IN THE IOWA DISTRICT COURT FOR POLK COUNTY

CARL OLSEN,	Case No. CVCV066477	
Petitioner,		
v.	CERTIFIED AGENCY RECORD	
IOWA DEPARTMENT OF INSPECTIONS, APPEALS, AND LICENSING,		
Respondent.		
COMES NOW, the Iowa Board of Pharmacy ("Respondent") and hereby		
files the agency record in this matter.		
1. Petition for Rule Making filed by Carl Olsen		
2. Petitioner's Supplemental Documentation		
3. Petitioner's Brief in Support of Rule Making		
4. Petitioner's Second Brief in Support of Rule Making		
5. Petitioner's Third Brief in Support of Rule Making		
6. Board of Pharmacy Response to Petitioner's Request for Rule Making		
7. Audio Recording of November 7, 2023 Board of Pharmacy Meeting, see Flashdrive		
Respectfully submitted,		

BRENNA BIRD Attorney General of Iowa

/s/Lindsey L. Browning Lindsey L. Browning Assistant Attorney General Iowa Department of Justice 1305 E. Walnut Street, 2nd Floor Des Moines, Iowa 50319 (515) 281-3441 lindsey.browning@ag.iowa.gov

ATTORNEY FOR THE IOWA BOARD OF PHARMACY

All parties served electronically and via U.S. Mail

Copies to:

Carl Olsen 130 E. Aurora Ave. Des Moines, IA 50313

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties of record by delivery in the following manner on February 14, 2024:

X U.S. Mail Hand Delivery Federal Express

Overnight Courier

Other

X EDMS

Signature: /s/ Josie Bollman

)	
Carl Olsen)	
Petitioner,)	
)	
VS.)	CERTIFICATION
)	
IOWA BOARD OF PHARMACY)	
Respondent.)	
)	

- I, Anne Schlepphorst, Chief Investigator for the Iowa Board of Pharmacy (the Board), having legal custody of the records of the Board, hereby certify that attached are a true and accurate copy of the following documents:
 - I. Petition for Rule Making filed by Carl Olsen
 - II. Petitioner's Supplemental Documentation
 - III. Petitioner's Brief in Support of Rule Making
 - IV. Petitioner's Second Brief in Support of Rule Making
 - V. Petitioner's Third Brief in Support of Rule Making
 - VI. Board of Pharmacy Response to Petitioner's Request for Rule Making
 - VII. Audio Recording of November 7, 2023 Board of Pharmacy Meeting

Anne Schlepphorst

Chief Investigator

Iowa Department of Inspections, Appeals and Licensing

Bureau of Investigations/Inspections

February 13, 2024

IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

Petition by Carl Olsen	
for the adoption of	PETITION FOR
rules relating to	RULE MAKING
Iowa Code Chapter 124	

- 1. The petitioner petitions the department to create an application process for religious exceptions to the Iowa Uniform Controlled Substances Act (Iowa Code Chapter 124).
- 2. The authority for this rule making action is Iowa Code § 124.204(4)(p) ("Peyote, except as otherwise provided in subsection 8").
- 3. Iowa has created an exception for the religious use of a controlled substance, peyote. A process should exist to accept applications for religious use of other controlled substances. Iowa has created an exception for the secular use of a controlled substance, cannabis. A process should exist to accept applications for the religious use of cannabis.

Existing Religious Exception

Iowa Code § 124.204(8) is a religious exception for the use of a Schedule I controlled substance in Iowa.

Federal regulations provide a process to apply for exceptions to the federal Controlled Substances Act. 21 C.F.R. § 1307.03. There is a federal regulation for religious use of peyote. 21 C.F.R. § 1307.31.

The listing of peyote in this subparagraph does not apply to non-drug use in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the Church are required to register and maintain appropriate records of receipts and disbursements of the article. FEDERAL REGISTER, Vol. 31, No. 54, Saturday, March 19, 1966, at page 4679; codified at 21 C.F.R. § 166.3(c)(3) (1968)

SEC. 2. Section three (3) of this Act shall not apply to the following: 12. Peyote used in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the church are required to register and maintain appropriate records of receipts and disbursements of the article. 1967 Iowa Acts, ch. 189 § 2(12)

Existing Secular Exception

Iowa Code Chapter 124E is a secular exception for the use of a Schedule I controlled substance without a prescription.

Although cannabis has "no legitimate medical use" in Iowa, *State v. Middlekauff*, 974 N.W.2d 781, 798 (Iowa 2022), Iowans can apply for the non-drug use of cannabis to treat qualifying medical conditions.

See health care practitioner certification, 641 IAC 154.2. "This document, the written certification in this case, is essentially a physical manifestation of the physician's and patient's First Amendment right to openly and candidly discuss appropriate medical treatments, including medical marijuana." *State v. Middlekauf*f, 974 N.W.2d 781, 800 (Iowa 2022).

Iowans that have a qualifying medical condition can apply for an exception to the Iowa Uniform Controlled Substances Act. Iowa Code § 124.401(5)(c) and Iowa Code Chapter 124E; 641 IAC 154.3(1)(d).

Iowans can petition to have new medical conditions added or petition for the addition of new forms of administration, 641 IAC 154.65. *Id*.

4. The petitioner is aware of two Schedule I controlled substances, both in the same subcategory as peyote (hallucinogens), that have documented religious use in the United States.

Cannabis

Cannabis is recognized in the county of Jamaica as a religious sacrament. Dangerous Drug Act Amendments of 2015.

The petitioner is a member of a religious organization in Jamaica that uses cannabis as its sacrament. *See*, *Town v. State*, *ex rel*. *Reno*, 377 So.2d 648, 649 (Fla. 1979) ("the Ethiopian Zion Coptic Church is not a new church or religion but the record reflects it is centuries old and has regularly used cannabis as its sacrament."). *Olsen v. State of Iowa*, United States District Court, S.D. Iowa, Central Division, Civ. No. 83–301–E, March 19, 1986, 1986 WL 4045 ("Testimony at his trial revealed the bona fide nature of this religious organization and the sacramental use of marijuana within it.").

Hoasca

Hoasca is recognized in the country of Brazil as a religious sacrament, and the use of hoasca is currently protected by federal regulations. Hoasca contains dimethyltryptamine (DMT), a hallucinogenic chemical. Under the federal Controlled Substances Act, DMT is a "Schedule I" controlled substance. *See*, *Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 546 U.S. 418 (2006). DMT is also a Schedule I controlled substance in Iowa. Iowa Code § 124.204(4)(j).

- 5. There is a religious organization in Iowa that uses hoasca. *See*, *Iowaska Church of Healing v. United States*, Case No. 21-02475, United States District Court for the District of Columbia (March 31, 2023); *Iowaska Church of Healing v. IRS*, Case No. 23-5122, United States Court of Appeals for the District of Columbia Circuit (July 3, 2023). *Iowa church wages four-year fight with IRS over hallucinogenic-drug ceremonies*, Iowa Capitol Dispatch, January 2, 2023
- 6. The petitioner requests a meeting provided for by rule 481—2.4(17A).

Dated this 26th day of September, 2023

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LINKS TO REFERENCES

https://www.legis.iowa.gov/docs/code/2023/124.pdf

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https://scholar.google.com/scholar_case?case=2428980221906 873954#p798

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https://iowacapitaldispatch.com/2023/01/02/iowa-church-wages-four-year-fight-with-irs-over-hallucinogenic-drug-ceremonies/

<u>Carl Olsen's Opening Statement</u> <u>Iowa Board of Pharmacy, November 7, 2023</u>

Although Iowa's "<u>Uniform Controlled Substances Act</u>" says it is uniform with the federal act, the department does not have rulemaking to request reclassification or exception. <u>Iowa Code §§ 124.601, 124.602</u>.

The federal "Controlled Substances Act" is implemented by regulations allowing anyone to petition for rulemaking or exceptions. 21 C.F.R. § 1308.43 is rulemaking to reclassify, and 21 C.F.R. § 1307.03 is for exceptions.

As an example, the federal exemption for religious use of peyote by the Native American Church is a regulation created by formal rulemaking, <u>21</u> <u>C.F.R. § 1307.31</u>.

In contrast to the federal act, the exception for the religious use of peyote found in Iowa's statutory list for Schedule 1. <u>Iowa Code § 124.204(8)</u>.

Compare this with how the Iowa legislature created an initial list of qualifying conditions for its Medical Cannabidiol program by statute, followed by rulemaking for adding additional conditions. <u>Iowa Code Chapter 124E</u>.

The department should create rulemaking for "other" traditional uses of non-prescription plants and fungi. In order to be uniform with federal drug law, Iowa should consider applications from "other" persons to determine if they are equally "qualified".

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IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

Petition by Carl Olsen for the adoption of rules relating to Iowa Code Chapter 124

BRIEF IN SUPPORT OF PETITION FOR RULE MAKING

Religious Exception

The federal government created the peyote exception by administrative regulation in 1966 and the Iowa legislature enacted it in 1967. The two are identical. The term "non-drug" indicates this substance is not an approved prescription medication.

FEDERAL EXCEPTION (1966):

The listing of peyote in this subparagraph does not apply to non-drug use

"... in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the Church are required to register and maintain appropriate records of receipts and disbursements of the article."

IOWA EXCEPTION (1967):

Section three (3) of this Act shall not apply to the following: Peyote used

"... in bona fide religious ceremonies of the Native American Church; however, persons supplying the product to the church are required to register and maintain appropriate records of receipts and disbursements of the article."

In 2006, the U.S. Supreme Court recognized an exception for the religious use of hoasca similar to the exception for the religious use of peyote. *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 432-433 (2006) ("... the Act itself contemplates that exempting certain people from its requirements would be 'consistent with the public health and safety' ...").

Secular Exception

Iowa has created a secular exception for the "non-drug" use of marijuana. Iowa Code Chapter 124E. Chapter 124E authorizes cultivation of marijuana for the production of highly concentrated marijuana extracts. These extracts do not have any accepted medical use and they are given to individuals who have serious medical conditions. *See State v. Middlekauff*, 974 N.W.2d 781, 798 (Iowa 2022):

"Whereas some other drugs can be dispensed and prescribed for medical use the same is not true for marijuana. Indeed, for purposes of the Controlled Substances Act, marijuana has 'no currently accepted medical use' at all." *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 491 (2001) (citation omitted); *see Gonzales v. Oregon*, 546 U.S. 243, 269 (2006) ("Congress' express determination that marijuana had no accepted medical use foreclosed any argument about statutory coverage of drugs available by a doctor's prescription."); *see also Bonjour*, 694 N.W.2d at 514.

Giving people with serious medical conditions a Schedule I controlled substance with no accepted medical use defies logic. However, the DEA is currently in the process of removing marijuana from Schedule I. See Statement from President Biden on Marijuana Reform, October 6, 2022 ("Federal law currently classifies marijuana in Schedule I of the Controlled Substances Act, the classification meant for the most dangerous substances. This is the same schedule as for heroin and LSD, and even higher than the classification of fentanyl and methamphetamine – the drugs that are driving our overdose epidemic.").

As the Drug Enforcement Administration Chief Administrative Law Judge said in 1988, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." DEA Docket No. 86-22, Sept. 6, 1988, pp. 58-59.

Chapter 124E has shown what the DEA ALJ said in 1988 is true. There haven't been any reports of adverse effects resulting from the use of these highly concentrated extracts in Iowa in a population of Iowans with severe medical conditions.

Establishment Clause

The Establishment Clause generally prohibits the government from granting certain preferences to religious or religious adherents which are not available to secular organizations or nonreligious individuals. *E.g.*, *Everson v. Board of Education*, 330 U.S. 1 (1947).

It is well accepted that the Establishment Clause prohibits a government from "prefer[ring] one religion over another." *See Everson*, 330 U.S. at 15:

"The 'establishment of religion' clause of the First Amendment means at least this: Neither a state nor the Federal Government can set up a church. Neither can pass laws which aid one religion, aid all religions, or prefer one religion over another."

Cause of Action

We must assume the Iowa legislature did not intend to establish a religion to the exclusion of all others. A religious exception for one church alone, and for one Schedule I controlled substance alone, is permissible as long as a process to consider equally worthy causes exists. Other exceptions must be considered for good cause (both for secular and religious uses). *See*, *Employment Division v. Smith*, 494 U.S. 872 (1990).

The federal Controlled Substances Act includes processes to petition for exemptions and to petition for the reclassification of controlled substances. See 21 U.S.C. § 811(a) (2021); 21 C.F.R. § 1308.43 (2023); 21 C.F.R. § 1307.03 (2023). The federal exception for peyote is found at 21 C.F.R. § 1307.31.

The Iowa legislature has created a means of redress through the Iowa Administrative Procedures Act (Petition for Rulemaking). Iowa Code § 17A.7.

In order to implement the intent of the Iowa legislature (interpreting legislative intent to be consistent with the Iowa Constitution), the department must implement rules to evaluate petitions for other exceptions.

Plants Historically Used in Religious Ceremonies and Folk Medicine

Plants and fungi have been used for traditional religious purposes and folk medicine for millennia. Carod-Artal FJ. *Hallucinogenic drugs in pre-Columbian Mesoamerican cultures*. Neurologia. 2015 Jan-Feb; 30(1):42-9. English, Spanish. doi: 10.1016/j.nrl.2011.07.003. Epub 2011 Sep 3. PMID: 21893367.

The peyote exemption embodies two parts: (1) a non-commercial exemption for members of the church; and (2) a federal registration for persons supplying peyote to the church. 21 C.F.R. § 1307.31; Iowa Code § 124.204(8). The hoasca exemption has the same two parts: (1) a non-commercial exemption for members of the church; and (2) a federal import license for persons supplying hoasca to the church.

Dated this 2nd day of October, 2023

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LINKS TO REFERENCES

https://tile.loc.gov/storage-services/service/ll/usrep/usrep546/usrep546418/usrep546418.pdf

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IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

Petition by Carl Olsen for the adoption of rules relating to Iowa Code Chapter 124

SECOND BRIEF IN SUPPORT OF PETITION FOR RULE MAKING

This is just a brief history of my previous efforts to obtain a religious exception like the one for peyote.

Olsen v. DEA, 878 F.2d 1458 (D.C. Cir. 1989), cert. denied, 495 U.S. 906 (1990).

Employment Division v. Smith, 494 U.S. 872, 889 (1990).

A state controlled substances act does not violate the federal constitution if it is both neutral toward religion and generally applicable. If either of those conditions is not met, then the state must apply a strict scrutiny analysis called the "compelling interest test" and the subordinate "least restrictive means" test.

- 1. Is there a compelling state interest in prohibiting the substance?
- 2. If condition 1 is met, is total prohibition the least restrictive means of enforcing the prohibition against a religious user?

Olsen v. Iowa Board of Pharmacy, Case No. CVCVo56841 (April 2, 2019). The board is not required to accept petitions to make scheduling recommendations to the legislature. It can accept petitions if it wants to, but it is not required to accept them.

2019 - Medical Cannabidiol Board recommends a federal exemption like the one for peyote for Iowa patients, after Carl Olsen requested it.

2020 - Iowa Legislature enacts a law requiring the department to apply for a federal exemption. Carl Olsen lobbied legislators for this in 2019, and the board recommended it in January of 2020.

2021 - Iowa Department of Health filed for the federal exemption. The U.S. Drug Enforcement Administration (DEA) hasn't responded.

Olsen v. Iowa Department of Public Health, Case No. CVCV062566 (May 4, 2022). Carl Olsen tried to bring a declaratory judgment action against the state for violating his religious freedom. The court denied the claim because the state cannot be sued. The state has sovereign immunity. A recent Iowa Supreme Court decision explains this in *Burnett v. Smith*, No, 22-1010 (May 5, 2023).

https://www.iowacourts.gov/courtcases/17340/embed/ SupremeCourtOpinion

2023 - Iowa Senate Judiciary Committee Chair introduced a bill to provide the Department with legal assistance in addressing the issue with the DEA's lack of a response. Carl Olsen requested the bill and the Medical Cannabidiol Board recommended it in January of 2023. Senate File 69.

Olsen v. Iowa Department of Health and Human Services, Case No. CVCV065114 (August 20, 2023). The court found that religious use of cannabis is not a qualifying condition for registration under Iowa Code Chapter 124E.

Dated this 4th day of October, 2023

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IOWA DEPARTMENT OF INSPECTIONS AND APPEALS

Petition by Carl Olsen for the adoption of rules relating to Iowa Code Chapter 124

THIRD BRIEF IN SUPPORT OF PETITION FOR RULE MAKING

Absence of Regulations is Unconstitutional

Creating rules to process requests for exceptions, adding religious use of peyote to a list of exceptions, and recommending the legislature repeal the statutory exemption for the Native American Church, resolves the inconsistency between Iowa Code Chapter 124 and the Iowa Constitution:

Establishment of Religion, <u>article 1, § 3</u> of the Iowa Constitution:

The general assembly shall make no law respecting an establishment of religion

Uniformity of Law, article 1, § 6 of the Iowa Constitution:

All laws of a general nature shall have a uniform operation; the general assembly shall not grant to any citizen, or class of citizens, privileges or immunities, which, upon the same terms shall not equally belong to all citizens

Consistency with Federal and Uniform Acts

The general assembly intended Chapter 124 to be consistent with federal and uniform acts.

Iowa Code § <u>124.601</u>

Uniformity of interpretation.

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

Iowa Code § 124.602

Short title.

This chapter may be cited as the "*Uniform Controlled Substances Act*".

Uniform Law Commission, 1990 Controlled Substances Act:

Prefatory Note

This Uniform Act was drafted to maintain uniformity between the laws of the several States and those of the federal government.

<u>Id</u>., at page 1. See Section 201 making control of substances an administrative process, at page 13, and comment, at page 16.

Regulation in Federal and Uniform Acts

Congressional Record, July 8, 1965

If the church is a bona fide religious organization that makes sacramental use of peyote, then it would be our view that H.R. 2, even without the peyote exemption which appeared in the House-passed version, could not forbid bona fide religious use of peyote. We believe that the constitutional guarantee of religious freedom fully safeguards the rights of the organization and its communicants.

<u>Id</u>., at page 15,978.

U.S. House Hearings, February 3, 1970

Under the existing law originally the Congress was going to write in a specific exemption but it was then decided that it would be handled by regulation and we intend to do it the same way under this law.

Id., at page 118. Available at: https://www.govinfo.gov/app/details/CHRG-91hhrg42121p1/context

Page 24 of the 1990 Uniform Act lists peyote in Schedule I without any exception. *See* this comment on page 26:

Although peyote is listed as a Schedule I controlled substance in this Act and under Schedule I of the federal act, a separate federal regulation (21 CFR 1307.31 (April 1, 1989)) exempts the nondrug use of peyote in bona fide religious ceremonies of the Native American Church.

Regulating Peyote is Uniform

Burnett v. Smith, 990 N.W.2d 289, 301 (Iowa 2023):

In <u>Collins v. State Board of Social Welfare</u>, 81 N.W.2d 4 (<u>Iowa 1957</u>), for example, we held that the plaintiffs could pursue an action for a declaratory judgment that their state welfare payments were unconstitutionally discriminatory in violation of article I, section 6 of the Iowa Constitution. <u>Id</u>. at 6-7. We said, "The rule is . . . well recognized that where no judgment or decree is asked against the State, but the suit is rather to require its officers and agents to perform their duty, there is no immunity recognized.

Employment Division v. Smith, 494 U.S. 872, 884 (1990):

As the plurality pointed out in <u>Roy</u>, our decisions in the unemployment cases stand for the proposition that where the State has in place a system of individual exemptions, it may not refuse to extend that system to cases of "religious hardship" without compelling reason. <u>Bowen v. Roy</u>, supra, at 708.

Dated this 15th day of October, 2023

Carl Olsen

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Iowa Board of Pharmacy

JILL STUECKER, MPA, MA INTERIM EXECUTIVE DIRECTOR

November 7, 2023

Carl Olsen 130 E Aurora Ave Des Moines, IA 50313

Via email: carl@carl-olsen.com

RE: Petition for Rulemaking

Dear Mr. Olsen,

The Board is in receipt of the Petition for Rulemaking that you submitted on September 26, 2023, for the adoption of rules relating to a religious exception to the Iowa Uniform Controlled Substances Act as well as the three supplemental Briefs in Support of Petition for Rulemaking submitted on October 2, 2023, October 4, 2023, and October 16, 2023.

In accordance with Iowa Code Section 17A.7 and 657 Iowa Administrative Code Chapter 26, the Board denies this Petition for Rulemaking and declines to engage in the requested rulemaking at this time. The petition requests that the Board adopt rules to create an application process for a religious exception to the Iowa Uniform Controlled Substances Act. However, the Board does not have statutory authority to promulgate administrative rules affecting religious exceptions to the Iowa Uniform Controlled Substances Act. Accordingly, the Legislature must take specific action to grant the Board rulemaking authority related to religious exceptions to the Iowa Uniform Controlled Substances Act before the Board could adopt any rules to that effect.

In light of the foregoing, the Board declines to engage in rulemaking related to this issue as it does not believe it has the statutory authority to do so. The Board appreciates your work on this issue and the materials that you have provided to the Board.

If you have any questions, please contact Emily DeRonde, General Counsel for the Department, at Emily.DeRonde@dia.iowa.gov or (515) 249-7038.

Sincerely,

Chairperson

Iowa Board of Pharmacy

athryn SSone

LAW NO. CVCV066477

AUDIO RECORDING OF NOVEMBER 7, 2023 BOARD OF PHARMACY MEETING