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, MAUREEN LEEHEY, MD, AND CAMILLE STEWART, 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

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