Corrected copy - with signature

NO. 22-1326



**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**

**January 13, 2023**

## STATEMENT OF ISSUES TO BE RAISED

1. Did the DEA err when claiming an FDA review is required to determine if Cannabis has accepted medical use in the United States now the The United States has accepted the medical use of Cannabis under International Law and recommended its removal from the most restrictive status of the Single Convention Treaty?

2. Can the DEA continue to leave Cannabis in Schedule 1 of the Controlled Substances Act, 21 U.S.C. 801 et. seq. Now that it has accepted medical use not only "in the United States", but "by the United States"?

3. Does the refusal of the DEA to act on Rev. Krumm's Rescheduling Petition and remove Cannabis from Schedule 1 of the Controlled Substances Act constitute a dereliction of duty by the DEA that is causing immediate harm to American Citizens?

## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to DC Circuit Rule 28(a)(1), petitioner certifies as follows:

### PARTIES TO THE PROCEEDING

*Petitioner*

Rev. Bryan A. Krumm, CNP

*Respondent*

United States Drug Enforcement Administration

### RULINGS

The ruling under review is the DEA determination that FDA review is still required to determine if Cannabis has accepted medical use in the United States even though the United States has officially accepted the medical use of Cannabis under International Law.

### RELATED CASES

This case has not previously been before this or any other court. Krumm is not aware of any related cases within the meaning of D.C. Circuit Rule 28(a)(1)(C).

# TABLE OF CONTENTS

# UNITED STATES COURT OF APPEALS
# DISTRICT OF COLUMBIA CIRCUIT

333 Constitution Avenue, NW
Washington, DC 20001-2866
Phone: 202-216-7000 | Facsimile: 202-219-8530

## AGENCY DOCKETING STATEMENT

*Administrative Agency Review Proceedings (To be completed by appellant/petitioner)*

1. CASE NO. 22-1326 2. DATE DOCKETED: 12/16/22
3. CASE NAME (lead parties only) Bryan Krumm, CNP v. Drug Enforcement Administration
4. TYPE OF CASE: ☐ Review ☒ Appeal ☐ Enforcement ☐ Complaint ☐ Tax Court
5. IS THIS CASE REQUIRED BY STATUTE TO BE EXPEDITED? ○ Yes ● No
   If YES, cite statute
6. CASE INFORMATION:
   a. Identify agency whose order is to be reviewed: Drug Enforcement Administration
   b. Give agency docket or order number(s): Letter from DEA
   c. Give date(s) of order(s): 9/23/22
   d. Has a request for rehearing or reconsideration been filed at the agency? ○ Yes ● No
      If so, when was it filed? By whom?
      Has the agency acted? ○ Yes ○ No If so, when? N/A
   e. Identify the basis of appellant's/petitioner's claim of standing. See D.C. Cir. Rule 15(c)(2):
      Petitioner has suffered irreparable harm due to schedule 1 status of Cannabis; he has suffered physically because ~~of~~ ovs~~
   f. Are any other cases involving the same underlying agency order pending in this Court or any other?
      ○ Yes ● No If YES, identify case name(s), docket number(s), and court(s)
   g. Are any other cases, to counsel's knowledge, pending before the agency, this Court, another Circuit Court, or the Supreme Court which involve *substantially the same issues* as the instant case presents?
      ○ Yes ● No If YES, give case name(s) and number(s) of these cases and identify court/agency:
   h. Have the parties attempted to resolve the issues in this case through arbitration, mediation, or any other alternative for dispute resolution? ● Yes ○ No If YES, provide program name and participation dates.
      I filed a rescheduling petition on 12/8/20 after the United States recognized the medical use of Cannabis & it was removed from the most restrictive status of the Singleton

Signature [signature] CNP Date 1/19/23

Name of Counsel for Appellant/Petitioner Bryan Krumm, Pro Se

Address 733 Monroe NE, Albuquerque NM 87110

E-Mail reeferdoc@hotmail.com Phone (505) 414-8120 Fax (___) ___

**ATTACH A CERTIFICATE OF SERVICE**

**Note:** If counsel for any other party believes that the information submitted is inaccurate or incomplete, counsel may so advise the Clerk within 7 calendar days by letter, with copies to all other parties, specifically referring to the challenged statement.

has been forced to use dangerous drugs like Tylenol + Ibuprofen for pain now has kidney damage. He has been harmed ~~the~~ psychologically by being denied safe/effective medication for his PTSD + by witnessing the suicides of friends and co-workers who may have survived had they had access to medical cannabis. In my clinical practice has proven to be the most effective medication for treating PTSD + decreasing suicidal thinking in my patients + they are denied the ability to travel with their medication + risk job loss. I witness daily the harm caused to society by the Schedule 1 placement of Cannabis.

V

## UNDERLYING DECISION FROM WHICH PETITION ARISES

This petition arises from a letter from the United States Drug Enforcement Administration dated September 23, 2022 in response to a rescheduling petition filed by petitioner December 8, 2020 requesting immediate removal of cannabis from schedule 1 to schedule 2 of the US Controlled Substances Act until a public review of Cannabis can be conducted by the FDA to determine where Cannabis would be most appropriately placed or if it should be exempted from control under the CSA like tobacco and alcohol. DEA has concluded that Cannabis must remain in Schedule 1 of the CSA until FDA recognizes its medical use even though the United States has now accepted the medical use of Cannabis under International Law and recommended its removal from the most restrictive status of the Single Convention Treaty.

## STATEMENT OF INTENT TO UTILIZE DEFERRED JOINT APPENDIX

Pursuant to Federal Rule of Appellate Procedure 30(c), D.C. Circuit Rule 30(c), and the Clerk's Order of January 12, 2016, Petitioner Rev Bryan KRUMM, CNP states that he intends to utilize a deferred joint appendix with Respondent U.S. Drug Enforcement Administration.

# TABLE OF AUTHORITIES

## Federal Regulations



## Rules



## Cases



## STATUTES

**TREATIES**

**OTHER AUTHORITIES**



**Exhibits (included in addendum)**

# Entry of appearance

## SUMMARY OF THE CASE

This is a petition requesting a Writ of Mandamus ordering the DEA to immediately move Cannabis to Schedule 2 of the CSA. In its response to my rescheduling petition the DEA has made a final determination that they they must first request a review by the FDA before removing Cannabis from Schedule 1 of the CSA. By DEA's own admission in 2016, moving Cannabis from Schedule 1 to Schedule 2 of the Controlled Substances Act (CSA) 21 U.S.C. 801 et seq, is a strictly legal matter the does not require review by the FDA, Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules 53767 - 53844.

## STATEMENT OF JURISDICTION

This Court has jurisdiction over this petition under 21 U.S.C. §877, as it stems from a final determination by the DEA denying Petitioner's request to remove Cannabis from Schedule 1 of the Controlled Substances Act (CSA) 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 Drug Enforcement Administration (hereafter "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. Petitioner sought the removal of Cannabis from Schedule I of the CSA because Cannabis no longer meets the findings required by the CSA of having no "accepted medical use in treatment in

the United States" 21 U.S.C. §812(b)(1)(B) now that the United States has officially accepted the medical use of Cannabis under International Law.

## 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.

## STATEMENT OF THE CASE

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).

The current case began with a rescheduling petition for Cannabis filed by Rev Bryan Krumm, CNP ("I", "my" and/or "petitioner") on December 8, 2020, requesting that Cannabis be removed from Schedule 1 of the Controlled Substances Act. This was 6 days after Cannabis had been removed from the most restrictive status of the Single Convention Treaty. Petitioner argues that Cannabis now has "accepted medical use" not only "in the United States", but "by the United States", in accordance with International Law ((Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020. Statements

following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, https://www.unodc.org/documents/commissions/CND/CND_Sessions/CND_63Reconvened/ECN72020_CRP24_V2007524.pdf) p12). Therefore Cannabis must be immediately removed from Schedule 1 of the CSA and placed into Schedule 2, until a full public review of Cannabis can be completed, to determine where Cannabis is most appropriately scheduled, or if it should be exempted from control under the Controlled Substances Act (21 U.S.C. § 811) and regulated in a manner more consistent with alcohol and tobacco.

Although Cannabis has been accepted as having medical use by 47 States "in the United States", and 21 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 contention that because the United States is a signatory to the Single Convention Treaty (SCT), we are prohibited from moving Cannabis away from the most restrictive schedules of the Controlled Substances Act (21 U.S.C. § 811). 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 Vienna, 2–4 December 2020

https:// www.unodc.org/documents/commissions/CND/CND_Sessions/CND_63Reconvened/statements/02Dec_partI/USA.pdf).

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" (Single Convention Treaty). Therefore, now that 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. Cannabis must immediately be moved to Schedule 2 of the CSA until a full review of its safety and efficacy can be conducted to determine which Schedule of the CSA Cannabis may legally be placed, or if it should be exempted from control under the CSA entirely.

## HISTORY OF THE CASE

On December 17, 2009, I, Rev. Bryan A. Krumm, CNP, filed a rescheduling petition requesting that Cannabis be removed from control under the Controlled Substances Act 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). In accordance with the CSA scheduling provisions, DEA 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 the he is 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)

For decades the DEA has blocked the Medical Cannabis research they require in order to demonstrate "accepted medical use in the United States". Evidence of the ongoing efforts by the DEA to prevent relevant Medical Cannabis research is found in the DEA's own "Denial of Petition to Initiate Proceedings to Reschedule Marijuana". 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).

The FDA excluded all studies of Cannabis extracts and single cannabinoids from the review. FDA also threw out dozens of studies with whole plant Cannabis and focused on 11 small studies. Even though those studies showed that Cannabis was effective for treating a variety of disorders, and found that Cannabis was that safe for treating these disorders, the FDA claimed there were sufficient omissions from the published reports to reject each one (Federal Register/Vol. 81, No. 156/ Friday, August 12, 2016, 53792). The DEA banned any public input providing evidence during the review. No outside experts were allowed to monitor or

comment on the "review process and findings". "Peer review" is a standard requirement of any legitimate medical and/or scientific endeavor and should demanded from agencies entrusted with our healthcare.

The outcome of FDA's "review" was predetermined by the unreasonable, arbitrary and capricious requirements put in place by the DEA so they can ensure an outcome in their own favor. This type of witness tampering to support the pseudo-scientific claims espoused by prohibitionists has been used for decades. It ignores reality and precludes findings of "fact". The FDA reported that the eleven studies evaluated in their review showed positive signals that marijuana may produce a desirable therapeutic outcome and has been shown to help chronic neuropathic pain, increase appetite in HIV, reduce spasticity in Multiple Sclerosis, produce bronchodilation in asthma, and reduce intraoccular pressure in glaucoma. (Federal Register/Vol. 81, No. 156/Friday, August 12, 2016/Proposed Rules, 53792). The DEA simply disregarded these findings based on unreasonable arbitrary and capricious standards, so they could support the false assertion that Cannabis has "no accepted medical use".

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.

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.

(FDA RECOMMENDATIONS ON THE SCHEDULING OF MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT (MAY 20,2015) (Exhibit 1)

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)

Although I attempted to appeal that decision, I failed to do so in a timely fashion and my appeal was denied.

Then, in January of 2017, the Committee on the Health Effects of Marijuana at the National Academies of Sciences, Engineering, and Medicine released The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research (National Academy Press 2017) finding "There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults (cannabis), As anti-emetics in the treatment of chemotherapy induced nausea and vomiting (oral cannabinoids) and for improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids). In May of 2017 I filed a new rescheduling based on Cannabis now having "accepted medical use in the United States". DEA rejected the conclusion of the National Academies of Sciences and rejected my petition, claiming it added nothing to the prior petition and pointed to no new studies that even purport to establish the safety and efficacy of marijuana. Although I appealed this decision, the Supreme Court declined to rehear the case.

In the end, the DEA simply uses circular logic to argue to the Court that "because the United States successfully had Cannabis listed in the most restrictive status of the Single Convention Treaty, it must be prohibited in the United States. And because Cannabis is in the most restrictive status of the CSA, we must prohibit medical research on Cannabis. And because we've prohibited medical Cannabis research you can't prove Cannabis has "accepted medical use. Therefore, Cannabis must remain totally prohibited."

All of that changed on December 2, 2020 when the "United States" officially recognized the medical value of Cannabis, declaring 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 Vienna, 2–4 December 2020. Statements following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, p12)

After the Supreme Court refused to rehear my rescheduling case, I began preparing a legal challenge to the placement of Cannabis in the most restrictive status of the Single Convention Treaty. Then, the SARS CoV-2 virus began the Covid-19 pandemic. I changed my focus to the potential of Cannabis for treating and/or preventing a pandemic that has now killed millions of humans around the globe. I expanded on research I had begun in 2002 when SARS CoV-1 threatened

to become a Worldwide pandemic. I drafted a review of the therapeutic potential of Cannabis in treating Covid 19 and suggested that Cannabis might help to prevent and/or treat Covid 19. I sent this to officials at the UN and WHO along with a letter requesting that Cannabis be removed from the most restrictive status of the Single Convention treaty and that research be conducted on the use of cannabis for treating Covid-19. I also sent the review to the FDA, NIH and CDC. Several months later I received a letter from The World Health Organization informing me that they were already reviewing the placement of Cannabis in the Single Convention Treaty and if I wanted to see research done those requests should be directed to my own State. Then, 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 Vienna, 2–4 December 2020). Because the United States has accepted medical use of Cannabis, Cannabis can no longer remain in Schedule 1 of the CSA.

**ARGUMENT:**

On December 2, 2020, the United States recommended that Cannabis be removed from the most restrictive status of the Single Convention Treaty and stated that Cannabis has proven medical value (Commission on Narcotic Drugs Reconvened sixty-third session Vienna, 2–4 December 2020. Statements

following the voting on the WHO scheduling recommendations on cannabis and cannabis-related substances, p12)

The DEA has previously noted that "As the Controlled Substances Act (CSA) recognizes, the United States is a party to the Single Convention on Narcotic Drugs (referred to here as the Single Convention Treaty), 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.

Therefore the medical and scientific evaluation and scheduling recommendation of the FDA and the Secretary of Health are not required to remove Cannabis from Schedule 1 of the CSA and move it to Schedule 2 as the DEA now asserts. Because the United States has officially recognized Cannabis as having accepted medical use and supported the removal of Cannabis from the most restrictive status of the Single Convention Treaty. Obligations required by the Single Convention Treaty now require that the United States remove Cannabis from schedule 1 of the CSA and place it into schedule 2 until the FDA can determine where it would be more appropriately placed, or determine if it should be removed from control under the CSA and regulated like alcohol and tobacco.

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. Although a public review of the safety and efficacy of Cannabis is required to determine where Cannabis should be appropriately placed in the CSA, or if it should be exempted from control under the CSA entirely, the immediate goal of

this petition is to have Cannabis removed from Schedule 1 of the CSA and placed into Schedule 2.

The DEA has ignored its responsibility to comply with the laws of the United States by keeping Cannabis in Schedule 1of the CSA, even though the United States has officially recognized its medical value under International Law. The choice of the DEA simply ignore this legal responsibility places the health and welfare of millions of Americans in jeopardy. As a Nurse Practitioner and as the Bishop of Medicine for the Zen Zion Coptic Orthodox Church, Krumm has ethical and moral responsibilities to advocate for the sick and suffering.

Now that the United States has officially accepted Cannabis as having medical use, the DEA has a duty to remove Cannabis from Schedule 1 of the CSA. The DEA also has a duty to request a full scientific evaluation of the medical use of cannabis. However, because seriously ill patients require immediate access to this lifesaving medication; and because the time to conduct a full review of Cannabis will be detrimental the the health and welfare of those patients; DEA must immediately move Cannabis from Schedule 1 to Schedule 2 of the CSA in order to remain compliant with the Single Convention Treaty and the CSA.

Furthermore, DEA must order a review to determine where Cannabis would be most appropriately placed within the CSA or if should be exempted from control under the CSA like tobacco and alcohol. Due to unethical actions by the DEA in the past, by excluding evidence and demanding unreasonable, arbitrary and capricious standards of review, the review must be held in public and must include testimony by outside experts familiar with the medical use of Cannabis.

Cannabis is safe for use under medical supervision. This has been determined the DEA's own administrative law judge. Safety for use under medical supervision, 21 U.S.C. § 812(b)(1)(C), was considered In The Matter of Marijuana Rescheduling, DEA Docket No. 86-22, September 6, 1988, which resulted in a finding that, "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man." Id. at pages 58-59. "The evidence in this record clearly shows that marijuana has been accepted as capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary, and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record." Id. At page 68

In comprehensive reviews conducted by the Federal Government on the use of smoked Cannabis, experts have consistently concluded that smoked Cannabis

has medical use. "The evidence is perfectly clear that smoking is an outstanding route of administration....it's a very safe drug and therefore it would be perfectly safe medically to let the patient determine their own dose through the smoking route". See National Institutes of Health. Transcript of the NIH Workshop on the Medical Utility of Marijuana. Tab B, Deliberations of the Ad Hoc Group of Experts; February 19&20, 1997. (Ace-Federal Reporters, Inc., Cr66002.0) See also Joy, Janet E., Stanley J., Watson, and John A. Benson, Jr., (eds) Marijuana as Medicine: Assessing the Science Base,. (National Academy Press 1999). "Until a nonsmoked rapid-onset cannabinoid drug delivery system becomes available, we acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting".

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) 16 (2); 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 simply ignore International Treaty obligations approved by the United States, or to violate their mandated duties under the Controlled Substances Act. These duties are owed to the American People for their safety. 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.

Cannabis is an ancient drug, not a new drug. It has been safely used as a medication for thousands of years and there has never been a death due to any toxic effects. Comprehensive study of legal medical Cannabis users in the Federal IND found only mild changes in pulmonary function associated with long term heavy use. No functionally significant attributable sequelae were noted in any other physiological system examined in the study, which included: MRI scans of the brain, pulmonary function tests, chest X-ray, neuropsychological tests, hormone and immunological assays, electroencephalography, P300 testing, history, and neurological clinical examination. (Russo et.al. 2002, "Chronic Cannabis Use

in the Compassionate Investigational New Drug Program: An Examination of Benefits and Adverse Effects of Legal Clinical Cannabis") (see http://acmed.org/data/pdf/2002-01-1.pdf). There is no legitimate rationale either medically or legally to continue placement of Cannabis in Schedule I of the CSA.

Because the United States has officially recognized the medical use of Cannabis under International Law, Cannabis can no longer legally remain in Schedule 1 of the CSA and the DEA must be ordered to remove Cannabis from Schedule 1. Research into the medical use of Cannabis must be encouraged, and in pursuit of that end a public review must be conducted to determine how Cannabis should best be regulated in the United States. It is clear from the legislative history, the language of the statute, and case law, that the findings required by 21 U.S.C. § 811 can never justify the inclusion of drugs or substances with "accepted medical use" in Schedule I of the CSA. No rational reason exists for treating Cannabis differently than other substances used for medical purposes.

## RELIEF SOUGHT

Whereas, Cannabis is officially recognized by the United States as having "accepted medical use" under International Law; and

Whereas, placement of Cannabis in the most restrictive status of the United States Controlled Substances Act violates both US Law and International Treaty obligations; and

Whereas, Cannabis is safe for use under medical supervision; and

Whereas, Cannabis has a low potential for abuse as compared to other substances which are already exempted from control under the CSA;

Therefore, The DEA must be ordered to immediately remove Cannabis from Schedule 1 of the CSA and place it into Schedule 2 in order to protect the health and welfare of the citizens of the United States; and

Furthermore, due to the futility of the current administrative process, which relies solely on the decisions of federal policy makers who have demonstrated gross incompetence and/or malfeasance in the case of Cannabis scheduling; And because these hearings` have been held behind closed doors, without oversight and without allowing for the expert testimony that should be required for medical policy decision making; the DEA must be ordered to initiate a full public review of Cannabis to determine where Cannabis may be appropriately placed within the CSA, or if it should be exempted from control under the CSA and regulated by the States like tobacco and alcohol.

# TABLE OF CONTENTS TO APPENDIX

**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

# 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 recommendations 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]

---

[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.)

---

[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.

[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



# HEALTH & HUMAN SERVICES RECOMMENDATION ON THE SCHEDULING OF MARIJUANA UNDER THE CONTROLLED SUBSTANCES ACT (JUNE 3, 2015)

DEPARTMENT OF
HEALTH & HUMAN SERVICES
Office of the Assistant Secretary for Health
Washington, D.C. 20201

The Honorable Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration
U.S. Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Dear Mr. Rosenberg:

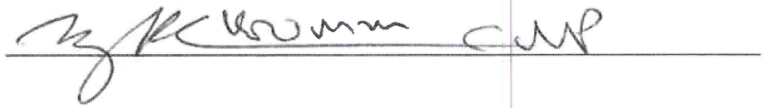
Pursuant to the Controlled Substances Act (CSA, 21 U.S.C. § 811(b), (c), and (f)), the Department of Health and Human Services (HHS) is recommending that marijuana continue to be maintained in Schedule I of the CSA.

The Food and Drug Administration (FDA) and the National Institutes of Health's National Institute on Drug Abuse (NIH/NIDA) have also considered the abuse potential and dependence-producing characteristics of marijuana.

Marijuana meets the three criteria for placing a substance in Schedule I of the CSA under 21 U.S.C. 812(b)(1). As discussed in the enclosed analyses, marijuana has a high potential for abuse, no currently

Respectfully submitted January 26, 2023

Resubmittted February 6, 2023 with the signature below



## CERTIFICATE OF SERVICE

I, Rev. Bryan A. Krumm, CNP,

petitioner

hereby certify that on January 23 2023

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

to: Anne Milgram, Director DEA

at Drug Enforcement Administration,

8701 Morrissette Drive, Springfield, VA 22152

By certified mail

BAKrumm CNP

Signature

2/6/23 - originally sent 1/26/23 without signature

Date