No. 18-1058

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

In Re: Rev Bryan A Krumm, CNP
pro se petitioner

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

May 01, 2018

Certificate as to Parties, Rulings, and Related Cases

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

A. Parties and Amici:

The petitioner is Rev. Bryan Krumm, CNP. The defendants are the US Drug Enforcement Administration (Robert Patterson, acting administrator) and US Attorney General's Office (Jeff Sessions, Attorney General).

B. Ruling Under Review:

The ruling under review is the January 16, 2018 ruling of Robert Patterson, acting administrator for the US Drug Enforcement Administration, denying the rescheduling petition filed by Krumm on May 22, 2017, demanding that Cannabis be exempted from federal control under the Controlled Substances Act (CSA) and that control be handed over to the States. A letter was issued to Krumm to notify him of the decision on January 16, 2018 (Exhibit 1). Petitioner filed a Petition for Review with this court on February 12, 2018.

Petitioner now respectfully requests that this Court issue a writ of Mandamus to the US Drug Enforcement Administration (DEA) and the US Attorney General's Office (AG) ordering them to exempt Cannabis from control under the Controlled Substances Act (CSA) 21 U.S.C. 801 et. seq., and allow the States to regulate Cannabis like tobacco and alcohol. In the alternative, Petitioner requests that this Court issue a Writ of Mandamus ordering the DEA and AG to remove Cannabis from Schedule 1 of the CSA, and to stop blocking Medical Cannabis research and approve more cultivators of Cannabis for research, as is required not only by the law, but by their own policies (Exhibit 2), which were changed in response to recommendations from FDA (Exhibit 3) and HHS (Exhibit 4) as a result of my 2009 rescheduling petition (Exhibit 5), that was settled August 12, 2016.

C. 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).

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Rev. Bryan Krumm, CNP
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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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SUMMARY

On January 16, 2018 Robert Patterson, acting administrator for the US Drug Enforcement Administration, notified petitioner by letter that he was denying my rescheduling petition for Cannabis (Exhibit 1). This petition was filed on May 22, 2017 demanding that Cannabis be exempted from federal control under the Controlled Substances Act (CSA) 21 U.S.C. 801 et seq, and that control be handed over to the States (Exhibit 2). This petitioner has previously filed a Rescheduling Petition for Cannabis that was settled on August 12, 2016 (see Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81, Fed. Reg. 156, August 12, 2016 / Proposed Rules, page 53767). DEA was forced to change its policies due to recommendations from Health and Human Services and the FDA, in response to that rescheduling petition. DEA is no longer allowed to block Medical Cannabis research and must allow more cultivators of Medical Cannabis for research purposes (Exhibit 3). However, Jeff Sessions ordered the DEA to illegally continue blocking Medical Cannabis research. By continuing to block needed Cannabis research and refusing to approve new Medical Cannabis cultivators. The Attorney General and DEA are ignoring HHS and the FDA. They are practicing medicine without a license and placing the lives of millions of Americans at risk. The Attorney General and DEA have proven that they cannot be trusted to

administer the CSA as it pertains to Cannabis, and the Petitioner has proven the futility of the administrative process for rescheduling.

The time has come for this Court to end the illegal actions of these agencies and order them to exempt Cannabis from control under the CSA, and allow States to regulate the use of Cannabis for medical, recreational, religious and industrial use. In the alternative, Petitioner requests that this Court issue a Writ of Mandamus ordering the DEA and AG to remove Cannabis from Schedule 1 of the CSA, to stop blocking Medical Cannabis research, and to immediately approve more cultivators of Cannabis for research, as is now required by the law.

Jurisdiction

This Court may issue writs of mandamus pursuant to 28 U.S.C. § 1651. It has jurisdiction to issue a writ in this case because this Court has exclusive jurisdiction to review orders "with respect to the Attorney General" (and by proxy the DEA) 21, U.S.C. § 877.

Background

A. Statutory Background

The Administrative Procedures Act ("APA"), 5 U.S.C. § 551 et seq, provides that a Court may "set aside agency actions, findings, and conclusions found to be…arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law…" 5 U.S.C. § 706(2). 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)(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 *Cannabis Therapeutics,* 15 F.3d at 1133.

To initiate the rescheduling process, "any interested party" may petition the Attorney General (or DEA) to analyze the properties and medical utility of a drug in efforts to have it rescheduled from one classification to another. 21 U.S.C. 811(a). Before initiating formal proceedings to schedule or reschedule a drug in accordance with 21 U.S.C. 811(a), the Administrator must request a scientific and medical evaluation and recommendation from the Secretary of HHS whether the substance "should be so controlled or removed as a controlled substance." 21 U.S.C. 811(b). This evaluation and recommendation must be in writing and submitted to the Attorney General "within a reasonable time." 21 U.S.C. 811(b).

When transmitted, the evaluation and recommendations of HHS are binding on the Administrator with respect to scientific and medical matters. See 21 U.S.C. 811(b).

B. Krumm's Petition for a Rulemaking

Petitioner has standing to bring this action because he and his patients have been harmed by the futility of the administrative process for rescheduling Cannabis. Although the FDA recommended continued placement in Schedule 1 of the CSA in my previous rescheduling petition, they acknowledged that the studies reviewed produced positive results, suggesting marijuana should be further evaluated as an adjunct treatment for neuropathic pain, appetite stimulation in HIV patients, and spasticity in MS patients. (see Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81, Fed. Reg. 156, August 12, 2016 / Proposed Rules, page 53792). As a result, HHS instructed the DEA to stop blocking Cannabis research and to allow more people to grow Cannabis for research purposes. DEA announced changes in policy to allow this on August 11, 2016 (Exhibit 3).

Jeff Sessions illegally ordered Chuck Rosenberg, former director of the DEA, to ignore the recommendations of HHS regarding Medical Cannabis, and to continue to block critical medical research. This appears to have played a role in Rosenberg's decision to resign from the Department of Justice. (See Devlin

Barrett and Matt Zapotosky, *DEA administrator plans to step down.* Washington Post, September 26, 2017).

Now, under the reign of Robert Patterson, the DEA has proposed a reduction in the supply of Cannabis for research purposes and has refused to take action on the over 2 dozen manufacturer applications that have been submitted to grow Cannabis for research. (See Tom Angell, *DEA Wants Feds To Grow Almost 1,000 Pounds Of Marijuana Next Year*. Forbes, Nov 7, 2017). Plaintiff brought this Petition because the actions of the DEA and Attorney General are causing immediate harm to his patients and placing millions of Americans at risk by denying them access to lifesaving medication, and by delaying needed research into the medical benefits of Cannabis. Krumm is also being denied the opportunity to conduct legitimate medical research with Cannabis. The Attorney General, and by proxy the DEA, clearly cannot be trusted to obey the law and act in good faith to protect the health and welfare of the citizens of the United States as it applies to Cannabis.

ARGUMENT

This Court should issue a writ of mandamus directing the Attorney General and the DEA to remove Cannabis from control under the federal CSA, and transfer control of Cannabis to the States to determine how best to use Cannabis for

medical, religious, recreational and industrial purposes. In the alternative, Petitioner requests that this Court issue a Writ of Mandamus ordering the DEA and AG to remove Cannabis from Schedule 1 of the CSA, and to stop blocking Medical Cannabis research, and to immediately approve more cultivators of Cannabis for research, as is required by the law (21 U.S.C. 811)

This Courts consideration of a mandamus petition "starts from the premise that issuance of the writ is an extraordinary remedy, reserved only for the most transparent violations of a clear duty to act." *PMOI*, 680 F3d at 836 (citing *in Re Core Commc'ns, Inc,* 531 F.3d 849, 855 (D.C. Cir, 2008)).

In his denial of my Rescheduling Petition, Patterson falsely asserts that there are no adequate and well controlled studies proving the safety and efficacy of Cannabis and falsely contends that "your latest petition adds nothing to your prior petition as you have pointed to no new studies that even purport to establish the safety and efficacy of marijuana" (Exhibit 1). My latest petition is 34 pages (Exhibit 2) and it includes significant quantities of information not addressed in my previous petition, which was only 6 pages (exhibit 4). My new petition discusses a comprehensive review published by the National Academies of Science in 2017 that finds "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 (Exhibit 5).

Patterson has also ignored my clinical findings, published in the Nurse Practitioner Journal in January 2016, that conclude "Cannabis is effective for treating PTSD, even when there are other co-occurring psychiatric and/or medical disorders" (Exhibit 6). Dozens of phase 2 clinical trials have been conducted by the Center of Medical Cannabis Research at UC San Diego but have been ignored by FDA, HHS and DEA. They even ignore HHS's own patent on Medical Cannabis extracts, US patent number 6630507 CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS, which claims that "Cannabinoids have been found to have antioxidant properties, unrelated to NMDA receptor antagonism. This new found property makes cannabinoids useful in the treatment and prophylaxis of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia." (Exhibit 7).

In his May 20, 2015 letter to HHS, 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. (Exhibit 8)

Karen DeSalvo substantiates the futility of the administrative process in her June 3, 2015 letter to Chuck Rosenberg (Acting Administrator of the Drug Enforcement Administration), when she states.

> "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." (Exhibit 9)

The Federal Defendants have acted in bad faith and have failed to fulfill their duty to administer the CSA. The longstanding stigma against "Marihuana" has

clearly impaired the ability of the AG, DEA, HHS and FDA to conduct an impartial review of the overwhelming evidence proving that Cannabis is safe and effective for medical use. The unreasonable, arbitrary and capricious actions of the DEA, and AG clearly demonstrate the futility of the administrative process. Americans are dying every day due to the incompetence, if not outright malfeasance, of these bureaucrats.

Due to the failure of the DEA and Attorney General to act in good faith to protect the health and welfare of American citizens, Cannabis must be exempted from control under the federal CSA. Control of Cannabis should handed over to the States to determine how Cannabis should be used for medical, religious, industrial and recreational purposes. The framework for such regulation is already in place for tobacco and alcohol. Although Patterson falsely asserts in his denial that transferring control of Cannabis to the States "is incompatible with Congress's basic intentions under the Act", Congress has clearly granted the AG's office and by proxy the DEA, with the authority to do just that, see *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 Cannabis Therapeutics, 15 F.3d at 1133.

Because Cannabis clearly has “accepted medical use in the United States”, as proven in my Rescheduling Petition, Cannabis cannot remain in Schedule 1 of the CSA. Due to the futility of an administrative process, which relies solely on the decisions of federal policy makers who have demonstrated gross incompetence and/or malfeasance, the States must be allowed to fulfill their constitutional right to determine what is “accepted medical practice” within their borders 21 U.S.C. § 903. *See Gonzales v. Oregon*, 546 U.S. 243 (2006). Cannabis must be exempted from Schedule 1 control under the federal CSA.

It is reasonable to require double blind, placebo controlled, phase 3 clinical trials of newly developed chemical concoctions to determine their safety and efficacy before allowing their use by the public as pharmaceuticals. It is not reasonable to require this of a plant that has been used for centuries as a safe and effective herbal remedy for multiple ailments. We don’t require clinical trials of parachutes to know that parachutes are reasonably safe and save lives. We have epidemiological proof that parachutes are a safe and effective means of preventing death from falling out of a plane. We also have an epidemiological database of millions of patients proving that Cannabis can save lives. However the DEA, HHS and FDA demand phase 3 clinical trials of Cannabis to prove its medical

value and they have blocked that research from being conducted for decades. We know from vast amounts of epidemiological evidence involving millions of American Citizens, and dozens of phase 2 clinical trials, that Cannabis is safe and effective for medical use. We don't need any more "proof". Millions of Americans gain relief from Cannabis every day.

The argument that Cannabis has "no accepted medical use in the United States" is an outright lie. Forty-five States now allow the medical use of Cannabis and/or Cannabis extracts. Thousands of medical providers have referred patients to State Medical Cannabis Programs because they know that Cannabis is safe and effective for medical use. The National Academy of Science has concluded that Cannabis is effective for medical use. Yet these voices have been ignored by the DEA during reviews of Medical Cannabis. The DEA and AG listen only to the FDA, which by its own admission "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". (see Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81, Fed. Reg. 156, August 12, 2016 / Proposed Rules, page 53792). By blocking research and continuing schedule 1 placement of Cannabis in the federal CSA, the DEA might as well be throwing people out of a plane without a parachute "because nobody can 'prove' that parachutes work". The outcome of either practice results in the needless death of American citizens.

This court routinely affirms the important purpose for the APA's public comment requirement. *See, e.g., Connecticut Light and Power Co, v Nuclear Regulatory Comm'n,* 673 F. 2d 525,530 (D.C. Cir. 1982) ("The purpose of the comment period is to allow interested members fo the public to communicate information, concerns, and criticisms to the agency during the rule-making process."). This Court has made it clear that "[n]otice of the agency's intention is crucial to "ensure that agency regulations are tested via exposure to diverse public comment,…to ensure fairness to affected parties, and …to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Int'l Union, United Mine Workers of Am v Mine Safety & Health Admin,* 626 F.3D 84, 95 (D.C. Cir, 2010). Such notice is typically provided by the agency when it publishes a notice of propose rule as required by law. *See* 5 U.S.C. § 552(b). However, public comment has not been allowed for either of Krumm's rescheduling petitions. In light of the importance of APA procedures and the DEA's refusal to remove Cannabis from schedule 1 of the CSA, without public comment regarding "accepted medical use of Cannabis, schedule 1 placement of Cannabis in the federal CSA is totally unreasonable, arbitrary and capricious abuse of discretion.

As with all substantive rules, the final agency determination regarding schedule 1 placement of Cannabis of the CSA is subject to APA review, and can be set aside if a court finds it to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law". 5 U.S.C. § 706(2)(a). The agency's final denial of Krumm's rescheduling petition and refusal to accept comment from both the public and agencies outside of the FDA, is completely unreasonable because it frustrates the statutory requirements set out by Congress in the APA.

Conclusion

For these reasons, DEA must be ordered to remove Cannabis from control under the federal CSA, and control of Cannabis must be handed over to the States to determine how best to use Cannabis for medical, religious, recreational and industrial purposes. In the alternative, Petitioner requests that this Court issue a Writ of Mandamus ordering the DEA and AG to remove Cannabis from Schedule 1 of the CSA, to stop blocking Medical Cannabis research, and to immediately approve more cultivators of Cannabis for research, as is required by the law.

Respectfully submitted on, 5/1/18

Rev. Bryan A. Krumm, CNP, Pro Se Party

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RULE 32(A) CERTIFICATE

I hereby certify that the foregoing Petition for Writ of Mandamus to Enforce the Court's Mandate complies with the typeface requirements of F.R.A.P. 32(a)(5) and the type-style requirements of Rule 32(a)(6). The brief is composed in a 14- point proportional typeface, Times New Roman, and complies with the 30-page limit of Rule 21(d).

Rev. Bryan A. Krumm, CNP
Pro Se Petitioner

XXXXXXXXXXXXX
Albuquerque, NM 87110

CERTIFICATE OF SERVICE

I, Rev. Bryan A. Krumm, CNP
[petitioner]

hereby certify that on April 30, 2018, I served a copy of the foregoing Petition for Writ of Mandamus by USPS express delivery to the last known addresses of,

Robert W. Patterson, Acting Administrator, Drug Enforcement Administration, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

Jeff Sessions, Attorney General of the United States, United States Department of Justice, 950 Pennsylvania Avenue, NW, Washington, DC 20530-0001

Jessie K Liu, US Attorney, District of Columbia, United States Attorney's Office, 555 4'th St, NW, Washington, DC 20530

[Defendants]

Signature

_____

Date 5/1/18