JUDGEMENT FILED SEPTEMBER 24, 2018

No. <u>18-1058</u>

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

Rev. Bryan A Krumm, CNP *pro se petitioner*

v

US Drug Enforcement Administration et al

On Petition for Review from a January 16, 2018 Decision of the Drug Enforcement Administration

PETITIONER REV. BRYAN KRUMM'S PETITION FOR REHEARING

EN BANC

Rev. Bryan A. Krumm, CNP

Pro Se Petitioner

STATEMENT PURSUANT TO FED. R. APP. P. 35(b)

A panel of this Court has rendered a dramatic and unprecedented ruling that purports to override the Supreme Court's explicit determination that the States, not the federal government, determine "accepted medical use" of Cannabis.

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, 258 (2006).

Furthermore, the panel failed to address allegations that DEA's five part test to determine if Cannabis has "accepted medical use" constitutes illegal witness tampering, because it prevents the FDA from including critical scientific evidence in their reviews, and excludes any expert testimony or evidence from experts in the scientific community and/or from States with Medical Cannabis Programs. This ensures that Jeff Sessions and the DEA can perpetuate the irrational and deranged argument that "Cannabis has no accepted medical use in the United States". DEA achieves the outcome it desires by illegally manipulating the testimony of the only witness it allows, the FDA. Because the FDA is forbidden from conducting a thorough evaluation of Cannabis, based on the best available scientific evidence, it now acknowledges 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".

Reschedule Marijuana, 81, Fed. Reg. 156, August 12, 2016 / Proposed Rules, page 53792).

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).

This case began when Krumm filed a rescheduling petition for Cannabis with the DEA December 17, 2009. After nearly 7 years of delay, on August 12, 2016, the DEA settled that petition, and although they kept cannabis listed in Schedule 1 of the CSA they were forced to adopt policies requiring them to stop blocking Cannabis research and to allow more people to grow Cannabis for research purposes. DEA was also forced to admit that Cannabis is not a "gateway drug", doesn't cause psychosis, doesn't cause lung cancer and doesn't cause cognitive impairment as you get old. When Jeff Sessions took control of the Depart of Justice he ordered the head of DEA, Chuck Rosenberg to block implementation of those policy changes. On May 22, 2017 I filed a new Rescheduling Petition requesting that Cannabis be removed from federal control, and that control be handed over to the States. This request was based on new information from the National Academies of Science which found conclusive evidence that Cannabis has proven medical value.

In September, Chuck Rosenberg resigned, stating he doesn't trust this administration to follow the law. After 6 months of delay, I sent a letter to the new head of DEA, Robert Patterson, requesting action, and January 16, 2018 he finally denied the petition. On February 12, 2018 I filed a Petition for Review of an Order of the United States Drug Enforcement Agency and on May 1, 2018 I filed a Petition for Writ of Mandamus to Enforce Requirements of the Controlled Substances Act, 21 U.S.C. 801 et. seq.. Now Robert Patterson has resigned, claiming he doesn't know enough about marijuana to be in that position.

The DEA and Attorney General can't be trusted to obey the law and therefore Cannabis should be exempted from control under the CSA, with control turned over to the States to regulate Medical, Recreational, Religious and Industrial use of Cannabis. In the alternative, Cannabis must be removed from schedule 1 of the CSA. The DEA is violating States rights by continuing Schedule 1 placement now that Cannabis has "accepted medical use" in 31 States and the District of Columbia and the National Academy of Sciences. DEAs application of its 5 part test to FDA reviews, forcing them to ignore the clear scientific evidence, is illegal witness tampering. The DEA's application of these standards to FDA reviews now amounts to illegal witness tampering. These are arguments that have never been considered by this or any other court, and are deserving of Rehearing and

Rehearing En Bank to protect the safety and wellbeing of the American People from the illegal, unethical and immoral actions of the DEA and Jeff Sessions.

ARGUMENT

I. THE PANELS DECISION CONFLICTS WITH GONZALES V. OREGON, 546 U.S. 243

This case thus sets up what may be the most important States rights cases in a generation. The DEA and Jeff Sessions have chosen to illegally ignore the laws of 31 States and the District of Columbia. Every day the Attorney General fails to fulfill his duty to administer the CSA and order DEA to remove Cannabis from the CSA, more Americans suffer from lack of needed medication. Every day the DEA fails to do its duty to remove Cannabis from control under the CSA, more Americans die needlessly. Although "accepted medical use" is not defined in 21 U.S.C. § 812, it is defined in 21 U.S.C. § 903, as noted in Gonzales v. Oregon, 546 U.S. 243, 251 (2006), which shows that the CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its pre-emption provision.

"No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together." §903.

If no state accepts the medical use of a drug or other substance, the DEA can determine whether it has accepted medical use. However, when a state accepts the medical use of a drug, the DEA is bound by that States decision. DEA relies on Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994) (approving a five part test based on scientific and medical factors) However, this was before any State had accepted the medical use of Cannabis. This decision didn't take into account the enactment of 31 state medical marijuana laws beginning in 1996. There was no conflict with State laws in 1994, because no State had accepted the medical use of Cannabis in treatment in 1994. See, e.g., Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987):

We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1) (B) reads "in the United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.

DEA wants to read the statutory language of 21 U.S.C. § 812(b) to exclude "States" from the meaning of "in the United States" contrary to the ruling of the United States Supreme Court in Gonzales v. Oregon, 546 U.S. 243, 258 (2006):

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. DEA dictates to the States which substances shall have accepted medical use, violating Congress' mandate to regulate medical practice, not define it. DEA ignores the extensive scientific record, and boldly claims that no evidence exists regarding the medical use of Cannabis, meanwhile obscuring the fact that they've blocked that research for decades. Krumm poses a strictly legal question which does not require any extensive scientific inquiry, "does Cannabis have accepted medical use in the United States?", and the answer is clearly yes. The question of safety and efficacy was already settled in 1988 by the DEA's own administrative law judge. (In the Matter of Marijuana Rescheduling Petition, Docket No. 86-22, U.S. Department of Justice, Drug Enforcement Administration). The only question that remained was that of "accepted medical use". Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 at 11.

"As is apparent, one salient concept distinguishing the two schedules is whether a drug has "no currently accepted medical use in treatment in the United States." This case turns on the appropriate definition and application of that phrase".

The courts have held that State laws apply in determining what constitutes

accepted medical use.

Our decision is consistent with principles of federalism that have left states as the primary regulators of professional conduct. See Whalen v. Roe, 429 U.S. 589, 603 n. 30, 51 L. Ed. 2d 64, 97 S. Ct. 869 (1977) (recognizing states' broad police powers to regulate the administration of drugs by health professionals); Linder v. United States, 268 U.S. 5, 18, 69 L. Ed. 819, 45 S. Ct. 446 (1925) ("direct control of medical practice in the states is beyond the power of the federal government").

We must "show[] respect for the sovereign States that comprise our Federal Union. That respect imposes a duty on federal courts, whenever possible, to avoid or minimize conflict between federal and state law, particularly in situations in which the citizens of a State have chosen to serve as a laboratory in the trial of novel social and economic experiments without risk to the rest of the country." Oakland Cannabis, 532 U.S. at 501 (Stevens, J., concurring) (internal quotation marks omitted).

Conant v. Walters, 309 F.3d 629, 639 (9th Cir. 2002)

DEA's interpretation is not entitled to deference when it creates a clear

violation of State sovereignty where no such conflict was intended by Congress.

Texas v. United States, 497 F.3d 491, 500-505 (5th Cir. 2007):

The authority of administrative agencies is constrained by the language of the statute they administer. See Massachusetts v. EPA, 549 U.S. 497, 127 S. Ct. 1438, 1462, 167 L. Ed. 2d 248 (2007). Under the Chevron doctrine, courts assess the validity of challenged administrative regulations by determining whether (1) a statute is ambiguous or silent concerning the scope of secretarial authority and (2) the regulations reasonably flow from the statute when viewed in context of the overall legislative framework and the policies that animated Congress's design. See Chevron U.S.A. Inc. v. NRDC, 467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781-82 (1984).

DEA asserts that Cannabis has no accepted medical use in treatment in the

United States, disregarding findings of the scientific community and with complete

disdain for the Tenth Amendment. U.S. CONST. amend. X. See, Bond v. United

States, 564 U.S. ____, 131 S. Ct. 2355, 2366, 180 L. Ed. 2d 269, 282 (2011):

The principles of limited national powers and state sovereignty are intertwined. While neither originates in the Tenth Amendment, both are expressed by it. Interference with state authority to regulate in the interest of the health and welfare of its citizens is a question of constitutional law, not a scientific and medical inquiry. Gonzales v. Oregon, 546 U.S. 243, 270 (2006):

[C]ongress regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally. The silence is understandable given the structure and limitations of federalism, which allow the States " 'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756, 105 S. Ct. 2380, 85 L. Ed. 2d 728 (1985)).

The CSA does not give the DEA administrator or the Attorney General 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 Controlled Substances Act 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 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.

In Gonzales v. Raich, 545 U.S. 1 (2005), the Court wrote: "We acknowledge that evidence proffered by respondents in this case regarding the effective medical uses for marijuana, if found credible after trial, would cast serious doubt on the accuracy of the findings that require marijuana to be listed in Schedule I." Id. at 28 n37. United States v. Oakland Cannabis Buyers' Cooperative, 532 U. S. 483 (2001), The Attorney General can include a drug in schedule I only if the drug "has no currently accepted medical use in treatment in the United States," "has a high potential for abuse," and has "a lack of accepted safety for use … under medical supervision." §§812(b)(1)(A)—(C). Under the statute, Cannabis can't be in schedule 1 if it has any accepted medical use. Because Cannabis has accepted medical use by 31 States, the District of Columbia and the National Academies of Science, Cannabis must be removed from Schedule 1 of the CSA and should be removed from control of the CSA entirely.

II. THE PANEL FAILED TO ADDRESS THE CONTINUOUS PATTERN OF ILLEGAL WITNESS TAMPERING BY DEA.

18 U.S. Code § 1512 (e) states:

"In a prosecution for an offense under this section, it is an affirmative defense, as to which the defendant has the burden of proof by a preponderance of the evidence, that the conduct consisted solely of lawful conduct and that the defendant's sole intention was to encourage, induce, or cause the other person to testify truthfully".

(f) For the purposes of this section—

(1) an official proceeding need not be pending or about to be instituted at the time of the offense; and

(2) the testimony, or the record, document, or other object need not be admissible in evidence or free of a claim of privilege.

There is nothing about the actions of the DEA to indicate that their intention has ever been to encourage, induce or cause the production a factually accurate review of Medical Cannabis. The evidence from Krumm's previous rescheduling petition is quite clear that DEA has instituted unreasonable and arbitrary rules to manipulate the testimony of the FDA by barring them from considering the vast epidemiological proof that Cannabis is safe and effective for medical use. In the immediate case, DEA has refused to forward new evidence from the National Academies of Science to the FDA for review. This behavior proves a pattern of conspiracy to keep Cannabis illegally in Schedule 1 of the CSA, and to tamper with and/or prevent any witness testimony which might expose the illegality of Schedule 1 placement.

Jeff Sessions is fully complicit in these actions because he is responsible for administering the CSA and he has directly ordered the DEA to violate the law by continuing to block Medical Cannabis research and to refuse to approve new producers of Medical Cannabis, in violation of the settlement from my previous Rescheduling Petition in 2016. Because of the ongoing criminal nature of both DEAs and Jeff Sessions' actions, they are not entitled to bar claims that could have been brought up in Krumms previous rescheduling petition. These claims show a pattern of ongoing witness tampering by the DEA and illegal conspiratorial activity between DEA and Sessions in violation of RICO laws.

DEA has ordered the FDA to adhere to irrational standards of review for Cannabis by creating rules are completely unreasonable, arbitrary, and capricious. They are an irrational abuse of authority and clear violation of Supreme Court precedent. These rules limit and control the testimony of the FDA, thus illegally tampering with the only witness the DEA allows to provide testimony. The DEA prohibits the FDA from considering the scientific record, bans experts testimony including that of the National Academies of Sciences, and excludes 31 States and the District of Columbia from the definition of "in the United States".

Krumm has proven the futility of the administrative process for moving Cannabis out of Schedule 1 of the CSA because the DEA is illegally tampering with the testimony of the FDA. Both FDA and HHS have concurred with Krumm's assessment of the futility of the administrative process as devised by 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.

Karen DeSalvo further substantiates the futility of the administrative process in her June 3, 2015 letter to Chuck Rosenberg, 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."

Unfortunately, for purposes of the CSA, the DEA has defined "accepted medical use in the United States" to require phase 3 clinical studies. At the same time, they continue to prohibit such research from being conducted. DEA has created an arbitrary definition of "accepted medical use" that utilizes circular logic to ensure Cannabis can never be recognized as having "accepted medical use in the United States". To ensure the outcome , DEA illegally tampers with and restricts the testimony of the FDA in order to ensure the outcome they seek.

Pure THC, the primary psychoactive component of Cannabis, has long been a schedule 3 drug. FDA has now concluded that cannabidiol CBD), does not have significant potential for abuse and could be removed from control under the CSA (letter to Robert Patterson, acting administrator of DEA from Brett P Giroir, asst Secretary of Health, dated May 16, 2018). However, the DEA continues to insist

that Cannabis has no accepted medical use. DEA simply orders the FDA to illegally ignore the vast scientific record as well as the will of 31 States and the District of Columbia, while basing their recommendation on irrational standards that are completely unreasonable, arbitrary and capricious.

In FDA's response to Krumm's previous rescheduling petition, "The Medical Application of Marijuana: A review of Published Clinical Studies" FDA admits that they excluded all studies of Cannabis extracts and single cannabinoids from the review. Then FDA threw out dozens of studies with whole plant Cannabis and focused on 11 small studies. Although these studies proved that Cannabis was effective for treating a variety of disorders and was determined to be safe for treating these disorders, FDA claimed there were sufficient omissions from the published reports to reject each one. The outcome of FDAs "review" was predetermined by the unreasonable, arbitrary and capricious parameters put in place by the DEA to ensure the outcome they wanted. Furthermore, DEA bars anyone else from providing evidence, or from monitoring the "review" process. Although this type of pseudoscientific approach has been used by prohibitionists for decades, it ignores reality and precludes findings of "fact".

The Data Quality Act, 44 U.S.C. 5 3516 ("DQA") requires administrative agencies to develop guidelines to ensure the "quality, objectivity, utility, and integrity of information" they disseminate to the American Public. The actions of DEA, HHS, FDA, NIH and NIDA have all contributed to an ongoing campaign of

misinformation which has been used to illegally maintain schedule I placement of

Cannabis in the CSA.

DEA denies that Cannabis meets none of the criteria for inclusion in Schedule 1 of the CSA. They have tampered with the testimony of the FDA by restricting evidence. They have consistently lied to the Courts and the American Public about the safety and efficacy of Cannabis. The most recent review from the National Academies of Science found that

"There is conclusive or substantial evidence that cannabis or cannabinoids are effective for the treatment of chronic pain in adults (cannabis), As antiemetics in the treatment of chemotherapy induced nausea and vomiting (oral cannabinoids) and for improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids)." (Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda; Board on Population Health and Public Health Practice; Health and Medicine Division; National Academies of Sciences, Engineering, and Medicine; The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research; (National Academy Press 2017))

Yet DEA continues to claim "Cannabis has no accepted medical in the United States"

CONCLUSION For the foregoing reasons, this Court should grant rehearing

and rehearing en banc.

Respectfully submitted this 31'st day of October, 2018

Rev. Bryan A. Krumm CNP XXXXXXXXX Albuquerque, NM XXXXX XXXXXXXXX In Propria Persona

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14point Times New Roman, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it is 15 pages and contains 3755 words, according to the count of Apple Pages.

This petition is timely filed because in all civil cases in which the United States or an agency or officer thereof is a party, the time within which any party may seek rehearing is 45 days after entry of judgment unless the time is shortened or enlarged by order. Fed. R. App. P. 40(a)(1).

Signature

Date 10/31/18

CERTFICATE OF SERVICE

CERTIFICATE OF SERVICE

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

I hereby certify that on October 31, 2018, I filed the foregoing Petition for Rehearing En Banc with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit and to the last known addresses of the following by USPS express delivery,

Uttam Dhillon, Acting Administrator, Drug Enforcement Administration, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

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[Respondents]

Signature

Date: 10/31/18