SUPPLEMENTAL ARGUMENT

Attached as Exhibit #1 is our Petition dated May 14, 2021, sent to: (1) the Drug Enforcement Administration (DEA) by certified mail return receipt number 7020 2450 0000 8179 6944 (and received by the DEA Administrator on May 19, 2021); and (2) the Office of Diversion Control by certified mail return receipt number 7020 2450 0000 8179 6968 (and received by the Office of Diversion Control on May 19, 2021).

ADMINSTRATION POLICY

The Biden Administration's policy on marijuana is to federally legalize medical use of cannabis and to leave decisions on non-medical use of cannabis up to the states:

> Decriminalize the use of cannabis and automatically expunge all prior cannabis use convictions. Biden believes no one should be in jail because of cannabis use. As president, he will decriminalize cannabis use and automatically expunge prior convictions. And, he will support the ***legalization of cannabis for medical purposes***, ***leave decisions regarding legalization for recreational use up to the states***, and reschedule cannabis as a schedule II drug so researchers can study its positive and negative impacts. –

https://joebiden.com/justice/ (emphasis added).

ARGUMENT FOR RULEMAKING

The petitioners requested rulemaking based on the exemption for the Schedule I substance peyote in 21 C.F.R. § 1307.31. The petitioners based their argument for rulemaking on state authority to exempt the use of Schedule 1 controlled substances, as referenced in the legislative history of the federal peyote exemption, *People v. Woody*, 61 Cal. 2d 716, 394 P.2d 813, 40 Cal. Rptr. 69 (1964).

The California Supreme Court ruling in *Woody* resulted in the federal regulation exempting the "non-drug" of peyote. The term "non-drug" means outside the scope of the Controlled Substances Act (CSA). The purpose of the CSA is to prevent the "abuse" of controlled substances, not their legitimate use. See *Gonzales v. Oregon*, 546 U.S. 243 (2006). A regulation exempting the "non-drug" use of peyote was created because of one state's decision (California) to exempt the "non-drug" use of peyote from that state's prohibition of the substance.

The federal exemption in 14 C.F.R. § 91.19(b) (2020) shows a continuous and consistent federal recognition of state laws providing an exception specifically for cannabis.

> Paragraph (a) of this section does not apply to any carriage of narcotic drugs, marihuana, and depressant or stimulant drugs or substances authorized by or under any Federal or State statute or by any Federal or State agency.

This exemption first appeared in 14 C.F.R. § 91.12(b) (1974). See, Federal Register: Vol. 38, No. 126, Monday, July 2, 1973, at page 17493.

The Model (Uniform) Controlled Substances Act (1994) (Last Revised or Amended in 1995), also uses similar phrasing, at page 18:

> SECTION 204. SCHEDULE I. Unless specifically excepted by state or federal law or state or federal regulation or more specifically included in another schedule, the following controlled substances are listed in Schedule I:

https://www.uniformlaws.org/committees/community-home?CommunityKey=9873a9bf-7335-4be7-855d-b17c9e8ff3dd

There are now a total of 47 states that have exempted the "non-drug" use of cannabis which they characterize as "medical" use. Because the DEA only uses the term "medical" in the context of the CSA, the DEA must acknowledge the states to have authorized the "non-drug" use of cannabis in the same sense that the DEA considers the use of peyote in 21 C.F.R. § 1307.31 to be a "non-drug" use. Whatever that use is, it's not "medical" as far as DEA is concerned. And, according to *Gonzales v. Oregon*, 546 U.S. 243 (2005), the state authorized use of a controlled substance is not "drug abuse" as that term is used in the CSA. So, that leaves "non-drug" use as a suitable description.

The petitioners argue that *Gonzales v. Raich*, 545 U.S. 1 (2005), is not controlling because Raich made a statutory challenge instead of seeking administrative relief under 21 C.F.R. § 1307.03 or 21 C.F.R. § 1308.43. Raich did not exhaust any administrative remedies and Raich did not appeal under 21 U.S.C. § 877, as Raich would have been required to do had Raich sought administrative relief. *Id*., 545 U.S. at 33 ("We do note, however, the presence of another avenue of relief. As the Solicitor General confirmed during oral argument, the statute authorizes procedures for the reclassification of Schedule I drugs"). To say that administrative relief is now foreclosed by *Raich* is contrary to the federal government's position in the *Raich* decision and the court's agreement with it.

The petitioners argue that denying an exemption for state laws authorizing the use of cannabis, like the one for "non-drug" use of peyote, puts the DEA squarely into the position of maintaining a positive conflict between state and federal drug law where none is required. Administrative relief would resolve the conflict and the DEA should not abuse its discretion by denying that relief. See 21 U.S.C. § 903.

The petitioners' request for rulemaking under 21 C.F.R. § 1308.43 goes beyond just Iowa and would apply to all 50 states like the exemption for the "non-drug" use of peyote in 21 C.F.R. § 1307.31. And, because the exemption for the "non-drug" use of peyote is not binding on the states, it only protects what the state itself protects and nothing more. *See Employment Division v. Smith*, 494 U.S. 872 (1990).

However, the petitioners must now point out that Iowa may, or may not, be equally situated to the other 46 states that have authorized the "non-drug" (meaning outside the context of the CSA)

use of cannabis. Because Iowa may be different than the other 46 states in some way, the petitioners have also requested an exemption under 21 C.F.R. § 1307.03, which gives the DEA authority to issue exemptions that are narrower than a broad exemption that would cover all 47 states that have authorized "non-drug" use of cannabis. If Iowa were granted such an exemption based on differences in our state authorization of the "non-drug" use of cannabis, Iowa would not have the requisite injury to insist on a broader exemption. States with more "expanded" use of cannabis would then have to deal with that as they see fit.

On April 23, 2021, the state of Iowa joined us (the petitioners) by requested federal funding guarantees from the DEA and three other federal agencies. Those four letters are attached to our May 14, 2021 petition. We also attached an opinion on September 4, 2020 from our state department of health expressing the opinion that federal funding guarantees can only be obtained by obtaining a federal exemption under 21 C.F.R. § 1307.03, exactly as we are proposing here.

Because the petitioners are all residents of Iowa, and because the petitioners want to focus on their request for a state exemption under 21 C.F.R. § 1307.03, the petitioners must acknowledge they have no federal injuries based on states they do not reside in.

Beyond the distinction that Raich did not apply for administrative relief and the decision in *Raich* could not have foreclosed administrative relief now, Iowa's Medical Cannabidiol Act, Iowa Code Chapter 124E, is significantly different than California's Compassionate Use Act as it existed in 2005 when *Raich* was decided.

> "Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient's primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician." § 11362.5(d) (West Supp. 2005).

Raich, 545 U.S. at 6 n.6.

One important distinction is that Iowa does not allow personal cultivation of cannabis or raw cannabis plant material as products. See Iowa Code Chapter 124E.

The other important distinction is that Iowa authorizes only the use of cannabis extracts, exactly matching a newly created DEA category for cannabis extracts.

> "Medical cannabidiol" means any pharmaceutical grade cannabinoid found in the plant Cannabis sativa L. or Cannabis indica or any other preparation thereof that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule.

See Iowa Code § 124E.2 (10). See, Federal Register: Vol. 81, No. 240, Wednesday, December 14, 2016, at page 90194. 21 C.F.R. § 1308.11(d)(58), DEA Controlled Substances Code Number 7350.

Iowa laws only allows cannabis extracts in forms approved by the Iowa Board of Medicine. See Iowa Code Chapter 124E, and 641 Iowa Administrative Code Chapter 154. Iowa's program is specifically tailored to prevent diversion. Because the products in Iowa must be approved by the Iowa Board of Medicine, they are clearly labelled and easily identifiable by Iowa law enforcement. And, there have been no instances of diversion.

The national cultural context has changed dramatically since *Raich* was decided as reflected in the current Administration's policy of leaving decisions on the "non-drug" use of cannabis up to the states. In 2005, when *Raich* was decided, there were only 9 states that had authorized "non-drug" use of cannabis, clearly a small minority of states at that time. Now, in 2021, there are 47 states, clearly a large majority of states at this time. It would make sense for the federal administration to work with the states rather than oppose them. As our state attorney general stated on September 23, 2019 the lack of a federal exemption for our state cannabis program poses a serious threat to public safety.[1]

The DEA could use the category of cannabis extracts as evidence that Iowa took the DEA's concerns in the *Raich* case seriously and acted accordingly.

CONCLUSION

Iowa has requested federal funding guarantees from the DEA and three other federal agencies, which Iowa interprets to mean an exemption under 21 C.F.R. § 1307.03. Iowa's request should be considered in the specific context of Iowa's "non-drug" use of cannabis (which creates an exception to Iowa's uniform controlled substances act) and the DEA should grant an exemption under 21 C.F.R. § 1307.03. DEA could base the exemption on its newly created category of "cannabis extract" which would eliminate Iowa's injuries. Such an exemption would recognize Iowa's legitimate "non-drug" use of cannabis as falling outside the context of "abuse" which the federal Controlled Substances Act was enacted to address. State authorized "non-drug" use is not abuse of a controlled substance. *Gonzales v. Oregon*, 546 U.S. 243 (2005).

The Biden Administration's official position is that state marijuana laws should be exempt from federal drug law. To be consistent with the Biden Administration, DEA must grant Iowa this exemption.

Cannabis extracts in carefully processed and carefully labelled products are much easier to distinguish from raw cannabis and personal cultivation found to be problematic in *Raich*.

Thank you!

Carl Olsen	Mary J. Roberts	Erin Bollman	Colin Murphy
Des Moines, Iowa	Coralville, Iowa	Dallas Center, Iowa	Ames, Iowa

[1] https://iowamedicalmarijuana.org/pdfs/States-Act-Letter-2019-09-23.pdf

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

D.E.A
Attn: DIVERSION CONTROL/DC
8701 MORRISSETTE DR.
SPRINGFIELD, VA 22152

9590 9402 5189 9122 6400 32

2. Article Number *(Transfer from service label)*

7020 2450 0000 8179 6968

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

☐ Agent
☐ Addressee

B. Received by *(Printed Name)*

C. Date of Delivery 5/19/21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Insured Mail
- ☐ Insured Mail Restricted Delivery (over $500)
- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

PS Form 3811, July 2015 PSN 7530-02-000-9053 Domestic Return Receipt

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

D-E-A
Attn: Administrator
8701 Morrissette Dr
Springfield, VA 22152

9590 9402 5189 9122 6400 25

2. Article Number *(Transfer from service label)*

7020 2450 0000 8179 6944

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

☐ Agent
☐ Addressee

B. Received by *(Printed Name)*

C. Date of Delivery 5/19/21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☒ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Insured Mail
- ☐ Insured Mail Restricted Delivery (over $500)
- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☒ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

PS Form 3811, July 2015 PSN 7530-02-000-9053 Domestic Return Receipt

May 14, 2021

Drug Enforcement Administration
Attn: Administrator
8701 Morrissette Drive
Springfield, Virginia 22152

Drug Enforcement Administration
Attn: Diversion Control Division/DC
8701 Morrissette Drive
Springfield, VA 22152
ODLP@usdoj.gov

Dear Administrator:

The undersigned, pursuant to 21 C.F.R. § 1321.01 (postal mailing addresses), hereby petition the administrator for an exception pursuant to 21 C.F.R. § 1307.03, and the initiation of proceedings for the issuance of a rule or regulation pursuant to 21 C.F.R. § 1308.43 and section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) Proposed rule or regulation in the form proposed by the petitioners.
(B) Statement of grounds upon which the petitioners rely for issuance of an exception pursuant to 21 C.F.R. § 1307.03 and issuance of a rule or regulation pursuant to 21 C.F.R. § 1308.43 and section 201 of the Controlled Substances Act.
(C) Four letters dated April 23, 2021, from the Iowa Department of Public Health to federal administrative agencies, including the Drug Enforcement Administration.
(D) A statement from the Iowa Department of Public Health on September 4, 2020, explaining the intent of the four letters it wrote on April 23, 2021.
(E) The letter from D. Christopher Evans, Acting Administrator, dated April 27, 2021.
(F) The letter from Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, dated February 1, 2021.
(G) The petition submitted by the petitioners on December 16, 2020.
(H) The letter from Brian Besser, Deputy Assistant Administrator, Diversion Control Division, dated November 10, 2020.
(I) The petition submitted by the petitioners on January 28, 2019.

All notices to be sent regarding the petition should be addressed as indicated below:

Respectfully,

Carl Olsen
130 NE Aurora Ave
Des Moines, IA 50313
carl@carl-olsen.com

Mary Roberts
1901 13th Street
Coralville, IA 52241
robertsmaryj@icloud.com

Erin Bollman
abrammayhem@live.com

Colin Murphy
2628 Camden Dr.
Ames, IA 50010
ccmurphy@grllaw.com

The proposed rule in the form proposed by the petitioners, to be inserted in Title 21 of the Code of Federal Regulations.

§1307.32 State Authority

The listing of marihuana as a controlled substance in Schedule 1 does not apply to the state authorized use of marihuana, and persons using marihuana in compliance with state law are exempt from registration.

STATEMENT OF GROUNDS RELIED ON BY THE PETITIONERS

Attached and made a part hereof are: (1) four letters dated April 23, 2021, from the Iowa Department of Public Health to federal administrative agencies including the Drug Enforcement Administration ("DEA" hereafter); (2) a statement from the Iowa Department of Public Health on September 4, 2020, explaining the intent of the four letters it wrote on April 23, 2021; (3) the letter ("second denial"), dated April 27, 2021, denying the petitioners' petition ("second petition"), dated December 16, 2020, signed by Acting Administrator, D. Cristopher Evans; (4) the petitioners' second petition; (5) the letter ("FOIA Response"), dated February 1, 2021, responding to Carl Olsen's request for a status report on the second petition, signed by Deputy Assistant Administrator, Thomas W. Prevoznik; (6) the letter ("first denial"), dated November 10, 2020, denying the petitioners' petition ("first petition"), dated January 28, 2019, signed by Deputy Assistant Administrator, Brian Besser; and (7) the petitioners' first petition.

BRIEF SUMMARY

The petitioners seek an exemption like the one granted for church use of peyote.

21 C.F.R. § 1307.31 Native American Church:[1]

> The listing of peyote as a controlled substance in Schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

The rule proposed by the petitioners' is based on church use of peyote as a template:

§ 1307.32 State Authority:

> The listing of marihuana as a controlled substance in Schedule 1 does not apply to the state authorized use of marihuana, and persons using marihuana in compliance with state law are exempt from registration.

The petitioners: (1) replace the Schedule I controlled substance peyote with the Schedule I controlled substance marijuana; and (2) replace "church" use with "state authorized" use.

ARGUMENT

Your agency rejected our previous petitions on the grounds that a regulation exempting state authorized use of marihuana is foreclosed by the U.S. Supreme Court ruling in *Gonzales v. Raich*, 545 U.S. 1 (2005). An exemption can't be foreclosed because an exemption already exists for a Schedule I controlled substance, peyote.

[1] https://www.govinfo.gov/content/pkg/CFR-2020-title21-vol9/xml/CFR-2020-title21-vol9-sec1307-31.xml

Raich challenged the federal Controlled Substances Act as a violation of her right under the Tenth Amendment to the U.S. Constitution. 545 U.S., at 8. The court found that federal regulation of marijuana is constitutional. The court pointed out that your agency can add to, remove from, and transfer between the schedules. 545 U.S., at 27, n.37. The court suggested Raich take up the matter with your agency, which Raich never did. The court did not mention the peyote exemption, but the fact an exemption exists for peyote proves beyond any doubt that your agency can also grant exemptions for Schedule I controlled substances.

And we know, as in *Raich*, the use of peyote is not protected by the U.S. Constitution. *Employment Division v. Smith*, 494 U.S. 872 (1990)

The peyote exemption would be precluded by *Smith*, if an exemption for marijuana were precluded by *Raich*.

Your agency prohibits an application for exemption where one is otherwise required by law. *Raich* says an exemption for marijuana is not required by law. *Smith* says an exemption for peyote is not required by law.

21 C.F.R. § 1307.03 Exceptions to regulations:[2]

> Any person may apply for an exception to the application of any provision of this chapter by filing a written request with the Office of Diversion Control, Drug Enforcement Administration, stating the reasons for such exception. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise **required by law** or the regulations cited in this section.

(emphasis added).

Peyote and marijuana are equally situated for equal protection analysis.

When reviewing the peyote exemption for your agency in 1981, the Office of Legal Counsel said: "… we think it likely that Congress could, consistently with the Free Exercise Clause, prohibit even the religious use of peyote if it chose to do so, …".[3] The decision in the *Smith* case, nine years later, validates that opinion.

If an exemption for church use of the Schedule I controlled substance peyote is not required by law, then DEA is discriminating against states in favor of churches. A regulation exempting the state authorized use of marihuana would be consistent with your agency's decision-making regarding church use of peyote, rather than intentionally creating positive conflict between state and federal law where conflict isn't required or even desirable. Denying equal protection to state authorized use of marihuana is an abuse of agency discretion. States created the federal government, not churches. DEA has authority to grant exemptions to churches only because states gave DEA that power.

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[2] https://www.govinfo.gov/content/pkg/CFR-2020-title21-vol9/xml/CFR-2020-title21-vol9-sec1307-03.xml
[3] https://www.justice.gov/olc/opinion/peyote-exemption-native-american-church, at page 415.

The history of the federal peyote exemption shows it was based on state court decisions in California and Arizona. Congressional Record, July 8, 1965.[4]

Federal Register, March 19, 1966[5] (regulatory exemption for church use of peyote); 21 C.F.R. § 166.3(c)(3) (1968)[6] (codified exemption for church use of peyote).

During U.S. House Hearings, February 3, 1970[7] (BNDD, the predecessor to DEA, testified, "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.")

It was the state authorization of church use that resulted in the DEA's peyote exemption.

A consistent theme emerges throughout showing deference to state authority. It makes sense that your agency has shown deference to state laws in the past, because states are the primary regulators of health and safety under the federal Controlled Substances Act.[8] It does not make sense that your agency now considers states to be its opponents rather than its partners.

Since the filing of our previous petitions, the state of Iowa has made its own application for federal exemption. Attached are letters Iowa sent to federal administrative agencies on April 23, 2021, including a letter to your agency. Also attached is a document filed with the Iowa Medical Cannabidiol Board on September 4, 2020, explaining that the state believes 21 C.F.R. § 1307.03 to be the only method of obtaining an exemption.

On November 10, 2020, your agency kindly pointed out that 21 C.F.R. § 1308.43 would be the proper method of obtaining an exemption like the one for peyote and accepted our petition as if it was filed under 21 C.F.R. § 1308.43, even though we filed it incorrectly under 21 C.F.R. § 1307.03. We think both the 21 C.F.R. § 1307.03 and 21 C.F.R. § 1308.43 applications are valid because we want both immediate and permanent exemptions. We ask that you interpret our state's application as filed with the intent that your agency create an exemption like that one that currently exists for peyote and that you notify the state it is exempt upon receipt of the state's April 23, 2021, letter to your agency.

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[4] https://files.iowamedicalmarijuana.org/imm/federal/111CongRec15977.pdf
[5] https://files.iowamedicalmarijuana.org/imm/federal/31FedReg4679-1996.pdf
[6] https://files.iowamedicalmarijuana.org/imm/federal/21CFR166-1968.pdf
[7] https://files.iowamedicalmarijuana.org/imm/federal/1970-Serial-No-91-45-117.pdf
[8] *See Gonzales v. Oregon*, 546 U.S. 243, 270 (2006), "… the structure and limitations of federalism, which allow the States 'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.' *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (quoting *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985))."; *Id*., at 271, "… regulation of health and safety is 'primarily, and historically, a matter of local concern,' *Hillsborough County v. Automated Medical Laboratories, Inc*., 471 U.S. 707, 719 (1985)".

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CONCLUSION

Please assist Iowa in obtaining a federal exemption for the state authorized use of cannabis.

Thank you!

Carl Olsen	Mary J. Roberts	Erin Bollman	Colin Murphy
Des Moines, Iowa	Coralville, Iowa	Dallas Center, Iowa	Ames, Iowa