DRUG ENFORCEMENT ADMINISTRATION

Petition by Bryan Krumm CNP)	
for the rescheduling of Cannabis)	PETITION FOR
pursuant to 21 U.S.C. § 811)	MARIJUANA
and 21 C.F.R. § 1308)	RESCHEDULING

May 22, 2017

Administrator,

Drug Enforcement Administration

Department of Justice

Washington, DC 20537

Dear Chuck Rosenburg:

The undersigned Bryan Krumm CNP hereby petitions the Administrator to initiate proceedings for the amendment of a regulation pursuant to section 201 of the Controlled Substances Act (CSA).

Cannabis (Marijuana), 21 U.S.C. § 812, Schedule I (c) (10), is incorrectly classified in 21 C.F.R. § 1308.11(d)(22) because it no longer fits the criteria for inclusion in any Schedule of the CSA as set forth in 21 U.S.C. § 812(b)(1)-(5); and should be immediately excluded form control under the CSA.

Schedule I. -

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

GROUNDS FOR REMOVAL OF CANNABIS FROM CONTROL UNDER THE CSA

Neither DEA nor the Attorney General have the authority to regulate medical practice in general. Legal authority granted under the CSA pertains only to the prohibition of prescription writing authority in order to promote drug abuse. Federal drug law, 21 U.S.C. § 903, gives the states the authority to determine accepted medical use. See, Gonzales v. Oregon, 546 U.S. 243, 269-270 (2006):

> The statute and our case law amply support the conclusion that Congress 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 Government, in the end, maintains that the prescription requirement delegates to a single Executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality. The text and

structure of the CSA show that Congress did not have this far-reaching intent to alter the federal-state balance and the congressional role in maintaining it." Gonzales v. Oregon, 546 U.S. at 275.

Cannabis, aka: "marihuana/marijuana", meets none of the criteria for placement in Schedule I of the Controlled Substances Act. Cannabis does not have the high potential for abuse required for placement in Schedule I. Cannabis has less potential for abuse than many drugs which are widely available including opioids, benzodiazepines, amphetamines, tobacco, alcohol, caffeine and sugar. However, DEA has historically insisted that because "marihuana" is illegal, any use is abuse, and because people use cannabis in spite of its illegal status, "marihuana" must have a high potential for abuse. This is a totally unreasonable, arbitrary and capricious abuse of circular logic designed to obfuscate the truth. Cannabis does not have the potential for abuse required to be placed in schedule 1 of the CSA. People continue to use Cannabis in spite of potential legal repercussions because it is often the only medication that is effective for treating their illnesses. DEA's interpretation of "abuse" allows them to stigmatize the sick and suffering as "drug abusers" and to deny Americans citizens fundamental rights.

Cannabis has accepted medical use in the United States. Twenty-nine States and the District of Columbia accept the medical use of Cannabis. Cannabis has been accepted as having medical use by dozens of professional medical and nursing organizations throughout the U.S. (see http://www.medicalcannabis.com/Grouplist.htm). DEA argues that no Investigational New Drug (IND) application has ever been filed for Cannabis. An IND is not appropriate for Cannabis. Cannabis is an ancient drug, not a new drug. It has been safely used as a medication for thousands of years. Certainly, when introducing a new pharmaceutical chemical concoction to market, it's appropriate to seek proof of safety and efficacy. People die from the side effects of pharmaceuticals every day. Cannabis has been used for thousands of years as a medication and

there has never been a death due to any toxic effects.

Furthermore, four individuals have been supplied with Cannabis for medical use by the federal government for decades. A comprehensive study of these legal medical Cannabis users 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).

Although DEA insists that there have been no phase 3 clinical studies conducted on Medical Cannabis, they have ignored the phase 3 trial conducted under the Lynn Pierson Therapeutic Research Program by the NM Department of Health, which proved the safety and efficacy of smoked Cannabis for treating the nausea and vomiting associated with cancer chemotherapy (Report of the Lynn Pierson Therapeutic Research Program, New Mexico State Department of Health" 1984), http://www.druglibrary.org/schaffer/hemp/medical/pierson.html. (study continued beyond date of report).

Several smaller studies of smoked Cannabis have recently confirmed its safety and efficacy for medical use (see http://www.cmcr.ucsd.edu/index.php/2015-11-20-20-53-40/scientific-publications). In my clinical practice, Cannabis has proven to be the only medication that is effective for treating every symptom cluster of PTSD and has also proven to be the only medication effective at rapidly reducing suicidality in most patients, http://journals.lww.com/tnpj/Fulltext/2016/01000/Cannabis_for_posttraumatic_stress_disorder__A.6.aspx .

Finally, Cannabis is safe for use under medical supervision. This has been determined by 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

Unfortunately, because no state had accepted the medical use Cannabis in 1988, the DEA Administrator was able to reject the conclusion of his own Administrative Law Judge in DEA Docket No. 86-22, that Cannabis must be transferred from schedule 1 to schedule 2 of the federal controlled substances act. Because 29 states and the District of Columbia have now accepted the medical use Cannabis, the Federal Government no longer has any compelling interest to justify total prohibition of Cannabis. The federal prohibition of Cannabis for medical use violates the substantive due process and equal protection guarantees of the US Constitution.

Medical Cannabis laws have been correlated with reductions in suicide rates (Anderson DM1, Rees DI, Sabia JJ. Medical marijuana laws and suicides by gender and age. Am J Public Health. 2014 Dec;104(12):2369-76. doi: 10.2105/AJPH.2013.301612. Epub 2014 Jan 16.), opioid overdoses (Bachhuber MA1, Saloner B2, Cunningham CO3, Barry CL4. Medical cannabis laws and opioid analgesic overdose mortality in the United States, 1999-2010. JAMA Intern Med. 2014 Oct;174(10):1668-73.), traffic fatalities (Santaella-Tenorio J1, Mauro CM1, Wall MM1, Kim JH1, Cerdá M1, Keyes KM1, Hasin DS1, Galea S1, Martins SS1. US Traffic Fatali-

ties, 1985-2014, and Their Relationship to Medical Marijuana Laws. Am J Public Health. 2017 Feb;107(2):336-342.), and the use of far more dangerous pharmaceuticals. (Bradford AC1, Bradford WD2. Medical Marijuana Laws May Be Associated With A Decline In The Number Of Prescriptions For Medicaid Enrollees. Health Aff May 2017 36:5945-951; Dyer O. US states that allow medical marijuana see drop in prescriptions for other drugs, study finds. BMJ. 2016 Jul 14;354; Bradford AC, Bradford WD. Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D. Health Aff (Millwood). 2016 Jul 1;35(7):1230-6). Therefore, not only is Cannabis safe for medical use, it actually increases public safety by effectively treating disease, and by reducing harms associated with pharmaceuticals and/or drugs of abuse.

Petitioner brings this action pursuant to the Controlled Substances Act (CSA), 21 USCA § 801 et seq., which explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its preemption 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.

The Government has no legitimate basis to totally prohibit the medical use of Cannabis. Unlike Cannabis, substances which have clear potential for abuse, are legally available for medical, religious and/or recreational use. Clearly, concerns about misuse of Cannabis can be protected in a less restrictive manner than the total prohibition that exists in the United States today. No rational reason exists for treating Cannabis differently than other substances used for medical, religious or recreational purposes.

Because Cannabis does not have the abuse potential for placement in Schedule I of the CSA, and because Cannabis now has accepted medical use in 29 states and the District of Columbia, and because the DEA's own Administrative Law Judge has already determined that Cannabis is safe for use under medical supervision, and because Cannabis has been legalized in 8 States, the federal definition for a schedule I controlled substance, 21 U.S.C. § 812(b)(1)(A)-(C), no longer applies to marijuana and federal law must be amended to reflect these changes. Cannabis should be immediately removed from the federal list of controlled substances and placed under regulation by the States.

Attorney Generals have repeatedly demonstrated that they cannot be trusted to fulfill their duty to administer the Controlled Substances Act, and DEA has consistently demonstrated that science and clear epidemiological evidence has nothing to due with scheduling decisions. DEA administrator Chuck Rosenberg simply calls Medical Cannabis "a joke". Attorney General Jeff Sessions calls Medical Cannabis "hype" and says "good people don't smoke marijuana". Now we are facing a new wave of intensified persecution of Cannabis users. To the DEA and Attorney General, Cannabis users are inherently bad people that must be stopped at all costs and the Constitution is just a worthless piece of paper.

The DEA and Attorney General are unlawfully interfering with medical decision making and violating rights granted to the States by the US Constitution. Billions of dollars are stolen from Cannabis users to line the coffers of law enforcement, often with the victims never even being charged with a crime. The actions of these bureaucratic administrators have no basis in science, public safety, or rational thought processes. These actions are based on ignorance, intolerance, political expediency and financial gain. Law enforcement must not be allowed to interfere with appropriate medical treatment for millions of Americans. The actions of the DEA is more

indicative of a RICO operation, than that of a legitimate law enforcement agency. The words of the Chuck Rosenberg and Jeffrey Sessions are diagnostic of narcissistic sociopaths with little regard for science, the safety and welfare of American Citizens, or for the Constitution of the United States.

Every day the Attorney General fails 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 job to remove Cannabis from control under the CSA, more Americans die needlessly. Krumm has proven the futility of the administrative process for moving Cannabis out of Schedule 1 of the CSA. 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."

DEA ignores the extensive scientific record, and boldly proclaims that because it has blocked Cannabis research for decades, that no evidence exists regarding the medical use of Cannabis. Therefore, Krumm poses a strictly legal question which does not require any extensive scientific inquiry. 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".

Unfortunately, for purposes of the CSA, the DEA has defined "accepted medical use in the United States", to require phase 3 clinical trials. At the same time, they have prohibited such research from being conducted. DEA has created an arbitrary definition that utilizes circular logic to ensure Cannabis can never be recognized as having "accepted medical use in the United States".

Dozens of recent phase 2 clinical studies have built on the phase 3 clinical trial conducted under the Lynn Pierson Program to provide scientific proof of the safety and efficacy of Cannabis. The daily clinical observations of over a million Medical Cannabis Patients, by thousands of Practitioners, has created an epidemiological laboratory providing prima facie proof

that Cannabis is safe and effective for medical use. The DEA, FDA, HHS and NIDA are ignoring the epidemiological and scientific evidence, and allowing Americans to die needlessly.

If cannabis truly "has no accepted medical use in the United States" why are 4 Americans still supplied with Cannabis through the Federal Investigational New Drug program? These patients have received 9-12 ounces of Cannabis a month for decades. Certainly, if there are any real concerns for safety, there would be some sort of data to support those concerns after 4 decades of running an IND.

If HHS truly believes that Cannabis does not have any accepted medical use, why do they own a US patent on Cannabis based medicine, 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."?

The Drug Enforcement Administration (DEA), under advisement from the Food and Drug Administration (FDA), the Department of Health and Human Services ("HHS"), the National Institute on Drug Abuse (NIDA), and the National Institutes of Health, denied the Cannabis Rescheduling Petition I filed in 2009. Now, they continue to deprive millions of seriously ill Americans of access to Medical Cannabis leading to countless deaths each day.

Krumm contends that these federal agencies have conflicts of interest that preclude them from being able to act in good faith to conduct a legitimate and unbiased scientific reviews of Medical Cannabis. Because the States, not the Federal government, have already been given the authority to regulate medical practice, and because 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, it is now completely Unconstitutional for the DEA to continue the prohibition of Cannabis. In doing so, DEA is infringing upon fundamental rights including equal protection, due process, and religious freedom. Cannabis should be removed from control under the CSA and regulations should be developed by the States regarding medical, religious and recreational use of Cannabis.

During three of the most comprehensive reviews conducted to date 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". The most recent review, Committee on the Health Effects of Marijuana: An Evidence Review and Research Agenda; Board on Population Health

and PublicHealth 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) found that "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).

"Accepted medical use" is not defined in 21 U.S.C. § 812, it is defined in 21 U.S.C. § 903. If no state accepts the medical use of a drug or other substance, the DEA can determine whether it has accepted medical use despite the lack of accepted medical use in any state. However, when a state accepts the medical use of a drug or other substance, then the DEA is bound by that state's decision. In this case, DEA, FDA, HHS and NIDA have simply ignored the findings of 29 States, the District of Columbia, and the findings of NIH and IOM.

The question of who makes the decision about whether a drug has "accepted medical use" in the United States was answered definitively 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.

Gonzales V. Oregon, 546 U.S. 243, 270, 126 S.Ct. 904, 923, 163 L.Ed.2d 748, 775 (2006) further notes that "the structure and operation of the CSA presume and rely upon a functioning medical profession regulated under the States' police powers." The CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its preemption 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.

In its decision in Oregon v. Ashcroft, 368 F.3d 1118, 1124 (9th Cir. 2004), the Ninth Circuit noted that in our system of federalism, [S]tate lawmakers, not the federal government, are "the primary regulators of professional [medical] conduct." Conant v. Walters, 309 F.3d 629, 639 (9th Cir. 2002); see also Glucksberg, 521 U.S. at 737 (O'Connor, J., concurring). The Supreme Court has made the constitutional principle clear:

> "Obviously, direct control of medical practice in the states is beyond the power of the federal government." Linder v. United States, 268 U.S. 5, 18, 69 L. Ed. 819, 45 S. Ct. 446 (1925); see also Barsky v. Bd. of Regents, 347 U.S. 442, 449, 98 L. Ed. 829, 74 S. Ct. 650 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.").

Unless Congress' authorization is "unmistakably clear," the Attorney General may not exercise control over an area of law traditionally reserved for state authority, such as regulation of medical care. Id. at 460-61 (quoting Atascadero State Hosp., 473 U.S. at 242); see also Solid Waste Agency of N. Cook County v. U.S. Army Corps of Eng'rs, 531 U.S. 159, 173, 148 L. Ed. 2d 576, 121 S. Ct. 675 (2001) ("This concern is heightened where an administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power."); United States v. Bass, 404 U.S. 336, 349, 30 L. Ed. 2d 488, 92 S. Ct. 515 (1971) ("Unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal state balance."). In divining congressional intent, it is a "cardinal principle" of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, [federal courts shall] construe the statute to avoid such problems un-

less such construction is plainly contrary to the intent of Congress." Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council, 485 U.S. 568, 575, 99 L. Ed. 2d 645, 108 S. Ct. 1392 (1988).

Congress intended to limit the CSA to problems associated with drug abuse and addiction. The preamble to the CSA states its purpose: "to provide increased research into, and prevention of, drug abuse and drug dependence; to provide for treatment and rehabilitation of drug abusers and drug dependent persons; and to strengthen existing law enforcement authority in the field of drug abuse." Comprehensive Drug Abuse Prevention and Control Act of 1970, P. L. 91-513, 84 Stat. 1236 (1970) (preamble). City of Garden Grove v. Superior Court, 157 Cal. App. 4th 355, 383, 68 Cal. Rptr. 3d 656, 675 (2007):

> Congress enacted the CSA to combat recreational drug abuse and curb drug trafficking. (Gonzales v. Oregon, supra, 546 U.S. at p. 271; Gonzales v. Raich, supra, 545 U.S. at pp. 10- 13.) Its goal was not to regulate the practice of medicine, a task that falls within the traditional powers of the states. (Gonzales v. Oregon, supra, 546 U.S. at p. 269.)

City of Garden Grove v. Superior Court, 157 Cal. App. 4th 355, 383-384, 68 Cal. Rptr. 3d 656, 676 (2007) notes:

> The issue of who defines medical practice under 21 U.S.C. § 903 was not considered in United States v. Oakland Cannabis Buyers Cooperative, 532 U.S. 483 (2001) (OCBC hereafter). The only question presented to the Supreme Court was whether the Federal CSA contains a "medical necessity defense". The Supreme Court declined to rule on whether the prohibition of medical marijuana exceeded Congress' Commerce Clause powers. OCBC, 532 U.S. at 494 ("Because the Court of Appeals did not address these claims, we decline to do so in the first instance."); OCBC, 532 U.S. at 495 ("Nor are we passing today on a constitutional question, such as whether the Controlled Substances Act exceeds Congress' power under the Commerce Clause."). OCBC, 532 U. S. 483 (2001) at 492, states 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).

The issue of who defines medical practice under 21 U.S.C. § 903 was not considered in Gonzales v. Raich, 545 U.S. 1, 9 (2005):

> "The case is made difficult by respondents' strong arguments that they will suffer irreparable harm because, despite a congressional finding to the contrary, marijuana does have valid therapeutic purposes. The question before us, however, is not whether it is wise to enforce the statute in these circumstances; rather, it is whether Congress' power to regulate interstate markets for medicinal substances encompasses the portions of those markets that are supplied with drugs produced and consumed locally. Well-settled law controls our answer. The CSA is a valid exercise of federal power, even as applied to the troubling facts of this case. However, the Court also 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.

In enacting the Controlled Substances Act, 21 U.S.C. 801 et seq. ("CSA"), in 1970, Congress explicitly recognized that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. 801(1). To this end, the CSA classifies substances into five categories based on their: (1) medical utility, (2) abuse potential, and (3) safety of use under medical supervision. 21 U.S.C. 812(b)(1)(A)-(C). The most restrictive category, Schedule I, is reserved for substances with no currently accepted medical use, the highest abuse potential, and lack of safety under medical supervision. See 21 U.S.C. 812. Schedule I substances may only be used for research purposes under strict guidelines. 21 U.S.C. 823. The government classifies marijuana as a Schedule I substance.' See 21 C.P.R. 1308.11.

When Congress initially placed Cannabis in Schedule I when enacting the CSA, it did not make any specific findings regarding Cannabis as medicine or its relative abuse potential. Rather, the House Report recommending Cannabis' initial placement in Schedule I reveals Congress' uncertainty about the harms associated with Cannabis and its medical benefits. See H.R. Rep. No. 91-1444, P.L. 91-513, U.S. Code Congo & Admin. News 1970, pp. 4566,4629 ("Some ques-

tion has been raised whether the use of the plant itself produces 'psychological or physical dependence' as required by a schedule I or even schedule II criterion. Since there is still a considerable void in our knowledge of the plant and effects of the active drug contained in it, our recommendation is that marihuana be retained within Schedule I at least until the completion of certain studies now underway to resolve this issue.") (quoting letter from Roger Egeberg, M.D.O. to Hon. Harley O. Staggers, dated August 14, 1970); National Org.for the Reform of Marijuana Laws v. Ingersoll ('NORML "),497 F.2d 654,657 (D.C. Cir. 1974); see also Gonzales v. Raich, 545 U.S. 1, 14 & n.22 (2005).

As an interim solution, Congress placed marijuana in Schedule I and convened a Commission on Marihuana and Drug Abuse ("Commission") to research the issue, which it viewed as an "aid in determining the appropriate disposition of this question in the future." See 21 U.S.C. ? 812(c)(10); H.R. Rep. No. 91-1444, P.L. 91-513, U.S. Code Congo & Admin. News 1970, pp. 4566, 4625-26; Ingersoll, 497 F.2d at 657 (quoting House Report); see also NORML V. Bell, 488 F.Supp. 123, 141 (D.D.C. 1980) ("In making the initial determination, Congress placed marijuana in Schedule 1. The clear meaning of section 812(c) is that Congress intended marijuana to remain in Schedule I until such time as it might be reclassified by the Attorney General on the basis of more complete scientific information about the drug."). Approximately one year later, on March 22, 1972, the Commission determined that the harms associated with marijuana were overstated and it recommended its decriminalization for personal medical use. See Commission, Marijuana: A Signal of Misunderstanding (General Accounting Press March 22, 1972) [found at:http://www:sciencemag.org/content/179/4069/167.2.citation].

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). Following the receipt of HHS' findings and recommendations, the DEA Administrator must take into account the following factors to determine whether to initiate rule making proceedings: [The drug's] actual or potential for abuse; Scientific evidence of its pharmacological effect if known; The state of current scientific knowledge regarding the drug or other substance; Its history and current pattern of abuse; The scope, duration, and significance of abuse. What, if any, risk there is to public health; Its psychic or physiological dependence liability; Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. 8lI(c). "If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a) of this section." 21 U.S.C. 811(b) (emphasis added). In addition, the Administrative Procedure Act, 5 U.S.C. 701 et seq. ("APA") requires agencies presented with such petitions to decide the petition "within a reasonable period of time." 5 U.S.C. 555(b). The 7 years it took DEA to respond to Krumm's 2009 rescheduling petition is completely unreasonable when we have over a hundred suicides in the US every day, and Cannabis is the only medication which has proven to be effective at reducing suicidality in most patients. There were over a quarter of a million suicides in the US since Krumm filed his 2009 rescheduling petition. Many, if not most, of these were preventable. The DEA, FDA, HHS and NIDA are now responsible for the deaths of more Americans than Al Qaeda, the Taliban and ISIS combined.

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) as authority to override state sovereignty and autonomy. App. 82, 87-88, 98-100, 109. This test was developed in 1992 by DEA Administrator Robert Bonner while he was practicing medicine without a license. Bonner signed the DEA's 1992 political denial of the legitimacy of Medical Cannabis, incorrectly stating that "no responsible physician could conclude that marijuana is safe and effective for medical use". However, the decision in 1994 did not take into account the enactment of 29 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 marijuana in treatment in 1994 (prior to 1996). 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" to produce an absurd result 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 interprets its role under the CSA as one of dictating to the states which substances shall have accepted medical use, which is completely contrary to the role assigned to the DEA by Congress to regulate medical practice rather than define it.

> The CSA's definition of "United States" plainly does not require the conclusion asserted by the Administrator simply because section 802(28) defines "United States" as "all places subject to the jurisdiction of the United States." 21 U.S.C. § 802(28) (emphasis supplied). Congress surely intended the reference to "all places" in section 802(28) to delineate the broad jurisdictional scope of the CSA and to clarify that the CSA regulates conduct occurring any place, as opposed to every place, within the United States. As petitioner aptly notes, a defendant charged with violating the CSA by selling controlled substances in only two states would not have a defense based on section 802(28) if he contended that his activity had not occurred in "all places" subject to United States jurisdiction. 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.

Grinspoon v. DEA, 828 F.2d 881, 886 (1st Cir. 1987).

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)

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. FDA determined the outcome they wanted to see before beginning the review and then set the parameters of their review to ensure the outcome they wanted. They barred Krumm from providing evidence, or from monitoring the "review" process, in violation of his due process rights. 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 has ignored the evidence that Cannabis meets none of the criteria for inclusion in Schedule 1 of the CSA per the 5 point analysis they developed, and has lied to the Courts about the safety and efficacy of Cannabis.

I. THE DRUG'S CHEMISTRY MUST BE KNOWN AND REPRODUCIBLE:

Fact: The chemistry of Cannabis is well known and consistency of cannabinoid profiles in specific strains of Cannabis is easily reproducible.

II. THERE MUST BE ADEQUATE SAFETY STUDIES:

Fact: Epidemiological and clinical data have proven the incredible safety of Cannabis as evidenced by DEA's own administrative law judge concluding in 1988 that "Marijuana in its natural form, is one of the safest therapeutically active substances known to man. By any rational analysis, marijuana can be safely used within a supervised routine of medical care" and went on to find that "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." (In the Matter of Marijuana Rescheduling Petition, Docket No. 86-22, U.S. Department

of Justice, Drug Enforcement Administration, at pages 58-59). This safety profile holds true of any strain of Cannabis. It is impossible to consume enough whole plant Cannabis to have a toxic overdose.

There are no studies proving any life threatening health risks associated with Cannabis, in spite of hundreds of well funded studies seeking to prove the dangers of "marijuana". The most serious risks associated with Cannabis use are the legal consequences resulting from prohibition. In spite of decades of efforts by federal agencies to block legitimate medical research and to promote "research" into anything showing harm with Cannabis, there are hundreds of well controlled studies proving the safety and medical value of Cannabis. Beyond that, epidemiological evidence proves the safety and efficacy of Medical Cannabis.

III. THERE MUST BE ADEQUATE AND WELL-CONTROLLED STUDIES PROVING EFFICACY:

Fact: There are dozens of well controlled clinical trials of both inhaled Cannabis and Cannabis extracts proving that Cannabis is effective for treating a broad range of diseases and disorders. The DEA, FDA, HHS and NIDA simply choose to ignore the scientific record and focus attention on presumed dangers that have never been proven. In spite of widespread use of Cannabis, the biggest risks are related to prohibition itself.

IV. THE DRUG MUST BE ACCEPTED BY QUALIFIED EXPERTS:

Fact: Thousands of qualified medical providers in 29 states and the District of Columbia have accepted the medical use of Cannabis. Dozens of professional medical organizations have accepted the medical use of Cannabis. Millions of American citizens who are using Cannabis to

treat debilitating medical conditions have accepted the medical use of Cannabis. These are the "qualified experts" as to the efficacy of Medical Cannabis. The DEA has no presumed expertise in medical decision making and should have no role in determining whether Cannabis has "accepted medical use in the United States".

The CSA does not give the DEA administrator the authority to determine whether or not a drug should be used as medicine. DEA Docket No. 86-22, 57 Fed. Reg. 10,499, 10,506 (March 26, 1992):

> Clearly, the 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.

Unfortunately, Courts have consistently deferred to the DEA's determination that marijuana has no currently accepted medical use of marijuana in the United States. NORML v. DEA, 559 F.2d 735, 743 Page 7 of 30 n.41 (D.C. Cir. 1977), quotes from a letter reproduced at 40 Fed. Reg. 44,165 (1975) – Theodore Cooper, M.D., Acting Assistant Secretary for Health wrote, "There is currently no accepted medical use of marihuana in the United States." In 1989, the DEA rejected a petition to transfer marijuana from Schedule I to Schedule II, 54 Fed. Reg. 53,767 (1989). The administrative record did not include evidence of any state law accepting the medical use of marijuana. The only evidence presented in the administrative record was that some patients and some physicians considered marijuana to have therapeutic value. Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936. Now Cannabis has accepted medical use in 29 States and the District of Columbia, and is recognized by thousands of medical professionals and dozens of professional medical associations as having accepted medical use.

On page 35 of DEA's report in my previous rescheduling petition, "Schedule of Controlled Substances: Maintaining Marijuana in Schedule 1 of the Controlled Substances Act", DEA falsely claims that The American Medical Association's report, "Use of Cannabis for Medicinal Purposes", does not conclude that there is a currently accepted medical use for marijuana. However, the executive summary of the report concludes that "results of short term controlled trials indicate that smoked Cannabis reduces neuropathic pain, improves appetite and caloric intake especially in patients with reduced muscle mass, and may relive spasticity and pain in patients with multiple sclerosis". Once again DEA, FDA, NIDA and HHS are misrepresenting the facts in order to ensure continued prohibition of Cannabis. Chuck Rosenberg, Acting Administrator of the DEA may consider Medical Cannabis "a joke", but he does not have the authority to determine if Cannabis has "accepted medical use". The unreasonable, arbitrary and capricious actions of the DEA, FDA, HHS and NIDA are responsible for the deaths of tens of thousands (if not hundreds of thousands) of Americans every year.

V. THE SCIENTIFIC EVIDENCE MUST BE WIDELY AVAILABLE:

Fact: The scientific evidence is widely available. Thousands of articles are available from the National Library of Medicine at pubmed.gov including hundreds of reviews of controlled clinical research with Cannabis and Cannabis extracts. Thousands of case reports are available online with a simple web search.

On page 69 of DEA's "Denial of Petition to Initiate Proceedings to Reschedule Marijuana" the FDA acknowledges that "the eleven studies evaluated in this review showed positive signals that marijuana may produce a desirable therapeutic outcome". FDA also 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".

In its review " The Medical Application of Marijuana: A Review of Published Clinical Studies", FDA acknowledges that Cannabis 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. Then they disregard these findings based on the arbitrary parameters they've put in place to support a false claim that Cannabis has "no accepted medical use".

DEA insists that Cannabis has a high potential for abuse because it is the most commonly used of all "illegal" drugs. Krumm proposes that the wide spread use of Cannabis is predominately a result of the unique therapeutic properties of Cannabis and that the use of Cannabis by millions of Americans proves that the American People have accepted its medical use. DEA simply calls all "use", "abuse", and demonizes millions of Americans who are benefiting from the medical use of this plant. Cannabis does not have the high potential for abuse required for placement in Schedule I of the CSA. Although millions of Americans have used Cannabis, it has had little negative impact on the lives of the vast majority of users. Cannabis lacks the abuse potential required for control under the CSA.

Cannabis has accepted medical use in 29 states and the District of Columbia. Dozens of professional medical organizations have accepted the medical use of Cannabis. Thousands of medical providers have accepted the medical use of Cannabis and have referred over a million patients into State Medical Cannabis Programs. 83% of American citizens accept the medical use of Cannabis. Hundreds of studies prove the medical value of Cannabis. Testimony of ex-

perts at the National Institutes of Health proves the medical use of Cannabis. The 4 remaining patients in the Federal Compassionate IND prove the safety and efficacy of Cannabis.

Marijuana is safer for use under medical supervision than any pharmaceutical. It impossible to induce a lethal overdose from whole plant Cannabis. It is unreasonable to assert that there are no New Drug Applications for Cannabis because Cannabis is not a "new" drug. It is an ancient drug that has been safely used as a medication for thousands of years. However, the FDA has been supplying smoked Medical Cannabis to patients in the Compassionate IND Program since the 1970's. Although no federal agencies have ever collected any significant scientific data from the IND program, the Missoula Chronic Clinical Cannabis Use Study evaluated the long term effects of heavy Cannabis use in 4 patients from the program. This study demonstrated clinical effectiveness in these patients in treating glaucoma, chronic musculoskeletal pain, spasm and nausea, and spasticity of multiple sclerosis. All 4 patients were stable with respect to their chronic conditions, and were taking many fewer standard pharmaceuticals than previously. Mild changes in pulmonary function were observed in 2 patients, while no functionally significant attributable sequelae were noted in any other physiological system examined in the study. http://www.cannabis-med.org/jcant/russo_chronic_use.pdf.

The benefits of Medical Cannabis far outweigh any interest the DEA, FDA, HHS and NIDA may have in maintaining total prohibition of Cannabis. There is no evidence that Cannabis is being abused by patients in the IND. There is no evidence of diversion from the IND. There is no evidence of serious adverse effects of Cannabis even with long term heavy use. However, there is ample evidence that Cannabis has "accepted medical use in the United States". In the wake of these facts, the current prohibition of Cannabis for medical use is untenable because Cannabis does not meet any of the criteria for control under the CSA.

Although DEA claims that "medical practitioners are not qualified by scientific training and experience to evaluate the safety and effectiveness of drugs", As an inpatient nurse, Krumm dispensed hundreds of thousands of doses of medication and was trained to monitor the effect of those medications for safety and efficacy. As a Psychiatric Nurse Practitioner, Krumm now manages over a thousand patients in New Mexico's Medical Cannabis Program for PTSD. Krumm has a peer reviewed, published a paper entitled "Cannabis for posttraumatic stress disorder: A neurobiological approach to treatment", for which he was made "Author of the Year" by the Nurse Practitioner journal. In this paper Krumm explains the neurobiological processes involved in the symptomology of PTSD, the role of the endocannabinoid system in regulating those processes and discusses why Cannabis is the only medication that's effective for treating PTSD. http://journals.lww.com/tnpj/Fulltext/2016/01000/Cannabis_for_posttraumatic_stress_disorder__A.6.aspx. Krumm may be one of the few individuals who possesses the expertise, training and experience to evaluate the safety and effectiveness of Medical Cannabis because he has spent decades doing just that. However, Krumm was excluded from the proceedings of the last rescheduling petition and therefore he formally requests that he be allowed to monitor the proceedings of any FDA review if reviewed is deemed necessary. The legal issues raised in this petition should provide adequate grounds for immediate removal of Cannabis from control under the Controlled Substances Act without review. Control of Cannabis must be handed over to the States to determine how medical, recreational and religious issues may best be handled.

The administrative review process for having Cannabis removed from Schedule 1 of the CSA has proven futile, a fact supported by statements from the FDA and HHS. The DEA simply denies due process and continues to interfere with medical treatment. There is no "rational" rea-

son to allow 22 Veterans to suicide every day when a safe, effective medication is available for treating PTSD in the form of Cannabis.

The Center for Medicinal Cannabis Research (CMCR, www.cmcr.ucsd.edu) has produced many published studies on marijuana's potential use for treating multiple sclerosis, neuropathic pain, appetite suppression and cachexia. However, DEA and FDA have chosen to arbitrarily ignore this evidence. DEA incorrectly asserts that no other state-level medical marijuana laws have produced scientific data on marijuana's safety and effectiveness while ignoring a large scale controlled clinical study conducted by the NM Department of Health on whole Cannabis vs. Dronabinol for treating side effects of chemotherapy, http://www.druglibrary.org/schaffer/hemp/medical/pierson.html.

The DEA has no compelling interest to justify total prohibition of Cannabis. In light of the absence of factual support, the present prohibition is, at best, an overreaction driven by political passions or, at worst, influenced by religious and racial insensitivity, if not outright hostility. The total prohibition of Cannabis is a totally arbitrary deprivation of liberty, which violates the substantive due process guarantee.

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, the Attorney General could not put Cannabis into sched-

ule I if Cannabis has any accepted medical use. Because Cannabis has accepted medical use in 29 states and the District of Columbia, all of which are "in the United States", Cannabis must be removed from Schedule 1 of the CSA and should be removed from control of the CSA entirely.

DEA claims to have the authority to decide that Cannabis has no accepted medical use in treatment in the United States, in blatant disregard of 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.

Gonzales V. Oregon 546 U. S. (2006) at p.11 points out that 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. The statute is also specific as to the manner in which the Attorney General must exercise this authority:

> " [regarding scheduling] shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by [the Administrative Procedure Act, 5 U. S. C. §553]." 21 U. S. C. §811(a).

Krumm was denied such a hearing in his last rescheduling petition and requests that an open public hearing be held on this rescheduling petition so that DEA and FDA cannot simply claim that "evidence was not found".

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)).

DEA's interpretation of "medical use in treatment in the United States" 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).

21 U.S.C. § 903, as noted in Gonzales v. Oregon, 546 U.S. 243, 251 (2006), provides evidence that Congress envisioned a significant role for the states in the federal CSA:

> The CSA explicitly contemplates a role for the States in regulating controlled substances, as evidenced by its pre-emption provision.

And see, Conant v. Walters, 309 F.3d 629, 639 (9th Cir. 2002), cert. denied, Walters v. Conant, 540 U.S. 946 (2003):

> 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).

The federal CSA must be interpreted by the DEA to create harmony between the states and the national government, not discord. The CSA gives the DEA administrator only "limited" authority to determine accepted medical use of new drugs that have not been accepted by state lawmakers or a majority of physicians.

While the Government may have some limited interest in preventing drug abuse, there is no legitimate basis to totally prohibit the medical use of Cannabis. The fact that substances which have clear potential for abuse, are available for medical use, indicates that concerns about misuse can be protected in a less restrictive manner than the total prohibition that exists in the United States today. No factual basis exists for treating Cannabis differently than other substances used for medical, recreational or religious purposes.

When Congress placed Cannabis in the Controlled Substances Act of 1970 (CSA), they expressed doubt about the need to control Cannabis as a controlled substance in the CSA, and they said the placement was temporary. Congress established a Presidential Commission to review the temporary placement and recommend final placement. See the Legislative History of the CSA, H.R. Rep. No. 91-1444, October 10, 1970, 1970 USCCAN 4566, at pages 4578-4580.

The Commission on Marihuana, established by Congress in the CSA and appointed for the very purpose of resolving Congress' doubt about the placement of marijuana in the CSA, found as a finding of fact that Marijuana is not a sufficient threat to public health and safety to justify arresting or prosecuting anyone for using Marijuana. The First Report of the National Commission on Marihuana and Drug Abuse, at page 150 states, "marihuana use is not such a grave problem that individuals who smoke marihuana, and possess it for that purpose, should be subject to criminal procedures." See Public Law 91-513 - Oct. 27, 1970 [84 Stat. 1280-1281] Part F - Advisory Commission - Establishment of Commission on Marihuana and Drug Abuse - SEC. 601. And see, H.R. Rep. No. 91-1444, October 10, 1970, 1970 USCCAN 4566, at pages 4578-1580 (explaining the uncertainty of Congress in placing marihuana in Schedule I of the CSA and the temporary nature of this placement while the Commission worked on its report). At page 56-57, the Commission wrote:

> "A large amount of research has been performed in man and animals regarding the immediate effect of marijuana on bodily processes. No conclusive evidence exist of any physical damage, disturbances of bodily processes or proven human fatalities attributable solely to even very high doses of marijuana. Recently, animal studies demonstrated a relatively large margin of safety between the psychoactive dose and the physical and behavioral toxic and lethal dose. Such studies seem to indicate that safe human study could be undertaken over a wide range of doses."

Following a lawsuit, a comprehensive review of the therapeutic uses of marijuana commissioned by the White House's Office of National Drug Control Policy, the prestigious Institute of Medicine ("IOM"), in 1999, reported that Cannabis may be used to treat a variety of conditions. They concluded "The accumulated data indicate a potential therapeutic value for cannabinoid drugs, particularly for symptoms such as pain relief, control of nausea and vomiting, and appetite stimulation.") See Joy, Janet E., Stanley J., Watson, and John A. Benson, Jr., (eds) Marijuana as

Medicine: Assessing the Science Base, at 4 (National Academy Press 1999) [found at http://books.nap.edu/openbook.php?record_id=6376&page=4]

On January 31, 2011 The Veterans Administration issued VHA DIRECTIVE 2011-004, which allows Veterans to participate in State Medical Cannabis programs http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2362

On 03/17/2011 the National Cancer Institute issued, an expert-reviewed information summary, about the use of Cannabis and cannabinoids in the treatment of cancer and cancer-related side effects. Although the initial release was retracted and replaced with a new version on 3/30/2011, downplaying the important antitumoral properties of cannabinoids, the experts still agreed that cannabinoids may have benefits in the treatment of cancer-related side effects http://www.cancer.gov/cancertopics/pdq/cam/cannabis/healthprofessional

Cannabis meets all criteria for "accepted medical use" as defined in Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1135 (D.C. Cir. 1994) Because Cannabis has "accepted medical use in treatment" in 29 states and the District of Columbia; and because Cannabis has been accepted as having medical use by numerous federal healthcare agencies including HHS; and because dozens of professional healthcare organizations have accepted the medical use of Cannabis; the Drug Enforcement Administration must remove Cannabis from schedule 1 of the CSA and should exempt it from control under the CSA entirely.

By refusing to provide accurate information about the safety and efficacy of Cannabis and by refusing to remove Cannabis from unlawful placement in Schedule I of the CSA, the DEA and Attorney General have neglected their clear statutory duty to administer the CSA and to provide accurate information to the public, thus causing direct and immediate harm to millions of Americans by denying them access to needed medication.

It is clear from the legislative history, the language of the statute, and the case law, that the findings required by 21 U.S.C. § 811 can never justify the inclusion of drugs or substances which have accepted medical use in treatment in the United States in Schedule I of the CSA. Congress explicitly recognized the authority of the states to determine accepted medical use. Congress explicitly expressed its intent not to preempt state laws regarding accepted medical use of drugs or substances. 21 U.S.C. § 903. Gonzales v. Oregon, 546 U.S. 243 (2006). Therefore, Krumm requests that the DEA immediately remove Cannabis from control under the CSA and transfer authority for regulating medical, recreational and religious use of Cannabis to the States, where such control belongs.

Respectfully submitted this 22nd day of May, 2017 to:.

Chuck Rosenberg, administrator; Drug Enforcement Administration; 8701 Morrissette Drive Springfield, VA 22152
US Attorney General Jeff Sessions; U.S. Department of Justice 950 Pennsylvania Avenue, NW; Washington, DC 20530-0001

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