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.

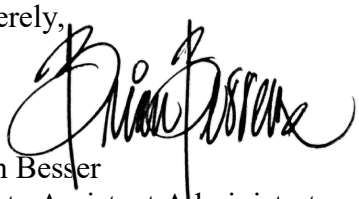
Your proposed rule reads as follows: "(t)he listing of marihuana as a controlled substance in schedule I does not apply to the authorized medical use of marihuana authorized by or under any State statute or by any State agency." Notably, your proposed rule does not seek to alter the federal scheduling 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
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