CASE BEING CONSIDERED FOR TREATMENT
PURSUANT TO RULE 34(j) OF THE COURT'S RULES

No. 18-1058

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRYAN KRUMM,

Petitioner,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

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

ANSWERING BRIEF FOR RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties

Petitioner is Bryan Krumm, an individual who filed a petition to reschedule marijuana with Respondent, the Drug Enforcement Administration (DEA). There have been no amici or intervenors.

B. Rulings Under Review

Krumm seeks judicial review of DEA's decision to deny his petition to reschedule marijuana under the Controlled Substances Act. DEA announced this denial in a letter to Krumm, which was not published in the Federal Register.

C. Related Cases

This case has not previously been before this Court or any other court. The related cases are:

1. ***Kuromiya v. United States*, No. 00-1085 (3d Cir.)**. Krumm was one of many plaintiffs-appellants who sought review of the district court's dismissal of their constitutional challenges to the classification of marijuana under the Controlled Substances Act. *Kuromiya v. United States*, 37 F. Supp. 2d 717 (E.D. Pa. 1999); *Kuromiya v. United States*, 78 F. Supp. 2d 367 (E.D. Pa. 1999). The Third Circuit dismissed the appeal for failure to prosecute. Order, *Kuromiya v. United States*, No. 00-1085 (3d Cir. Apr. 28, 2000).

2. ***Americans for Safe Access v. DEA*, No. 11-1265 (D.C. Cir.)**. Krumm was a signatory of a petition for DEA to reschedule marijuana under the Controlled

Substances Act. *See Krumm v. Holder*, 594 F. App'x 497, 498-99 (10th Cir. 2014) (describing Krumm's participation). DEA declined to reschedule marijuana, and this Court denied the ensuing petition for review. *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013).

3. ***Krumm v. Holder*, No. 14-2085 (10th Cir.)**. Krumm sued several federal officers in district court, raising statutory and constitutional challenges to marijuana's classification under the Controlled Substances Act. *Krumm v. Holder*, 2014 WL 11497804 (D.N.M. Mar. 19, 2014). The district court dismissed the complaint and the Tenth Circuit affirmed. *Krumm v. Holder*, 594 F. App'x 497 (10th Cir. 2014).

4. ***Krumm v. DEA*, No. 16-9557 (10th Cir.)**. Krumm sought judicial review of DEA's 2016 denial of his petition to reschedule marijuana. 81 Fed. Reg. 53,767 (Aug. 12, 2016). The Tenth Circuit dismissed the case for lack of jurisdiction because Krumm did not file his petition for review within the statutory time period. Order, *Krumm v. DEA*, No. 16-9557 (10th Cir. Dec. 15, 2016).

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GLOSSARY

The Act	Controlled Substances Act
The Administrator	The Administrator of the Drug Enforcement Administration
APA	Administrative Procedure Act
Br.	Petitioner's Opening Brief
Br. Add.	Addendum to Krumm's opening brief
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
National Academies	National Academies of Sciences, Engineering, and Medicine
THC	Tetrahydrocannabinol

STATEMENT OF JURISDICTION

Bryan Krumm petitioned the federal government to reschedule marijuana under the Controlled Substances Act. 21 U.S.C. § 811(a). The government declined to initiate rulemaking proceedings to reschedule marijuana. Krumm seeks this Court's review under 21 U.S.C. § 877.

STATUTORY PROVISIONS

An addendum to this brief sets forth the pertinent statutes.

INTRODUCTION AND STATEMENT OF THE ISSUE

Bryan Krumm petitioned the federal government to reschedule marijuana under the Controlled Substances Act. In 2016, the Drug Enforcement Administration, in conjunction with the Department of Health and Human Services and the Food and Drug Administration, issued a 79-page decision in the Federal Register that responded to Krumm's petition, evaluated hundreds of scientific studies, and determined that marijuana should remain classified as a schedule I substance.

Krumm did not timely seek judicial review of that decision. Instead, in 2017, he filed a new petition to reschedule marijuana. The Drug Enforcement Administration denied that petition, explaining that Krumm had not identified any new evidence that would alter its 2016 decision.

The issue presented is: Whether the denial of Krumm's 2017 petition was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

STATEMENT OF THE CASE

I. Statutory and Regulatory Framework

The Controlled Substances Act, 21 U.S.C. §§ 801-971, establishes a comprehensive federal scheme to regulate the manufacture and distribution of controlled substances. The Act divides controlled substances into five schedules, based on their potential for abuse, medical uses, and risk of physical or psychological dependence. *Id.* § 812(a)-(b). Generally speaking, a schedule I substance has no accepted medical use and a high risk for abuse, while schedule II-V substances have accepted medical uses and decreasing risk of abuse and dependence. *Id.* Congress initially designated scores of substances under the schedules, *id.* § 812(c), and authorized the Attorney General to add, remove, or reschedule substances through rulemaking, *id.* § 811(a). The Attorney General, in turn, delegated this authority to the Administrator of the Drug Enforcement Administration (DEA). 28 C.F.R. § 0.100.[1]

Congress initially designated marijuana as a schedule I substance. *See* Pub. L. No. 91-513, title II § 202(c) (schedule I(c)), 84 Stat. 1242, 1249 (1970). Schedule I substances have "a high potential for abuse," have "no currently accepted medical use in treatment in the United States," and lack "accepted safety for use * * * under

[1] For simplicity, this brief refers to authority exercised by the DEA Administrator whenever the Controlled Substances Act grants authority to the Attorney General and the Attorney General has in turn delegated that authority to the DEA Administrator.

medical supervision." 21 U.S.C. § 812(b)(1). To determine whether a substance has a currently accepted medical use,[2] DEA evaluates whether:

1. The substance's chemistry is known and reproducible;
2. There are adequate safety studies;
3. There are adequate and well-controlled studies proving efficacy;
4. The substance is accepted by qualified experts; and
5. The scientific evidence is widely available.

57 Fed. Reg. 10,499, 10,506 (Mar. 26, 1992); *see also Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013) (noting that the Court "expressly approved" of this five-factor test). All five factors must be met for a substance to "be deemed to have a currently accepted medical use." *Americans for Safe Access*, 706 F.3d at 450.

The DEA Administrator can, if the evidence warrants, transfer a substance from one schedule to another by rulemaking. 21 U.S.C. § 811(a)(1). Such rulemaking proceedings "may be initiated" by the Administrator "(1) on his own motion, (2) at the request of the Secretary [of Health and Human Services], or (3) on the petition of any interested party." *Id.* § 811(a). "[B]efore initiating [rulemaking] proceedings," the Administrator gathers all "necessary data" and obtains a written "scientific and medical evaluation" and a recommendation from the Secretary of Health and Human

[2] For a substance to be placed in schedules II through V of the Controlled Substances Act, it must have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b). For sake of brevity, this brief will use the phrase "currently accepted medical use" or "medical use" as shorthand for currently accepted medical use in the United States or a currently accepted medical use with severe restrictions.

Services (HHS) as to whether a substance should be rescheduled. *Id.* § 811(b). The Secretary's views on "scientific and medical matters" are binding. *Id.* If the Administrator determines that substantial evidence supports moving the substance to a different schedule, then "he shall initiate proceedings" to reschedule the substance. *Id.*

II. Prior Proceedings

A. Krumm's Prior Litigation Concerning Marijuana's Status as a Schedule I Substance

In 1998, petitioner Bryan Krumm and a number of other plaintiffs sued the United States to challenge, on constitutional grounds, marijuana's classification as a schedule I substance under the Controlled Substances Act. *Kuromiya v. United States*, No. 98-3439 (E.D. Pa.). The district court dismissed the complaint in two orders, *Kuromiya v. United States*, 37 F. Supp. 2d 717 (E.D. Pa. 1999); *Kuromiya v. United States*, 78 F. Supp. 2d 367 (E.D. Pa. 1999), and the Third Circuit dismissed plaintiffs' appeal for failure to prosecute, Order, *Kuromiya v. United States*, No. 00-1085 (3d Cir. Apr. 28, 2000).

In 2002, Krumm was one of several signatories to a petition for DEA to reschedule marijuana. *See Americans for Safe Access*, 706 F.3d at 441-42 (describing the petition); *Krumm v. Holder*, 594 F. App'x 497, 498-99 (10th Cir. 2014) (describing Krumm's participation). DEA referred the petition to HHS, which conducted a scientific review and issued a number of findings concerning marijuana's chemistry, its

physiological effects, its potential medical use, and its potential for abuse. 76 Fed. Reg. 40,552, 40,552-66 (July 8, 2011). DEA, in turn, issued its own findings and concluded that marijuana should remain classified as a schedule I substance. *Id.* at 40,552, 405,66-89. This Court denied a petition for review from that decision, holding that there was "nothing in the record" to demonstrate that there were "adequate and well-controlled studies" that might "confirm[] marijuana's medical efficacy." *Americans for Safe Access*, 706 F.3d at 452. Accordingly, the Court held, DEA did not abuse its discretion in denying the petition for rulemaking to reclassify marijuana. *Id.*

Six months after this Court's decision in *Americans for Safe Access*, Krumm filed a complaint challenging marijuana's classification as a schedule I substance, raising constitutional and statutory claims. Compl. ¶¶ 49-51, 82-83, *Krumm v. Holder*, No. 13-cv-562 (D.N.M. June 17, 2013). The district court dismissed the complaint and the Tenth Circuit affirmed, holding that Krumm had "already litigated and lost most of the claims and arguments he now asserts," and had failed to state a claim on the new arguments he did present. *Krumm*, 594 F. App'x at 500-01.

B. Krumm's 2009 Petition to Reschedule Marijuana and DEA's 2016 Denial

In 2009, Krumm filed a petition with DEA to reschedule marijuana, arguing that marijuana does not have a high potential for abuse and does have an accepted medical use. Br. Add. 42.

The DEA Administrator referred Krumm's petition to the Secretary of HHS to obtain her findings and opinions on scientific and medical matters, in accordance with 21 U.S.C. § 811(b). 81 Fed. Reg. 53,767, 53,792 (Aug. 12, 2016). The Secretary, in turn, referred the petition to the Food and Drug Administration (FDA) to evaluate the scientific and medical data, assess whether marijuana has a currently accepted medical use, and provide a scheduling recommendation for marijuana. *Id.* at 53,792-93. FDA conducted its scientific review, *id.* at 53,791-819, and referred the petition back to the Secretary, who issued a series of factual findings concerning marijuana's chemistry, its physiological effects, its potential medical use, and its potential for abuse, *id.* at 53,768-91. The Secretary concluded that "[m]arijuana does not meet any of the elements for having a 'currently accepted medical use.'" *Id.* at 53,786. The Secretary then referred the petition back to DEA, which issued additional findings, *id.* at 53,820-45, and the DEA Administrator ultimately concluded that marijuana should remain a schedule I substance, *id.* at 53,767. For ease of reference, this brief refers to the findings and conclusions of this collaborative process as being the Administrator's.

In concluding that marijuana does not have a currently accepted medical use, the Administrator applied the five-factor test set out in the governing regulations, and concluded that none of the factors were met. 81 Fed. Reg. at 53,835-36.

1. *The substance's chemistry must be well known and reproducible.* The Administrator explained that marijuana samples come from a variety of cultivated strains, which can

have "very different chemical constituents." 81 Fed. Reg. at 53,771. In particular, each marijuana plant will possess approximately 100 cannabinoid chemical compounds, but the concentration of these compounds will vary across different strains. *Id.* at 53,771, 53,777. This variation in marijuana's chemical profile "complicate[s] the interpretation of clinical data using marijuana." *Id.* at 53,777. For example, a 1-gram marijuana cigarette might have as little as 3 milligrams of THC (tetrahydrocannabinol, marijuana's principal psychoactive chemical) or as much as 150 milligrams of THC, thus making it difficult to evaluate studies that test the efficacy of smoking marijuana. *Id.* at 53,777-78. In considering whether to reschedule marijuana, the Administrator concluded that it was not possible to reproduce a consistent, standardized dose for all of marijuana's potential strains. *Id.* at 53,779; *see also id.* (noting that this might be possible for a particular marijuana strain if it was consistently cultivated under strict conditions).

2. *There must be adequate and well-controlled studies proving efficacy.* The Administrator reviewed the abstracts of 566 scientific articles, which contained terms indicating that they might be an adequate and well-controlled study of marijuana's efficacy. 81 Fed. Reg. at 53,794 & n.30. Of these, only 11 studies were determined to be "randomized, double-blind, placebo-controlled clinical studies conducted with marijuana to assess marijuana's efficacy in any therapeutic indication." *Id.* at 53,794; *see also id.* at 53,795 (explaining why other studies did not meet this criteria). The Administrator concluded that these 11 studies did not demonstrate efficacy, but were

best understood as "[p]roof of concept studies" that can "provide preliminary evidence on a proposed hypothesis involving a drug's effect." *Id.* at 53,780.

Five studies showed "positive results" for using marijuana as an analgesic for chronic neuropathic pain. 81 Fed. Reg. at 53,801. But the subjects in these studies continued to use their preexisting analgesic drugs in addition to marijuana, making it difficult to conclude if marijuana had effective analgesic properties on its own. *Id.* at 53,796-99. The subjects also suffered from many different kinds of neuropathic pain, "making it difficult to identify whether a specific set of symptoms might be more responsive to the effects of marijuana." *Id.* at 53,801. Some subjects also had to withdraw from the studies based on adverse effects from marijuana. *Id.* at 53,797 (one subject "developed an intractable smoking-related cough" while the only "marijuana-naïve" subject "experienced an incident of acute cannabis-induced psychosis").

Two studies showed "positive results" for using both marijuana and dronabinol (synthetic THC) to increase appetite and weight gain in HIV-positive patients. 81 Fed. Reg. at 53,801. However, all of the subjects in these studies were chronic marijuana users, and the doses of THC given to the subjects were several times greater than the typical doses for appetite stimulation. *Id.* Thus, the studies did not address whether patients with little prior exposure to marijuana would be able to tolerate the high THC levels used in these studies, or whether marijuana would still show positive results with limited adverse effects for such patients. *Id.* at 53,801-02.

One study showed some "positive results" for treating spasticity in multiple sclerosis patients with smoked marijuana. 81 Fed. Reg. at 53,802. However, the patients continued to use their preexisting medication regime, and it was difficult to conclude marijuana's efficacy as a stand-alone treatment. *Id.* Moreover, it was "concerning" that five out of thirty subjects withdrew from the study "because they were unable to tolerate the psychiatric [adverse events] induced by marijuana." *Id.* at 53,800, 53,802.

While one study showed "positive results" for treating asthma patients with smoked marijuana, there was an obvious concern about administering "harmful and irritating substances" into the lungs of asthma patients by instructing them to smoke. 81 Fed. Reg. at 53,802. Additionally, the patients smoked marijuana while they were at rest and not suffering bronchospasms, leaving it uncertain whether marijuana was effective at treating asthma attacks. *Id.*

Two studies had shown "positive results" for treating glaucoma with marijuana, but "the effect is short-lasting, requires a high dose, and is associated with many [adverse events]. Thus, the potential harmful effects may outweigh any modest benefit of marijuana for this condition." 81 Fed. Reg. at 53,802.

The Administrator noted a number of other complicating factors in these studies that limited their usefulness in determining marijuana's efficacy as a medical treatment. The treatment groups in these studies were small (ranging from 10 to 25 subjects) and were "statistically inadequate to support a showing of safety or efficacy."

81 Fed. Reg. at 53,802. No study lasted longer than five days, but they were attempting to demonstrate marijuana's efficacy for treating chronic medical conditions that could last a lifetime. *Id.* at 53,803. And, as a general matter, it was "not recommended" to prescribe smoking as a medical treatment, because this would necessarily put smoke "into the lungs of individuals with a disease state * * * when their bodies may be physically compromised." *Id.* Finally, all of these studies had an inherent difficulty in ensuring that the subjects were truly "blind," *i.e.*, that they did not know if they were receiving marijuana or a placebo. *Id.* Because marijuana has a "rapid onset of psychoactive effects," test subjects will likely know if they are receiving marijuana instead of a placebo, which could lead to an expectation bias that changes the subjects' "perceived responsivity to the therapeutic outcome." *Id.*

3. The Administrator then determined that none of the remaining three factors supported a finding that marijuana had a currently accepted medical use. The Administrator concluded that there were no adequate safety studies for marijuana, because in order to determine whether marijuana could be safe for treatment, there needs to be a "risk-benefit analysis" for whether marijuana's side effects are outweighed by its "potential benefits for a particular indication." 81 Fed. Reg. at 53,780. Because the Administrator concluded that marijuana has not been shown to be an effective treatment for any medical condition, it similarly could not be shown to be safe for treating such conditions. *Id.*

Likewise, given the absence of any adequate, well-controlled studies, the Administrator concluded that there was "no evidence that there is a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder." 81 Fed. Reg. at 53,780.

Finally, the Administrator found that there was not widely available scientific evidence of a cultivated marijuana strain "that could produce standardized and reproducible doses." 81 Fed. Reg. at 53,781.

Accordingly, the Administrator found that the current scientific evidence "has not progressed to the point where marijuana is considered to have a 'currently accepted medical use' or a 'currently accepted medical use with severe restrictions,'" 81 Fed. Reg. at 53,781, and it therefore must remain classified as a schedule I substance, *id.* at 53,767.[3]

C. Krumm's 2016 Petition for Judicial Review

DEA published its denial of Krumm's petition on August 12, 2016. 81 Fed. Reg. at 53,767. Although Krumm had thirty days in which to file a petition for judicial review, 21 U.S.C. § 877, Krumm did not do so. Instead, Krumm filed a petition for judicial review with the Tenth Circuit on November 8, 2016, eighty-eight

[3] The Administrator also found that marijuana poses health risks from acute use, including impaired psychomotor performance, dysphoria, and prolonged psychological distress, including prolonged anxiety reactions. 81 Fed. Reg. at 53,783. The Administrator further found that marijuana has a widespread potential for abuse through non-medical use. *Id.* at 53,822, 53,825, 53,839.

days after DEA's denial. *See* Order at 1-2, *Krumm v. DEA*, No. 16-9557 (10th Cir. Dec. 15, 2016). The Tenth Circuit *sua sponte* questioned whether it had jurisdiction over Krumm's petition and, after considering Krumm's response, dismissed his petition as untimely. *Id.* Krumm did not seek further review.

D. Krumm's 2017 Petition to Reschedule Marijuana

Five months after the Tenth Circuit's dismissal, Krumm filed a new petition with DEA to reschedule marijuana. Br. Add. 3. Krumm argued that marijuana does not have a high potential for abuse, *id.* at 5, that smoked marijuana has an accepted medical use, *id.* at 13, and that any strain of marijuana is safe, *id.* at 25. In support of his position, Krumm cited several articles that had found some positive effects related to marijuana use or which discussed the enactment of state laws permitting medical marijuana use. *See, e.g.*, *id.* at 6-8. Krumm also asserted that "dozens of well controlled clinical trials" proved that marijuana "is effective for treating a broad range of diseases and disorders." *Id.* at 25. Krumm requested DEA "immediately remove Cannabis from control under the [Controlled Substances Act] and transfer authority for regulating medical, recreational and religious use of Cannabis to the States." *Id.* at 38.

The DEA Administrator summarily denied Krumm's petition in a two-page letter, explaining that Krumm had failed to demonstrate that marijuana has a currently accepted medical use in treatment in the United States. Br. Add. 1-2. The Administrator summarized the reasons for denying Krumm's prior petition, and

stated that Krumm's "latest petition adds nothing to [his] prior petition." *Id.* While Krumm had cited several articles DEA had not considered in its 2016 denial, the Administrator explained that these citations "consist only of reviews of other studies—none of which was designed to, or purports to, demonstrate the safety and efficacy of marijuana." *Id.* at 2. The Administrator declined to refer Krumm's petition to HHS for additional scientific findings and recommendations, reasoning that a referral was not necessary "where the petition, on its face, fails to meet the established criteria for rescheduling." *Id.*; *see also* 21 C.F.R. § 1308.43(c) ("[A] petition may be denied by the Administrator * * * if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.").

Krumm now seeks judicial review.

SUMMARY OF ARGUMENT

I. The DEA Administrator appropriately denied Krumm's 2017 petition to reschedule marijuana. Krumm had an opportunity to seek judicial review of the Administrator's 2016 denial of his previous petition, but he did not timely do so. Instead, he filed another petition with the Administrator, which presented no new evidence to support a conclusion that marijuana has a currently accepted medical use in the United States. And without a currently accepted medical use, marijuana must remain a schedule I substance. 21 U.S.C. § 812(b). Although Krumm claims that his petition provided evidence of marijuana's medical efficacy, he cited no adequate and well-controlled scientific studies that demonstrated marijuana's efficacy for a

particular treatment—and in several instances, the evidence had already been considered by the Administrator in his 2016 denial.

II. Krumm makes a cursory argument that the Administrator erred by denying his petition without notice-and-comment. But the notice-and-comment requirements of 5 U.S.C. § 553 only apply when an agency proposes to engage in rulemaking. Here, the Administrator chose not to engage in rulemaking and denied Krumm's petition to do so. No notice and comment was required.

STANDARD OF REVIEW

DEA's decision not to initiate rulemaking proceedings is reviewed to determine whether it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013) (quoting 5 U.S.C. § 706(2)(A)). The Court "will not disturb the decision of an agency that has examined the relevant data and articulated a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (quotation simplified); *see also Defenders of Wildlife v. Gutierrez*, 532 F.3d 913, 919 (D.C. Cir. 2008) ("[A]n agency's refusal to institute rulemaking proceedings is at the high end of the range of levels of deference we give to agency action.").

ARGUMENT

I. The DEA Administrator Correctly Denied Krumm's 2017 Petition

A. Krumm Is Precluded from Relitigating the Administrator's Earlier Denial

In 2009, Krumm petitioned the DEA to reschedule marijuana under the Controlled Substances Act. In 2016, the DEA Administrator denied Krumm's petition in a 79-page decision published in the Federal Register, which incorporated extensive findings and recommendations from HHS and FDA. *See* 81 Fed. Reg. 53,767, 53,767-845 (Aug. 12, 2016). Krumm had thirty days to seek judicial review from that decision, 21 U.S.C. § 877, and he failed to do so.

To the extent Krumm seeks to challenge the 2016 denial's factual findings and conclusions here, he is precluded from doing so. The Administrator's denial was a "final and conclusive decision[] of the matters involved," and Krumm chose not to challenge that decision properlly. 21 U.S.C. § 877. Issue preclusion generally applies to agency adjudications and rulemakings, and to avoid it a petitioner "must show [that] circumstances have changed in a way that require[s] the agency to reconsider" its previous decision. *Sorenson Commc'ns, Inc. v. FCC*, 765 F.3d 37, 44 (D.C. Cir. 2014). *See also B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1302 (2015) (a party who chooses not to seek judicial review of an adverse agency decision may be precluded from relitigating issues decided by the agency). In a similar scenario involving citizen-petitions for rulemaking, this Court has explained that if "a party

files a second petition similar to an earlier one, [the agency] can summarily deny it, citing the reasons given in its response to the first petition." *Trumpeter Swan Soc'y v. EPA*, 774 F.3d 1037, 1041 (D.C. Cir. 2014). The DEA Administrator followed that procedure here.

B. Krumm's 2017 Petition Presented No New Evidence of Adequate, Well-Controlled Studies That Might Demonstrate Marijuana's Efficacy as a Medical Treatment

In order for marijuana to be rescheduled from schedule I, it must be shown to have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(2)-(5).[4] And to have a currently accepted medical use, marijuana must satisfy all five parts of the DEA's five-factor test, whose use this Court has approved. *Americans for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013). To satisfy the test: (1) marijuana's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) marijuana must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *Id.* at 449. The Administrator may appropriately deny a petition to reschedule marijuana if there are no adequate and well-controlled

[4] A substance may be placed under schedule II if it has "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B). Under this standard, a substance without a currently accepted medical use does not qualify for placement under schedule II, because it necessarily does not have a currently accepted medical use "even under conditions where its use is severely restricted." 81 Fed. Reg. at 53,781.

studies that prove marijuana's medical efficacy. *Id.* at 450-52 (denying petition for review solely on this ground).

As discussed *supra* pp. 6-11, the Administrator's 2016 denial found that none of these factors were met. In particular, the Administrator reviewed the current medical studies on marijuana and concluded that there were no adequate, well-controlled studies that could demonstrate marijuana's efficacy as a medical treatment for a particular condition. Although Krumm's 2017 petition claims that smoking marijuana is a proven effective medical treatment (Br. Add. 6, 13), and points to several studies to support this claim, none of these studies is an adequate or well-controlled study that demonstrates marijuana's efficacy for medical use.[5]

1. The National Academies' 2017 Report on *The Health Effects of Cannabis and Cannabinoids*

Krumm briefly asserts that a 2017 systematic review by the National Academies of Sciences, Engineering, and Medicine (National Academies) demonstrates that there are adequate and well-controlled studies proving marijuana's efficacy. Br. 6-7. This

[5] In his petition for rulemaking, Krumm asserted that every part of DEA's five-factor test supported the conclusion that marijuana has a currently accepted medical use. Br. Add. 24-28. In his opening brief, Krumm argues that there are adequate and well-controlled studies demonstrating marijuana's efficacy. But he does not argue that any of the other four factors are satisfied (*i.e.*, that marijuana's chemistry is known or reproducible, that there are adequate safety studies, that it is accepted by qualified experts, or that scientific evidence of its medical use is widely available). Because Krumm's opening brief does not present any argument on these four other factors, Krumm has waived any argument that marijuana satisfies them. *AMSC Subsidiary Corp. v. FCC*, 216 F.3d 1154, 1161 n.** (D.C. Cir. 2000).

review is not itself a clinical study of marijuana's effects, but rather a summary of the findings of other studies, some of which were meta-studies that collected and analyzed the findings of other clinical studies. While reviews and meta-studies can provide a starting point for research, evidence of marijuana's efficacy must come from "adequate and well-controlled clinical trials" that are "scientifically rigorous" and provide primary evidence of marijuana's use in treating a particular condition. *Americans for Safe Access*, 706 F.3d at 450-51; *see also* 21 C.F.R. § 314.126 (defining "adequate and well-controlled study"); 81 Fed. Reg. at 53,794 (discussing 21 C.F.R. § 314.126).

The National Academies' review explained that "conclusive evidence regarding the short- and long-term health effects (harms and benefits) of cannabis use remains elusive." Nat'l Acads. Sciences, Eng'g, & Med., *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* 1 (2017) (*Health Effects of Cannabis*), available at https://www.nap.edu/read/24625/chapter/1. The systematic review went on to state that there was "substantial evidence" that marijuana is an effective treatment for chronic pain in adults, *id.* at 88-90, "substantial evidence" that oral cannabinoids are effective for improving patient-reported multiple sclerosis spasticity symptoms, *id.* at 91-94, and "conclusive evidence" that oral cannabinoids are effective antiemetics for treating chemotherapy-induced nausea and vomiting, *id.* at 101-03. For each of these conclusions, however, there was no

underlying evidence of adequate, well-controlled studies demonstrating smoked marijuana's efficacy.

a. Chronic Pain. The National Academies reviewed five meta-studies analyzing marijuana's treatment of chronic pain, but none of these meta-studies identifies any adequate or well-controlled studies. *Health Effects of Cannabis* 88-89. Two meta-studies "did not contribute unique studies or findings." *Id.* at 88. Another meta-study "did not include any studies that used cannabis" but rather analyzed only one study using dronabinol, *id.*, a synthetic cannabinoid that is classified as a schedule II or schedule III drug (depending on its method of preparation), 21 C.F.R. §§ 1308.12(f)(2), 1308.13(g)(1).[6] The last two meta-studies reviewed studies that had already been considered by the Administrator in his 2016 denial of Krumm's petition. *Compare* 81 Fed. Reg. at 53,804-05 (citing Abrams et al. (2007); Ellis et al. (2009); Ware et al. (2010); Wilsey et al. (2013); and Wilsey et al. (2008)), *with* Penny F. Whiting et al.,

[6] Cannabinoids, like dronabinol and nabilone, are distinct from marijuana. 81 Fed. Reg. at 53,770-71. Marijuana contains approximately 100 different cannabinoid compounds, *id.* at 53,771, which can be extracted from marijuana or synthetically produced, *see* 21 C.F.R. § 1308.11(d)(31). When marijuana is smoked, its cannabinoids and other compounds can be absorbed into the body "within seconds," and are generally processed differently than an isolated cannabinoid that is administered orally. 81 Fed. Reg. at 53,778. For these reasons, studies involving dronabinol or other cannabinoids do not speak to the medical efficacy of smoked marijuana, and the Administrator has previously explained that "[s]tudies or reports involving drug substances other than the precise substance at issue" are "irrelevant to the determination of currently accepted medical use." 57 Fed. Reg. 10,499, 105,06-07 (Mar. 26, 1992).

Cannabinoids for Medical Use: A Systematic Review and Meta-analysis, 313 JAMA 2456 (2015), Suppl. App. 5.A, available at https://jamanetwork.com/data/Journals/JAMA/934167/JOI150059supp2_prod.pdf (reviewing these same studies as the only studies involving smoked marijuana), and Michael H. Andreae et al., *Inhaled Cannabis for Chronic Neuropathic Pain: A Meta-analysis of Individual Patient Data*, 16 J. Pain 1221, 1222 (2015) (same).[7]

The National Academies also reviewed two individual studies of marijuana's efficacy, both of which suffered from significant methodological flaws. *Health Effects of Cannabis* 89. The first study explained that its findings were limited by "possible lack of blinding due to the psychoactive effects of THC and cross-over design, the brief duration of the trial, a restricted assessment of neuropsychiatric and other [adverse effects], and the small number of subjects in the study." Mark S. Wallace et al., *Efficacy of Inhaled Cannabis on Painful Diabetic Neuropathy*, 16 J. Pain 616, 625 (2015). Although the preliminary findings were positive, the study recognized that "[l]arger randomized trials with longer-term follow-up are warranted to assess the analgesic effectiveness of cannabis." *Id.* at 625. The second study did not include a control group—all subjects were initially treated with marijuana, and only afterwards were subjects given either more marijuana or a placebo. Barth L. Wilsey et al., *A Preliminary Evaluation of the Relationship of Cannabinoid Blood Concentrations with the Analgesic Response to*

[7] Full citations to these studies are included in the Table of Authorities.

Vaporized Cannabis, 9 J. Pain Res. 587, 589 (2016). Given all this, the Administrator correctly concluded that Krumm had not pointed to any adequate, well-controlled studies that demonstrated marijuana's efficacy for treating pain.

b. Chemo-induced Nausea and Vomiting. The National Academies stated that there was "conclusive evidence" that some oral cannabinoids could effectively treat chemotherapy-induced nausea and vomiting. *Health Effects of Cannabis* 94. But marijuana's efficacy was a different matter. "Despite an abundance of anecdotal reports of the benefits of plant cannabis, either inhaled or ingested orally, as an effective treatment for chemotherapy-induced nausea and vomiting, there are no good-quality randomized trials investigating this option." *Id.* at 93. Indeed, the National Academies relied primarily on a systematic review by Whiting et al., *id.* at 91-92, which in turn concluded that there was only "low-quality evidence" for marijuana's efficacy for this kind of treatment, and "further research is very likely to have an important impact on the group's confidence in the estimate of [its] effect and is likely to change the estimate." Whiting et al., *Cannabinoids for Medical Use*, 313 JAMA at 2456, 2462.

c. Spasticity in Multiple Sclerosis Patients. Although the National Academies stated that there was "substantial evidence that oral cannabinoids are an effective treatment" for patient-reported multiple sclerosis spasticity symptoms, *Health Effects of Cannabis* 103, the Administrator found that this conclusion was not based on an adequate or well-controlled study of marijuana's efficacy, Br. Add. 2. The National Academies

reviewed the meta-study by Whiting et al., but this meta-study only reviewed studies of marijuana that had already been considered by the Administrator in his 2016 denial of Krumm's petition. *Compare* 81 Fed. Reg. at 53,800, 53,802 (discussing Corey-Bloom et al. (2012)), *with* Whiting et al., *Cannabinoids for Medical Use*, 313 J. Am. Med. Assoc. 2456 (2015), Suppl. App. 5.A, available at https://jamanetwork.com/data/Journals/JAMA/934167/JOI150059supp2_prod.pdf (reviewing same study as the only one involving smoked marijuana).

The other two studies did not claim to make any efficacy findings on marijuana as a treatment. *Health Effects of Cannabis* 102-03 (citing Koppel et al. (2014) and Leocani et al. (2015)). The meta-study by Koppel et al. twice stated that smoked marijuana is of "unclear" or "uncertain" efficacy for treating spasticity. Barbara S. Koppel et al., *Systematic Review: Efficacy and Safety of Medical Marijuana in Selected Neurologic Disorders*, 82 Neurology 1556, 1559 (2014). And the study by Leocani et al., analyzed how subjects reacted to Sativex (a synthetic version of THC with cannabidiol), rather than marijuana. Letizia Leocani et al., *Sativex® and Clinical-neurophysiological Measures of Spasticity in Progressive Multiple Sclerosis,* 262 J. Neurology 2520 (2015).

In sum, while the National Academies' report provided a helpful summary of the existing research, the Administrator concluded that it does not identify any new or overlooked adequate, well-controlled studies that prove marijuana's efficacy as a medical treatment. Br. Add. 2. As the Administrator previously explained, "the effectiveness of a drug must be established in well-controlled, well-designed, well-

conducted, and well-documented scientific studies, including studies performed in a large number of patients." *Americans for Safe Access*, 706 F.3d at 450 (quoting 76 Fed. Reg. 40,552, 40,579 (July 8, 2011)). And still to date, "such studies have not been performed" to prove that marijuana has an accepted medical use. *Id.*

2. Lynn Pierson Therapeutic Research Program

In his petition, Krumm asserted that a study by the Lynn Pierson Therapeutic Research Program had "proved the safety and efficacy of smoked Cannabis for treating the nausea and vomiting associated with cancer chemotherapy." Br. Add. 6. Krumm had previously made the same argument about this study in his 2009 petition. Br. Add. 43. The Administrator rejected this argument when he denied Krumm's original petition in 2016, and Krumm offers no reason to believe that rejection was erroneous.

3. Krumm's Article—*Cannabis for Posttraumatic Stress Disorder*

Krumm argues that the Administrator "ignored my clinical findings, published in the Nurse Practitioner Journal in January 2016." Br. 7. Krumm is referring to a three-and-a-half page article, half of which discusses post-traumatic stress disorder, and half of which addresses the potential therapeutic benefits of marijuana. Bryan A. Krumm, *Cannabis for Posttraumatic Stress Disorder: A Neurobiological Approach to Treatment*, 41 Nurse Practitioner 50 (2016); Br. Add. 53-56. Krumm's article does not identify

any adequate, well-controlled studies to prove marijuana's efficacy, and does not itself describe any studies that Krumm has conducted to prove marijuana's efficacy.

Krumm's petition also identified several articles that studied the correlation between state medical-marijuana laws and suicide rates, opioid overdoses, car crashes, and other effects. Br. Add. 7-8. None of these cited studies, however, purport to analyze whether marijuana is an effective medical treatment for a particular disorder.

* * *

In sum, because Krumm identified no new evidence that there were adequate and well-controlled studies proving marijuana's efficacy, there was no basis to disturb the Administrator's previous determination that marijuana "has no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B); 81 Fed. Reg. at 53767. Accordingly, the Administrator's decision was supported by the fact that "such studies confirming marijuana's medical efficacy do not exist," *Americans for Safe Access*, 706 F.3d at 452, and the Administrator did not abuse his discretion in declining to initiate rulemaking.

II. Notice and Comment Was Not Required Because the Administrator Did Not Engage in Rulemaking

Krumm argues that the Administrator's denial of his petition for rulemaking violates the Administrative Procedure Act (APA) because the Administrator did not

provide for notice and comment under 5 U.S.C. § 553(b). Br. 12.[8] Section 553 generally requires federal agencies to provide "notice of proposed rulemaking" and to "give interested persons an opportunity to participate in the rule making" through written comment. 5 U.S.C. § 553(b), (c). If the Administrator chooses to initiate rulemaking to reschedule a drug under the Controlled Substance Act, 21 U.S.C. § 811(b), that rulemaking is subject to notice and comment, *Eisai, Inc. v. FDA*, 134 F. Supp. 3d 384, 387-88 (D.D.C. 2015).

But here, the Administrator declined to initiate rulemaking to reschedule marijuana. There was therefore no occasion for the Administrator to issue a notice of proposed rulemaking or for a period of public comment. The Controlled Substances Act permits any interested person to petition the Administrator to initiate rulemaking, 21 U.S.C. § 811(a), but the Administrator may deny that petition without engaging in notice and comment. *See generally Americans for Safe Access*, 706 F.3d at 440-41.

[8] Krumm cites 5 U.S.C. § 552(b), Br. 12, but we assume he meant to refer to § 553(b), which contains the APA's notice requirement.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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June 22, 2018

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 14-point Garamond, 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 contains 6,060 words, excluding the parts of the brief exempted under Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1), according to the count of Microsoft Word.

/s/ Daniel Aguilar
Daniel Aguilar

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

I further certify that I caused two copies of the brief to be served on petitioner by mail to his court-listed address:

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Daniel Aguilar

ADDENDUM

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5 U.S.C. § 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

21 U.S.C. § 811. Authority and criteria for classification of substances

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e) of this section, the Attorney General may by rule—

(1) add to such a schedule or transfer between such schedules any drug or other substance if he—

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) of this section to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) of this section and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. 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. § 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such

drug or other substance. The findings required for each of the schedules are as follows:

(1) 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.

(2) Schedule II—

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

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

21 U.S.C. § 877. Judicial review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.