No. 20-71433

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; WILLIAM BARR, ATTORNEY GENERAL; TIMOTHY SHEA, ACTING ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION

Respondents

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

BRIEF OF LORI WALKER, PHD, STEPHEN DEFELICE, MD, LYLE E. CRAKER, PHD, DANIELA VERGARA, PHD, CHRISTOPHER J. HUDALLA, PHD, RACHNA PATEL, MD, WENDY AND TOM TURNER, AND MAUREEN LEEHEY, MD AS AMICUS CURIAE IN SUPPORT OF PETITION FOR REVIEW

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IDENTITY AND INTEREST OF AMICUS CURIAE

Each of the doctors, scientists and researchers below has experience in the scientific and medical fields, including research on medical marijuana. As reaffirmed below, the views expressed in this brief are their own as individuals only and are not attributed to any affiliated entities, research institutions, or universities.

The amici listed below are likewise familiar with both the research limitations created by the Schedule I classification and the general clinical research landscape. They offer this brief in support of Petitioners' request to initiate rulemaking hearings regarding the rescheduling of cannabis (i.e., marijuana) under the Controlled Substances Act.

Lori Walker, PhD is a cardiovascular scientist in the Department of Medicine, Division of Cardiology at the University of Colorado Anschutz Medical Campus. Dr. Walker has expertise in vascular and cardiac muscle mechanics, the biochemistry of cardiovascular pathologies, and cardiovascular wellness. Currently, Dr. Walker focuses her research on delineating the cardiovascular effects of marijuana in healthy adults and in patients with cardiac disease. Dr. Walker has a history of successful funding through the NIH and other agencies including the American Heart Association, the Colorado Clinical and Translational Science Institute, the Center for Women's Health, and the Colorado Department of

Public Health and Environment. With over 60 publications, she has a published track record investigating molecular regulation of cardiac and vascular signaling changes with health and disease.

Stephen DeFelice, MD is the founder and chairman of FIM, the Foundation for Innovation in Medicine, a nonprofit organization established in 1976 whose purpose is to accelerate medical discovery by establishing a more productive clinical research community. A graduate of Temple University, Dr. DeFelice received his M.D. from Jefferson Medical College in Philadelphia. He was an NIH fellow in endocrinology, diabetes, and metabolic disease at Jefferson and a fellow in clinical pharmacology at St. Vincent's Hospital and Medical Center in New York City. Dr. DeFelice was the former Chief of Clinical Pharmacology at the Walter Reed Army Institute of Research (WRAIR). He was a member of the Harvard School of Public Health's International Faculty on the Management of Biomedical Research and the Tufts' Faculty on the Principles of Clinical Research. He was also a member of the team that brought lithium into the United States and was the doctor responsible for its launch. His 40-year experience with carnitine, a naturally occurring substance with multiple medical benefits, sparked his interest and determination to encourage medical discovery. Largely through his efforts, it is now FDA approved as an Orphan Drug for various types of carnitine deficiencies as well as for renal dialysis patients. He is currently involved in

clinical research on carnitine in ovarian cancer patients. His experience taught him that the promise of medical technology is exploding but the barriers, costs, and risks of clinically testing their promise, a critical step in medical discovery, are also exploding.

Lyle E. Craker, PhD is a Professor in the Department of Plant, Soil, and Insect Sciences at the University of Massachusetts, and Executive Editor of the Journal of Medicinally Active Plants. Since 2005, Dr. Craker has been trying to obtain a permit from the United States Drug Enforcement Administration to grow marijuana for research purposes. Dr. Craker holds a B.S. degree in agronomy from the University of Wisconsin, Madison and a Ph.D. in agronomy and plant genetics with a specialty in plant physiology from the University of Minnesota. Dr. Craker is known for proposing that medical grade marijuana be available for scientific studies into its possible health benefits. Dr. Craker serves as the editor of "The Journal of Herbs, Spices, and Medicinal Plants," and past Editor, Past-Chairman of International Society for Horticultural Science Section on Medicinal and Aromatic Plants.

Daniela Vergara, PhD is an evolutionary biologist researching cannabis genomics at the University of Colorado Boulder. In addition to her multiple publications on cannabis, she founded and directs a non-profit organization, the Agricultural Genomics Foundation (AGF). AGF's aim is to make cannabis

science available to a broad public. Dr. Vergara's latest scientific publications include the comparison of the federal cannabis to that produced by the private market, showing that the government's cannabis lacked potency and variation. These results were featured in news platforms such as *Science* and *FiveThirtyEight*. Some of her other scientific publications are a compilation on the existing genomic tools available for cannabis research, and the maternally inherited genomes (chloroplast and mitochondria). Dr. Vergara has authored these publications advised by Dr. Nolan Kane whose group at CU Boulder she joined in 2013. These publications are a product of collaborations between graduate and undergraduate students, and scientists from the cannabis industry.

Christopher J. Hudalla, PhD is analytical chemist with more than 30 years of research experience in analytical chemistry, spectroscopy, and chromatographic method development. He is recognized worldwide as an expert in the field of traditional Reverse Phase Liquid, Supercritical Fluid, and Convergence Chromatography and an active leader in the development and implementation of the UltraPerformance Convergence Chromatography instrumentation. Dr. Hudalla is the founder and Chief Scientific Officer of ProVerde Laboratories, Inc., a premier analytical testing, CO2 extraction and derivative product formulation consultancy for the regulated medical cannabis and hemp industries. ProVerde is among the first laboratories in the United States to receive an ISO 17025

accreditation that specifically governs hemp and medical cannabis testing. ProVerde Laboratories operates at the cutting edge of medical cannabis extraction, purification and product formulation techniques, supported by expert analytical testing, with expertise that will move research into cannabis and its effects on various medical conditions forward as the medical cannabis industry progresses. Dr. Hudalla plays an integral part in providing clients operating in the Medical Marijuana and hemp industries the ability to deliver new products and product formulations that meet the highest standards for quality, consistency, safety and labeling. Dr. Hudalla received his M.S. and Ph.D. from the University of California at Santa Barbara and was a Postdoctoral Fellow at the Eppley Institute for Cancer Research within the University of Nebraska Medical Center. Dr. Hudalla has delivered presentations all over the world in his areas of expertise, including analytical testing and research specific to medical cannabis and serves on the Cannabis Expert Panel with the United States Pharmacopeia (USP).

Rachna Patel, MD is a world recognized expert in the field of cannabinoid medicine. She offers consultations and courses, so that people can relieve their symptoms, transform their health, and live a better quality life with cannabinoid products. She consults with patients about how to use cannabinoid products and what to expect when using cannabinoid products, while also dispelling fears people may have about these treatments and putting their minds at ease. Dr. Patel

completed her undergraduate studies at Northwestern University in Chicago, Illinois and earned her medical degree from Touro University in Vallejo, California. Dr. Patel has been interviewed on over 200 podcasts, has taken the stage internationally to spread awareness regarding the health benefits of cannabinoid products, has been featured in articles for Lifehacker and MindBodyGreen, and has appeared on major news networks such as NBC. She also authored the book, *The CBD Oil Solution: Treat Chronic Pain, Anxiety, Insomnia and more without the High*.

Maureen Leehey, MD is a Professor of Neurology and Chief of the Movement Disorders Division at the University of Colorado Denver and a Fellow Member of the American Academy of Neurology. She specializes in movement disorders and Fragile X associated disorders and sub-specializes in movement disorders and Botox therapy. She sees patients at the University of Colorado Hospital Anschutz Centers for Advanced Medicine. She is board certified in Neurology and Psychiatry, and is a fellowship-trained movement disorders specialist. She is the senior movement disorders neurologist in the Rocky Mountain region and has mentored numerous neurologists. During her 29 years at the University of Colorado, she has managed thousands of patients with Parkinson's disease, is Lead Investigator in the International Parkinson Disease

Study Group, and has been the Primary Investigator for over 20 Parkinson's disease clinical trials.

Wendy and Tom Turner are the founders of the Coltyn Turner Foundation, a non-profit research organization dedicated to researching therapeutic uses of medical cannabis. The first patient of the Coltyn Turner Foundation was their son, Coltyn, who was the first pediatric Crohn's patient in the United States to find clinical remission using cannabis.

* * *

The statements contained in this brief represent the personal beliefs and opinions of the *amici curiae*. They do not represent the beliefs or opinions of the institutions that employ the *amici curiae* or with which they are affiliated, including without limitation the University of Colorado Anschutz Medical Campus.

Respondents have consented to the filing of this brief.

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STATEMENT OF AUTHORSHIP AND FINANCIAL CONTRIBUTIONS

No party's counsel authored the brief in whole or in part, no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and no person, other than the above referenced amicus, and their counsel, contributed money that was intended to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

Schedule I classification of cannabis under the Controlled Substances Act (CSA) materially and significantly limits the ability of researchers to continue to undertake research necessary to test therapeutic uses within the medical and scientific community.

Among other things, Schedule I classification severely limits the availability of research material available for scientific research to only cannabis products approved by the United States Drug Enforcement Administration (DEA) and the National Institute on Drug Abuse (NIDA), which currently consist only of cannabis grown and processed by the University of Mississippi. When researchers are able to obtain federally sanctioned cannabis, it is dissimilar in potency and formulation from cannabis products widely used by patients and other consumers, undermining the reliability of scientific research. Restrictions on storage and control of cannabis necessitate the purchases of specialized equipment, such as double-locked refrigerators, which increase the expense of cannabis research without any material benefit. Despite this, scientific and medical communities have made great strides in cannabis research. Since 2016, multiple national collectives of scientists and doctors, including the National Academies of Sciences, Engineering, and Medicine (the "National Academies") and the National Center for Complementary and Integrative Health (NCCIH), a branch of the National

Institutes of Health for the Department of Health and Human Services, have acknowledged the "conclusive" and "substantial" benefits of medical cannabis, including in the context of managing chemotherapy care and side effects, chronic pain management, and the management of multiple sclerosis. This scientific research post-dates the August 12, 2016 (the "2016 Denial") proceedings before the Federal Register, on request from the Hon. Lincoln D. Chafee and the Hon. Christine O. Gregoire in a petition dated November 30, 2011 to initiate rulemaking proceedings under the rescheduling provisions of the CSA—precisely what Petitioners do here. 1ER 2. The 2016 Denial served as the sole basis for the Department of Justice's 2020 summary denial, which gives rise to Petitioner's appeal here. *Id.*

Because the Government failed to consider an important aspect of the scheduling of cannabis (i.e., prevailing and evolved research and widespread medical acceptance) when denying the petition, this Court should reverse the Government's denial of the petition and order that the DEA initiate rulemaking proceedings that include consideration of the post-2016 evidence, which is clearly inconsistent and irreconcilable with a Schedule I classification.

ARGUMENT

I. Schedule I Classification and DEA Inaction Has Obstructed Meaningful Research on Medical Cannabis

To understand the research implications of the Schedule I classification, a brief primer of the CSA is in order. The CSA regulates, among other things, the way drugs are scheduled based on several factors, including a drug's susceptibility for abuse and/or dependence, compared with the drug's medicinal value when used properly. 21 U.S.C. § 812.

The CSA classifies drugs on a five-category schedule, based on medical and scientific data regarding the potential uses and abuses of the drug, which are analyzed by the Food & Drug Administration and the NIDA. *Drug Scheduling*, U.S. Drug Enforcement Admin., https://www.dea.gov/drug-scheduling (last visited Oct. 6, 2020). Drugs are classified on Schedules I to V, with V being the safest, and accordingly the least regulated, and I being the most highly controlled. Mike Stone, Esq. & Professor Jason Robert, Ph.D., *The Cannabis Catch-22: DEA Suffocates Cannabis Research Because We Don't Understand Cannabis*, 47 S.U. L. Rev. 383, 402–03 (2020). For a drug to be classified as a Schedule V drug, it must have a low potential for abuse. 21 U.S.C. § 812(b)(5)(A). Potential for abuse is a relative factor, meaning Schedule V drugs must have a low potential for abuse as compared to Schedule IV drugs. *Id.* at § 812(b). Conversely, for a drug to be classified as Schedule I, that drug or other substance must meet three criteria.

First, that drug must have a "high potential for abuse." *Id.* § 812(b)(1)(A). Second, that drug must have "no currently accepted medical use in treatment in the United States." *Id.* at § 812(b)(1)(B). Lastly, "[t]here is a lack of accepted safety for use of the drug or other substance under medical supervision." *Id.* at § 812(b)(1)(C). The second and third requirements diverge from the standards for all other controlled drugs, all of which have "currently accepted medical use[s]," even if they come with "severe restrictions." *Id.* at § 812(b)(2)(B).

A. The Schedule I Classification Arbitrarily Restricts Cannabis Research

Schedule I classification materially restricts the amount and type of research that can be conducted on all Schedule I controlled substances, including cannabis. The practical effect of these limitations is that experienced and qualified researchers who seek to study the effects of cannabis—particularly the type of cannabis that is commercially available in state-legal, medical cannabis markets—are forced to wade through a complex regulatory scheme that imposes time-consuming, costly, and arbitrary requirements. Given what we now know about commercially and medically available cannabis under state-legal regulatory regimes, there is no legitimate reason for such onerous restrictions, which serve no purpose other than to impede meaningful re-evaluation of research that would support the scheduling of cannabis.

Under the CSA, all persons—including physicians and researchers—who seek to manufacture or distribute any controlled substance must apply for a DEA registration. *See* 21 U.S.C. § 822(a)(1). The CSA directs the DEA to grant registration if it would be "consistent with the public interest," outlining the criteria the DEA must consider when evaluating the public interest. *See id.* §§ 823(a)-(f). The criteria vary depending on (1) whether the applicant is a manufacturer, researcher, or practitioner; and (2) the classification of the controlled substance that is the focus of the application. *Id.* Applicants who seek to research Schedule I controlled substances face the most time-consuming registration process:

> Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use.

Id. § 823(f). In other words, a researcher seeking to conduct a cannabis-related study must wait several months, if not longer, just to obtain a DEA registration.

The hurdles and limitations do not stop at the application stage. Researchers of Schedule I controlled substances are subjected to frequent, disruptive inspections. *See id.* § 822(f). While it is the intent of the DEA to inspect distributors of Schedule II through V controlled substances "as circumstances may

require," distributors of controlled substances listed in Schedule I are subject to inspections as frequent as "once each year." 21 C.F.R. § 1316.13.

Cannabis researchers are also subjected to onerous storage requirements, as cannabis must be stored "in a securely locked, substantially constructed cabinet." *See id.* § 1301.75(a). As a practical matter, this requirement is typically only satisfied through the use of specialized, approved equipment that typically runs approximately $15,000 for a refrigeration and storage device. This requirement adds another extraordinary administrative expense that would be unnecessary if cannabis was appropriately de- or re-scheduled.

Finally, and most problematic, cannabis researchers are required to use a specific type of cannabis that does not reflect the type of cannabis that consumers actually purchase and consume.

Since 1968, the National Center for Natural Products Research at the University of Mississippi has held the sole registration and government contract to grow cannabis for research purposes. Generally containing the equivalent of 6–12% Tetrahydrocannabinol (THC) by weight, this plant material differs considerably from cannabis products widely used by the public, which have a potency equivalent of 18 to 25% THC (or higher). 4ER827–33; *see also* Pet. Br. at 37. In addition, this product is usually subject to long periods of storage, which further results in potency loss. 4ER827–33; Pet. Br. at 37–38.

Recognizing the legitimate need to facilitate cannabis research and the research limitations imposed by the cannabis product from the University of Mississippi, in August 2016, the DEA issued a Policy Statement indicating that it intended to increase the number of entities allowed to grow cannabis to supply to researchers in the United States. *See* 81 Fed. Reg. 53846 (Aug. 12, 2016). Three years later, the DEA announced that it would provide notice of pending applications from entities applying to be registered to manufacture marijuana for researchers. *See* Department of Justice, "DEA Announces Steps Necessary to Improve to Marijuana Research," *available at* https://www.justice.gov/opa/pr/dea-announces-steps-necessary-improve-access-marijuana-research; *see also* 84 Fed. Reg. 44920–23. But in that same notice, the DEA expressly stated that "[b]efore making decisions on these pending applications, DEA intends to propose new regulations that will govern the marijuana growers program for scientific and medical research." *Id.*

Over four years have passed since the DEA issued this Policy Statement and dozens of growers and manufacturers have applied for a registration. Yet, despite these efforts, no new licenses have been granted. Pet. Br. at 40. Under the current scheme—a scheme exacerbated by DEA inaction—cannabis researchers are forced to rely on cannabis products dissimilar in potency and formulation from cannabis products widely used by patients and other consumers.

De-scheduling or, alternatively, appropriate re-scheduling of cannabis would remove many of the unnecessary administrative obstacles imposed by the DEA's regulations.

B. The Practical Reality of Clinical Research Under Schedule I

The classification of cannabis as a Schedule I controlled substance erects a plethora of unnecessary obstacles to even research cannabis, which, in turn, obstruct the ability of the medical and scientific community to demonstrate that cannabis does, in fact, have accepted medical use in the United States.

Perhaps due to its classification as a Schedule I controlled substance, cannabis research is severely underfunded. If a researcher is lucky enough to receive funding to conduct a cannabis-based study, she must comply with the expensive and time consuming registration and storage requirements that are unique to Schedule I classification. And the DEA's recent willingness to allow the sourcing of importation of cannabinoid materials from other countries, e.g., Importer of Controlled Substances Registration: Catalnt CTS, LLC, 80 Fed. Reg. 75692-02 (2015), as an alternative to the NIDA monopoly, only exacerbates these problems because the importation of product is extremely costly and even researchers with approved funding do not have the means to sustain those further inflated costs. *See, e.g.*, Britt E. Erickson, Chemical & Engineering News (June

29, 2020), *available at* https://cen.acs.org/biological-chemistry/natural-products/Cannabis-research-stalled-federal-inaction/98/i25.

Once the cannabis researcher has cleared the initial regulatory obstacles, she faces additional difficulties. In order to conduct an effective clinical study, a researcher must be allowed to control the type of cannabis used in the study, how the cannabis is administered (i.e., is it inhaled or ingested), and the dosing. But, in a recent clinical study of veterans with Post-Traumatic Stress Disorder, marijuana from the National Center for Natural Products Research had two major problems. Stone, 47 S.U. L. Rev. at 414–15. First, the marijuana contained mold spores, rendering the marijuana unsuitable for use in human patients. *Id.* Second, researchers expressed serious concerns because the potency of the marijuana was not as potent or even representative of the strains of marijuana available at local dispensaries. *Id.*; 6 ER1415 at ¶ 21.

Thus, researchers are required to rely on an inferior cannabis product that is not widely used or even representative of the product used by consumers for medical or recreational purposes. A study based on this product would lead to findings and conclusions that have no practical application to the real world. Stone, 47 S.U. L. Rev. at 414–15. The DEA's refusal to register other cannabis manufacturers or otherwise re-schedule cannabis leads to this unfortunate and untenable result. *Id.*

Due to the Schedule I limitations, researchers have been forced to rely on other research methods, including "observational stud[ies],"[1] in which subjects are required to provide their own cannabis products. Under this type of study—and given the significant regulations that are the product of Schedule I classification—a researcher is precluded from providing cannabis to the study subjects, dictating where the cannabis comes from, or controlling dosing or administration.

A researcher's ability to demonstrate the medical efficacy of cannabis is dependent on the researcher's ability to conduct a reliable study. Inability to control these variables can challenge the reliability of the observational study methodology. Indeed, these research methods have been criticized by the scientific community as susceptible to biases and structural limitations, especially with regard to drug exposure (i.e., potency) and the vehicle of delivery. *See, e.g.*, Francois Gueyffier & Michael Cucherat, *The Limitations of Observation Studies for Decision Making Regarding Drugs Efficacy and Safety*, Therapies (Vol. 74, Iss. 2 2019) at 181-185, available at https://doi.org/10.1016/j.therap.2018.11.001 ("After looking at some case studies, we will remind in this paper how observational studies regarding drug exposure or delivery are prone to various biases and structural limitations. These biases lead us to be extremely cautious

[1] An "observational study" is a study where the researcher collects data merely by watching or asking questions of the subjects.

regarding the implementation of results from such studies in clinical practice, and to question the reliability of such studies to determine the position of a given treatment into the therapeutic strategy.").

C. Conclusive Evidence Shows Medically-Accepted Uses for Cannabis

As previously explained, Schedule I controlled substances are defined as substances that carry "a high potential for abuse[,]" have "**no currently accepted medical use in treatment in the United States[,]**" and are unsafe even "under medical supervision." 21 U.S.C. § 812(b)(1) (emphasis added). It cannot be reasonably disputed that there are widely-accepted and safe medical uses of cannabis in the United States, particularly since the significant number of states who have adopted medical marijuana laws since 2016.

As of June 2019, 14 states and territories of the United States have passed laws removing state prohibitions on medical and recreational cannabis use by adults age 21 or older. *See* NAT'L CONFERENCE OF STATE LEGISLATURES, STATE MEDICAL MARIJUANA LAWS (March 10, 2020), http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited Oct. 6, 2020). More importantly for the purposes of this brief, and further acknowledging the therapeutic benefits of cannabis, **33 states**, along with the District of Columbia, Puerto Rico, Guam, and the U.S. Virgin Islands, have passed laws permitting medical use of cannabis. *See id.*

While Schedule I classification continues to hinder widespread research into the medical benefits of cannabis, a growing body of literature and physicians supports the conclusion that cannabis carries with it significant therapeutic benefits, which are now medically accepted in the scientific community. *See, e.g.*, Charles W. Webb, M.D. & Sandra M. Webb, RN, BSN, *Therapeutic Benefits of Cannabis: A Patient Survey*, 73 Hawaii J. Med. & Public Health 109-11 (Apr. 2014) (noting that the "[a]verage reported pain relief from medical cannabis was substantial"; "[a]verage pre-treatment pain on a zero to ten scale was 7.8, whereas average post-treatment pain was 2.8, giving a reported average improvement of 5 points"). In fact, a 2013 report by the *New England Journal of Medicine* showed that 76 percent of doctors surveyed support the use of cannabis for medicinal purposes. *See* Jonathan N. Adler & James A. Colbert, *Medicinal Use of Marijuana – Poling Results*, 2013 New Eng. J. Med. 368 (May 2013), available at www.nejm.org/doi/full/10.1056/NEJMclde1305159.

In 2017, ***after*** the DEA hearing on which the Government relies to summarily deny the underlying petition, the National Academics "convened a committee of experts to conduct a comprehensive review of the literature regarding the health effects of using cannabis and/or its constituents. . . ." National Academies of Sciences, Engineering, Medicine (2017) *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and*

Recommendations for Research (hereinafter the "National Academies Research"); Stone, 47 S.U. L. Rev. at 405 (discussing results of study).

Specifically opining on the therapeutic uses of cannabinoids, the National Academies reached three key conclusions that bear directly upon medical acceptance of cannabis in the United States: (1) "[i]n adults with chemotherapy-induced nausea and vomiting, oral cannabinoids are effective antiemetics"; (2) "[i]n adults with chronic pain, patients who are treated with cannabis or cannabinoids are likely to experience a clinically significant reduction in pain symptoms"; and (3) "[i]n adults with multiple sclerosis (MS)-related spasticity, short-term use of oral cannabinoids improves patient-reported spasticity symptoms."[2] National Academies Research at 85. In connection with each of the aforementioned conclusions, the National Academies concluded that there is "***conclusive or substantial evidence*** (ranging in modest to moderate effect) for benefit from cannabis or cannabinoids for chronic pain, chemotherapy-induced nausea and vomiting, and patient reported symptoms of spasticity associated with multiple sclerosis." *Id.* at 127 (emphasis).

[2] For each of these therapeutic benefits, the National Academies noted that the "effects of cannabinoids are modest" and "for all other conditions evaluated there is inadequate information to assess their effects." National Academies Research at 85.

Joining the growing number of states and organizations that recognize the medical benefits of cannabis, in January 2019, the Director General of the World Health Organization (WHO) expressly recommended to the Secretary-General of the United Nations that cannabis and cannabis-related substances be rescheduled from Schedule IV to Schedule I.[3] *See* Letter from Dr. Tedros Adhanom Ghebreyesus, Director-General, WHO, to António Guterres, Secretary-General, United Nations (Jan. 24, 2019), available at https://www.who.int/medicines/access/controlled-substances/UNSG_letter_ECDD41_recommendations_cannabis_24Jan19.pdf?ua=1 (last visited Oct. 6, 2020). This recommendation from the WHO came after "critical reviews of these substances." *Id.*

Earlier this year, the NCCIH, a branch of the National Institutes of Health for the Department of Health and Human Services, opined that "[d]rugs containing cannabinoids may be helpful in treating certain rare forms of epilepsy, nausea and vomiting associated with cancer chemotherapy, and loss of appetite and weight loss associated with HIV/AIDS. In addition, some evidence suggests modest

[3] The international drug classification system is ordered in the opposite direction of the one used in the United States. Schedule IV under the international drug classification is similar to Schedule I under the United States drug classification system (i.e., both are the most restrictive and apply to substances that do not have any recognized medical benefit).

benefits of cannabis or cannabinoids for chronic pain and multiple sclerosis symptoms." NCCIH, *Cannabis (Marijuana) and Cannabinoids: What You Need to Know*, available at https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know.

Even with the obstructive limitations to research imposed by the Schedule I classification, contemporary, scientific evidence from large coalitions of scientists and doctors demonstrates that there is no basis on which a fact finder could reasonably examine the record in January 2020 (the date the original petition was filed), particularly the record of scientific evidence that has been published since 2016, and conclude (as the DEA nonetheless did) that there are no medically accepted uses for cannabis.

II. The DEA's 2020 Denial Was an Abuse of Discretion, and the Court Should Order the DEA to Initiate Rulemaking Proceedings In Light of the Medically-Accepted Uses Set Out Above.

In light of the foregoing, the DEA's summary denial of the Petition on the basis of the 2016 Denial was an abuse of discretion because it fails to consider the significant "conclusive" evidence, which has evolved particularly since 2016 regarding medically accepted uses of marijuana. 1ER2-4, 6, 86; National Academies Research at 85, 127.

As this Court knows, this action arises from a January 3, 2020 Petition filed by individual Stephen Zyszkiewicz petitioning the DEA "under the Constitution

and 21 U.S.C.S. 811, 812," to "remove or reschedule cannabis (marijuana) in all its forms." 1ER1. The Petition, though a single page and hand-written, clearly identifies compelling grounds for DEA's review: "Petitioner finds the current situation of cannabis in Schedule I completely untenable. Half the states allow for medical use . . . ." *Id.*

Indeed, the DEA's decision to maintain cannabis in Schedule I is completely at odds with the emerging widespread acceptance of cannabis as a medical treatment in this country. Two-thirds of states have enacted legislation permitting use of cannabis as medicine. This growing acceptance confirms that, under the current interpretation of the CSA, the DEA should initiate a hearing and formal rulemaking proceedings where such evidence can be presented to the DEA. Medical professionals across the country have recommended cannabis to their patients treat a variety of illnesses, including epilepsy and PTSD, and have witnessed its healing capabilities.

Yet the DEA, in ruling on the 2020 Petition, considered none of the recent wave of developments in the medical cannabis landscape. Instead, the DEA summarily denied Mr. Zyszkiewicz's petition, based exclusively on its August 12, 2016's denial of a 2011 petition. 1ER2–3. The DEA simply stated that the Department of Health and Human Services (HHS), based on its evaluation in response to the 2011 petition, concluded in 2016 that "marijuana has a high

potential for abuse, has no accepted medical use in the United States, and lacks an acceptable level of safety for use even under medical supervision." *Id.* Nowhere did the DEA mention or address the wealth of evidence, particularly published evidence by standard-setting industry associations and even governmental agencies, to the contrary that has accumulated in the years since the HHS's previous evaluation, or the recent state legislative findings approving cannabis for medicinal use. *See id.*

The current Petitioners in this action, Dr. Sisley and SRI, sought review of this summary denial under 21 U.S.C. § 877, which permits "any person aggrieved by a final decision of the Attorney General" to seek review in the United States Courts of Appeals. Review of the 2020 Ruling is governed by the Administrative Procedures Act, under which "[t]he reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D); *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (explaining "'the APA provides the appropriate default standard" for review under 21 U.S.C. § 877: "A court must set aside agency action it finds to be "arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law.") (quoting *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001)).

Thus, the Court may vacate the DEA's 2020 Denial if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Morall*, 412 F.3d at 177 (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *cf. Inland Empire Pub. Lands Council v. Glickman*, 88 F.3d 697, 701 (1996) ("An agency's decision is arbitrary and capricious if 'the agency has relied on factors which Congress has not intended it consider [or] entirely failed to consider an important aspect of the problem.'") (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43).

Under any of these articulations, the DEA's 2020 Denial constitutes a clear abuse of discretion because there is substantial and compelling evidence post-2016 of numerous widespread medically-accepted uses of cannabis in the United States, which makes the Administrator's reliance on the 2016 denial, and by implication the 1992 Ruling on which it relies, arbitrary and capricious. *Morall*, 412 F.3d at 177; *Inland Empire*, 88 F.3d at 701.

This Court should therefore vacate the DEA's denial on the 2020 Petition and order the DEA to initiate rulemaking proceedings under 21 U.S.C. § 811(a).

CONCLUSION

For the foregoing reasons, the Court should grant the petition for review and order the DEA to initiate rulemaking proceedings under 21 U.S.C. § 811(a) in a manner that takes into account the research set forth above.

RESPECTFULLY SUBMITTED this 6th day of October, 2020.

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CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be electronically filed with the Clerk of Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on October 1, 2020.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

RESPECTFULLY SUBMITTED this 6th day of October, 2020.

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CERTIFICATE OF COMPLIANCE
9th Cir. Case No. 20-71433

I certify as the attorney for amicus curiae Lori Walker, PhD, Stephen DeFelice, MD, Lyle E. Craker, PhD, Daniela Vergara, PhD, Christopher J. Hudalla, PhD, Rachna Patel, MD, Wendy and Tom Turner, and Maureen Leehey, MD that this brief complies with the type-volume limitation of Fed R. App. P. 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), the document contains 3, 568 words. I further certify that this document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in Times New Roman 14-point font for text and footnotes using Microsoft Word.

I further certify that this brief is an amicus brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).

RESPECTFULLY SUBMITTED this 6th day of October, 2020.

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