No. 20-71433

In the 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

RESPONSE IN OPPOSITION TO GOVERNMENT'S MOTION TO DISMISS PETITION FOR REVIEW

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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; KENDRIC SPEAGLE; AND GARY HESS

INTRODUCTION

Seeking dismissal before the merits, the Motion argues that Petitioners cannot challenge DEA's decision to deny a petition to institute rulemaking because these Petitioners have not exhausted available administrative remedies. In so doing, the government does not cite, let alone address, on-point controlling precedent that refutes the entire basis of its Motion. In *Darby v. Cisneros*, 509 U.S. 137, 146-47 (1993), the Court spoke clearly: In APA cases, courts cannot require exhaustion of available administrative remedies unless the relevant statute or agency rules "clearly mandat[e]" it.

This case arises under the APA, and neither the Controlled Substances Act nor agency rules require further exhaustion. Instead, § 877 of the Act makes judicial review broadly available to "any person aggrieved by a final decision"—not just the party that submitted a petition. Under *Darby*, the Motion must be denied.

Petitioners challenge DEA's final determination denying the Zyszkiewicz Petition (the "Petition") because an untenable situation persists in this country that impedes research and jeopardizes public health. More than two-thirds of states permit medical marijuana use in treatment; millions of Americans, including scores of veterans, use marijuana to treat symptoms ranging from breakthrough pain to PTSD; but US scientists cannot do safety and efficacy studies using real-world, dispensary-quality medicinal marijuana because DEA maintains that marijuana has

"no currently accepted medical use in treatment in the United States" and should remain in Schedule I. And it all stems from the reason the agency denied the Petition and many rescheduling petitions before it: a longstanding, misinterpretation of law.

The Petition is one-page, handwritten, and fundamentally correct. Because physicians in most parts of this country, following state law and accepted state medical practices, can prescribe (or recommend) marijuana in treatment to patients, marijuana has a "currently accepted medical use in treatment in the United States." But DEA says otherwise, pointing to a misinterpretation of this statutory phrase, a five-part test from 1992 that requires, among other things, a demonstration of adequate evidence showing efficacy. By invoking the test to deny the Petition, DEA squarely puts the core legal issue before this Court: properly construing the statute using the traditional tools of construction and in light more recent precedents, does marijuana have a "currently accepted medical use in treatment in the United States"? The answer, as we will explain in merits briefing, is "yes." *See* Pet. 10-12.

Rather than address *Darby*, the Motion—under the guise of remedies exhaustion—mixes up other issues like standing, issue exhaustion, and the quality of the Petition. Because the government fails to raise these as grounds for dismissal, it may not assert them for the first time on Reply. *See* Fed. R. App. P. 27(a)(2)(A).

In any case, these points also all lack merit. First, as "persons aggrieved" under § 877 of the CSA, Petitioners have standing and a right to seek review of

DEA's denial of the Petition. Second, issue exhaustion doesn't apply for several reasons: the Petition raised the core issue; Petitioners raise pure legal challenges; the agency proceedings are non-adversarial; and most important, the agency injected the issue into the agency proceedings by relying on its longstanding 1992 Rule and the 2016 Denial as the sole basis for denying the Petition. Third, the brevity of the administrative record is no reason to require more agency proceedings before deciding the pure legal issues presented. On the contrary, it is ideal.

Finally, notwithstanding *Darby*, even if prudential exhaustion could apply to a petition for review under § 877, it should be excused. Requiring Petitioners to submit a petition before resolving the pure legal questions presented would serve none of exhaustion's underlying goals, especially when the public health is at stake.

BACKGROUND

1. Petitioner Suzanne Sisley is an Arizona-based psychiatrist and a pioneer in the field of medical marijuana research. For the past decade, in addition to maintaining a full-time private telemedicine practice, she has dedicated her life to conducting rigorous clinical studies with marijuana, educating the public about the difficulties in conducting rigorous scientific research with real-world marijuana in the United States. She also advocates for American scientists seeking to do clinical research with medical marijuana. *See* Sisley Decl. ¶¶ 1-22, 29.

Petitioners L. Lorenzo Sullivan, Kendric Speagle, and Gary Hess are disabled former service members. Though they live in states with laws permitting the use of medical marijuana, marijuana's status under federal law makes it impossible for them to obtain medical marijuana through the Department of Veterans Affairs. VA doctors will not even discuss marijuana with them because it is a Schedule I substance. *See* Sullivan Decl. ¶¶ 1-5.

2. Like many, long ago Dr. Sisley did not believe marijuana had potential as medicine. The shift came from her private practice. Repeatedly, veteran patients told her marijuana treated symptoms of PTSD better than FDA-approved medicines. While skeptical at first, Dr. Sisley found these anecdotes impossible to ignore once she began losing patients to suicide. *See* Sisley Decl. ¶¶ 6-8.

In 2009, seeking rigorous proof of efficacy, Dr. Sisley put together a protocol to do FDA-approved trials with smoked marijuana. It took her seven years to amass the necessary licenses, including a DEA Schedule I license in 2016, because unlike other controlled substances, clinical research with marijuana requires approval from four federal agencies and an Institutional Review Board. *See id.* ¶¶ 9-16.

3. In January 2017, Dr. Sisley and SRI began FDA-approved clinical trials of smoked whole-plant marijuana for treatment-resistant PTSD in veterans, funded by a $2.1 million grant from the Colorado Department of Public Health and Environment. *See id.* ¶ 16.

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