December 16, 2020

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

Dear Administrator:

The undersigned, pursuant to 21 C.F.R. § 1321.01, hereby petition the administrator for an exemption 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) An amended statement of the grounds upon which the petitioners rely for the issuance of the rule pursuant to 21 C.F.R. § 1308.43 and section 201 of the Controlled Substances Act.
(B) The proposed rule in the form proposed by the petitioners.
(C) An amended statement of the grounds upon which the petitioners rely for the issuance of an exemption pursuant to 21 C.F.R. § 1307.03.
(D) The letter from Brian Besser, Deputy Assistant Administrator, Diversion Control Division, dated November 10, 2020.
(E) The petition submitted by the petitioners on January 28, 2019.

All notices to be sent regarding the petition should be addressed to:

Carl Olsen
Des Moines, Iowa

Mary J. Roberts
Coralville, Iowa

Colin Murphy
Ames, Iowa

Respectfully yours,

_____
Carl Olsen

Respectfully yours,

_____
Mary Roberts

Respectfully yours,

_____
Colin Murphy

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 Authorization

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 is a letter ("denial letter"), dated November 19, 2020, denying the petitioners' previous petition (dated January 28, 2019), signed by Brian Besser, Deputy Assistant Administrator, Diversion Control Division.

Also attached and made a part hereof is the previous petition ("previous petition") submitted by the petitioners on January 28, 2019.

## BRIEF SUMMARY OF AMBIGUOUS LANGUAGE USED IN PREVIOUS PETITION

The previous petition submitted by the petitioners requested a rule or a regulation exempting the state authorized "medical" use of marihuana. This current petition does not use the term "medical" as an adjective. This current petition simply requests the Administrator of the Drug Enforcement Administration (DEA) to recognize an exemption for the "state authorized" use of marihuana.

The term "medical" is ambiguous. Approximately 47 states, like the state of Iowa, use the term "medical" as an adjective in describing their state authorized exceptions for the use of marihuana.[1] However, none of those states has "rescheduled" or removed marihuana from their state scheduling as a method of "authorizing" its use.

Congress uses the term "medical" as an adjective in describing these state laws, providing an exception for state authorized "medical" use of marihuana.[2] But, again, Congress also hasn't used scheduling as the method of "authorizing" such use, so the term "medical" is being used in a different context than it is used for scheduling.

The petitioners acknowledge the term "medical" as used in their previous petition was not appropriate in the context of the petition, because the "state authorized" use of marihuana is completely outside the scope of scheduling. It is exempt.

The adjective "medical" is used by the state of Iowa in Iowa Code Chapter 124E, but not in the context of scheduling in Iowa's Uniform Controlled Substances Act, Iowa Code Chapter 124. Iowa continues to list marijuana as a schedule 1 controlled substance in the Iowa Uniform Controlled Substance Act, Iowa Code Chapter 124, Section 204(4)(m). Consistent with the federal CSA, Iowa's CSA finds marihuana has no "medical" use in the context of scheduling.

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[1] https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

[2] In December 2014, Congress enacted the Rohrabacher-Farr Amendment as part of an omnibus appropriations bill. Pub. L. No. 113-235, § 538, 128 Stat. 2130, 2217 (2014). The Amendment has been renewed every year and has been in force without interruption. The Amendment, in its current form, states that the Department of Justice's appropriated funds may not be used "to prevent [47 states, the District of Columbia, and the territories of Puerto Rico, Guam, and the Northern Mariana Islands] from implementing their own State laws that authorize the use, distribution, possession, or cultivation of medical marijuana." Pub. L. No. 116-6, § 537, 133 Stat. 13, 138 (2019).

Iowa Code Chapter 124E provides an exception to Iowa's CSA. See Iowa Code 124E.12 – Use of medical cannabidiol — affirmative defenses.

Although both states and Congress use the term "medical" in describing state laws authorizing the use of marihuana, the authorized use of marihuana under state law falls entirely outside of the scope of scheduling within the federal Controlled Substances Act (CSA), which is precisely why it is exempt from scheduling.

This petition simply seeks acknowledgement from the Drug Enforcement Administration (DEA), that the state authorized use of marihuana is entirely outside of the scope of the scheduling and is exempt for that same reason.

## FACTS RELIED UPON BY THE PETITIONER

There is further ambiguity in Iowa Code Chapter 124E, the Iowa Medical Cannabidiol Act, 2017 Act 162,[3] where Iowa Code 124E.2(6) defines cannabidiol as "any" cannabinoid. Cannabidiol is just one of "many" cannabinoids in marihuana, not "all" of the cannabinoids. The ambiguity in the use of the terms "medical" and "cannabidiol" are not the issue here, however, because they are not used in the context of scheduling. What matters is that the Iowa act authorizes the cultivation of "marihuana", and the manufacture, production, distribution, and possession of cannabis extracts, all of which fall entirely outside of the scope of scheduling.

Regardless of any ambiguities, the use of "marihuana" is authorized by state law and the meaning of the law is understood. Citizens can understand what the state law says and what the state law does and does not allow.

The federal CSA contains an explicit presumption against federal preemption, 21 U.S.C. §903.

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

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

DEA cannot reject constitutionally enacted state law within the context federal CSA, when a way to reconcile the two exists. 21 C.F.R. §1307.03 provides DEA with the ability to reconcile the two, just as Iowa Code 124E.12 reconciles Iowa's authorized use of marihuana within the context of Iowa Code 124 (the Iowa Uniform Controlled Substances Act). DEA does not have

[3] https://www.legis.iowa.gov/docs/publications/iactc/87.1/CH0162.pdf

any discretion to create positive conflicts between state and federal drug laws by denying an exception under 21 C.F.R. §1307.03.

Petitioners do not ask the Drug Enforcement Administration (DEA) to agree with the Iowa's determination that marijuana has medical use. Iowa has a state legislature and a Medical Cannabidiol Board that make that determination in Iowa. The petitioners do not present medical or scientific evidence considered by the state legislature or the Iowa Medical Cannabidiol Board because the state law is proof that the state has accepted the use of marihuana for the purpose described in the state law. The state authorized use of marijuana is outside the scope of DEA's decision-making authority under 21 U.S.C. §811(b) and 21 U.S.C. §811(c). The DEA Administrator is authorized to consider medical and scientific evidence within the scope of 21 U.S.C. §811(b) and 21 U.S.C. §811(c), not outside of that context.

This is a petition for an exemption, so this petition does not invoke agency decision-making within the scope of 21 U.S.C. §811(b) and 21 U.S.C. §811(c).

## ISSUES NOT IN DISPUTE

This petition resolves a majority of the issues raised by DEA in the November 10, 2020, denial letter by removing the term "medical" as an adjective in describing the state authorized use of marihuana. Just as the petitioners do not ask the DEA to determine whether cannabidiol is "many" cannabinoids or just a "single" cannabinoid, the petitioners do not ask the DEA to determine whether marihuana has any medical use.

The petitioners do not dispute the five part test the DEA Administrator uses to determine medical use in the context of scheduling under 21 U.S.C. §811(c).[4]

The petitioners do not dispute the DEA Administrator's determination that international treaties may require the placement of marihuana in Schedule 1 or Schedule 2.[5]

[4] Denial letter at page 2. DEA uses a five-part test to assess whether marijuana has a "currently accepted medical use": (1) The drug's chemistry must be known and reproducible; (2) There must be adequate safety studies; (3) There must be adequate and well-controlled studies proving efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013). These criteria have been repeatedly set forth by DEA and upheld by the United States Courts of Appeals. See, e.g., id. (citing *All. for Cannabis Therapeutics v. Drug Enf't Admin*., 15 F.3d 1131, 1135 (D.C. 1994)).

[5] Denial letter at page 3. Because marijuana is controlled under Schedule I of the Single Convention, the placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the treaty. *NORML v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977).

The petitioners do not dispute that determinations of medical use within the context of 21 U.S.C. §811(b) are made by the Secretary of Health and Human Service and not by the states.[6]

The petitioners do not dispute that 21 U.S.C. §811(d) requires scheduling to be consistent with the 1961 Single Convention and the 1972 Convention on Psychotropic Substances.[7]

## ISSUES THAT ARE IN DISPUTE

### Gonzales v. Raich

Gonzales v. Raich simply affirms that the CSA is a constitutionally valid exercise of federal authority. The Raich decision says nothing about precluding an exemption under 21 C.F.R. §1307.03.[8] Raich never notified the DEA Administrator that she was exempt under 21 C.F.R. §1307.03 and did not raise it as an issue in her defense. Raich never notified her state that her activity was exempt under 21 C.F.R. §1307.03. 21 C.F.R. §1307.03 has never been considered by the U.S. Supreme Court. 21 C.F.R. §1307.03 has never been considered by the DEA in the context of state authorized use of marihuana, which is why this petition is being submitted.

### Single Convention

There is nothing in 21 U.S.C. §811(d) or the 1961 Single Convention that would support the denial of an exemption for state authorized use of marihuana.[9] Beyond the requirement that marihuana be placed in Schedule 1 or Schedule 2, the 1961 Single Convention does not require DEA to deny exemptions, and 21 U.S.C. §903 makes it clear that Congress did not authorized the DEA to create a positive conflict between state and federal governments by denying an exemption.

The 1961 Single Convention contains an explicit exception for "constitutional limitations" in Article 36. The denial letter says DEA relies on the CSA's implementation of the Single Convention, but an exception for domestic law is explicitly authorized by that convention.

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[6] Denial letter at page 2. Furthermore, in *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court observed that the CSA explicitly allocates medical judgments in the scheduling context to the Secretary of HHS—and not, as you argue, to the states. See *Oregon*, 546 U.S. at 265.

[7] Denial letter at page 3. Further, the DEA Administrator is obligated under 21 U.S.C. 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). Because marijuana is controlled under Schedule I of the Single Convention, the placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the treaty. *NORML v. Drug Enforcement Admin.*, 559 F.2d 735, 751 (D.C. Cir. 1977).

[8] Denial letter at page 2. In *Gonzales v. Raich*, the Supreme Court held that Congress has the power, and has exercised that power via the CSA, to ban the personal cultivation and medical use of marijuana, even where otherwise authorized by state law. 545 U.S. 1, 29 (2005).

[9] *U.N. Reclassifies Cannabis as a Less Dangerous Drug*, by Isabella Kwai, New York Times, Wednesday, December 2, 2020 – https://www.nytimes.com/2020/12/02/world/europe/cannabis-united-nations-drug-policy.html

The 1971 Convention on Psychotropic Substances also contains the same explicit exception for "domestic law" in Article 22, Section 2. DEA's reliance on the CSA's implementation of the Convention on Psychotropic Substances required the exception for domestic law that is explicitly authorized by that convention.

The conventions recognize exceptions for domestic law rather than opposing them. Rather than waiving their sovereign rights, signatories to the conventions wisely reserved their sovereign rights to preserve their constitutional forms of government and their domestic laws as a condition to signing on to those conventions. DEA is constitutionally forbidden by the CSA's implementation of these conventions, by the existence of 21 U.S.C. §903, and by the existence of 21 C.F.R. §1307.03, from denying these rights.

**Congress**

Beyond the presumption against preemption contained in 21 U.S.C. §903, Congress has recently recognized exceptions for state authorized use of marihuana, beginning in 2014 and continuously since that time.[10]

The current intent of Congress, the intent of Congress expressed in 21 U.S.C. §903, and the explicit protections for domestic laws in the international conventions, make it clear that Congress did not authorize the DEA to create positive conflicts with state laws authoring the use of marihuana. 21 C.F.R. §1307.03 has been in existence since 1970 (previous codified at 21 C.F.R. §307.03), so it expresses a clear understanding that the CSA accommodates exceptions. An exemption also exists for another Schedule I controlled substance at 21 C.F.R. §1307.31, so there is no argument that Schedule I cannot accommodate exceptions. States have as much right as churches, if not more. It was the states that created the federal government, not churches. It would turn the Constitution upside down to suggest that churches now have more rights under the Constitution and federal drug laws than states.

Just as DEA has not been authorized by Congress to forbid states from enacting laws authorizing the use of marihuana, DEA has not been authorized by Congress to deny exemptions to states that authorize the use of marihuana.

## CONCLUSION

DEA is forbidden by 47 states' domestic laws and by Congress from claiming it has discretion to deny exceptions for state authorized use of marihuana, creating conflicts between state and federal law where none exist.

There are sufficient grounds to initiate rule making under 21 C.F.R. §1308.43.

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[10] *See supra* text accompanying footnote 2.

Because constitutional principles at the very heart of federalism are at stake here, an interim rule recognizing the exemption under 21 C.F.R. §1307.03 should issue immediately.

Thank you!


Carl Olsen
Des Moines, Iowa

Mary J. Roberts
Coralville, Iowa

Colin Murphy
Ames, Iowa

**U. S. Department of Justice**
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

*www.dea.gov*

November 10, 2020

Carl Olsen
P.O. Box 41381
Des Moines, Iowa 50311-0507

Dear Mr. Olsen:

This letter responds to your petition and your supplement to that petition, received by DEA on February 4, 2019, and August 31, 2020, respectively, asking the Drug Enforcement Administration (DEA) to initiate rule making proceedings pursuant to the Controlled Substances Act (CSA). Specifically you petitioned DEA to exempt the state-authorized use of cannabis for medical use pursuant to 21 CFR 1307.03. DEA accepted your petition for filing despite its failure to comply procedurally with the requirements of 21 CFR 1308.43(b). Specifically, your petition must be submitted in quintuplicate and in the proper format set forth in 21 CFR 1308.43(b).

Your petition is **denied** because the CSA controls marijuana under schedule I, and your requested exemption would result under the circumstances in the lapse of regulatory controls and administrative, civil, and criminal sanctions applicable to substances placed on the various CSA schedules.

Marijuana[1] has been listed in schedule I since the CSA took effect. Under the CSA, a substance is properly placed in schedule I if it (A) "has a high potential for abuse," (B) "has no currently accepted medical use in treatment in the United States," and (C) lacks "accepted safety for use under medical supervision." 21 U.S.C. 812(b)(1). These findings have been made repeatedly with respect to marijuana. *See, e.g.*, *Krumm v. DEA*, 739 F. App'x. 655 (D.C. Cir. 2018) (Mem) (denying petition for review challenging DEA's denial of petition to reschedule marijuana); "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 FR 53688 (Aug.12, 2016) ("August 2016 Denial"); "Denial of Petition To Initiate Proceedings To Reschedule Marijuana," 76 FR 40552 (July 8, 2011); *Olsen v. DEA*, 332 F. App'x 359 (8th Cir. 2009) (finding no standing to challenge DEA's denial of marijuana rescheduling petition); Notice of Denial of Petition,"66 FR 20038 (Apr.18, 2001); *Olsen v. DEA*, 99 F.3d 448 (D.C. Cir. 1996) (Table) ("Petitioner's rescheduling request was not supported by grounds sufficient to justify the initiation of rescheduling

1 The CSA defines "marihuana" as "[a]ll parts of the plant Cannabis Sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." 21 USC 802(16)(A). Marihuana does not include "hemp," as defined in 7 USC 1639o, or "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 USC 802(16)(B). This definition encompasses the various terms used for marijuana or compound of marijuana you used in your petition. This response uses the CSA spelling "marihuana" and the contemporary spelling "marijuana" interchangeably.

proceedings."); "Marijuana Scheduling Petition; Denial of Petition," 54 FR 53767 (Dec. 29, 1989).

You base your request that DEA exempt the state-authorized use of cannabis for medical use on your assertion that, as a matter of law, "medical cannabidiol or any other form of cannabis, tetrahydrocannabinols and cannabis extracts have 'accepted medical use in treatment'" in states that have exempted "lawful possession or use of medical cannabidiol by qualified patients and caregivers" from the respective state's controlled substance acts.[2]

This assertion is incorrect. DEA uses a five-part test to assess whether marijuana has a "currently accepted medical use": (1) The drug's chemistry must be known and reproducible; (2) There must be adequate safety studies; (3) There must be adequate and well-controlled studies proving efficacy; (4) The drug must be accepted by qualified experts; and (5) The scientific evidence must be widely available." *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013). These criteria have been repeatedly set forth by DEA and upheld by the United States Courts of Appeals. *See*, *e.g., id.* (citing *All. for Cannabis Therapeutics v. Drug Enf't Admin.*, 15 F.3d 1131, 1135 (D.C. 1994)).

The August 2016 denial relied on the assessment of the Department of Health and Human Services (HHS) to conclude that marijuana has no currently accepted medical uses in the United States. Specifically, HHS's assessment concluded that "[m]arijuana does not meet any of the five elements necessary for a drug to have a 'currently accepted medical use.'" 81 FR 53688, 53700, 53707. HHS "identified several methodological challenges in the marijuana studies published in the literature" and recommended that these challenges be "addressed in future clinical studies with marijuana to ensure that valid scientific data are generated in studies evaluating marijuana's safety and efficacy for therapeutic use." *Id.*

Your petition cites no evidence or clinical studies relating to medical uses of marijuana and, therefore, casts no doubt on HHS's findings. Rather, you assert in your petition that the State of Iowa is "the sole authority" to determine whether marijuana has accepted medical use in treatment in Iowa. This assertion is flatly contradicted by binding Supreme Court precedent. In *Gonzales v. Raich*, the Supreme Court held that Congress has the power, and has exercised that power via the CSA, to ban the personal cultivation and medical use of marijuana, even where otherwise authorized by state law. 545 U.S. 1, 29 (2005). The Court based this finding on the long-standing rule "that federal power over commerce is 'superior to that of the States to provide for the welfare or necessities of their inhabitants.'" *Id.* At 29 (quoting *Sanitary Dist. of Chicago v. United States*, 266 U.S. 405, 426 (1925)). Furthermore, in *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court observed that the CSA explicitly allocates medical judgments in the scheduling context to the Secretary of HHS—and not, as you argue, to the states. *See Oregon*, 546 U.S. at 265.

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2 Because your petition does not contest that marijuana has a high potential for abuse and lacks accepted safety for use under medical supervision, this letter addresses only whether your petition demonstrates the existence of accepted medical use in treatment in the United States.

Moreover, the structure of the CSA itself disproves your contention that federal drug law gives states the authority to determine whether a drug law has a currently accepted medical use within the meaning of the CSA. Section 903 of the CSA provides that, where there is a "positive conflict between [a] provision of [the CSA] and [a] State law so that the two cannot consistently stand together," the CSA prevails to the exclusion of the state law. *See* 21 U.S.C. 903; *Raich*, 545 U.S. at 29. Thus, section 903 of the CSA codifies within the CSA what is generally true of federal law under the supremacy clause of the United States Constitution—that where state and federal law directly conflict, state law is preempted by federal law.

The Court's holding in *Raich* likewise contradicts the assertion in your supplement that "DEA has no authority to create a conflict [between state and federal drug laws] if there is a way to resolve it." "The Supremacy Clause unambiguously provides that if there is any conflict between federal and state law, federal law shall prevail." *Id.* For this reason, your assertion that manufacture, possession, and use of medical marijuana in Iowa is only "*perceived*" to be illegal under federal law is incorrect. Congress's placement of marijuana on schedule I prevails over a state law that ends state penalties for use, possession, or manufacture of marijuana for medical purposes. Manufacture, possession, and use of marijuana in a manner contrary to relevant CSA provisions and DEA regulations *is* illegal under federal law, regardless of state law. *See* 21 U.S.C. 841, 844. Any potential "federal interference," as you style it in your petition, flows naturally from those statutes and regulations.

Your reliance on *Gonzales v. Oregon* to support your assertion that the "Attorney General of the United States . . . is not authorized to make a rule declaring illegitimate a medical standard for care and treatment for patients that is authorized under state law" is misplaced. In *Gonzales*, the Supreme Court was interpreting the requirement set forth in 21 CFR 1306.04 that all prescriptions for controlled substances "must be issued for a legitimate medical purpose." *Gonzales*, 546 U.S. at 254. Specifically, the question was whether a prescription of a controlled substance for use in assisted suicide is a legitimate medical purpose, not whether a particular substance had accepted medical uses. *Id.* And in deciding that question, the Court noted that "Congress' express determination that marijuana had no accepted medical use foreclosed any argument about statutory coverage of drugs available by a doctor's prescription." *Id.* at 269.

Further, the DEA Administrator is obligated under 21 U.S.C. 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention on Narcotic Drugs, 1961 (Single Convention). Because marijuana is controlled under Schedule I of the Single Convention, the placement of marijuana in either schedule I or schedule II of the CSA is "necessary as well as sufficient to satisfy our international obligations" under the treaty. *NORML v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977).

For these reasons, absent evidence showing a currently accepted medical use for marijuana in the United States, it must be placed on CSA schedule I. Marijuana is thus subject to the CSA's schedule

I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research,

and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. Registration with DEA pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.
2. Security requirements, including handling and storage pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, and employee screening requirements of 21 CFR 1301.90–1301.93.
3. Labeling and packaging in compliance with 21 U.S.C. 825 and 958(e) and in accordance with 21 CFR part 1302.
4. Manufacture in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.
5. Inventorying of all stocks of controlled substances on hand on the date the registrant first engages in the handling of controlled substances and every two years thereafter pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.
6. Maintaining records and submitting reports with respect to marijuana pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304 and 1312.
7. Compliance with order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.
8. Importation and exportation of marijuana in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

Any activity involving marijuana not authorized by, or in violation of the CSA or its implementing regulations is unlawful, and could subject the person to administrative, civil, and/or criminal sanctions.

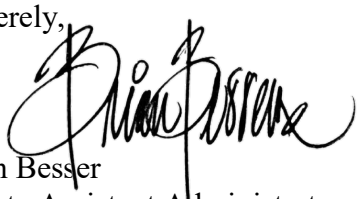
Your proposed rule reads as follows: "(t)he listing of marihuana as a controlled substance in schedule I does not apply to the authorized medical use of marihuana authorized by or under any State statute or by any State agency." Notably, your proposed rule does not seek to alter the federal scheduling of marijuana, but rather to exempt the application of the CSA's controls to marijuana. But exempting the foregoing controls over marijuana would be inconsistent with United States obligations under the Single Convention, as noted above. *See also* 81 FR at 53767-68 (noting that U.S. obligations under the Single Convention are carried out by applying the controls specified in schedules I or II of the CSA to marijuana). Moreover, although DEA's Administrator is authorized by 21 CFR 1307.03 to grant an exception to the application of any regulatory provision contained in 21 CFR part 1300 to end, the Administrator does not have the authority to grant exceptions to requirements enacted by Congress in the text of the CSA, including the eight categories of control listed above that are required by statute for all schedule I controlled substances. Because your proposed rule would override the statutory requirements of the CSA enacted by Congress, it is beyond DEA's authority to enact. Additionally, your proposed rule would result in far fewer

controls on marijuana than rescheduling marijuana to schedule II and would lead to the presence of marijuana in the market without the many controls designed to limit the abuse of both schedule I and schedule II drugs.

For these reasons, your proposed rule would be contrary to the purposes of the CSA and to obligations arising from the Single Convention. Your petition is therefore **denied**.

If you have additional information or questions, please contact Terrence L. Boos, Ph.D., Chief, Drug and Chemical Evaluation Section, at (571) 362-3249 or DPE@usdoj.gov.

Sincerely,



Brian Besser
Deputy Assistant Administrator
Diversion Control Division

2628 Camden Drive
Ames, Iowa 50010
January 28, 2019

Drug Enforcement Administration
Attn: Diversion Control Division/DC
8701 Morrissette Drive
Springfield, VA 22152

**Re: Petition to Exempt State-Authorized Use of Medical Cannabis**
**Certified Mail Receipt No. 7017 2680 0000 3373 5200**

Dear Administrator:

Please find attached five copies of the Petition for Exemption for State-Authorized Use of Medical Cannabis for your review.

Thank you.

Sincerely,

Colin Murphy

CCM:cm
Encl.

cc: The Honorable Kim Reynolds
Governor of Iowa
1007 East Grand Ave.
Des Moines, Iowa 50319
Certified Mail Receipt No. 7017 2680 0000 3373 5217

The Honorable Tom Miller
Office of the Attorney General of Iowa
Hoover State Office Building
1305 E. Walnut Street
Des Moines IA 50319
Certified Mail Receipt No. 7017 2680 0000 3373 5224

DRUG ENFORCEMENT ADMINISTRATION
Diversion Control Division/DC
8701 Morrissette Drive
Springfield, VA 22152

| | | |
|---|---|---|
| Petition for Administrative Rule Pursuant to 21 C.F.R. § 1307.03 | ) ) ) | PETITION TO EXEMPT THE STATE-AUTHORIZED USE OF MEDICAL CANNABIS |

**COME NOW** Petitioners, pursuant to 21 C.F.R. § 1307.03 (2019),[1] and for the Petition to Exempt the State-Authorized Use of Medical Cannabis state:

1. On May 12, 2017 Iowa Governor Terry Branstad signed into law House File 524, known as the "Medical Cannabidiol Act," which is now codified at Iowa Code chapter 124E (2017) (the "**Act**").[2]

2. The Act allows Iowa residents over the age of 18 (or their primary caregiver), who submit written certification by a health care practitioner that they are suffering from a certain debilitating medical condition, to apply to the Iowa Department of Public Health for a medical cannabidiol registration card.[3]

3. The registration card allows Iowans access to medical cannabidiol through a state-regulated system of manufacturers and dispensaries.[4]

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1. The regulation provides:

> 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 Sec. 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.

21 C.F.R. § 1307.03 (2019).

2. *See generally* IOWA CODE ch. 124E (2017). The administrative rules promulgated by the Iowa Department of Public Health to interpret and enforce Chapter 124E are found at IOWA ADMIN. CODE r. 641–154 (2019).

3. *Id.* § 124E.4 (2017).

4. Medical cannabidiol may be legally manufactured in Iowa by only two companies that hold Iowa manufacture licenses. It can be legally dispensed only at five locations across the state by companies that hold dispensary licenses *available at* http://idph.iowa.gov/Portals/1/userfiles/234/Files/IDPH%20Position%20Statement%20on%20CBD%20-%2012_1_2018.pdf. As of January 11, 2019 there are 1,197 patients and caregivers with active registration cards, who have been certified by 463 healthcare practitioners in the state, *available at* https://idph.iowa.gov/cbd/Program-Data-and-Statistics.

4. "Medical cannabidiol" is "any pharmaceutical grade cannabinoid found in the plant *Cannabis sativa L.* or *Cannabis indica* . . . that has a tetrahydrocannabinol level of no more than three percent and that is derived in a form . . . adopted by the [Iowa Department of Public Health] pursuant to rule."[5]

5. On December 1, 2018 medical cannabidiol first became available for purchase by Iowa patients.[6]

6. The lawful possession or use of medical cannabidiol by qualified patients and caregivers is exempt from the penalties provided under the Iowa's controlled substance and tax-stamp acts.[7]

7. However, because the manufacture, possession and use of medical cannabidiol is *perceived* to be illegal under *federal* law, Iowa manufacturers, dispensaries, patients, primary caregivers and others remain vulnerable to federal interference, whether by arrest, prosecution, incarceration, forfeiture, taxation or denial of benefits, including, but not limited to:

(a) the inability for medical cannabidiol producers and processors to deduct business expenses besides the cost of goods sold;[8]

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[5]. IOWA CODE § 124E.2(6) (2017). Medical cannabidiol is *not* scheduled as a controlled substance under Iowa's Uniform Controlled Substances Act (Chapter 124) despite the fact that it contains up to three percent tetrahydrocannabinol by dry weight (mg/g), and therefore, would otherwise fall under the definition of "*marijuana*," which is listed as a schedule I controlled substance in the state. *See* IOWA CODE § 124.204(4)(m) (2017) (marijuana in Iowa schedule I); *see also* 124.124.101(20) (2017) ("[m]arijuana means 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 see of the plant which is incapable of germination") (emphasis added).

This definition is virtually indistinguishable from the term "*marihuana*" under federal law. *See* 21 U.S.C. § 802(16) (2019) (defining term as "all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination).

[6]. *Iowa Medical Cannabidiol Dispensaries Opening December 1* (11/2/18) *available at* https://idph.iowa.gov/ News/ArtMID/646/ArticleID/158242/Iowa-Medical-Cannabidiol-Dispensaries-Opening December-1-11218.

[7]. IOWA CODE § 124E.16(1) (2017) (providing penalties under Iowa Code chapters 124 and 453B for possession or use of medical cannabidiol in violation of chapter 124E).

[8]. *See* 26 U.S.C.§ 280E (2019) ("[n]o deduction or credit shall be allowed for any amount paid or incurred during the taxable year in carrying on any trade or business if such trade or business (or the activities which comprise such trade or business) consists of trafficking in controlled substances (within the meaning of schedule I and II of the Controlled Substances Act) which is prohibited by Federal law or the law of any State in which such trade or business is conducted"). The implications here are massive. Cannabis businesses pay taxes on gross income. For example, if a cannabis business has gross revenue of

(b) the inability of medical cannabidiol dispensaries to deduct any business expenses such as rent, advertising, labor costs, etc.;[9]
(c) the refusal by medical providers with the Department of Veterans Affairs to provide veterans under their care with written certification to obtain a registration card;[10]
(d) the prohibition against traveling with medical cannabidiol in carry-on or checked baggage;[11]
(e) the prohibition against purchasing or receiving a firearm by one who certifies on ATF Form 4473 that they are an "unlawful" user of substances containing marijuana;[12] and
(f) the denial of admission by owners of federally assisted housing to any household with a member who the owner determines is, at the time of application for admission, illegally using marijuana.[13]

8. The State of Iowa is the sole authority to determine whether medical cannabidiol or any other form of cannabis, tetrahydrocannabinols and cannabis extracts have "accepted medical use in treatment" in the state.[14]

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$10 million, incurred another $2 million in business-related expenses and cost of the cannabis was $6.5 million (cost of goods sold), the taxable income is not $1.5 million, *but instead $3.5 million*. At a tax rate of 30%, this amounts to $1.05 million in taxes for an *effective* tax rate (tax/income before tax) of 70%. This significantly restricts the owner's ability to reinvest profits both back into the business and the local community.

9. *Id.* Several types of business expenses are scrutinized under section 280E including employee salaries, utility costs such as electricity, telephone and internet service, health insurance premiums, marketing and repairs and maintenance. Cannabis businesses have been allowed to make deductions on their non-cannabis business activities by capitalizing on indirect costs such as administrative (bookkeeping, legal, technology) and inventory (storage, depreciation) costs and amounts paid in state excise taxes, but it is anticipated these deductions will be challenged.

10. *Access to VHA Clinical Programs for Veterans Participating in State-Approved Marijuana Programs*, VHA Directive 1315 (Dec. 8, 2017) *available at* https://www.va.gov/vhapublications/.

11. The Transportation Security Administration advises: "[p]ossession of marijuana and cannabis infused products, such as Cannabidiol (CBD) oil, is illegal under federal law. TSA officers are required to report any suspected violations of law, including possession of marijuana and cannabis infused products. TSA's screening procedures are focused on security and are designed to detect potential threats to aviation and passengers. Accordingly, TSA security officers do not search for marijuana or other illegal drugs, but in the event a substance that appears to be marijuana or a cannabis infused product is observed during security screening, TSA will refer the matter to a law enforcement officer" *available at* https://www.tsa.gov/travel/security-screening/whatcanibring/items/medical-marijuana.

12. Question 11(e) on the form asks "Are you an unlawful user of, or addicted to, marijuana or any depressant, stimulant, narcotic drug, or any other controlled substance? **Warning: the use or possession or marijuana remains unlawful under Federal law, regardless of whether it has been legalized or decriminalized for medicinal or recreational purposes in the state where you reside**," *available at* https://www.atf.gov/file/61446/download (emphasis in original). In answering the question truthfully, by checking yes, a patient's application will be denied. That may also hold true for any license renewal involving a patient that has since received a registration card. If the patient does not answer question 11(e) truthfully, then he will be subject to federal criminal sanctions, including perjury and illegal firearm possession.

13. 42 U.S.C. 13662(a) (2019).

14. *See* Iowa Code §§ 124.203(1)(b), (2) (2017). The term "currently accepted medical use for treatment in the United States" is not defined under federal law. *See* 21 U.S.C. § 812(b) (2019). "Neither the statute, nor its legislative history precisely define the term." *See Alliance for Cannabis Therapeutics*, 930 F.2d 936,

9. The Attorney General of the United States has rulemaking authority to fulfill his duties under the federal Controlled Substances Act, but he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment for patients that is authorized under state law.[15]

10. Federal law already recognizes an exemption for marijuana or other substances authorized by any state statute or agency in other contexts.[16]

11. Petitioners contend the fact that medical cannabidiol has been available for lawful use in Iowa since December 1, 2018 without objection by the Drug Enforcement Administration is tacit recognition of the federal exemption that has always existed for the authorized use of medical cannabis at the state level.

12. In order to harmonize the *perceived* conflict between Iowa and federal law, while simultaneously leaving both federal and Iowa schedule I intact regarding marijuana, Petitioners request the Drug Enforcement Administration formally acknowledge the existing exemption for the state-authorized use of medical cannabis and promulgate a new rule as follows:

> *21 C.F.R. § 1307.xx (2019). The listing of marihuana as a controlled substance in Schedule I does not apply to the authorized medical use of marihuana authorized by or under any State statute or by any State agency.*

**WHEREFORE**, Petitioners respectfully request the Drug Enforcement Administration codify the requested exemption.

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939 (D.C. Cir. 1991) Congress did not intend the term to require a finding of recognized medical use in *every* state. *See Grinspoon v. DEA*, 881 F.2d 877, 886 (1987).

[15]. *See Gonzales v. Oregon*, 546 U.S. 243, 258, 126 S. Ct. 904, 916, 163 L. Ed. 748 (2006).

[16]. *See* 14 C.F.R. § 91.19(a)-(b) (2019) ("[e]xcept as provided . . . of this section, no person may operate a civil aircraft within the United States with knowledge that narcotic drugs, marihuana, and depressant or stimulant drugs or substances as defined in Federal or State statutes are carried in the aircraft. [This] 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.")