UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

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Rev. Bryan A. Krumm, CNP
Petitioner

v. Case Number:_____

United States Drug Enforcement Administration, et.al.
Respondent

MOTION IN SUPPORT OF PETITION FOR REVIEW OF AN AGENCY DECISION

On January 16, 2018 Robert Patterson, acting administrator for the US Drug Enforcement Administration, denied the rescheduling petition I filed 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 (See exhibit 1). This rescheduling petition was filed in response to DEA's failure to implement the August 11, 2016 policy changes (see exhibit 2) implemented as result the Rescheduling Petition I filed December 17, 2009 (See Exhibit 3).

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. 8II(b). This evaluation and recommendation must be in writing and submitted to the Attorney General "within a reasonable time." 21 U.S.C. 8II(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. 8II(b).

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. As a result of my 2009 rescheduling petition, HHS and FDA instructed the DEA to stop blocking Cannabis research and to allow more people to grow Cannabis for research purposes. 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 September 26, 2017. https://www.washingtonpost.com/world/national-security/dea-administrator-plans-to-step-down/2017/09/26/c89d7424-a2fc-11e7-ade1-76d061d56efa_story.html?utm_term=.c997e0a7b693. 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 purposes. https://www.forbes.com/sites/tomangell/2017/11/07/dea-wants-feds-to-grow-almost-1000-pounds-of-marijuana-next-year/#61870f797362 Plaintiff has standing to bring 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 delaying needs research into the lifesaving 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.

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". My latest petition is 34 pages (see exhibit 1) and it includes significant quantities of information not addressed in my previous petition, which was only 6 pages (see exhibit 3). It also includes information which was ignored by FDA, HHS, and DEA, during their last review. It 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 4).

Patterson has also ignored my findings, published in the Nurse Practitioner Journal in January 2016, that concludes "Cannabis is effective for treating PTSD, even

when there are other co-occurring psychiatric and/or medical disorders" (see exhibit 5). 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 ignored 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 6). All of these issues have been addressed in the new petition but were not addressed in my previous petition.

Furthermore, DEA did not disclose all of the information received from FDA and HHS when they denied Krumm's rescheduling petition. Krumm filed a FOIA request with the FDA asking for all communication related to his rescheduling petition. His FOIA was initially denied by Douglas Throckmorton, who claimed all information had already been provided to Krumm and the public. Then,

several weeks later, Krumm received a CD Rom containing additional information including the original communications from FDA to HHS and from HHS to DEA.

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. (exhibit 7)

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 8)

Efforts to deny Krumm access to this information is consistent with the bad faith actions of the federal defendants. The longstanding stigma against "Marihuana" has clearly impaired the ability of 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 Attorney General clearly demonstrate the futility of the administrative process. Americans are dying every day due to the incompetence, if not outright malfeasance, of these agencies.

Due to the failure of these agencies to act in good faith to protect the health and welfare of American citizens, Cannabis must be exempted from control under the CSA, and control must 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 that transferring control of Cannabis to the States "is incompatible with Congress's basic intentions under the Act", Congress has clearly granted him 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. Cannabis must be exempted from control under the federal CSA. We don’t require double blind, placebo controlled, phase 3 clinical trials of parachutes to know that parachutes are reasonably safe and save lives. We have epidemiological proof that parachutes are a safe effective means of preventing death from falling out of a plane. Since throwing 300 people out of an airplane and only giving half of them a parachute to conduct a clinical trial would be considered cruel and unusual, we accept that parachutes work based on the available evidence. Yet the DEA, HHS and FDA demand phase 3 clinical trials of Cannabis to prove that Cannabis can be used to save lives. We know from vast amounts of epidemiological evidence and dozens

of phase 2 clinical trials, that Cannabis is safe and effective for medical use. We don't need any more "proof" than the millions of Americans who gain relief from Cannabis every day, with far fewer adverse effects than any pharmaceutical medication. By blocking research, the DEA might as well be throwing everyone out of the plane without a parachute, until someone "proves" that parachutes work.

For these reasons, DEA should be ordered to remove Cannabis from control under the CSA and that control of Cannabis be handed over to the States to determine how best to use it for medical, religious, and industrial purposes.

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

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CERTIFICATE OF SERVICE

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

hereby certify that on February 12, 2018, I served a copy of the foregoing Memorandum in Support of Petition for Review to the last known addresses, by USPS express delivery to:

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

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Date _____