UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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DOCKETING STATEMENT

Case Name: Krumm v DEA
Appeal No. (if available):
Court/Agency Appealing From: _ <u>Final decision of DEA Denying Rescheduling petition</u> <u>filed by Rev. Bryan Krumm, CNP_</u>
Court/Agency Docket No.: <u>16-9557</u>
Party or Parties Filing Notice of Appeal/Petition: <u>Reverend Bryan A. Krumm, CNP</u>
I. TIMELINESS OF APPEAL OR PETITION FOR REVIEW
A. APPEAL FROM FINAL DECISION OF THE DRUG ENFORCE- MENT ADMINISTRATION
1. Date Petition for Review filed: 11/8/16

a. Was a motion filed for an extension of time to file the notice of appeal? If so, give the filing date of the motion, the date of any order disposing of the motion, and the deadline for filing notice of appeal? Yes, Motion for leave to file Notice of Ap-

peal and extension of time to file mailed on 10/12/16	peal and	extension	of time	to file	mailed	on	10/	12/	16
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- b. Is the United States or an officer or an agency of the United States a party to this appeal?

 YES
- 2. Authority fixing time limit for filing notice of appeal:

Fed. R. App. 4 (a)(1)(A)	Fed. R. App. 4(a)(6)
Fed. R. App. 4 (a)(1)(B) _X	Fed. R. App. 4(b)(1)
Fed. R. App. 4 (a)(2)	Fed. R. App. 4(b)(3)
Fed. R. App. 4 (a)(3)	Fed. R. App. 4(b)(4)
Fed. R. App. 4 (a)(4)	Fed. R. App. 4(c)
Fed. R. App. 4 (a)(5)	
Other:	

- 3. Date final judgment or order to be reviewed was **entered** in the Federal Register on <u>8/12/16</u>
- 4. Does the judgment or order to be reviewed dispose of **all** claims by and against **all** parties? *See* Fed. R. Civ. P. 54(b).

 YES

(If your answer to Question 4 above is no, please answer the following questions in this section.)

- a. If not, did district court direct entry of judgment in accordance with Fed. R. Civ. P. 54(b)? When was this done?
- b. If the judgment or order is not a final disposition, is it appealable under 28 U.S.C. ' 1292(a)?

	C.	If none of the above applies, what is the specific statutory basis for determining that the judgment or order is appealable?
5.	Toll	ing Motions. See Fed. R. App. P. 4(a)(4)(A); 4(b)(3)(A).
	a.	Give the filing date of any motion that tolls the time to appeal pursuant to Fed. R. App. P. 4(a)(4)(A) or 4(b)(3)(A):
	b.	Has an order been entered by the district court disposing of any such motion, and, if so, when?
6.	Cros	ss Appeals.
	a.	If this is a cross appeal, what relief do you seek beyond preserving the judgment below? See United Fire & Cas. Co. v. Boulder Plaza Residential, LLC, 633 F.3d 951, 958 (10th Cir. 2011)(addressing jurisdictional validity of conditional cross appeals).
	b.	If you do not seek relief beyond an alternative basis for affirmance, what is the jurisdictional basis for your appeal? <i>See Breakthrough Mgt. Group, Inc. v. Chukchansi Gold Casino and Resort</i> , 629 F.3d 1173, 1196-98 and n. 18 (10th Cir. 2010)(discussing protective or conditional cross appeals).

B. **REVIEW OF AGENCY ORDER** (To be completed only in connection with petitions for review or applications for enforcement filed directly with

the	court	of	appea	ls.)
(11C	COUL	V.	appea	10, 1

	1.	Date petition for review was filed: attempted to file 10/11/16 - filed on 11/8/16
	2.	Date of the order to be reviewed: 8/12/16
	3.	Specify the statute or other authority granting the court of appeals jurisdiction to review the order: <u>This Court's jurisdiction arises from</u>
the All Writs	Act, 281	U.S.C 1651(a), which provides that "the Supreme Court and all courts es-
tablished by a	n Act of	Congress may issue all writs necessary or appropriate in aid of their re-
spective juriso	lictions.	"See Telecommunications Research & Action Ctr. v. FCC, 750 F.2d 70, 76
(D;C. Cir. 198	(4); see	also Sierra Club v. Thomas, 828 F.2d 783, 795-96 (D.C. Cir.1987) This
Court's jurisda	iction al	so arises from its statutory authority to review findings on rescheduling
petitions unde	r the CS	SA, 21 U.S.C. 877, Venue is proper in this Court because the District of
New Mexico	is where	Rev. Bryan Krumm, CNP resides and where Damon Martinez, US Attor-
ney, maintains	his prii	ncipal office.
	4.	Specify the time limit for filing the petition (cite specific statutory section or other authority):60 days per Fed. R. App. 4 (a)(1) (B)
C.	APPE	AL OF TAX COURT DECISION
	1.	Date notice of appeal was filed: (If notice was filed by mail, attach proof of postmark.)
	2.	Time limit for filing notice of appeal:
	3.	Date of entry of decision appealed:

4.	Was a timely motion to vacate or revise a decision	on made under the
	Tax Court=s Rules of Practice, and if so, when?	See Fed. R. App. F
	13(a)	

II. LIST ALL RELATED OR PRIOR RELATED APPEALS IN THIS COURT WITH APPROPRIATE CITATION(S). If none, please so state.

I previously filed 2 actions in this court regarding the same case. One requesting that DEA be ordered to respond to this rescheduling petition and the other appealing the denial of the District Court to issue a writ of mandamus or certiorari ordering the DEA to remove Cannabis for schedule 1 of the CSA. Case No. 14-2080 and Case No. 14-2085

These requests were denied by this court because there was no final determination by the DEA regarding Plaintiff's rescheduling petition and because DEA delays of many years in responding to my rescheduling petition were considered reasonable.

III. GIVE A BRIEF DESCRIPTION OF THE NATURE OF THE UNDERLYING CASE AND RESULT BELOW.

In 2009 I, Bryan Krumm, filed a rescheduling petition with the DEA demanding that Cannabis be removed from schedule 1 of the Controlled Substances Act because it now has "accepted medical use in the United States". Therefore Cannabis can no longer legally remain in schedule 1 by statutory definition. On August 12, 2016, DEA notified Krumm that they were denying Krumm's rescheduling petition, arguing that "Cannabis has no accepted medical use in the United States".

IV. IDENTIFY TO THE BEST OF YOUR ABILITY AT THIS STAGE OF THE PROCEEDINGS, THE ISSUES TO BE RAISED IN THIS APPEAL.

The States, not the Federal government, have been given the authority to regulate medical practice. 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. Even in the event that that court upholds the validity of the FDA review in Krumm's case, the defendants still have no legal authority to overturn the laws of 25 States. In *Gonzales v. Oregon*, 546 U.S. 243, 269-270 (2006), the court found "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 (1996) (quoting Metropolitan Life Ins. Co. v. Massachusetts, 471 U. S. 724, 756 (1985))."

The DEA has no authority to question the determination by 25 States and the District of Columbia that Cannabis has "accepted medical use". The DEA lacks the authority to over-ride the opinion of a significant my of physicians that "accept the medical use of Cannabis". The DEA lacks the authority to deny the reality that for over a million American Citizens in state sanctioned Medical Cannabis Programs have "accepted the medical sue of Cannabis". Because Krumm has raised issues of fundamental rights, strict scrutiny should be applied to determine if the DEA has a compelling interest in denying access to a safe/ effective medication for millions of Americans and if they do have a compelling interest, is total prohibition the least restrictive means of furthering that interest?

V. ADDITIONAL INFORMATION IN CRIMINAL APPEALS.

A.	Does this appeal involve review under 18 U.S.C. ' 3742(a) or (b) of the sentence imposed?
B.	If the answer to A (immediately above) is yes, does the defendant also challenge the judgment of conviction?
C.	Describe the sentence imposed.

Was the sentence imposed after a plea of guilty?
If the answer to D (immediately above) is yes, did the plea agreement include a waiver of appeal and/or collateral challenges?
Is defendant on probation or at liberty pending appeal?
If the defendant is incarcerated, what is the anticipated release date if the judgment of conviction is fully executed?
Does this appeal involve the November 1, 2014 retroactive amendments to §§ 2D1.1 and 2D1.11 of the U.S. Sentencing Commission's Guidelines Manual, which reduced offense levels for certain drug trafficking offenses?

NOTE:

In the event expedited review is requested and a motion to that effect is filed, the defendant shall consider whether a transcript of any portion of the trial court proceedings is necessary for the appeal. Necessary transcripts must be ordered by completing and delivering the transcript order form to the Clerk of the district court with a copy filed in the court of appeals.

VI. ATTORNEY FILING DOCKETING STATEMENT:

NOTE:

A copy of the final judgment or order appealed from, any pertinent findings and conclusions, opinions, or orders, any tolling motion listed in Fed. R. App. P. 4(a)(4)(A) or 4(b)(3) (A) and the dispositive order(s), any motion for extension of time to file notice of appeal and the dispositive order must be submitted with the Docketing Statement.

The Docketing Statement must be filed with the Clerk via the court's Electronic Case Filing System (ECF). Instructions and information regarding ECF can be found on the court's website, www.ca10.uscourts.gov.

CERTIFICATE OF SERVICE

I, Rev. Bryan A. Krumm, CNP: petitioner

hereby certify that on

December 5, 2016, I served a copy of the foregoing docketing statement to:

Chuck Rosenberg, Acting Administrator, Drug Enforcement Administration, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152,.

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

Damon P. Martinez United States Attorney for the District of New Mexico, U.S. Attorney's Office, P.O. Box 607, Albuquerque, New Mexico 87103

Douglas Throckmorton, Deputy Director for Regulatory Programs, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Sylvia Mathews Burwell, Secretary the United States Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201

Karen B. Desalvo, Acting Assistant Secretary for Health 200 Independence Avenue, S.W., Washington, D.C. 20201

Francis S. Collins, Director of the National Institutes of Health, National Institutes of Health, 9000 Rockville Pike, Bethesda Maryland 20892

Nora D. Volkow, M.D., Director of the National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Blvd. Bethesda, MD 20892

[Defendants]

at the last known addresses, by certified mail

Signature

Date 12/5/16



U.S. Department of Justice Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

August 11, 2016

The Honorable Gina M, Raimondo Governor of Rhode Island 82 Smith Street Providence, Rhode Island 02903

The Honorable Jay R. Inslee Governor of Washington P.O. Box 40002 Olympia, Washington 98504-0002

Mr. Bryan A. Krumm

Dear Governor Raimondo, Governor Inslee, and Mr. Krumm:

The enclosed materials provide the legal and factual bases for our decision, in response to your petitions, regarding the rescheduling of marijuana. I will get to that decision, but I will first highlight broader considerations with respect to (1) the law regarding drug scheduling and (2) the current state of marijuana research.

The Law Regarding Drug Scheduling:

The Controlled Substances Act (CSA) mandates that scheduling decisions be based on medical and scientific data and other data bearing on the relative abuse potential of the drug. Under the CSA, the Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), reviews, analyzes, and assesses that data and its medical and scientific conclusions legally bind the Drug Enforcement Administration (DEA).

The FDA and the DEA make a determination based on a full review of the relevant scientific and medical literature regarding marijuana. That process, too, is outlined in the enclosed materials.

A substance is placed in Schedule I if it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. These criteria are set by statute.

¹ Governors Raimondo and Inslee succeeded petitioner Governors Chafee and Gregoire, respectively.

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Schedule I includes some substances that are exceptionally dangerous and some that are less dangerous (including marijuana, which is less dangerous than some substances in other schedules). That strikes some people as odd, but the criteria for inclusion in Schedule I is not relative danger.

In that sense, drug scheduling is unlike the Saffir-Simpson scale or the Richter scale. Movement up those two scales indicates increasing severity and damage (for hurricanes and earthquakes, respectively); not so with drug scheduling. It is best not to think of drug scheduling as an escalating "danger" scale – rather, specific statutory criteria (based on medical and scientific evidence) determine into which schedule a substance is placed.

Marijuana Research:

Research is the bedrock of science, and we will – as we have for many years – support and promote legitimate research regarding marijuana and its constituent parts. For instance, DEA has never denied an application from a researcher to use lawfully produced marijuana in a study determined by the Department of Health and Human Services (HHS) to be scientifically meritorious.

In fact, during the last two plus years, the total number of individuals and institutions registered with DEA to research marijuana, marijuana extracts, derivatives, and tetrahydrocannabinols (THC) has more than doubled, from 161 in April 2014 to 354 at present. Some of the ongoing research includes studies of the effects of smoked marijuana on human subjects. Folks might be surprised to learn that we support this type of research. But, we do.

DEA and NIDA have also increased the amount of marijuana available for research. Indeed, we consistently meet legitimate demand by researchers for marijuana. Currently, NIDA is filling requests for research marijuana in an average of 25 days.

We will continue to work with NIDA to ensure that there is a sufficient supply of marijuana and its derivatives (in terms of quantity and the variety of chemical constituents) to support legitimate research needs. This includes approving additional growers of marijuana to supply researchers. Details of this proposal to support legitimate research will be published in the Federal Register.

Further, in December 2015, we waived certain regulatory requirements for researchers conducting FDA-authorized clinical trials on cannabidiol (CBD), a constituent part of marijuana. These waivers, when granted, enable researchers to modify or expand the scope of their studies more easily. Currently, there are 90 researchers registered with the DEA to conduct CBD research on human subjects. We have approved every waiver application that has been submitted by these researchers – to date, a total of 47.

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If, for instance, CBD proves to be safe and effective for the treatment of a specific medical condition, such as childhood epilepsy (some trials have shown promise), that would be a wonderful and welcome development. But we insist that CBD research – or any research – be sound, scientific, and rigorous before a product can be authorized for medical use. That is specifically – and properly – the province of the FDA.

DEA continues to work on other measures to support marijuana research. For instance, DEA is building an online application system for researchers to apply for Schedule I research registrations, including for marijuana. DEA also is drafting clear guidance to assist Schedule I researchers in that application process.

The Decision:

The FDA drug approval process for evaluating potential medicines has worked effectively in this country for more than 50 years. It is a thorough, deliberate, and exacting process grounded in science, and properly so, because the safety of our citizens relies on it.²

Using established scientific standards that are consistent with that same FDA drug approval process and based on the FDA's scientific and medical evaluation, as well as the legal standards in the CSA, marijuana will remain a schedule I controlled substance. It does not have a currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

If the scientific understanding about marijuana changes – and it could change – then the decision could change. But we will remain tethered to science, as we must, and as the statute demands. It certainly would be odd to rely on science when it suits us and ignore it otherwise.

The FDA's scientific assessment determines the safety and efficacy of drugs intended for human consumption. The FDA's team, charged with conducting that assessment, consists of clinical pharmacologists, epidemiologists, toxicologists, physicians, chemists, statisticians and other scientists, working together to ensure approved drugs are safe and effective. As our partners at HHS note, "[An] expert [in this discipline] is an individual qualified by scientific training and experience to evaluate the safety and effectiveness of a drug." Although medical doctors are highly trained and qualified to treat patients with FDA-approved drugs, as HHS notes, "[m]edical practitioners who are not expens in evaluating drugs are not qualified to determine whether a drug is generally recognized as safe or effective or meets NDA (New Drug Application) requirements." 57 FR 10499. Simply put, evaluating the safety and effectiveness of drugs for their intended use is a highly specialized endeavor undertaken by the FDA's Center for Drug Evaluation and Research.

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The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.

We fully support legitimate medical and scientific research on marijuana and its constituent parts and we will continue to seek ways to make the process for those researchers more efficient and effective.

Chuck Rosenberg

Acting Administrator

Enclosures

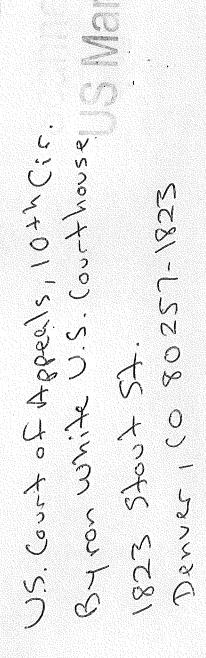
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