol program to the Department of Public Health and the Board of Medicine, and not to the Board of Pharmacy. *See* Iowa Code chapter 124E. Even assuming Petitioner's presumption is true, the Board has provided a document to Mr. Olsen that he can provide to legislators who make such an inquiry; the letter will undoubtedly answer a legislator's question about the Board's stance on the scheduling issue.

The Board's response did not "simply redirect Petitioner to lobby the General Assembly." Petitioner Brief at 8. Rather, the Board set forth its rationale for not making the requested recommendation *and* provided a suggestion as to where Petitioner could focus his efforts if he wished to pursue a legislative change. Petitioner's assertion that the Board has some sort of "responsibility" to consider private individuals' requests ignores the plain language of the statute authorizing the Board to make recommendations when *the Board* deems necessary or advisable.

The Board does not have unlimited resources to consider whatever issue any private individual wants it to consider, particular when the private individual is not even a licensee or registrant of the Board. The Board should not be required to serve as the messenger for any grievance a private individual may have with a statute that the Board itself cannot amend. Again, a recommendation from the Board is *not* required for the legislature to amend chapter 124. Given that further consideration of Petitioner's request would have required the Board to exceed its statutory authority in Iowa Code section 124.201, and to engage in a procedure that does not exist, the Board's action cannot constitute an abuse of discretion.

**E. CONCLUSION**

**WHEREFORE**, the Board respectfully requests that the Court affirm the Board's action and dismiss the Petition for Judicial Review.

Respectfully submitted,

THOMAS J. MILLER  
ATTORNEY GENERAL OF IOWA

*/s/ Laura Steffensmeier* \_\_\_\_\_  
LAURA STEFFENSMEIER  
Assistant Attorney General  
Hoover Building, 2nd Floor  
1305 East Walnut Street  
Des Moines, Iowa 50319  
Telephone: (515) 281-6690  
Facsimile: (515) 281-4209  
E-mail: [laura.steffensmeier@ag.iowa.gov](mailto:laura.steffensmeier@ag.iowa.gov)  
ATTORNEYS FOR THE IOWA BOARD  
OF PHARMACY

All parties served electronically.