No. 22-1718

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DR. SUNIL AGGARWAL, MD, PHD; ADVANCED INTEGRATIVE MEDICAL SCIENCE INSTITUTE, PLLC,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; AND MERRICK GARLAND IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL

Respondents.

BRIEF OF *AMICUS CURIAE* THE NATIONAL ORGANIZATION FOR THE REFORM OF MARIJUANA LAWS IN SUPPORT OF PETITIONERS

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DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 29(a)(4), amicus curiae The National Organization for the Reform of Marijuana Laws ("NORML") is a non-profit corporation and does not have any parent corporations. NORML is not a publicly held corporation, does not issue stock, and has no parent corporation.

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STATEMENT OF IDENTITY, INTEREST OF AMICUS CURIAE, AND SOURCE OF AUTHORITY TO FILE

NORML's mission is to move public opinion sufficiently to legalize the responsible use of marijuana by adults, and to serve as an advocate for consumers to assure they have access to high quality marijuana that is safe, convenient and affordable.

All parties have consented to the filing of this brief.[1]

[1] In accordance with Federal Rule of Appellate Procedure 29(a)(4)(E), no counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae, or its counsel, made a monetary contribution intended to fund its preparation or submission.

SUMMARY OF ARGUMENT

History repeats itself. This brief provides a detailed historical account of NORML's efforts to decriminalize cannabis for medicinal purposes for the past half-century and the never-ending efforts of the federal government to delay, resist, and obstruct the progress of science and medicine. While the federal government is unlikely to learn any lessons from the past, NORML hopes that this Court will acknowledge and heed the legal and procedural lessons learned from those past administrative petition litigations so that innocent dying patients – who are the true victims of the government's misbehavior – are not denied readily available medicine.

ARGUMENT

I. THE DEA SHOULD BE BOUND BY PROCEDURAL DUE PROCESS PRECEDENT ESTABLISHED BY LENGTHY EXPERIENCE LITIGATING AGAINST NORML SO THAT HISTORY DOES NOT REPEAT ITSELF HERE

The past is prologue. For more than a half-century, NORML has advocated for the decriminalization of cannabis for medicinal purposes. It has utilized the legal process available under the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 812 *et seq*., to petition the Food and Drug Administration ("FDA") to reschedule cannabis for greater research and treatment opportunities. In the face of such administrative challenges, and there is no basis for rejecting them, the Drug Enforcement Administration ("DEA"), is required to gather necessary data and request from the FDA a scientific and medical evaluation and recommendation as whether a scheduled drug, in NORML's challenges it was the Schedule I status of cannabis, should remain, be transferred, or be removed from its present schedule. Each and every such recommendation over the past 53 years has found that it should remain as originally designated.

Indeed, getting the DEA to forward those petitions to the FDA for investigation, evaluation, and recommendation did not come easily to the DEA – in many cases it had to be admonished or compelled to act on the often years-long pending petition. The DEA has come to defer such matters

to the prior determinations of the FDA rather than promptly gather and submit necessary data as it is required to do for the FDA to fulfill its duty by conducting a new scientific and medical evaluation and make a scheduling recommendation back to DEA. Such a lapse in the administrative process that deprives FDA of the chance to conduct a new evaluation has permitted the DEA to engage in dilatory tactics that run afoul of the rescheduling pathway set forth in the statute. This obstructive conduct of the DEA seems unfettered notwithstanding the voluminous and unassailable body of scientific research to be gathered by it for FDA to evaluate showing cannabis' genuine therapeutic effects that have benefited millions of patients. The FDA, even when it has undertaken new evaluations, has overlooked the vast medical applications and results from the 41 states that have legalized medical cannabis and the transformed legal landscape resulting therefrom.

Here, the DEA, again neglects and avoids medical and scientific evaluation of the next promising frontier of medicine: psilocybin. Patients, who are each in their end stage of life, should not be forced to suffer through rescheduling petition litigation, which may not be resolved until after their death, as cannabis patients and medical professional virtually represented by NORML had to do. DEA ought not again be allowed to reject a properly

filed petition and reject it without medical and scientific evaluation from FDA.

This Court should accept the legal and procedural lessons learned from those past administrative petition litigations that the federal government refuses to acknowledge so that innocent dying patients – who are the true victims of the government's misbehavior – are not denied readily available medicine. This brief gives a historical overview showing that every advance in the availability of medicinal cannabis has been hard-earned overcoming the obstructive efforts of the federal government, which remains obstinate and intransigent.

A. The Passage of the Controlled Substances Act and the Criminalization of Cannabis Through Schedule I Status

In October 1970, as part of its "war on drugs," Congress passed, and the President signed, the CSA into law, which went into effect on May 1, 1971. 21 U.S.C. 801, *et seq*. The CSA established five schedules of controlled substances, ranging from I to V. 21 U.S.C. § 812. Schedule I is the most stringent providing that drugs in this category only may be used in extremely limited research settings. Licensed medical professionals who are not part of a federal research program are prohibited from prescribing a Schedule I drug to patients in any and all circumstances. On the other end of the spectrum, Schedule V drugs have the lowest potential for abuse and the

fewest restrictions placed upon them. The CSA provides that the Attorney General of the United States may – under his rulemaking authority – "add substances to a schedule, transfer them between schedules, or remove any drug or other substance from the schedules." *NORML v. Ingersoll* ("*NORML I*"), 497 F.2d 654, 656-57 (D.C. Cir. 1974) (internal quotation marks deleted) (citing 21 U.S.C. § 811(a)).

Before a drug may be placed in Schedule I, the federal government must – on the basis of science and evidence – determine that the drug (1) "has a high potential for abuse[,]" (2) "has no currently accepted medical use in treatment in the United States[,]" and (3) "[t]here is a lack of accepted safety for use of the drug . . . under medical supervision." 21 U.S.C. § 812(b)(1). The CSA expressly provides that "unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of . . . [m]arihuana . . . [or] [t]etrahydrocannabinols, except for tetrahydrocannabinols in hemp" must be placed in Schedule I. 21 U.S.C. § 812(c)(10) and (17).[2]

At the time of passage of the CSA, Congress placed cannabis in Schedule I upon the temporary recommendation of the then-Department of

[2] By contrast, some of the most common performing-enhancing substances, such as anabolic steroids, are placed in Schedule III. 21 U.S.C. § 812(e).

Health, Education, and Welfare ("HEW") pending further inquiry into the matter by National Commission on Marihuana and Drug Abuse led by Raymond Shafer, the former governor of the Commonwealth of Pennsylvania (the "Shafer Commission"). *See* H.R. Rep. 91-1444 at 2111 (1970). The role of the Shafer Commission, which was established by the CSA and consisted of four members of Congress and four medical doctors, was to study the pharmacological makeup of cannabis and determine what relationship, if any, cannabis had with the use of other drugs. See P.L. 91-513, 84 Stat. 1281.

After conducting more than fifty projects, the Shafer Commission ultimately concluded that cannabis was not harmful and should be de-scheduled altogether. Among other things, the Shafer Commission found that "[n]o significant physical, biochemical, or mental abnormalities could be attributed solely to . . . marihuana smoking" and "[n]either the marihuana user nor the drug itself can be said to constitute a danger to public safety." It also found that "[t]he actual and potential harm of use of the drug is not great enough to justify intrusion by the criminal law into private behavior, a step which our society takes only with the greatest reluctance." Accordingly, the Shafer Commission recommended that cannabis be decriminalized for personal use by both the federal and state governments.

Notwithstanding the findings of the Shafer Commission, the Nixon administration refused to reschedule cannabis and left it in Schedule I. This unacceptable state of affairs would not go unchallenged for long.

B. NORML's Attempts to Decriminalize Cannabis for Medicinal Purposes Were Stymied by the Federal Government for More than Fifty Years

There have been numerous petitions submitted over the years to change the scheduling of cannabis, including several filed by NORML. None have succeeded to move it from Schedule I due in part to the federal government's repeated and continued obstruction, delay, and obfuscation of the administrative process itself during the pendency of the petition. In particular, the DEA has either declined to gather mandated data for FDA, docket petitions for rescheduling, or denied petitions on the "merits" only after years, and sometimes more than a decade, of delay. *See, e.g.*, Drug Enforcement Administration, *Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 81 Fed. Reg. 53687, 53687-89 (Aug. 12, 2016).

The first petition attempt by NORML to reschedule cannabis after the passage of the CSA was filed on May 18, 1972. The petition, which sought to move it from Schedule I to Schedule II, was rejected by the Director of the then-Bureau of Narcotics and Dangerous Drugs without any consideration. It was instead done on the basis that the United States would not be

compliant with its international treaty obligations under the 1961 Single Convention on Narcotic Drugs ("Single Convention") if cannabis was moved from Schedule I. After NORML appealed, the United States Court of Appeals for the District of Columbia Circuit held that the federal government had unlawfully rejected the filing of petition and remanded the matter "for further consideration . . . on the merits." *NORML I*, 497 F.2d at 660.

On remand, a hearing was held before an administrative law judge who concluded that, "consistent with the Single Convention, 'cannabis' and 'cannabis resin' — as defined by the treaty — could be rescheduled to CSA Schedule II, cannabis leaves could be rescheduled to CSA Schedule V, and cannabis seeds and 'synthetic cannabis' could be decontrolled." *NORML v. DEA* ("*NORML II*"), 559 F.2d 735, 742 (D.C. Cir. 1977). The Acting Administrator of the DEA rejected the administrative law judge's recommendation and "denied NORML's petition for rescheduling in all respects." *Id.* (citing 40 Fed. Reg. 44164, 44168 (1975)). The DEA based its decision on a one-page conclusory and self-serving letter from HEW, the then government department where FDA was housed, stating that cannabis had no currently accepted medical use. *Id.* at 743.

On appeal, the D.C. Circuit found that HEW's letter "was not an adequate substitute for the procedures enumerated in Section 201(a)-(c) [of

the CSA" and remanded for further proceedings. *Id.* at 749-50. In particular, the court of appeals ordered the Secretary of HEW to make "separate evaluations and recommendations . . . within the limits authorized by [the Single Convention]" with respect to cannabis, cannabis resin, cannabis leaves, cannabis seeds, and synthetic THC. *Id.* at 757.

On remand, HEW concluded that cannabis should remain on Schedule I. *See* Drug Enforcement Administration, *Marihuana and Synthetic THC; Scheduling of Controlled Substances*, 44 Fed. Reg. 36123 (Jun. 20, 1979). FDA then denied NORML's rescheduling petition, and another appeal followed. However, the D.C. Circuit did not reach the merits of NORML's appeal because the DEA asked for a partial remand, which the court of appeals granted. *NORML v. DEA* ("*NORML III*"), No. 79-1660, 1980 U.S. App. LEXIS 13099, at *1 (D.C. Cir. Oct. 16, 1980). The D.C. Circuit noted: "We regrettably find it necessary to remind [the DEA] of an agency's obligation on remand not to 'do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case.'" *Id.* at *2.

In 1988, Administrative Law Judge Francis Young issued a determination arising from a petition by NORML to reschedule cannabis. *See In the Matter of Marijuana Rescheduling*, DEA Docket No. 86-22 (Sep.

6, 1988). Judge Young found that cannabis was a recognized, well-accepted and superior method of treatment of cancer patients suffering from nausea, emesis, and wasting. He therefore held that "marijuana has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotherapy treatments in some cancer patients. *Id.* To conclude otherwise, on this record, would be unreasonable, arbitrary, and capricious." *Id.* He made the same findings with respect to multiple sclerosis, spasticity, and hyperparathyroidism. Accordingly, Judge Young concluded that "the marijuana plant considered as a whole has a currently accepted medical use in treatment in the United States, that there is no lack of accepted safety for use of it under medical supervision and that it may lawfully be transferred from Schedule I to Schedule II." *Id.*

Unsurprisingly, the Administrator of the DEA overturned Judge Young's recommendations and refused to reschedule cannabis. NORML again appealed. In 1994, the D.C. Circuit affirmed the DEA's decision notwithstanding the substantial body of physicians and patients who had testified about the medical benefits of cannabis. *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994).

The following year, in 1995, the then-Executive Director of NORML petitioned the DEA to reschedule cannabis and several other substances.

After six years of delay, the DEA eventually denied his petition. Drug Enforcement Administration, *Notice of Denial of Petition*, 66 Fed. Reg. 20038 (Mar. 20, 2001). Among other reasons, the DEA noted that the FDA "has not approved a new drug application for marijuana" and "marijuana does not have a currently accepted medical use for treatment in the United States nor does it have an accepted medical use with severe restrictions." *Id.* at 20051.

On October 9, 2002, NORML filed another petition to reschedule cannabis. The DEA did not respond for nearly nine years. On July 8, 2011, the DEA denied the petition stating that HEW's successor, the Department of Health and Human Services ("DHHS") has "concluded" that marijuana "has no accepted medical use in the United States[.]" Drug Enforcement Administration, *Denial of Petition To Initiate Proceedings To Reschedule Marijuana*, 76 Fed. Reg. 40552 (Jul. 8, 2001). This decision was then challenged in the D.C. Circuit. *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013).

The court of appeals found that "[o]n the record before us, . . . the DEA's denial of the rescheduling petition survives review under the deferential arbitrary and capricious standard." *Id.* at 440. In particular, the D.C. Circuit found that the five-factor test established by DEA – which

requires "a known and reproducible drug chemistry, adequate safety studies, adequate and well-controlled studies demonstrating efficacy, acceptance of the drug by qualified experts, and widely available scientific evidence" – had not been satisfied. *Id.* at 442. Notably, the panel found that a military veteran had standing because of "his inability to have the [Veteran Affairs] system complete his state medical marijuana forms[.]" *Id.* at 449. All further attempts for review by the panel or the full court sitting *en banc* were denied.

The most recent case of note challenging the placement of cannabis on Schedule I is *Washington v. Barr*. 925 F.3d 109 (2d. Cir. 2019). In *Washington*, the petitioners included "individuals who plausibly allege that the current scheduling of marijuana poses a serious, life-or-death threat to their health." *Id.* at 113. The district court dismissed the complaint for failure to exhaust administrative remedies. *Id.* The Second Circuit agreed with the lower court but was "troubled by the [DEA's] history of dilatory proceedings" and decided to hold the appeal "in abeyance and retain jurisdiction . . . to take whatever action might become appropriate if the DEA does not act with adequate dispatch." *Id.*

In particular, the court of appeals opined that the petitioners "should not be required to live indefinitely with uncertainty about their access to allegedly life-saving medication or live in fear that pursuing such medical

treatment may subject them or their loved ones to devastating consequences." *Id.* at 120. After observing that "the average delay in deciding petitions to reclassify drugs under the CSA is approximately nine years[,]" the Second Circuit stated that "under the unusual health-related circumstances of this case, what has counted as appropriate speed in the past may not count as appropriate speed here." *Id.* at 120-21. The petitioners eventually declined to file a new petition with the DEA, the Second Circuit dismissed the case, and the Supreme Court denied certiorari. *Washington v. Barr*, No. 18-859 (2d Cir. Feb. 3, 2020), *cert. den.* 141 S. Ct. 555 (Oct. 13, 2020).

As this comprehensive history of NORML's efforts to reschedule cannabis demonstrates, the federal government – particularly, the DEA – in the face of rescheduling petitions, has engaged in a deliberate and dangerous pattern of delay, resistance, and obstruction at every juncture for more than fifty years. Once goaded or compelled into gathering data and information for FDA's evaluation after receipt of a petition, the FDA's recommendation DEA's final determination fails to account for the wealth of information from 41 states have adopted some form of medical cannabis legalization programs. The harm suffered by NORML and patients repeatedly forced to use legal process to seek a rational, science-based cannabis policy at the federal level

should not be inflicted upon another generation of individuals seeking to benefit from the therapeutic effects of psychedelics, such as Appellee's patients.

II. UNLESS THIS COURT INTERVENES, PETITIONERS WILL SUFFER YEARS, POSSIBLY DECADES, OF DELAY AND DENIAL THUS EXPERIENCING UNNECESSARY PAIN AND SUFFERING

A. Petitioners Have a Procedural Due Process Right to Have Their Petition Properly Considered on the Merits in Accordance with the CSA

The Controlled Substances Act has a procedural due process right to challenge the designation of cannabis as a Schedule I drug. 21 U.S.C. 811. The Fifth Amendment of the United States Constitution provides, in pertinent part: "No person shall be . . . deprived of life, liberty, or property, without due process of law[.]" The due process clause, along with other important provisions of the Bill of Rights, are based on the English common law dating back to June 15, 1215, when the then-monarch, King John, was forced to sign the Magna Carta by rebellious barons.[3] The following century, the phrase

[3] The modern English translation of Clause 39 reads as follows: "No free man shall be seized or imprisoned, or stripped of his rights or possessions, or outlawed or exiled, or deprived of his standing in any other way, nor will we proceed with force against him, or send others to do so, except by the lawful judgement of his equals or by the law of the land." *The Text of Magna Carta*, Internet History Sourcebooks Project, Fordham University (1995), available at https://sourcebooks.fordham.edu/source/magnacarta.asp (last accessed on Feb. 10, 2023).

"due process of law" first appeared in an Act of the English Parliament in 1354.[4]

The Supreme Court has recognized the Due Process Clause of the Fifth Amendment imbues individuals with broad protections. For instance, the Court has determined that "[i]f the [due process clause's] right of privacy means anything, it is the right of the individual . . . to be free of unwarranted governmental intrusion in matters so fundamentally affecting a person[.]" *Carey v. Population Servs. Int'l*, 431 U.S. 678, 686 (1977); *see also Griswold v. Connecticut*, 381 U.S. 479, 487 (1965) (Goldberg, J., concurring) ("The Court stated many years ago that the Due Process Clause protects those liberties that are 'so rooted in the traditions and conscience of our people as to be ranked as fundamental.'") (citing *Snyder v. Massachusetts*, 291 U.S. 97, 105 (1934)).

Although the concept of procedural due process varies by situation, "[t]he fundamental requirement of due process is the opportunity to be heard at a meaningful time and in a meaningful manner." *Magassa v. Wolf*, 545 F. Supp. 3d 898, 906 (W.D. Wash. 2021) (internal quotation marks deleted) (quoting *Armstrong v. Manzo*, 380 U.S. 545, 552 (1965)); *see also*

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[4] Liberty of Subject, 28 Edw. 3 (1354), available at https://www.legislation.gov.uk/aep/Edw3/28/3 (last accessed on Feb. 10, 2023).

Morrissey v. Brewer, 408 U.S. 471, 481 (1972) ("[D]ue process is flexible and calls for such procedural protections as the particular situation demands.").

Here, procedural due process required the DEA to gather data in response to the petition and forward it to the FDA to conduct a medical and scientific evaluation of psilocybin. This means that the DEA should have provide available data and FDA and FDA should have been able to conduct an investigation pursuant to 21 U.S.C. § 811(b) for "a scientific and medical evaluation" and "recommendation respect to the appropriate schedule, if any, under which such drug or other substance should be listed." That did not happen here.

Rather, DEA waited eight months after the petition was filed seeking rescheduling of psilocybin to respond with a *pro forma* four-sentence denial letter to Petitioners/Appellants that simply parroted legal conclusions of a bygone era that it has no medical benefit. There was no evidence and information collection or transmission of it with the petition to FDA. As it stands, it is unclear if FDA was even aware of the petition prior to DEA's kneejerk rejection of it based on an old recommendation that was not reinvestigated in light of the pending petition.

The DEA's threadbare response without any FDA investigation bears many similarities to the one-page letter that the D.C. Circuit found so

woefully lacking in *NORML II* nearly forty-five years ago. Neither response complied with the scientific and medical evaluation requirement of the CSA, neither response had any substance supporting its barefaced conclusions, and neither response provided the respective petitioners with the procedural due process required by statute.

In light of the DEA's actions in this matter and the resulting procedural violation, an outside observer can only reach the conclusion that the administration has not learned from the past. Just as NORML and others, through the legal process forced the federal government to conduct scientific and medical studies in the past, this Court should compel the DEA to follow its required duty under the CSA and gather available data and compel the FDA to investigate psilocybin and make a recommendation about its scheduling status.

B. IN MANY INSTANCES, INDIVIDUALS IN NEED OF BREAKTHROUGH MEDICAL THERAPIES ARE AT THE END OF THE LIVES AND CANNOT AFFORD THE DEA'S PATTERN OF DELAYS

While the consistent pattern of delays in forwarding or deciding rescheduling petitions – whether for cannabis or psilocybin – is unfortunate and unjustifiable in general, it is, in effect, life threatening for petitioners-appellants and others. Many of the individuals who often seek to benefit from the breakthrough therapies have not had success with more

conventional treatment options. They often have a limited lifespan remaining and have exhausted all other treatment options. For them, delay is simply not an option because time is, unfortunately, not on their side.

The federal courts have long recognized that certain controversies – due to their unique nature – are "capable of repetition, yet evading review." *See Super Tire Eng'g Co. v. McCorkle*, 416 U.S. 115, 122 (1974) ("[S]ince this case involves governmental action, we must ponder the broader consideration whether the short-term nature of that action [leaves the] petitioners . . . adversely affected by government 'without a chance of redress.'"); *S. Pac. Terminal Co. v. Interstate Commerce Comm.*, 219 U.S. 498, 515 (1911).

Irrespective of whether a case or controversy is actually rendered moot by the passing of an individual who would otherwise benefit from rescheduling and the then legalized form of palliative care, the reality is that the consistent delay tactics and perfunctory decisions unsupported by recent scientific or medical evidence only leaves individuals with often fatal conditions without any recourse under the CSA. That is inhumane and unconstitutional. When considering appeals from the denials of rescheduling petitions, this Court should consider the real-world effect that

lengthy delays have on patients who have no other options available and wish to try breakthrough therapies, such as psilocybin or cannabis.

These procedural delays of the past – which often amounted to years, if not decades – should not be countenanced going forward.

CONCLUSION

For these reasons, and the reasons set forth in Petitioners' opening brief, NORML respectfully submits that the Court should vacate the decision under review and remand for further proceedings.

Dated: February 15, 2023

Respectfully submitted,

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