NO.

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

REV. BRYAN A. KRUMM, CNP,

Petitioner,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION
ANNE MILGRAM, DIRECTOR

Respondent.

Petition for Writ of Mandamus to the United States Drug Enforcement Agency to Enforce Requirements of the Controlled Substances Act, 21 U.S.C. 801 et. seq.

PETITION FOR WRIT OF MANDAMUS

Rev Bryan A. Krumm, CNP
Petitioner Pro Se
733 Monroe Street NE
Albuquerque, NM 87110
(505) 414-8120

February 2, 2024

PARTIES TO THE PROCEEDING

Petitioner is Rev. Bryan A. Krumm, CNP

733 Monroe NE

Albuquerque, NM 87110

Respondent is the United States Drug Enforcement Administration

Anne Milgram, Director.

8701 Morrissette Drive Springfield, VA 22152

And

Matthew M. Graves, US Attorney for the District of Columbia United States

US Attorney's Office

601 D Street, NW

Washington, DC 20579

CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure and DC Circuit Rule 26.1, Petitioner makes the following disclosure: Rev. Bryan A. Krumm, CNP is a private citizen and is not acting on the accord of any corporation.

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Signed

2/2/24
Date

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RELIEF SOUGHT

Because Petitioner presents indisputable evidence showing that Cannabis has accepted medical use in the United States and can not legally remain in Schedule 1 of the Controlled Substance Act (CSA) (21 U.S.C. 801 et seq); and because the United States has officially recognized the accepted medical use Cannabis under International law (The Single Convention Treaty) (Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020); and because the US Food and drug administration (FDA) has determined that Cannabis has "accepted medical use in the United States" (Exhibit 1); and because the US Department of Health and Human Services (HHS) has formally recommended to the United States Drug Enforcement Administration (DEA) that Cannabis be moved to Schedule 3 of the CSA (Exhibit 1); and because DEA has failed its duty to administer the CSA (28 C.F.R. § 0.100(b); Petitioner respectfully requests that this Court issue a Writ of Mandamus ordering DEA to immediately remove Cannabis from Schedule 1 of the CSA and place it into Schedule 3, in order to protect the Health, Safety and Welfare of the Citizens of the United States.

QUESTIONS PRESENTED

1. Is the DEA required to remove Cannabis from Schedule 1 of the United States Controlled Substance Act, 21 U.S.C. 801 et seq; now that the United States has formally recognized that Cannabis has "accepted medical use" and voted to

remove Cannabis from the most restrictive status of the Single Convention Treaty? (Commission on Narcotic Drugs Reconvened sixty-third session)

2. Is the United States Drug Enforcement Administration (DEA) required to move Cannabis into Schedule 3 of the United States Controlled Substance Act (21 U.S.C. 801 et seq) now that FDA has acknowledged that Cannabis has "accepted medical use in the United States" and both FDA and HHS have recommended that DEA move Cannabis into Schedule 3 of the CSA? (Exhibit 1).

3. Has DEA failed in its duty to comply with International Law; by failing to perform its duties to remove Cannabis from Schedule 1 of the CSA now that Cannabis has been removed from the most restrictive status of the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session)

4. Has DEA failed in its duty to comply with United States Law by failing to move Cannabis onto schedule 3 of the CSA now that the FDA has formally recognized that Cannabis has "accepted medical use in the United States" and because both FDA and HHS have recommended that DEA remove Cannabis from schedule 1 of the CSA and place it in schedule 3? (Exhibit 1).

STATEMENT OF RELATED CASES

Petitioner is unaware of any previous cases challenging the Schedule 1 placement of Cannabis in Controlled Substance Act, 21 U.S.C. 801 et seq, following review by the US Food and Drug Administration (FDA) which found that Cannabis has "accepted medical use" and following a formal recommendation to DEA by the US Department of Health and Human Services (HHS) to place Cannabis into Schedule 3 of the CSA (Exhibit 1). However, Petitioner does have a rescheduling petition for Cannabis pending with the DEA that was filed December 8, 2020 (Exhibit 2) and Petitioner did file a previous case challenging unreasonable delays by the DEA to act on that rescheduling petition, which was dismissed for untimely filing (Krumm v DEA, US Court of Appeals for the District Of Columbia Circuit, No. 22-1326).

STATEMENT OF JURISDICTION

This Court has jurisdiction over this petition under 21 U.S.C. §877, as it stems from DEA's failure to remove Cannabis to Schedule 1 of the Controlled Substances Act 21 U.S.C. 801 et seq, in violation of its responsibility to comply with International Treaty obligations and the Laws of the the United States. The DEA has jurisdiction over this action under 21 U.S.C. § 811 and 21 C.F.R. §1308.43, as the claims set forth in the Petition arise under the Controlled Substances Act, 21 U.S.C. § 801 et seq.

FACTS NECESSARY TO UNDERSTAND PETITION

On December 2, 2020 the United States voted, along with the majority of other Countries in the United Nations, to accept the medical use of Cannabis, and remove it from the most restrictive category of the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session). In voting to support this measure, the United States noted that in recent years, well controlled clinical trials have identified legitimate medical use of cannabis preparations, stating that "the legitimate use of a Cannabis preparation has been established through scientific research, and Cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention" (Commission on Narcotic Drugs Reconvened sixty-third session). On December 8, 2020 I filed a new Rescheduling Petition because Cannabis had been recognized by the United States as having medical use under International Law (exhibit 2).

On September 23, 2022, the DEA responded to my inquiry on the Status of the Rescheduling Petition, claiming that "a prerequisite to removing a substance from scheduling under the CSA is for the Food and Drug Administration (FDA) to determine if a substance has a currently accepted medical use in treatment in the United States" (Exhibit 2). I attempted to appeal that decision but followed the wrong rule. Rather than following 21 U.S.C. § 877, I followed Federal Rules of Appellate Procedure Rule 4 (a) (1) (ii) and filed too late, resulting in the case being

dismissed for untimely filing (*Krumm v DEA, US Court of Appeals for the District Of Columbia Circuit, No. 22-1326*).

FDA has now completed that review and concluded that Cannabis has a currently accepted medical use in treatment in the United States; and on August 29, 2023, Rachel Levine (HHS Assistant Secretary for Health) provided a formal recommendation to Anne Milgram (Agency Administrator) at the United States Drug Enforcement Agency (DEA) to reclassify cannabis from a Schedule I drug to a Schedule III drug under the Federal CSA (Exhibit 1). DEA has testified in response to questioning at a congressional hearing in 2020 that it is bound by FDA's recommendations on scientific and medical matters (Exhibit 3). DEA has a legal duty to move Cannabis to Schedule 3 of the CSA.

Therefore, because the United States has officially accepted the medical use of Cannabis, under both International Law and the Laws of the United States, Cannabis can no longer legally remain in Schedule 1 of the CSA and must be moved to schedule 3. Sadly, the DEA has failed to fulfill its legal obligations, and patients in need of Medical Cannabis are still denied access to a life saving FDA approved medication due to the unreasonable, arbitrary and capricious actions of the DEA. Petitioner acts sua sponte in filing for Writ of Mandamus in order to

protect the Health, Safety and Welfare of American Citizens who require access to this life saving medication.

REASONS FOR GRANTING WRIT

1. Writ of Mandamus is necessary in order to protect the health, safety and welfare of American Citizens who are currently being harmed by DEA's failure to fulfill its duties under the CSA, 21 U.S.C. 801 et seq.

2. Writ of Mandamus is appropriate because DEA is violating both United States and International Law by keeping Cannabis in the most restrictive schedule of the CSA, 21 U.S.C. 801 et seq.

3. A writ of mandamus is warranted where "(1) no other adequate means exist to attain the relief [the party] desires, (2) the party's right to issuance of the writ is clear and indisputable, and (3) the writ is appropriate under the circumstances." *Hollingsworth v. Perry, 558 U.S. 183, 190 (2010) (quoting Cheney v. United States Dist. Ct., 542 U.S. 367, 380–81 (2004)*) (internal quotation marks and alterations omitted).

STATEMENT OF THE CASE AND ARGUMENT

Petitioner would like to remind the Court that he is not an attorney and respectfully requests a liberal interpretation of all pleadings under Haines v. Kerner, 404 U.S. 519 (1972).

On December 8, 2020 I filed a rescheduling petition requesting the removal of Cannabis From Schedule I of the CSA because the United States had officially recognized the medical use of Cannabis. Because I never received a response from the DEA, I re-filed the petition with the current administration on July 14, 2021. DEA acknowledged receipt of the petition on July 21, 2021 and stated "your petition is currently under review". On the 12'th day of October, 2022, DEA notified me that they had denied my request to remove Cannabis from Schedule 1 of the CSA and place it into schedule 2, claiming they must first defer to FDA for review to determine if Cannabis has "accepted medical use". (Exhibit 2).

On August 29, 2023, in accordance with the recommendation of FDA, the U.S. Department of Health and Human Services ("HHS") recommended to the DEA that Cannabis be removed from Schedule 1 of the CSA and placed into schedule 3 (Exhibit 1).

When transmitted, the evaluation and recommendations of HHS are binding on the DEA Administrator with respect to scientific and medical matters. See 21 U.S.C. 811(b). The Administrative Procedure Act, 5 U.S.C. 701 et seq. ("APA") requires agencies presented with such petitions to decide the petition "within a reasonable period of time." 5 U.S.C. 555(b). The DEA has now delayed complying with the recommendation of HHS for 5 months, jeopardizing the lives of countless American Citizens.

The DEA has previously noted that "As the Controlled Substances Act recognizes, the United States is a party to the Single Convention on Narcotic Drugs, 21 U.S.C. 801 (7). Parties to the Single Convention are obligated to maintain various control provisions related to the drugs covered by the treaty. Many of the provisions of the CSA were enacted by Congress for the specific purpose of U.S. compliance with the treaty. Among these is a scheduling provision, 21 U.S.C. 811 (d)(1). Section 811 (d)(1) provides that where a drug is subject to control under the Single Convention, the DEA administrator (by delegation from the Attorney General) must "issue an order controlling such drug under the schedule he deems most appropriate to carry out such treaty obligations, without regard to the findings required by [21 U.S.C. 811 (a) or 812 (b)] and without regard to the procedures prescribed by [21 U.S.C 811 (a) and (b)]……..Thus, since the only determinative issue in evaluating the present

scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that final determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings" Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016, Page 53767-53768.

The CSA grants the Attorney General the authority to administer its provisions. See, e.g., 21 U.S.C. § 811. The Attorney General has delegated that authority to the DEA Administrator. See 28 C.F.R. § 0.100(b). In accordance with the laws of the United States, DEA must remove Cannabis from Schedule 1 of the CSA if it has any accepted medical use in the United States, which it now has. FDA has concluded that Cannabis should be removed from schedule 1 of the CSA and placed into Schedule 3, and HHS has forwarded that recommendation to DEA. DEA has failed to comply with the Law by continuing Schedule 1 placement in the CSA after the United States has officially recognized that Cannabis has medical use, and DEA now defies it's legal obligation to follow the recommendation of HHS to move Cannabis to Schedule 3. 21 U.S.C. 811(b).

Under the CSA, the Attorney General has the authority to reschedule a drug if he finds that it does not meet the criteria for the schedule to which it has been

assigned. 21 U.S.C. 811(a); see also *Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133 (D.C. Cir.1994); Kuromiya v. United States, 37 F.Supp.2d 717,722 (E.D. Pa.1999)* ("There are provisions by which the Attorney General may change the designation of a particular controlled substance, either to move it up, down, or off of the schedules.") (citing 21 U.S.C. 811). The Attorney General has delegated this authority to the Administrator of the DEA ("Administrator"). See *Alliance for Cannabis Therapeutics, 15 F.3d at 1133*.

Neither the DEA nor the Attorney General have the authority to regulate medical practice in general. However, they have been mandated to administer the CSA. They can not legally ignore recommendations from HHS and FDA, anymore than they they can legally ignore International Treaty obligations approved by the United States. The DEA is violating their mandated duties under the CSA. These duties are owed to the American People for their health, safety and welfare. Legal authority granted under the CSA pertains only to the prohibition of prescription writing authority in order to promote drug abuse, not to deny an entire class of medications to the American People.

The facts of this case prove that Cannabis does not meet the legal definition of a Schedule 1 drug, because Cannabis has “accepted medical use in the United States”. Petitioner argues that because Cannabis now has “accepted medical use”

not only "in the United States", but "by the United States"; and because after review by FDA, HHS has recommended that DEA remove Cannabis from Schedule 1 of the CSA and place it in Schedule 3 (Exhibit 1) ; and because in accordance with not only the laws of the United States, but also International Law, Cannabis can not remain in Schedule 1 of the CSA. Therefore the DEA must immediately remove Cannabis from Schedule 1 of the CSA and place it into Schedule 3.

On December 17, 2009, I, filed a previous rescheduling petition requesting that Cannabis be removed from control under the CSA and that control of Cannabis be placed under control of the States. After nearly 7 years of delay, on August 12, 2016, the DEA settled that petition (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844).

> "Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule 1.....since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing

> on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence." (Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016/Proposed Rules 53767-53768)

As a result of that petition, the FDA admitted that "notably, it is beyond the scope of this review to determine whether these data demonstrate that marijuana has a currently accepted medical use in the United States" (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016, 53792). Therefore, review by FDA has previously proven to be a futile endeavor given the restrictions the DEA has created to restrict the medical research DEA requires of an FDA review. However, now that FDA has recognized that Cannabis has "accepted medical use in the Unites States: the DEA must remove Cannabis from Schedule 1 of the CSA and place it into schedule 3 per the recommendations of both FDA and HHS. 21 U.S.C. 811(b).

DEA has previously acknowledged that it need not consider either the safety, efficacy or abuse potential of Cannabis in maintaining its placement in Schedule 1 of the CSA. DEA claims they need not defer to States recognition that Cannabis

has medical value. They claim that they need not defer to the expert opinions of the National Academy of Sciences or the National Institutes of Health. When DEA has been forced to request FDA review of Medical Cannabis, they have set unreasonable, arbitrary and capricious standards of review in order to tamper with FDA testimony to ensure DEA's predetermined outcome. They have prohibited any testimony from experts in the field of Medical Cannabis. DEA has refused to hear from the thousands of Medical Providers who use Cannabis to help save the lives of their patients. DEA has refused to hear the testimony of any of the millions of Americans who use Cannabis to help alleviate their suffering. Now, the DEA must follow the law and reschedule Cannabis in compliance with HHS recommendation, 21 U.S.C. 811(b).

In his May 20, 2015 letter to Karen DeSalvo (Acting Assistant Secretary for Health), Stephen Ostroff (Acting Commissioner of Food and Drugs) discusses 5 distinct areas of the federal regulatory system that have blocked efficient and scientifically rigorous research with marijuana and its constituents. (Exhibit 4)

1. DEA has refused registration of additional cultivators of Cannabis for research.

2. PHS review is required for Cannabis research but not for other Schedule 1 substances.

3. DEA review of all research with Schedule 1 substances and registration requirements restrict research.

4. Certain Cannabis constituents have never been properly evaluated by HHS to determine if they should remain in Schedule 1.

5. DOJ/DEA and HHS need to reassess the legal and regulatory framework as applied to 1) assessment of abuse liability and 2) the assessment of currently accepted medical use for drugs that have not been approved by the FDA.

Karen DeSalvo further substantiated the futility of the administrative process in her June 3, 2015 letter to Chuck Rosenberg, when she stated "Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana derived drugs." (Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016/Proposed Rules, 53768)

DEA has refused to acknowledge that Cannabis has "accepted medical use in the United States" and as a means of ensuring this goal they have actively engaged in witness tampering by manipulating the FDA in order to hide the scientific evidence supporting medical use of Cannabis. The DEA has simply ignored "medical science" while manipulating the "law" in order to maintain the total prohibition of Cannabis.

Although Cannabis has been accepted as having medical use by 47 States "in the United States", and 24 States have legalized recreational use due to the safety of Cannabis compared to other recreational substances (ie: alcohol and tobacco), the Courts have thus far deferred to the DEA and considered these facts as irrelevant. The courts have supported DEA's long held contentions that because the United States is a signatory to the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session), we were prohibited from moving Cannabis away from the most restrictive schedules of the Controlled Substances Act (21 U.S.C. § 811); and because there had not been phase 3 clinical research trials conducted on Cannabis, the FDA could not claim Cannabis had "accepted medical use" in the United States.

However, on December 2, 2020 the United States voted, along with the majority of other Countries in the United Nations, to accept the medical use of

Cannabis, and remove it from the most restrictive category of the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session). In voting to support this measure, the United States noted that in recent years, well controlled clinical trials have identified legitimate medical use of cannabis preparations, stating that "the legitimate use of a Cannabis preparation has been established through scientific research, and Cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention" (Commission on Narcotic Drugs Reconvened sixty-third session)

Previously, after nearly 7 years of delay, DEA responded to a rescheduling petition I filed December 17, 2009, and on August 12, 2016, the DEA settled that petition (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844). The DEA had requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS) after which DEA concluded that there is no substantial evidence that marijuana should be removed from schedule I because:

(1) Marijuana has a high potential for abuse.

(2) Marijuana has no currently accepted medical use in treatment in the United States.

(3) Marijuana lacks accepted safety for use under medical supervision.

DEA went on to note,

> "Although the HHS evaluation and all other relevant data lead to the conclusion that marijuana must remain in schedule I, it should also be noted that, in view of United States obligations under international drug control treaties, marijuana cannot be placed in a schedule less restrictive than schedule II."

The DEA Administrator argued that he was obligated under section 811(d) to control marijuana in the schedule that he deems most appropriate to carry out the U.S. obligations under the Single Convention.

> "Because schedules I and II are the only possible schedules in which marijuana may be placed, for purposes of evaluating this scheduling petition, it is essential to understand the differences between the criteria for placement of a substance in schedule I and those for placement in schedule II. These criteria are set forth in 21 U.S.C. 812(b)(1) and (b)(2), respectively. As indicated therein, substances in both schedule I and schedule II share the characteristic of "a high potential for abuse." Where the distinction lies is that schedule I drugs have "no currently accepted medical use in treatment in the United States" and "a lack of accepted safety for use of the drug . . . under medical supervision," while schedule II drugs do have "a currently accepted medical use in treatment in the United States." "

> "Accordingly, in view of section 811(d)(1), this scheduling petition turns on whether marijuana has a currently accepted medical use in treatment in the United States. If it does not, DEA must, pursuant to section 811(d), deny the petition and keep marijuana in schedule 1.....since the only determinative issue in evaluating the present scheduling petition is whether marijuana has a currently accepted medical use in treatment in the United States, DEA need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination, and DEA likewise need not follow the procedures prescribed by sections 811(a) and (b) with respect to such irrelevant findings. Specifically, DEA need not evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence." (Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016/Proposed Rules 53767-53768)

As of December 2, 2020, the "United States" officially recognized the medical value of Cannabis by declaring that "the legitimate use of a Cannabis preparation has been established through scientific research and declared that Cannabis no longer meets the criterion for placement in Schedule IV of the Single Convention" (Commission on Narcotic Drugs Reconvened sixty-third session),. Statements following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, id at p12). Therefore, Cannabis no

longer meets the legal definition of a Schedule 1 drug because it now has "accepted medical use in the United States".

The DEA has determined that the CSA does not give the DEA administrator the authority to determine whether or not a drug should be used as medicine. DEA Docket No. 86-22, 57 Fed. Reg. 10,499, 10,506 (March 26, 1992): Clearly, the CSA does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he/she is limited to determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

The CSA gives the DEA administrator the "limited" authority to determine accepted medical use of new drugs that have not been accepted by state lawmakers or a majority of physicians. *Gonzales v. Oregon, 546 U.S. 243, 258 (2006)*, discusses the limited authority of the DEA administrator:

> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law. *Gonzales v. Oregon, 546 U.S. 243, 259 (2006)*

> The CSA gives the Attorney General limited powers, to be exercised in specific ways. His rulemaking authority under the CSA is described in two provisions: (1) "The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals," 21 U.S.C. § 821 (2000 ed. and Supp. V); and (2) "The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter," 21 U.S.C. § 871(b). As is evident from these sections, Congress did not delegate to the Attorney General authority to carry out or effect all provisions of the CSA. Rather, he can promulgate rules relating only to "registration" and "control," and "for the efficient execution of his functions" under the statute. *Gonzales v. Oregon, 546 U.S. 243, 262 (2006)*

By DEA's own admission in 2016, moving Cannabis from Schedule 1 to Schedule 2 of the Controlled Substances Act 21 U.S.C. 801 et seq, is a strictly legal matter that does not require review by the FDA, Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844. On December 2, 2020 the United States officially recognized the "accepted medical use of Cannabis", and voted to remove Cannabis from the most restrictive status of the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session). On August 29, 2023 HHS officially notified DEA that Cannabis should be moved to Schedule 3 of the CSA (Exhibit 1) . Because the United States has accepted the medical use of Cannabis; and because FDA has concluded that Cannabis has "accepted medical use"; and because HHS has recommended that

DEA move Cannabis to schedule 3 of the CSA; Cannabis can no longer remain in Schedule 1 of the CSA and must be moved to schedule 3.

CONCLUSION

Because the DEA has never had "medical science" on their side, they have instead used delay tactics and they have argued "legal" issues based on 2 main assumptions in order to keep Cannabis in Schedule 1 of the CSA:

1. Because Cannabis is in the most restrictive status of the Single Convention Treaty (Commission on Narcotic Drugs Reconvened sixty-third session) it must remain in the most restrictive status of the US Controlled Substances Act, 21 U.S.C. 801 et seq. However, Cannabis has now been removed from the most restrictive status of the Single Convention Treaty and the United States formally acknowledged that Cannabis has "accepted medical use".

2. Because the FDA had not been able to review phase 3 clinical trials, as required by DEA in order to determine if Cannabis had "accepted medical use in the United States", Cannabis had to remain in Schedule 1 pending the outcome of research the DEA had banned. Now, based on both the available science and the law, the FDA and HHS have finally acknowledged that Cannabis has accepted medical use in the United States. In accordance with both United States and

International Law, Cannabis must be removed from Schedule 1 of the CSA and placed into Schedule 3.

Petitioner has exhausted all other administrative remedies available to him. Petitioner filed a rescheduling petition for Cannabis on December 8, 2020. That Rescheduling Petition is still pending with the DEA and they previously refused to act on that rescheduling request by claiming that they must first obtain a review from the FDA to determine if Cannabis has "accepted medical use in the United States" (Exhibit 2). Now that FDA has conducted a review of Cannabis and determined that Cannabis does have "accepted medical use", and HHS has made a formal recommendation to DEA that Cannabis must be placed in Schedule 3 of the CSA, DEA is legally required to follow the recommendation of HHS. However, DEA has failed to fulfill its legal duty to properly administer the CSA and in doing so, the DEA is endangering the Citizens of the United States.

There is no other plain and adequate remedy at law for Petitioner. In order for another legal option to qualify as an "adequate remedy in the ordinary course of law," it must be "complete, beneficial, and speedy." *State ex rel. Chagrin Falls v. Geauga Cty. Bd. of Commrs., 96 Ohio St.3d 400, 2002-Ohio-4906, ¶6, 775 N.E.2d 512.* The indisputable evidence indicates that the Petitioner has proven his case against the DEA and this Court must issue a Writ of Mandamus in order to protect

the Health, Safety and Welfare of the American People. Because Petitioner has presented indisputable evidence proving that cannabis has "accepted medical use in the United States; and because FDA and HHS have recommended that Cannabis be placed in Schedule 3 of the CSA; and because DEA has waited 5 months without acting on the recommendation of FDA and HHS; and because DEA has history of unreasonable delays which have lasted many years before they have acted on previous rescheduling petitions; Therefore, Cannabis must be immediately removed from Schedule 1 of the CSA and moved to Schedule 3.

Respectfully Submitted,

February 2, 2024

/s/ Krumm CNP

Rev. Bryan A. Krumm, CNP

2/2/24

APPENDIX

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Office of the Assistant Secretary for Health
Washington, D.C. 20201

August 29, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Anne Milgram:

Pursuant to the Controlled Substances Act (CSA), 21 U.S.C. 811(b) and (c), I, the Assistant Secretary for Health, am recommending that marijuana, referring to botanical cannabis (*Cannabis sativa L.*) that is within the definition "marihuana" or "marijuana" in the CSA, be controlled in Schedule III of the CSA.

Upon consideration of the eight factors determinative of control of a substance under 21 U.S.C. 811(c), the Food and Drug Administration (FDA) recommends that marijuana be placed in Schedule III of the CSA. The National Institute on Drug Abuse has reviewed the enclosed documents (which were prepared by FDA's Controlled Substance Staff and are the basis for FDA's recommendation) and concurs with FDA's recommendation. Marijuana meets the findings for control in Schedule III set forth in 21 U.S.C. 812(b)(3).

Based on my review of the evidence and FDA's recommendation, it is my recommendation as the Assistant Secretary for Health that marijuana should be placed in Schedule III of the CSA.

Should you have any questions regarding this recommendation, please contact FDA's Center for Drug Evaluation and Research, Office of Executive Programs (cderexsec@cder.fda.gov), at (301) 796-3200.

Sincerely,

Rachel L. Levine, M.D.
ADM, USPHS
Assistant Secretary for Health

Enclosure

Exhibit 2

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator *Springfield, VA 22152*

September 23, 2022

Rev. Bryan A. Krumm
733 Monroe NE
Albuquerque, New Mexico 87110

Dear Rev. Krumm:

This letter responds to your letters dated December 8, 2020, and July 14, 2021, requesting that the Drug Enforcement Administration (DEA) initiate rulemaking proceedings pursuant to the Controlled Substances Act (CSA) to "remove marijuana from scheduling under the CSA."

A prerequisite to removing a substance from scheduling under the CSA is for the Food and Drug Administration (FDA) to determine that a substance has a currently accepted medical use in treatment in the United States. *See, e.g., Americans for Safe Access v. DEA,* 706 F.3d 438 (D.C. Cir. 2013) (describing five-part test for demonstrating that); *see also* 21 U.S.C. § 812(b)(1). To date, the FDA has not articulated any accepted medical use for marijuana in treatment. Accordingly, the CSA requires that marijuana remain scheduled.

Sincerely,

Kristi O'Malley Digitally signed by KRISTI O'MALLEY Date: 2022.09.23 14:59:03 -04'00'

Kristi O'Malley
Assistant Administrator
Diversion Control Division

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INSIGHT

Department of Health and Human Services Recommendation to Reschedule Marijuana: Implications for Federal Policy

September 13, 2023

On August 29, 2023, the Department of Health and Human Services (HHS) recommended to the Drug Enforcement Administration (DEA) that marijuana be rescheduled from Schedule I to Schedule III under the Controlled Substances Act (CSA). This recommendation is based on the Food and Drug Administration's (FDA's) review of marijuana (as requested by President Biden in 2022) and related findings that are not currently available to the public. DEA has testified in response to questioning at a congressional hearing in 2020 that it is bound by FDA's recommendations on scientific and medical matters, and if past is prologue it could be likely that DEA will reschedule marijuana according to HHS's recommendation.

If marijuana is rescheduled to Schedule III, it would have broad implications for federal policy. Also, this move would have significant implications for state medical marijuana programs and users of medical marijuana, but fewer implications for state recreational marijuana programs and those who use marijuana recreationally. This Insight discusses both the potential rescheduling and select policy implications.

Rescheduling Marijuana to Schedule III

The CSA classifies various substances in one of five schedules based on their medical use, potential for abuse, and safety or risk of dependence. The five schedules are progressively ordered, with substances regarded as the least dangerous and addictive controlled in Schedule V and those considered the most dangerous and addictive controlled in Schedule I.

Marijuana as a Schedule I Controlled Substance

As described in the CSA, Schedule I substances have "a high potential for abuse" with "no currently accepted medical use in treatment in the United States" and cannot safely be dispensed under a prescription. As a Schedule I controlled substance, the CSA prohibits the manufacture, distribution, dispensation, and possession of marijuana except for federal government-approved research studies. The

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available supply of marijuana for research is subject to production quota limitations determined by DEA based on an annual assessment of need.

In 2016, FDA and DEA concluded that marijuana should remain in Schedule I.

Marijuana as a Schedule III Controlled Substance

The CSA defines a Schedule III controlled substance as having "a potential for abuse less than the drugs or other substances in schedules I and II" and "a currently accepted medical use in treatment in the United States." It also states that "[a]buse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence." A move to any lower schedule would allow for medical use of marijuana while maintaining federal criminal control over the substance pursuant to the CSA.

According to a recent report, in 2023 FDA concluded that marijuana should move to Schedule III (for more information regarding FDA's recommendation, see the article in Bloomberg News (link requires paid subscription).

Next Steps in Rescheduling Process

DEA is to conduct its own review of marijuana (a test it established in 1992 that examines the drug's chemistry, safety, and scientific evidence). If DEA opts to move forward with rescheduling marijuana to Schedule III, it would do so through the rulemaking process. CRS is unaware of any instance where DEA has rejected an FDA recommendation to reschedule. As a comparative example, in September 1998 FDA recommended to DEA that Marinol be rescheduled to Schedule III, and in July 1999 DEA rescheduled Marinol to Schedule III.

Potential Implications of a Move to Schedule III

A change to Schedule III would mark a major shift in the federal government's policy on marijuana. For over 50 years, marijuana has remained on Schedule I. Violations of CSA law involving marijuana have resulted in criminal sanctions for thousands of offenders. There are many federal policy implications of such a shift, particularly because most states now have comprehensive medical marijuana programs. The following are selected federal policy implications if marijuana were to be rescheduled:

- Those who manufacture, distribute, dispense, and possess medical marijuana may now be able to do so lawfully (under the CSA).
- States' medical marijuana programs may now be able to comply with the CSA, and will still be subject to CSA/DEA criminal and regulatory control, federal public health laws such as the Federal Food, Drug, and Cosmetic Act, and agricultural laws such as the Agricultural Marketing Act of 1946.
- The scope of and demand for FDA oversight for medical marijuana and related products may grow considerably. In the short term, FDA may need to generate or update a substantial amount of technical information to clarify its regulatory approach to marijuana for relevant stakeholders. Given that marijuana is a complex substance containing various pharmaceutical components and is available to consumers in numerous formats, FDA may also need to consider long-term resource allocation to ensure that marijuana products consistently meet applicable regulatory standards.
- Marijuana producers and retailers would be able to deduct the costs of selling their product (e.g., payroll, rent, advertising) for the purposes of federal income tax filings.
- Those who use medical marijuana lawfully may now be eligible to (1) access public housing, (2) obtain immigrant and nonimmigrant visas, and (3)

- purchase and possess firearms. Those who use marijuana recreationally would still face restrictions in these areas.
- Researchers would face less strict regulatory controls in researching marijuana as a Schedule III controlled substance, which may in turn promote further research on marijuana.
- DEA would no longer set production quota limitations for marijuana.
- Those who use medical marijuana lawfully may contend with fewer barriers to federal employment and eligibility to serve in the military.

Considerations for Congress

Congress may choose to address any number of issues related to the potential rescheduling of marijuana. First, Congress could take legislative action to keep marijuana on or remove marijuana from Schedule I. If Congress removed marijuana from Schedule I, it might (1) place marijuana on one of the other schedules of controlled substances, (2) create another schedule or separate classification for marijuana under the CSA, or (3) remove marijuana as a controlled substance altogether. If the administrative scheduling process moves forward, Congress may consider whether to devote additional resources to FDA and the U.S. Department of Agriculture (USDA) to ensure the safety and quality of the many different products already available in many state markets.

Author Information

Lisa N. Sacco
Analyst in Illicit Drugs and Crime Policy

Hassan Z. Sheikh
Analyst in Health Policy

Disclaimer

Exhibit 4

FDA RECOMMENDATIONS ON THE SCHEDULING OF MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT (MAY 20, 2015)

DEPARTMENT OF
HEALTH & HUMAN SERVICES
Food and Drug Administration
Silver Spring, MD 20993

TO: Acting Assistant Secretary for Health

FROM: Acting Commissioner of Food and Drugs

SUBJECT: Recommendation to Maintain Marijuana in Schedule I of the Controlled Substances Act

ACTION

Attached are the Food and Drug Administration's (FDA) scientific and medical evaluations and recommendations on the scheduling of marijuana under the Controlled Substances Act (CSA), prepared in response to two petitions submitted to the Drug Enforcement Administration (DEA). Each contains the same recommendation to maintain marijuana in Schedule 1 of the CSA.

On December 17, 2009, Mr. Bryan Krumm submitted a petition to DEA, requesting that proceedings be initiated to repeal the rules and regulations that place marijuana in Schedule I of the CSA. Mr. Krumm contends that marijuana has an accepted medical use in the United States, has proven safety and efficacy, is safe for use under medical supervision,

and does not have the abuse potential for placement in Schedule I of the CSA. In 2011, the DEA Administrator requested that the U.S. Department of Health and Human Services (HHS) provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811(b).

On November 30, 2011, Governors Lincoln D. Chafee of Rhode Island and Christine a Gregoire of Washington also submitted a petition to DEA requesting that proceedings be initiated to repeal the rules and regulations that place marijuana in Schedule I-of the CSA. Specifically, they requested the reclassification of marijuana from Schedule Ito Schedule II of the CSA. The petition contends that marijuana has an accepted medical use in the United States, is safe for use under medical supervision, and has a relatively low abuse potential compared to Schedule II substances in the CSA. In June 2013, the DEA Administrator requested that HHS provide a scientific and medical evaluation of the available information and a scheduling recommendation for marijuana, in accordance with the provisions of 21 U.S.C. 811.(b).

FDA and the National Institute on Drug Abuse (NIDA) have carefully considered the available scientific and medical evidence for marijuana presented under the eight factors determinative of control under the CSA, 21 U.S.C. 811(c). Pursuant to the requests in the petitions, FDA broadly evaluated marijuana, and did not focus its evaluation on particular strains of marijuana or components or derivatives of marijuana. In the development of this scientific and medical evaluation for the purpose of scheduling, we reviewed and analyzed considerable data related to marijuana's

abuse potential. The data include the pharmacology of marijuana and its components, the prevalence and frequency of marijuana use, the widespread availability of marijuana for nonmedical use, the ease of obtaining or manufacturing marijuana, and at-risk populations including children and adolescents. In addition, we reviewed the scientific literature on whether marijuana has a currently accepted medical use, and we analyzed studies evaluating medical treatment with marijuana. Our review of the published clinical studies is also attached.

DISCUSSION

FDA recommends that marijuana be maintained in Schedule I of the CSA. NIDA concurs with this recommendation.

Since our 2006 scientific and medical evaluation and scheduling recommendation responding to a previous DEA petition, research with marijuana has progressed. However, more research should be conducted into marijuana's effects, including potential medical uses for marijuana and its derivatives. Our review of the available evidence and the published clinical studies indicated some study design challenges that need to be addressed to ensure that future studies generate scientific data that can be used to determine whether marijuana has an accepted medical use. For example, we recommend that studies need to focus on consistent administration and reproducible dosing of marijuana, potentially through the use of administration methods other than smoking. A summary of our review of the published literature on the clinical uses of marijuana, including our recom-

mendations for future research, is attached to this document.

FDA and NIDA also believe that work continues to be needed to ensure support by the federal government for the efficient conduct of clinical research using marijuana and its derivatives. Concerns have been raised about whether the existing federal regulatory system is flexible enough to respond to increased interest in research into the potential therapeutic uses of marijuana and marijuana-derived drugs. For instance, several states have moved to facilitate marijuana research and have directly questioned whether, for instance, research marijuana may be procured from sources other than the existing single NIDA contractor.[1] The leaders of the Senate Caucus on International Narcotics Control have asserted that DEA registration "present[s] significant practical problems for researchers."[2] In addition, they stated that "it is unclear why marijuana is the only Schedule I substance for which [Public Health Service (PHS)] review and approval is required."[3]

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[1] A Colorado statute directs the state attorney general to "seek authority from the federal government to permit Colorado institutions of higher education to contract with [NIDA] to cultivate marijuana and its component parts for use" in state-funded marijuana research (C.R.S.A. § 25-1.5-106.5).

[2] Letter from Sen. Dianne Feinstein and Sen. Charles Grassley to Att'y Gen. Eric Holder, and Sec'y Sylvia M. Burwell (Oct. 20, 2014).

[3] *Id.*

Discrete Aspects of Federal Marijuana Oversight for Potential Review

Upon examining the current federal regulatory system, FDA and NIDA note the following discrete aspects of marijuana oversight that might be reviewed by HHS or Dal/DEA, as appropriate, with the goal of promoting efficient and scientifically rigorous research with marijuana and its constituents. Interagency coordination may be necessary to ensure that any revisions to federal marijuana regulations result in an appropriate level of oversight and are consistent with treaty obligations.

1. DEA registration of additional cultivators of marijuana for research

There is currently only one cultivator of marijuana that is registered with DEA for that purpose. DEA may wish to review whether, consistent with statutory requirements and any applicable treaty obligations, it may register additional cultivators of marijuana. •

2. PHS review of marijuana research protocols

PHS review of research protocols is not required in order to conduct research of other substances, including research of other Schedule I substances. Many aspects of PHS review arguably duplicate FDA's review of investigational new drug (IND) applications. HHS may wish to consider whether the PHS review process is unnecessary and could be

discontinued.[4]

3. Registration requirements for researchers of marijuana-derived drugs

Researchers of Schedule I drugs, including marijuana and marijuana-derived drugs, must submit research protocols to be reviewed by DEA in order to become registered to conduct such research. DEA may wish to consider whether it may invoke its statutory waiver authority, under 21 USC § 822(d), to waive the registration requirement for certain researchers of marijuana or marijuana-derived drug products.[5] For instance, DEA may wish to consider whether such a waiver might be appropriate if it were subject to certain conditions, such as compliance with FDA requirements (*e.g.*, an effective IND), or by limiting the waiver's applicability to research with certain marijuana-derived constituents (*e.g.*, cannabidiol (CBD)) that may have reduced abuse potential. (An HHS analysis of the abuse potential of these constituents, as described in #4 below, may be useful to inform this decision.)

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[4] In 2014, FDA and NIDA separately endorsed dissolving the PHS committee and presented that recommendation to the Office of the Assistant Secretary for Health.

[5] 21 USC 822(d) provides: "The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety."

4. Evaluation of the abuse potential of certain marijuana constituents

Similar to the current "8-factor analysis" conducted for marijuana, HHS may wish to consider whether a similar evaluation conducted for CBD or other constituents of marijuana could help inform decision-making about those constituents. For example, depending on the outcome, such an evaluation could help provide a basis for a recommendation to remove those constituents from Schedule I or could support reduced restrictions on research of the constituents, such as the limited DEA registration waiver for researchers discussed in #3 above. Removal of certain marijuana constituents from Schedule I may make it easier to conduct rigorous scientific studies of those constituents to support submission of a new drug application to FDA. We note that the leaders of the Senate Caucus on International Narcotics Control have recently requested that HHS and DOJ evaluate the appropriate schedule of CBD.[6] In order to meet this request, a study of the human abuse potential of CBD would likely be needed, because sufficient information in this area is not yet available.

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[6] On May 13, 2013, the Caucus leaders requested that "HHS, in concert with DOJ, immediately evaluate the factors determinative of control or removal from [CSA] schedules for CBD, and make a scheduling recommendation for it. . . ." Letter from Sen. Dianne Feinstein and Sen. Charles Grassley to Sec'y Sylvia M. Burwell (May 13, 2015).

5. Reassessment of the Legal and Regulatory Framework for Marijuana Rescheduling

> NIDA points out that another potential area for review is the legal and regulatory framework applied to (1) the assessment of abuse liability for substances in Schedule I (including the comparative standard used to assess the relative risk of abuse) and (2) the assessment of currently accepted medical use for drugs that have not been approved by FDA. While potentially daunting (depending on its scope and nature), re-evaluation of the legal and regulatory framework by DOJ/DEA and HHS could identify ways to encourage appropriate scientific research into the potential therapeutic uses of marijuana and its constituents.

In summary, both FDA and NIDA believe that it is important to continue to review the federal support for research into the potential therapeutic uses of marijuana, and that there is a potential public health value in exploring options like those outlined above with a goal of promoting efficient and scientifically rigorous research.

CONCLUSION

FDA and NIDA have evaluated the medical and scientific information available on marijuana in accordance with 21 U.S.C. § 811 (b)-(c) and recommend that the available data warrant that marijuana be maintained in Schedule I of the CSA. We recommend that these findings be conveyed to the DEA Administrator.

We have prepared, for your signature, a letter of transmittal to the DEA Administrator, which includes the necessary scientific and medical evaluation and scheduling recommendation documents in response to the two petitions/requests from DEA recommending the maintaining of marijuana in Schedule I of the CSA. We have also attached our review of the published clinical studies.

/s/ Stephen M. Ostroff
Stephen M. Ostroff, M.D.

Attachments

DECISION

Approved _____ Disapproved _____ Date 6/3/15

CERTIFICATE OF SERVICE

I, Rev. Bryan A. Krumm, CNP, Petitioner

hereby certify that on February 2, 2024

I served a copy of the foregoing Petition for Writ of Mandamus

to Anne Milgram, Director,
Drug Enforcement Administration,
8701 Morrissette Drive
Springfield, VA 22152

and Matthew M. Graves, US Attorney for the District of Columbia United States
US Attorney's Office
601 D Street, NW
Washington, DC 20579

By certified mail

/s/ Bryan A. Krumm CNP

Signature

2/2/24

Date

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Receipt Date: Feb 6, 2024 1:13PM

BRYAN KRUMM
PO BOX 18044
ALBUQUERQUE, NEW MEXICO 87185-0044

Rcpt. No: 2891 Trans. Date: Feb 6, 2024 1:13PM Cashier ID: #JR

CD	Purpose	Case/Party/Defendant	Qty	Price	Amt
203A	Docketing Fee		1	600.00	600.00

CD	Tender			Amt
CH	Check	#0099325932	02/1/2024	$600.00

Total Due Prior to Payment:	$600.00
Total Tendered:	$600.00
Total Cash Received:	$0.00
Cash Change Amount:	$0.00

Comments: PETITION FOR WRIT OF MANDAMUS

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