NO. 20-148

In the Supreme Court of the United States

MARVIN WASHINGTON; DB, AS PARENT OF INFANT AB; JOSE BELEN; SC, AS PARENT OF INFANT JC; AND CANNABIS CULTURAL ASSOCIATION, INC.,

Petitioners,

v.

WILLIAM PELHAM BARR, IN HIS OFFICIAL CAPACITY AS UNITED STATES ATTORNEY GENERAL; UNITED STATES DEPARTMENT OF JUSTICE; TIMOTHY J. SHEA, IN HIS OFFICIAL CAPACITY AS ACTING DIRECTOR OF THE DRUG ENFORCEMENT ADMINISTRATION, UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, AND THE UNITED STATES OF AMERICA,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF AMICI CURIAE CReDO SCIENCE; THE AMERICAN JOURNAL OF ENDOCANNABINOID MEDICINE; ETHAN RUSSO, M.D.; AND JAHAN MARCU, Ph.D. IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the court should grant Petitioners Marvin Washington, DB, as parent of infant AB, Jose Belen, SC, as parent of infant JC, and Cannabis Cultural Association, Inc. ("Petitioners") Writ of Certiorari to determine whether the federal scheduling and criminalization of marijuana based on 21 USC § 812, without exception, violates the Due Process Clause of the Fifth Amendment to the U.S. Constitution and whether the requirement that an injured party must first exhaust administrative remedies to seek relief is consistent with the Due Process Clause of the Fifth Amendment.

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INTERESTS OF AMICI CURIAE

Pursuant to Supreme Court Rule 37, CReDO Science, the American Journal of Endocannabinoid Medicine, Ethan Russo, MD, and Jahan Marcu, Ph.D., respectfully submit this brief *amicus curiae* in support of petitioner.[1]

CReDO Science ("CReDO") is an intellectual property holding company researching cannabis[2] and the endocannabinoid system. CReDO focuses on non-tetrahydrocannabinol ("THC") cannabis chemical varieties, hemp-derived nutritional supplements and endocannabinoid system related diagnostics.

The American Journal of Endocannabinoid Medicine ("AJEM") is a U.S.-based peer-reviewed scientific publication with a print circulation of over 45,000. The AJEM, is the first and only American medical authority committed to scientific study of the endocannabinoid

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[1] Pursuant to Rule 37.2, all parties with counsel listed on the docket have consented to this brief's filing and their respective counsel have received notice at least 10 days prior to the due date of the *Amicus Curiae's* intention to file this brief. Letters evidencing such consent have been filed with the Clerk of the Court. Pursuant to Rule 37.6, *Amicus Curia* affirm that no counsel for any party authored this brief in whole or in part and no counsel or party made a monetary contribution intended to fund this brief's preparation or submission. No person other than *Amicus Curiae*, its members or counsel made a monetary contribution to its preparation or submission.

[2] This amicus brief refers to both "cannabis" and "marijuana." The term "cannabis" is used to refer to the genus family *Cannabis Sativa L.*. The term "marijuana" is used as defined pursuant to 21 U.S.C. § 802(16).

system. The objective of the AJEM is to help educate medical professionals about the role of the endocannabinoid system in homeostasis, as a therapeutic target for cannabis and cannabinoid prescription, and non-prescription products. AJEM aims to present the currently available authoritative research, while stimulating questions regarding the role of medical cannabis in all forms, as a growing methodology in the field of treatment and patient care. The intent of AJEM is to be utilized as a clinical resource and contribute to the examination and overall scientific discussion of the endocannabinoid system.

Ethan Russo, M.D., is a Clinical Child and Adult Neurologist, Adjunct Associate professor of pharmacy at the University of Montana, former editor of the Journal of Cannabis Therapeutics, former president of the International Cannabinoid Research Society, and former chairman of the International Association for Cannabinoid Medicines. In 1999, Dr. Russo obtained approval from the Food and Drug Administration ("FDA") (IND #58,177) to conduct a human pilot study to research the risk and benefits of smoked cannabis in patients suffering from treatment-resistant migraines. Despite FDA approval, Dr. Russo was unable to conduct this research because the National Institute of Drug Administration ("NIDA") refused to sell any of its cannabis to him. Dr. Russo has worked for foreign companies for 14 years, 11 of which as the Senior Medical Advisor, Medical Monitor and Study Physician to GW Pharmaceuticals in 23 Phase I-III clinical trials in the development programs of Sativex®, nabiximols, and Epidiolex®. Dr. Russo currently serves as CReDO Science Founder and Chief Executive Officer ("CEO") and Senior Medical Advisor to Andira Pharma-

ceuticals, a Canadian-based company developing pharmaceutical products from cannabis designed to treat metastatic cancer and antibiotic-resistant "superbug" bacterial infections including as vancomycin-resistant Enterococcus ("VRE") and methicillin-resistant *Staphylococcus aureus* ("MRSA").

Jahan Marcu, Ph.D. has over 15 years of cannabinoid research, policy, and operations experience, and is also among a select group of professionals globally that has earned a Ph.D. focused on the endocannabinoid system with research on cannabinoid receptors' structure and function and endocannabinoid system molecular pharmacology and role in bones. Currently serving as American Journal of Endocannabinoid Medicine Editor-In-Chief, Dr. Marcu is also the co-founder and former Chief Science Officer of the International Research Center on Cannabis and Health's (also known as the Institute of Cannabis Research), founder and former-chair of the American Chemical Society's Cannabis Chemistry sub-division (the world's largest and oldest professional scientific society), and has served on multiple expert government advisory and trade association committees, as well as scientific organizations including ASTM (D37 Subcommittee chair), past-chair of the AHPA Cannabis committee, ACS Cannabis Chemistry Subdivision ("CANN"), AOCS, AOAC, IACM (past BOD), and co-founder of IMCPC.

Dr. Marcu's work has been instrumental to facilitating and supporting fact-based, scientific approaches vital to the industry and patients including research focused on solving cannabinoid receptors structure and function, cannabis compounds' anti-cancer properties, and method development and validation for analyzing complex formulations. Dr. Marcu's efforts include

developing international certification and training programs, co-authoring American Herbal Pharmacopeia's Cannabis Quality Control and Therapeutic Monographs, and, as chair of the American Herbal Products Association ("AHPA") cannabis committee, co-creating the first industry standards. Dr. Marcu participated in the co-development of a biotech application to predict drug interactions between cannabis and commonly prescribed pharmaceutical drugs and published one of the first CBD products safety studies. Honored with the Mahmoud Elsohly award for excellence in cannabis chemistry and the Billy Martin research achievement award from the International Cannabinoid Research Society for his work on THC and CBD synergy in aggressive brain cancers, Dr. Marcu is a court-qualified synthetic cannabinoid and cannabis expert and his work has been published and covered in Science, Nature, Journal of the American Medical Association ("JAMA"), the Washington Post, and CNN.

SUMMARY OF ARGUMENT

Petitioners filed a complaint in the United States District Court for the Southern District of New York for determination that the federal status of marijuana as a Schedule I controlled substance under the Controlled Substances Act ("CSA") is unconstitutional and sought an injunction against the enforcement of the CSA's marijuana provisions.[3] The district court dismissed Petitioners' complaint for failure to state a claim

[3] *Washington v. Barr*, 925 F.3d 109, 114 (2d Cir. 2018).

and to exhaust administrative remedies.[4] The United States Court of Appeals for the Second Circuit affirmed in part and held that Petitioners were first required to exhaust administrative remedies.[5] Petitioners now seek a writ of certiorari.

Petitioners argue that the federal status of marijuana violates the Due Process Clause of the Fifth Amendment as it deprives Petitioners access to life.[6] *Amici* join Petitioners in these arguments.

In addition to Petitioners' arguments, *amici* respectfully submit that the Court should grant the writ of certiorari because the Schedule I status has created obstacles that have been detrimental to America's public health. The federal scheduling of marijuana is a matter of significant public concern because the Schedule I status prevents researchers from conducting marijuana research to gather medical and scientific data. U.S. based researchers are unable to study the benefits and risks of marijuana use, to explore potential uses, and innovate solutions because of the federal status. Thus, *amici* respectfully request that the Court grant Petitioner's Writ of Certiorari.

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[4] *Id.* at 114-115.

[5] *Id.*

[6] *Washington v. Barr*, Petition for a Writ of Certiorari, 22-31 (2020).

ARGUMENT

I. LEGAL BACKGROUND

Marijuana is classified as a Schedule I controlled substance. All Schedule I controlled substances are subjected to control limitations in an effort to promote public safety. These protective measures, however, have impeded, and continue to impede, upon marijuana research. Beyond causing a "brain drain," these measures hinder the generation of public health data to understand the risks and benefits of the marijuana products that are available in state-legal marijuana programs. Rather, the federal status has created obstacles for researchers which have had detrimental effects on public health and has limited domestic drug development.

The federal prohibition and system of criminalizing marijuana is irrational and has resulted in regulatory agencies abdicating their duty to protect the public by halting researchers from developing marijuana-based medicines and serving other public health needs. In order for researchers to be able to study the benefits and risks associated with marijuana use, legal pathways must be forged and regulated.

II. THE FEDERAL SCHEDULING OF MARIJUANA UNDERMINES PUBLIC HEALTH

Marijuana's federal status creates significant public health concerns as it severely impairs the ability to conduct medical and scientific research and the publishing of such information. The prohibition of marijuana-related research has created a knowledge

gap; this absence of scientific data amounts to a failure to protect public health.

a. The Federal Status of Marijuana Impedes Upon Scientific Research and Obstructs the Publishing of Findings

The federal scheduling of marijuana prevents the generation and compilation of data that would be useful to guide regulatory agencies and public health efforts. The origin of marijuana's federal status was intended to be a placeholder in 1970 when the CSA was implemented. The status was pending investigation by the Shafer Commission ("Commission").[7] The Commission recommended decriminalizing marijuana for medical use, however, President Richard M. Nixon vetoed the Commission's recommendation and politics has trumped science since.

Marijuana's schedule I status prevents research and meaningful drug development in the U.S. of marijuana-derived pharmaceuticals. Schedule I controlled substances are defined as substances with high potential for abuse, no currently accepted medical treatment use, and are unsafe, even when prescribed and supervised by a physician.[8] Researchers consequently face onerous regulatory hurdles and must continually advocate on behalf of the collective marijuana industry and consumers. As more state-legal marijuana markets emerge, and as the spectrum of available marijuana

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[7] United States Commission on Marihuana and Drug Abuse, *Marihuana: A Signal of Misunderstanding; First Report*, 184 (1972); RC Randall, United States Drug Enforcement Administration, *Marijuana, Medicine & the Law* (Vol. 1 1988).

[8] 21 USC § 812(b)(1).

products diversifies, public health officials must engage with the real issue of rapid commercialization and press for policies based on public health best practices.[9]

In order to conduct research involving Schedule I controlled substances, researchers must obtain specified approvals from the Drug Enforcement Administration ("DEA"). DEA approvals impose an extremely difficult and time-consuming process upon researchers. DEA spot inspections, for example, disrupt researcher and physician schedules and patient care, lengthy documentation procedures consume time and resources, and onerous storage requirements mirror those for highly radioactive or infectious materials. The DEA provides no clear guidance to assist Schedule I applicants prepare for the DEA approval inspections of their facilities. Further, a legal marijuana program licensee is ineligible to obtain DEA approval to conduct much needed research despite the resources and expertise they possess. Descheduling and regulation would remove the obstacles imposed by the DEA's onerous policies.

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[9] C.M. Bowling, A.Y. Hafez, S.A. Glantz, *Public Health and Medicine's Need to Respond to Cannabis Commercialization in the United States: A Commentary*, JOURNAL OF PSYCHOACTIVE DRUGS, 1–6 (2020); J. Marcu, *Regulators Need to Rethink Restrictions on Cannabis Research*, NATURE, 572, S19–S19 (2019); Russo EB, Mead AP, Sulak D., *Current Status and Future of Cannabis Research*, CLINICAL RESEARCHER, 58-63 (April 2015); A. Mead, *The Legal Status of Cannabis (Marijuana) and Cannabidiol (CBD) Under U.S. Law*, EPILEPSY & BEHAVIOR, 70, 288-91, (May 2017); A. Mead, *Legal and Regulatory Issues Governing Cannabis and Cannabis-Derived Products in the United States*, FRONT PLANT SCIENCE, 10, 697 (2019).

Furthermore, researchers are limited to use NIDA grown marijuana, not products that consumers actually purchase and consume. This obstacle centers around the monopoly NIDA holds over the available marijuana grown for research purposes and the policies in place to reinforce the *status quo*. For example, a NIDA-related policy restriction is that the University of Mississippi scientists selectively breed marijuana to increase its biochemical diversity, the cannabis yielded from which is less potent in cannabinoid concentration than that available in state-legal markets and often suffers over 80% terpenoid loss resulting from long periods of storage.[10] Additionally, because of the requirement to use NIDA cannabis, reproducing positive clinical trial results in subsequent pivotal studies is rendered impossible.

As a result, current law prevents American companies from developing cannabis-derived pharmaceuticals from a domestic source thereby ceding commercial cannabis pharmaceutical development to foreign companies capable of importing pharmaceutical candidate drugs into the country where clinical trials occur. This is evident for both Sativex® and Epidiolex®. The extent of federal marijuana prohibition is unique to the U.S. and as a result, marijuana-derived pharmaceuticals are imported from other countries.

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[10] EB Russo, ML Mathre, A Byrne, R Velin, PJ Bach, J Sanchez-Ramos, *et al.*, *Chronic Cannabis Use in the Compassionate Investigational New Drug Program: an Examination of the Benefits and Adverse Effects of Legal Clinical Cannabis*, JOURNAL OF CANNABIS THERAPEUTICS, 2:1, 3-57 (2002); RN Bloor, TS Wang, P Spanel, D Smith, *Ammonia Release from Heated 'Street' Cannabis Leaf and Its Potential Toxic Effects on Cannabis Users*, ADDICTION, 103 (2008); EB Russo, *Current Therapeutic Cannabis Controversies and Clinical Trial Design Issues*, FRONT PHARMACOL, 7:309 (2016).

To generate meaningful marijuana products data, researchers are forced to navigate the obstructions imposed by the CSA. Dr. Marcu co-authored a first of its kind study regarding public health and cannabidiol product labeling.[11] This study is used by regulators to inform consumers and to promote public health efforts through accurate labeling of cannabidiol-based products, which currently lacks due to the absence of federal law.[12]

Descheduling marijuana will allow researchers to obtain representative and standardized products that will allow studies to be reproduced to provide valuable data to guide regulations and public health efforts. Despite its federal scheduling, rapid marijuana commercialization has outpaced state and federal regulatory rulemaking and a myriad marijuana products are quickly becoming available to the public. In the absence of federal regulation, this dynamic became acutely evident with severe lung disease's widespread appearance in those vaping THC and/or nicotine containing products (although illnesses were later attributed to lipoid pneumonia from use to excipient vitamin E acetate).[13] Because of marijuana's Schedule I classification, researchers are prevented from conducting

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[11] J. Marcu, *Regulators Need to Rethink Restrictions on Cannabis Research*. NATURE. 572, S19–S19 (2019); M.O. Bonn-Miller, M.J.E. Loflin, B.F. Thomas, J.P. Marcu, *et al., Labeling Accuracy of Cannabidiol Extracts Sold Online,* JAMA, 318, 1708–1709 (2017).

[12] *Id.*

[13] C.G. Perrine, C.M. Pickens, T.K. Boehmer, B.A. King, et al., *Characteristics of a Multistate Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping—United States*, 2019, MORBIDITY MORTAL WEEKLY REPORT, 68, 860–864 (2019).

representative studies and it is nearly impossible to study marijuana products and THC devices consumers use regardless of public health threat's severity.[14]

Because it would relieve the regulatory gridlock without simultaneously opening the floodgates for illicit uses under the disguise of "research", a research exemption may be quick, yet calculated, solution for the existing obstacles researchers face. Descheduling marijuana and creating a research exemption would allow for researchers to efficiently and safely conduct studies that include a representative array of marijuana products. Beyond assisting in understanding marijuana from a health perspective, a research exemption will guide the rulemaking process regarding specific concerns (such as labeling, advertising, and packaging) and allow stakeholders, the FDA, and states to collaborate throughout the rulemaking process. This would track the Agricultural Improvement Act of 2018 implementation in which the United States Congress granted the United States Department of Agriculture ("USDA") with cultivation authority and the FDA authority over finished products containing hemp-derived ingredients.

As more states launch medical and adult-use marijuana programs, promulgating uniform public health standards and rules to ensure public safety becomes increasing critical. Descheduling marijuana and carving out a defined legal pathway to enable the safe and efficient research to guide the creation

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[14] C.M. Bowling, A.Y. Hafez, S.A. Glantz, *Public Health and Medicine's Need to Respond to Cannabis Commercialization in the United States: A Commentary*, JOURNAL OF PSYCHOACTIVE DRUGS, 1:6 (2020).

of the U.S.'s marijuana regulatory framework including increased FDA oversight of medical claims assessment and developing standard protocols for assessing drug efficacy and overall product safety. The FDA's involvement will also remedy a number of complications the domestic marijuana industry faces including a patchwork of state-specific marijuana products' warning labels and universal THC symbols[15] creating a universally recognized standard.

Descheduling marijuana with federal and state regulatory oversight will mitigate public health risks and promote our knowledge. Without reliable data and replicable studies, it is impossible to regulate marijuana. Accordingly, it is necessary for the federal government to forge a legal pathway to encourage research to guide rulemaking that will allow Petitioners and Americans to access safe marijuana products.

b. Advocates and Opponents Agree that Rescheduling will not resolve the Obstacles Researchers Face

Advocates and opponents agree that rescheduling marijuana to another schedule will not resolve research, medicine, and overall product concerns. Marijuana opponents including Bertha Madras, Ph.D and Kevin Sabet, president of Smart Approaches to Marijuana ("SAM") have spoken on this issue, with Dr. Madras publicly conceding that rescheduling marijuana as schedule II will not "open the floodgates for research"[16]

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[15] A.J. Soroosh, R. Henderson, L. Dodson, C.S. Mitchell, J.W. Fahey, *Mitigating Potential Public Health Problems Associated with Edible Cannabis Products Through Adequate Regulation: a Landscape Analysis*, CRITICAL REVIEWS IN FOOD SCIENCE AND NUTRITION, 1–9 (2020).

[16] Bertha Mardas, *5 Reasons Marijuana is Not Medicine,* THE

and both Dr. Madras and Mr. Sabat stating that there is no benefit for public health.[17]

NIDA director Nora Volkow acknowledged that marijuana's legal status makes research "very difficult"[18] and Mr. Sabet opined that marijuana's federal status impedes studies and that moving cannabis to another schedule is not "desirable."[19]

Former supporter of Mr. Sabet and SAM, former Congressman Patrick Kennedy (D-MA) recently suggested that descheduling marijuana may be "our best chance to actually dedicate resources toward consumer safety, abuse prevention, and treatment for those who need it."[20]

WASHINGTON POST, (April 29, 2016), https://www.washingtonpost.com/news/in-theory/wp/2016/04/29/5-reasons-marijuana-is-not-medicine/.

17 Chris Roberts, *Prohibitionist Group Co-Founder Backs Reclassifying Marijuana in Congressional Bid,* MARIJUANA MOMENT, (January 26, 2020), https://www.marijuanamoment.net/wife-of-prohibitionist-group-co-founder-backs-reclassifying-marijuana-in-congressional-bid/.

18 Kyle Jaeger, *Formerly Anti-Marijuana Congressman Cosponsors Comprehensive Legalization Bill*, MARIJUANA MOMENT, (January 9, 2020), https://www.marijuanamoment.net/formerly-anti-marijuana-congressman-cosponsors-comprehensive-legalization-bill/.

19 Roberts, *supra*.

20 Jaeger, *supra*.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that the Court grant the Petition for Writ of Certiorari.

Respectfully submitted,

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