#### UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

#### Form 3. Petition for Review of Order of a Federal Agency, Board, Commission, or Officer

Name of Federal Agency, Board, Commission, or Officer: DEA; William Barr, Atty Gen; and Timothy Shea, Acting Administrator, DEA Date of judgment or order you are challenging: 04/22/2020 Fee paid for petition? Yes  $\bigcirc$  No List all Petitioners (List each party filing the petition. Do not use "et al." or other abbreviations.) Suzanne Sisley, M.D.; Scottsdale Research Institute, LLC; Battlefield Foundation d/b/a Field To Healed; Lorenzo Sullivan; Kendrick Speagle; and Gary Hess For immigration cases: Alien Number(s): Is petitioner(s) detained? O Yes  $\bigcirc$  No Has petitioner(s) moved the BIA to reopen?  $\bigcirc$  Yes  $\bigcirc$  No Has petitioner(s) applied to the district director for an ○ Yes  $\bigcirc$  No adjustment of status? Have you filed a previous petition for review from this agency? ○ Yes  $\bullet$  No If Yes, what is the prior 9th Circuit case number? Your mailing address: Yetter Coleman LLP, 811 Main Street, Suite 4100 Zip Code: |77002 Houston State: TX City: Prisoner Inmate or A Number (if applicable): **Date** | May 21, 2020 Signature /s/Matthew C. Zorn Complete and file with the attached representation statement and the order being challenged.

See, e.g., Circuit Rule 15-4.

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### **Representation Statement for Petition for Review**

Petitioner(s) (List each party filing the petition, do not use "et al." or other abbreviations.)
Name(s) of party/parties:
Suzanne Sisley, M.D.; Scottsdale Research Institute, LLC; Battlefield Foundation d/b/a Field To Healed; Lorenzo Sullivan; Kendrick Speagle; and Gary Hess
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Is counsel registered for Electronic Filing in the 9th Circuit? • Yes O No
Respondent(s) (List only the names of parties and counsel (if known) who will oppose you in the petition. List separately represented parties separately.)  Name(s) of party/parties:
Drug Enforcement Administration; William Barr, Attorney General of the United States; and Timothy Shea, Acting Administrator, Drug Enforcement Administration
Name(s) of counsel (if any known):
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To list additional parties and/or counsel, attach additional pages as necessary.

Form 3 2 Rev. 12/01/2018

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### CONTINUATION OF FORM 3. REPRESENTATION STATEMENT FOR PETITION FOR REVIEW SERVICE LIST (NINTH CIR. RULE 3-2)

#### **PETITIONERS**

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The Honorable Timothy Shea Drug Enforcement Administration 7000 Army-Navy Dr. Arlington, VA 22202

No.		

# In the United States Court of Appeals for the Ninth Circuit

SUZANNE SISLEY, M.D.; SCOTTSDALE RESEARCH INSTITUTE, LLC; BATTLEFIELD FOUNDATION D/B/A FIELD TO HEALED; LORENZO SULLIVAN; KENDRICK SPEAGLE; AND GARY HESS,

Petitioners,

ν.

DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; AND TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents

#### **PETITION FOR REVIEW**

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#### CORPORATE DISCLOSURE STATEMENT

Petitioner Scottsdale Research Institute, LLC is a privately held company and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

Petitioner Battlefield Foundation d/b/a Field to Healed is a private corporation and, other than Scottsdale Research Institute, LLC, does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

May 21, 2020

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Attorneys for Petitioners Suzanne Sisley, M.D.; Scottsdale Research Institute, LLC; Battlefield Foundation d/b/a Field To Healed; Lorenzo Sullivan; Kendrick Speagle; and Gary Hess Pursuant to 21 U.S.C. § 877 of the Controlled Substances Act ("CSA"), 5 U.S.C. §§ 702, 706 of the Administrative Procedure Act ("APA"), and Rule 15 of the Federal Rules of Appellate Procedure, Petitioners hereby petition the Court for review of the Drug Enforcement Administration's ("DEA") final determination denying Stephen Zyskiewicz's January 3, 2020 petition to reschedule. Mr. Zyskiewicz's petition is attached as **Exhibit 1** (the "2020 Petition"). A copy of the letter containing and memorializing DEA's final determination (the "2020 Determination"), which was not publicly disclosed, followed by the cover e-mail and other attachments, is attached as **Exhibit 2**.

As grounds for denying Mr. Zyskiewicz's petition, the 2020 Determination incorporates, reasserts, and applies the "Denial of Petition to Initiate Proceedings to Reschedule Marijuana," 81 Fed. Reg. 53,767 (Aug. 12, 2016) (the "2016 Denial"), which in turn applies and relies on "Marijuana Scheduling Petition; Denial of Petition; Remand," 57 Fed. Reg. 10,499 (Mar. 26, 1992) (the "1992 Rule"), attached as **Exhibit 3** and **Exhibit 4**, respectively.

Petitioners seek review of the 2020 Determination as well as the 2016 Denial and the 1992 Rule. *See Functional Music, Inc. v. F.C.C.*, 274 F.2d 543, 546 (D.C. Cir. 1958) (court may substantively examine propriety of a rule when further agency action applies it). *See also Wind River Min. Corp. v. United States*, 946 F.2d 710, 715 (9th Cir. 1991) ("The government should not be permitted to avoid all

challenges to its actions, even if *ultra vires*, simply because the agency took the action long before anyone discovered the true state of affairs.").

#### Petitioners Seeking Review

1. Petitioner **Suzanne Sisley, M.D.** is an Arizona licensed physician who lives in Arizona and whose principal place of business is in Arizona, within this Circuit. Dr. Sisley is the President and Founder of Petitioner Scottsdale Research Institute, LLC.

In her private practice, Dr. Sisley treats approximately 40% military veterans, 20% police and fire, and 40% patients enrolled with 8 different Native American tribes based in Arizona. Her specialties include treating chronic pain, opioid dependence, and Post Traumatic Stress Disorder ("PTSD").

Dr. Sisley is a pioneer in the field of marijuana research. Now more than a decade ago, her first-hand experience in private practice treating veteran clients that used marijuana to treat PTSD, which did not respond to conventional medications, inspired her to conduct clinical trials on the safety and efficacy of marijuana use. Through the company she founded, Scottsdale Research Institute, LLC, she recently completed the only federally authorized study of medical marijuana for PTSD for military veterans and first responders in the United States.

2. Petitioner Scottsdale Research Institute, LLC ("SRI") is a non-commercial, Arizona limited liability company with its principal place of business in Arizona, within this Circuit.

Dr. Sisley formed SRI to conduct high-quality, controlled scientific studies to ascertain the general medical safety and efficacy of marijuana products and to examine various forms of marijuana administration. For its first clinical trial, SRI had to use marijuana from the University of Mississippi through the National Institute of Drug Abuse ("NIDA"), the only federally legal source of marijuana for research. The quality of the marijuana provided by the federal government was poor. It contained sticks and seeds. Third-party testing confirmed it had mold. The poorquality marijuana had an adverse impact on the study results and on some study subjects. This marijuana was not only inadequate for the Phase II trial SRI completed, but it is inadequate for further studies SRI intends to conduct, such as Phase III clinical trials or other Phase II clinical trials.

In August 2016, toward the end of the Obama Administration, DEA announced a new policy to increase the number of entities permitted to manufacture cannabis for research. 81 Fed. Reg. 53,846 (Aug. 12, 2016) (the "2016 Policy Statement"). This announcement in the Federal Register reversed a longstanding agency policy related to medical marijuana research where DEA had determined that an exclusive supply arrangement with a single marijuana supplier was the best way

to fulfill our nation's obligations under the Single Convention of Narcotic Drugs of 1961 (the "Single Convention"). The Single Convention limits the manufacture and distribution of marijuana for medical or research purposes.

Because of the poor-quality marijuana provided by the federal government, in October 2016, SRI applied to cultivate its own marijuana for its clinical trials. SRI's application is still pending. To this day, DEA has not granted or denied a single application to cultivate marijuana for research that it received after the 2016 Policy Statement.

In June 2019, after years of delay and silence, SRI filed a mandamus petition in the United States Court of Appeals for the D.C. Circuit seeking to compel perfunctory, ministerial action on SRI's application. *See In re Scottsdale Research Institute, LLC*, Case No. 19-1120 (D.C. Cir.). The court ordered DEA to respond to SRI's petition by August 28, 2019. The day before the court deadline, DEA noticed SRI's application as well as all the other pending applications, mooting SRI's mandamus action. *See* 84 Fed. Reg. 44,920 (Aug. 27, 2019). At the same time, DEA indicated that new rules were needed to "evaluate the applications under the applicable legal standard and conform the program to relevant laws" before SRI's application or any of the other pending applications could move forward any further.

After seven months more delay, in late March 2020, in the middle of a national health crisis, DEA released its proposed rule. 85 Fed. Reg. 16,292 (Mar. 23, 2020).

DEA says the proposed rule would amend the agency's existing regulations "only to the extent necessary to comply with the CSA and to ensure DEA grants registrations that are consistent with the Single Convention as it pertains to marihuana."

Until April, neither DEA nor DOJ had fully explained its basis for delaying the applications. Unbeknownst to SRI, the other applicants, Congress, or the public, in secret, in June 2018, the Justice Department ("DOJ"), through the Office of Legal Counsel ("OLC"), had reinterpreted the relevant statutory provision governing the pending applications, 21 U.S.C. § 823(a), effectively blocking them. OLC concluded that DEA could register applicants to cultivate marijuana only if the registration scheme is consistent with the Single Convention on Narcotic Drugs. See Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs 42 Op. O.L.C. -- (June 6, 2018). Therefore, according to the OLC memo, because the existing scheme was non-compliant, DEA could not register any of the pending applicants. DEA continued to register the University of Mississippi, however, into its purportedly non-compliant regime. See 84 Fed. Reg. 2,578 (Feb. 7, 2019). Despite almost a dozen congressional inquiries, DOJ only released this memo in late-April as part of a settlement after SRI brought claims against DOJ and DEA under the Freedom of Information Act. See Scottsdale Research Institute, LLC, 2:20ev-00605-JJT (D. Ariz.).

Marijuana's schedule I status and DEA's determinations hinder SRI's clinical research—the very clinical research that DEA requires under its unlawful interpretation of 21 U.S.C. § 812(b)(1)(B) to consider removing marijuana from schedule I—in several key respects.

First, marijuana's schedule I status requires all cultivators be registered under 21 U.S.C. § 823(a). According to the statute and the OLC memo, because of that status, section 823(a) requires DEA and the federal government to severely restrict the quality and quantity of marijuana available for clinical research and comply with draconian international treaty obligations from 1961. A lower schedule could take marijuana out of section 823(a)'s ambit.

Second, because of marijuana's schedule I status, SRI has had to delay FDA-approved clinical trials to investigate the safety and efficacy of smoked marijuana in treating breakthrough pain in terminal cancer patients. SRI has been ready to do this research for more than a year. If marijuana were in a less restrictive schedule, SRI would have been able to complete its research by now. Instead, it has had to turn to importing marijuana from other countries because of inadequate supply, which is directly attributable to marijuana's schedule I status.

Third, SRI's research focuses on veterans. But because federal law prohibits the Department of Veterans Affairs ("VA") from providing or researching marijuana regardless of state laws, the local VA has blocked SRI's recruitment efforts.

3. Petitioner **Battlefield Foundation d/b/a Field To Healed** is an Arizona non-profit corporation based in Arizona, within this Circuit. It is the 501(c)(3) non-profit arm of SRI and helps support SRI's mission.

Founded by Dr. Sisley and Roberto Pickering, Field to Healed is dedicated to medical research and charitable services for veterans and first responders.

4. Petitioner **L. Lorenzo Sullivan** is a disabled Army veteran who serves on the honorary board of Field to Healed. He lives in Arizona, within this Circuit.

Mr. Sullivan was honorably discharged from the Army after serving in the Vietnam War. Because of his service, he suffers from PTSD and has been classified by the VA as 85% unemployable. In addition, he was treated for prostate cancer resulting from Agent Orange exposure in Vietnam. Over the years, Mr. Sullivan has had difficulty with numerous VA-prescribed medications. He attempted to have a conversation with a VA doctor after a retired heart surgeon suggested marijuana, but because of marijuana's status under federal law, he was told that the VA could not help him or even discuss marijuana with him.

5. Petitioner **Kendric Speagle** is a Navy veteran who served as an aviation logistician onboard USS George Washington. He was deployed in the Persian Gulf enforcing No Fly Zones in Southern Iraq and in the Adriatic Sea, leading NATO missions over Bosnia Herzegovina. He lives in Arizona, within this Circuit.

In his late 30's, Mr. Speagle began to develop severe fluctuations in the intraocular pressure of his right eye, consistent with glaucoma. He reached out to the VA
and inquired about using marijuana to reduce the pressure and the painful symptoms,
but was told that the VA was legally unable to recommend or provide marijuana for
medical purposes. Mr. Speagle had surgery and took multiple medications, but
nothing seemed to reduce the painful pressure in his right eye. Mr. Speagle
discovered that marijuana successfully, immediately, and drastically reduced his
intra-ocular pressure and pain. Unfortunately, it was too late to prevent an acute
episode of glaucoma, which left the muscles in the iris of his right eye completely
dead. Had the VA been less encumbered by DEA's classification as a schedule I
drug, Mr. Speagle would have avoided years of pain, and might have the ability to
see clearly today.

6. Petitioner **Gary Hess** is a Marine Corps Veteran who served as an Infantry Officer during the heaviest levels of fighting in Iraq. He lives and works in Louisiana. Joinder of Mr. Hess in this action is practicable under Rule 15(a).

In 2008, Mr. Hess was honorably discharged with service-connected disabilities consisting of Traumatic Brain Injury, chronic pain, and PTSD, among others. For example, in December of 2006 while operating in Iraq, the house Mr. Hess was occupying was hit with a vehicle-born improvised explosive device, decapitating one of his Marines and wounding the remaining three, including Mr.

Hess. Mr. Hess reached out to the VA for help. From 2009 to 2017, he was prescribed the pharmaceutical "combat cocktail," which was a failure. After trying medicinal marijuana, many of Mr. Hess's most distressing and untreatable symptoms abated.

#### Grounds for Review

Petitioners challenge and seek judicial review of the following aspects of the 2020 Determination, the 2016 Denial, and the 1992 Rule.

1. Petitioners seek review of the agency's interpretation of the statutory phrase "no currently accepted medical use in treatment in the United States" and its determination that marijuana has "no currently accepted medical use in treatment in the United States."

To determine whether a drug or other substance has a "currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B), DEA applies a conjunctive five-part test that originated in the 1992 Rule:

- (1) whether a drug's chemistry is known and reproducible;
- (2) whether there are adequate safety studies;
- (3) whether there are adequate and well controlled studies proving efficacy;
- (4) whether the drug is not accepted by qualified experts; and
- (5) whether the scientific evidence is not widely available.
- 2016 Denial at 53,779 & n.10 (citing 1992 Rule at 10504–06).

This agency created test has no basis in the statute; is contrary to the statutory text, structure, history, and purpose; departs from the original understanding of the statute; and rests on flawed and outdated case law.

In Alliance for Cannabis Therapeutics v. Drug Enf't Admin., 15 F.3d 1131 (D.C. Cir. 1994) ("Alliance II") and All. for Cannabis Therapeutics v. Drug Enf't Admin., 930 F.2d 936, 939 (D.C. Cir. 1991) ("Alliance I"), the appellate court deferred to DEA's five-part test under Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984) because "neither the statute nor its legislative history precisely defines the [statutory] term." Alliance I, 930 F.2d 936 at 939 (emph. added); Alliance II, 15 F.3d at 1134 (relying on Alliance I).

But since then, the Supreme Court has clarified that courts do not defer to agency interpretations simply because a term is not "precisely" defined. Rather, courts must "exhaust" the traditional tools of statutory construction until the "legal toolkit is empty." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (citing *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 696 (1991)); *see also SAS Institute v. Iancu*, 138 S. Ct. 1348, 1359 (2018) ("Even under *Chevron*, we owe an agency's interpretation of the law no deference unless, after 'employing traditional tools of statutory construction,' we find ourselves unable to discern Congress's meaning."). Here, applying the traditional tools of statutory construction as the Supreme Court

instructs, there is no uncertainty that warrants deference to DEA's test. *See Iancu*, 138 S. Ct. at 1358.

In any case, more recent Supreme Court precedent regarding *Chevron* deference refutes *Alliance I* and *II* and forecloses deference from the outset. *See, e.g., Gonzales v. Oregon*, 546 U.S. 243, 258 (2006) (explaining and holding that the Attorney General is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law). *Chevron* deference is also inappropriate because the CSA is a dual-application statute. *See generally Esquivel-Quintana v. Lynch*, 810 F.3d 1019, 1027-32 (6th Cir. 2016) (Sutton, J.) (concurring in part, dissenting in part).

Deference is also inappropriate because section 812(b)(1)(B) is unambiguous. Based on the statutory text, structure, history, purpose—and the original understanding the statute—"currently accepted medical use" means "legitimate" or "lawful medical purpose." This is the only interpretation that captures the cooperative federalism vision of the CSA and respects state sovereignty. And under that interpretation, the 2020 Petition, the 2016 Denial itself, and judicially noticeable facts present conclusive evidence that precludes a finding that marijuana has "no currently accepted medical use in treatment in the United States." The 2020 Petition should be granted.

Accordingly, Petitioners respectfully request the Court vacate and set aside the 1992 Rule and the five-factor test; reverse the agency's final determination that marijuana has "no currently accepted medical use in treatment in the United States"; and remand with instructions to initiate rulemaking under section 811(a).

2. Petitioners seek review of the agency's final determination that rescheduling turns *solely* "on whether marijuana has a currently accepted medical use in treatment in the United States."

The 2016 Denial concludes, "the only determinative issue in evaluating [a] petition is whether marijuana has a currently accepted medical use in treatment in the United States." 2016 Denial at 53,768. Thus, according to DEA, it need not consider the findings of sections 811(a) or 812(b) that have no bearing on that determination nor follow the procedures prescribed by sections 811(a) and (b), because schedule I is the only schedule for drugs with "no currently accepted medical use in treatment in the United States." This conclusion is arbitrary, capricious, and contrary to law.

A drug can meet the criteria for multiple schedules concurrently. For example, a drug may have "no currently accepted medical use in treatment in the United States" (schedule I, 21 U.S.C. § 812(b)(1)(B)) but a "currently accepted medical use with severe restrictions" (schedule II, 21 U.S.C. § 812(b)(2)(B)). For example, FDA in the past concluded that the criteria for both schedules I and II can be met

concurrently. *See* "Proposed Recommendation to the Drug Enforcement Administration Regarding the Scheduling Status of Tetrahydrocannabinol," 47 Fed. Reg. 10,080, 10,084-85 (March 9, 1982) (concluding that THC met all three criteria for schedule I and schedule II and that placement of THC in IND Group C status, a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside a controlled clinical trial, met the definition of "currently accepted medical use with severe restrictions").

Similarly, the conclusion that "the lack of accepted medical use for a specific, recognized disorder precludes the use of marijuana even under conditions where its use is severely restricted," 2016 Denial at 53,786, is incorrect. This conclusion ignores the textual difference between "currently accepted medical use *in treatment* in the United States" and "currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2)(B).

## 3. Petitioners seek review of DEA's final determination that "[t]here is a lack of accepted safety for use of marijuana under medical supervision."

DEA concludes that there is a "lack of accepted safety for use" of marijuana "under medical supervision" because there are no FDA-approved marijuana drug products, marijuana "does not have a currently accepted medical use in treatment in the United States," and marijuana does not have "a currently accepted medical use with severe restrictions." 2016 Denial at 53,786. This conclusion misconstrues the

statute and is arbitrary, capricious, and contrary to law because the agency has improperly imported a clinical efficacy requirement into section 812(b)(1)(C).

## 4. Petitioners seek review of DEA's final determination that marijuana must be placed in either schedule I or II.

DEA has determined that, because 21 U.S.C. § 811(d) applies, marijuana cannot be placed in Schedules III, VI, or V. 2016 Denial at 53,768-70. But section 811(d)(1) is an unconstitutional delegation of legislative authority under Article I and violates core separation of powers principles.

Section 811(d)(1) impermissibly delegates to the Attorney General the power and obligation to issue an order placing a drug in the schedule "he deems most appropriate" to carry out international treaties, conventions, or protocols in effect on or before October 27, 1970, "without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section." 21 U.S.C. § 811(d). Thus, the statute outsources regulatory power to create domestic criminal law to international organizations and subordinates domestic law to treaty obligations, conventions, and protocols. Then, it entrusts the Attorney General, a member of the executive branch, to execute non-self-executing international treaty obligations, providing him no intelligible principle, instructions, standards, or criteria whatsoever against which to measure what "he deems most appropriate." This is unconstitutional. *See A.L.A.* 

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Schechter Poultry Corp. v. United States, 295 U.S. 495, 537-42 (1935) (holding unconstitutional a delegation of authority to unelected trade associations to propose poultry codes with criminal penalties, layered with delegation to President to approve code provisions "in his discretion" he thinks necessary "to effectuate the policy" unconstitutional).

Because section 811(d)(1) is invalid, it cannot constrain the Attorney General and DEA's authority to reschedule a drug or other substance. DEA's determination that placement of marijuana must be in either schedule I or II should be vacated and section 811(d)(1) should be held unconstitutional.

Dated: May 21, 2020 Respectfully submitted,

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#### **CERTIFICATE OF SERVICE**

I certify that this Petition for Review was filed with the Court via the court's electronic filing system, on the 21st day of May, 2020, and copy of the Petition was served on all counsel of record, as listed below, via Federal Express:

Respondent

Respondent

The Honorable William Barr Attorney General of the United States U.S. Department of Justice 950 Pennsylvania, NW Washington, DC 20530 The Honorable Timothy Shea Drug Enforcement Administration 7000 Army-Navy Dr. Arlington, VA 22202

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