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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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.

Federal law requires all researchers who do safety/efficacy trials with marijuana to use marijuana from a 12-acre farm at the University of Mississippi. *See* Ex. 3, Britt Erickson, "Cannabis research stalled by federal inaction," 98 Chem. & Eng. News 25 (June 29, 2020) ("Erickson") (explaining that "no clinical studies have been conducted on cannabis products purchased from state-authorized dispensaries"). *See also* 81 Fed. Reg. 53,846 (Aug. 12, 2016) (explaining researchers must use NIDA marijuana). The quality of this marijuana is poor and unlike the marijuana widely available at medical dispensaries around the country:

This is, supposedly, by design. *See* Erickson (quoting supervisor as saying, "our charge is not to make material similar to what is out there on the illicit market or in the state-authorized medical marijuana programs"). Research suggests it is genetically closer to hemp than medical marijuana. Ex. 4.

4. This situation results from a regulatory Catch-22. In 1992, DEA interpreted the statutory phrase "no currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B), to require "adequate and well-controlled studies proving efficacy." Pet., Ex. 4 (57 Fed. Reg. 10,499, "1992 Rule")

at 503-08. But more than twenty-five years later, the clinical research remains thin because the only marijuana researchers can legally use for efficacy trials is the inadequate varietal shown above. So, marijuana remains in Schedule I.

Next, 21 U.S.C. § 823(a), which governs registration to manufacture Schedule I and II substances, states that DEA can only register applicants if registration is consistent with the public interest "and with United States obligations under international treaties." Until 2016, DEA understood the statute to require a government-supervised monopoly run by NIDA. *See* 74 Fed. Reg. 2,101 at 2,102-2,104 (Jan. 14, 2009). DEA has only ever licensed one cultivator to supply researchers with marijuana: the University of Mississippi. *See* 81 Fed. Reg. at 53,846.

5. The legalization of medical marijuana in the states dramatically increased the need for more suppliers of research-grade marijuana. In August 2016, after consulting with NIDA and the FDA, DEA no longer viewed international obligations as precluding the registration of more manufacturers of marijuana for research. *See id.* at 53,848 (explaining how licensing additional cultivators would be consistent with the Single Convention). Following this announcement, SRI applied to be registered as a cultivator to support its clinical trials. *See* Sisley Decl. ¶ 23.

But nearly four years later, the number of additional cultivators DEA has approved to support marijuana clinical research is ***zero***. *See generally* Erickson. A June 6, 2018 memo from DOJ's Office of Legal Counsel explains why. Ex. 5 (OLC

Memo). In brief, it explains that DEA *can* register additional cultivators, but only if it develops a comprehensive regulatory framework that complies with the Single Convention on Narcotics of 1961. According to OLC, the government has been violating the Single Convention for more than fifty years, and it must bring the licensing framework into compliance before registering additional manufacturers. Hence, DEA's own failure to implement a satisfactory regulatory framework has prevented it from approving additional cultivators.

6. Petitioners request relief that would loosen restrictions on research, allowing DEA-licensed scientists to study the medical marijuana millions around the country already use. Relevant here, the parallel registration provision for lower scheduled substances is less restrictive and does *not* require conformity with treaty obligations. *See* 21 U.S.C. § 823(d). So, rescheduling marijuana, as the Petition urges, could take marijuana out of § 823(a)'s ambit, dramatically improving the supply of real-world medical marijuana for efficacy research. *See* Pet. at 4-7.[1]

ARGUMENT

I. Under *Darby*, exhaustion doesn't apply.

In *Darby v. Cisneros*, 509 U.S. 137, 146-47 (1993), the Supreme Court held that § 704 of the APA bars federal courts from imposing exhaustion requirements not "clearly mandate[d] … by the statute or agency rules." *See also Young v. Reno*,

[1] Petitioners no longer seek review on grounds (2) and (3) stated at Pet. at 13-15.

114 F.3d 879, 882 (9th Cir. 1997) (*Darby* "limits the discretion of courts to impose exhaustion requirements" above and beyond the statute or agency rules). The CSA doesn't mandate (and certainly doesn't "clearly mandate[]") the exhaustion requirement the government would have the Court impose.[2] Section 877 broadly permits "any person aggrieved" by a final DEA decision to obtain judicial review. *See* 21 U.S.C. § 877. There is nothing more to exhaust.

This straightforward application of *Darby*—controlling precedent not cited, much less addressed, by the government—dooms the Motion. The government asks this Court to impose non-statutory exhaustion "as a rule of judicial administration where the agency action has already become 'final' under § [704]." *Darby*, 509 U.S. at 154. But because the government doesn't identify any provision of the CSA or DEA's rules "clearly mandating" the exhaustion requirement it attempts to impose here (there is none), that ask must be denied.

None of the government's cases has the posture of this case where *Darby* applies. *Agua Caliente Tribe of Cupeno Indians of Pala Reservation v. Sweeney*, 932 F.3d 1207, 1209 (9th Cir. 2019) is an appeal from a mandamus-based APA action

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[2] The APA applies to §§ 811(a) and 877. *See* 21 U.S.C. § 811(a) ("Rules … shall be made on the record after opportunity for a hearing pursuant to the [APA] rulemaking procedures."); *John Doe, Inc. v. DEA*, 484 F.3d 561, 566 n.4 (D.C. Cir. 2007) ("[T]he cases applying the final aspect of the APA guide us in construing finality under 21 U.S.C.§ 877.").

to compel agency action unlawfully withheld. There was an unused agency process, no final agency action, and no statute like § 877 where Congress provided for judicial review of a final determination. *See id.* at 1216-18. *See also* 5 U.S.C. § 704 ("Agency action made reviewable by statute …"). None of that is true here.

In *Cabaccang v. U.S. Citizenship & Immigration Servs.*, 627 F.3d 1313, 1315 (9th Cir. 2010), removal proceedings were pending so there was no final agency action, and unlike here, there was a right to renew the application before an immigration judge. *See id.* at 1316 ("[A] motion for reconsideration, an appeal to a superior agency authority, or an intra-agency appeal to an administrative law judge" render a decision non-final). Here, there is no pending agency process and notably, the right to request a hearing attaches only after DEA *grants* a petition to institute rulemaking. 21 U.S.C. § 812(a)(2). That is part of the problem: there is no hearing when DEA denies a petition based on the five-part test. *See* Pet. at 13 (requesting instruction to initiate rulemaking under § 811(a), which then permits hearing).

Paul G. by and through Steve G. v. Monterey Peninsula Unified School Dist., 933 F.3d 1096, 1098-1102 (9th Cir. 2019), is far afield. *See* Mot. at 7 (citing page 1098 and page 1102). The issue there was whether plaintiff could file a case in district court under one statute, without first exhausting a second statute. The second statute required exhaustion of the second statute's administrative procedures before bringing a lawsuit under the first. *Paul G.*, 933 F.3d at 1099-1100 (citing 20 U.S.C.

§ 1415(l)). Because of the statute's precise exhaustion command, the "crucial issue" was whether the relief sought was "available under the [second statute]." *Id.* at 1101.

The identification of *Washington v. Barr*, 925 F.3d 109 (2d Cir. 2019) as a case arising under "similar circumstances" is telling. Mot. 8. Procedurally, it couldn't be more different. There, plaintiffs raised a constitutional challenge to marijuana's Schedule I status in district court. *Washington*, 925 F.3d at 114. The constitutional claims were dismissed for failure to exhaust administrative remedies. *Id.* Because the case didn't arise under § 877 and the APA, *Darby* didn't apply. Here, by contrast, Petitioners bring APA-based claims under § 877 challenging DEA's denial of a petition to institute rulemaking. *Darby* applies. The very (maybe only) reason the *Washington* court affirmed dismissal is because that case, unlike this one, *didn't* arise under § 877 and the APA.

II. The government's other points lack merit.

Remedies exhaustion aside, the Motion suggests three other avenues for dismissal. None has merit.

i. Petitioners' ability to file their own § 811(a) petition under § 811(a) has no bearing on exhaustion.

The government acknowledges the relief Petitioners seek in this case is an order holding unlawful and setting aside DEA's final decision denying the Petition. *See* Pet. 2; *see also* Mot. 1 ("Stephen Zyszkiewicz and Jeramy Bowers petitioned [DEA] to initiate rulemaking, and DEA denied that request. Petitioners … have filed

this action seeking judicial review of *that decision*.") (emph. added)). According to the government, however, before Petitioners can obtain that relief, they must file their own petition "as Zyszkiewicz and Bowers did." Mot. 5 (cites omitted).

Submitting a different petition to embark on a separate administrative track, whatever the result, could not possibly assist Petitioners in remedying DEA's unlawful denial of the Petition. The question isn't whether remedies have been exhausted on a petition that hasn't been submitted, but whether they're exhausted with respect to the Petition and if, under § 877, Petitioners can challenge DEA's final determination denying the Petition.

The government's real grievance is the last point: Petitioners are challenging a decision denying another's rescheduling petition. *See* Mot. 1. But neither the CSA nor any DEA rule limits the class of persons who can seek judicial review to the *parties* of administrative proceedings underlying those decisions. On the contrary, the statute affirmatively says "*any person aggrieved* by a final decision" can seek judicial review. 21 U.S.C. § 877 (emph. added). This language invokes traditional standing principles. The government cannot deny Petitioners qualify as "person[s] aggrieved" by the unlawful denial of the Petition—a decision it concedes is final and appealable. Mot. 3-4. This should be the end of the matter.

The government's position requires rewriting § 877, changing the "any *person* aggrieved" standard to the more restrictive "any *party* aggrieved." But courts,

including this one, have recognized the difference. In *Pacific Maritime Ass'n v. NLRB*, 827 F.3d 1203, 1211 (9th Cir. 2016), for example, this Court explained that the "person aggrieved" standard in § 10(f) of the National Labor Relations Act meant a non-party could seek judicial review of a final NLRB order:

> While, in the typical case, a "person aggrieved" usually will have been a party to the Board proceeding, party status is not necessary. Courts have recognized entities as "aggrieved persons" even though they were not parties in the underlying administrative proceedings.

"Party aggrieved" limits those who can seek review to those who participated in agency proceedings. *Am. Civil Liberties Union v. F.C.C.*, 774 F.2d 24, 25 (D.C. Cir. 1985). "Person aggrieved," by contrast, carries the same meaning it does under § 702 of the APA: that the petitioner be injured and arguably within the relevant statute's zone of interests. *See Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 396 (1987).

Consistent with this approach, both circuits that have looked at the issue have construed "any person aggrieved" in § 877 to require a litigant to meet the injury-in-fact and zone-of-interests requirements. *Bonds v. Tandy*, 457 F.3d 409, 412 (5th Cir. 2006); *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 793 (D.C. Cir. 2004). In *PDK Labs*, for example, the court explained that a pharmaceutical manufacturer had standing under § 877 to petition for review of an order requiring importers to suspend shipments of ephedrine to that manufacturer. 362 F.3d at 792-93. Noting that "[v]ery rarely has Congress withheld judicial review from those who have suffered an Article III injury at the hands of an administrative agency" and "[t]ime and again the

Supreme Court has emphasized that there is a 'strong presumption' in favor of judicial review," *id.* at 792 (citation omitted), the court concluded that no language in § 877 supported limiting judicial review beyond its express language, *id.* at 793.

The scheme confirms this conclusion. Unlike § 877's broad "any *person* aggrieved" language, § 811(a) permits "any interested *party*" to petition the agency. *Compare* 21 U.S.C. § 811(a) (emph. added) *with* § 877 (emph. added). Congress's use of "interested party" in § 811(a) and "person aggrieved" in § 877 was not accidental. Section 811(a)'s use of "interested party" allows anyone interested to petition the agency, while § 877 uses "person aggrieved" to ensure that anyone with standing may obtain judicial review of a final agency determination, regardless of whether they were a party to the underlying agency proceedings.

Thus, the government's assertion that "a person who petitions the DEA Administrator to reschedule a substance may seek judicial review if the Administrator denies that petition," Mot. 4, is incorrect. An "interested party" can submit a petition under § 811(a) but not have standing to seek judicial review. *See Gettman v. DEA*, 290 F.3d 430, 433 (D.C. Cir. 2002) (§ 811(a) doesn't provide "'automatic standing' to appeal the DEA's denial of [a] petition"). Likewise, a non-party to a denied petition may have standing to challenge the denial.

Boiled down, the Motion's core flaw is that it conflates the concepts of standing and exhaustion. *See, e.g.*, Mot. 1 ("Because *these petitioners* have not

exhausted their administrative remedies …") (emph. added). Exhaustion isn't something a litigant must do, but rather something that must be done. Remedies can be exhausted by a party other than the one appearing before the court.

The judicial review provision of the Communications Act offers a useful point in contrast. Like § 877 of the CSA, § 405 of the Communications Act allows "person[s] aggrieved," including non-parties to agency proceedings, to obtain judicial review. 47 U.S.C. § 405. But unlike § 877, it clearly mandates that non-parties must first file a petition for reconsideration before seeking judicial review. *See Coal. for Pres. of Hispanic Broad. v. F.C.C.*, 931 F.2d 73, 76 (D.C. Cir. 1991). Thus, under *Darby*, non-parties would need to exhaust that step before coming to court. Here, such a requirement is plainly absent, so *Darby* bars imposing further exhaustion. *See Reno*, 114 F.3d at 882.

In sum, because Petitioners are "person[s] aggrieved" by DEA's final decision denying the Petition, judicial review is available under § 877. Given *Darby* and that further administrative exhaustion with respect to that decision is impossible, the suggestion that Petitioners must file a new petition or take additional steps before seeking judicial review must be rejected.

ii. Issue exhaustion doesn't apply.

At times, the government suggests dismissal is appropriate because the issues Petitioners raise weren't raised in the Petition. Mot. 7. This argument sounds not in *remedies* exhaustion—the basis of the Motion—but *issue* exhaustion. The

distinction is important because the separate doctrines demand different legal standards. *E.g.*, *Vaught v. Scottsdale Healthcare Corp. Health Plan*, 546 F.3d 620, 622 (9th Cir. 2008) (applying each doctrine separately).

"The requirement that a claimant obtain a final decision on his claim is a remedy-exhaustion requirement, while the requirement that a claimant must also specify that issue in his request for review by the agency is an issue-exhaustion requirement." *Id.* at 630 (quot. omitted). Issue exhaustion is typically a creature of statute or regulation. In *Sims v. Apfel*, 530 U.S. 103, 107-08 (2000), the Court held it isn't generally required in non-adversarial or inquisitorial settings. *Id.* Just so here.

First, the Petition squarely raises the issue. It contends maintaining marijuana as a Schedule I drug is untenable because "[h]alf the states allow for medical use." Pet., Ex. 1. That is the issue. To reject this argument, the agency applied its unlawful five-part test. Pet., Ex. 2. If the Petition didn't implicate the validity of DEA's five-part test, one wonders why DEA made it the centerpiece of its final determination denying that Petition.

Second, even if the Petition didn't squarely raise the issue, DEA's denial did, by relying on the 1992 Rule and 2016 Denial as the authority for refusing to initiate a rulemaking. *Wind River Min. Corp. v. United States*, 946 F.2d 710 (9th Cir. 1991) is instructive on this point. There, this Court held that a challenger may call into

question the substance of an earlier agency decision even outside the limitations period if a later agency action applies the earlier decision. *Id.* at 715-16.

As in *Wind River*, Petitioners challenge recent final agency action applying an unlawful test the agency developed years earlier. Petitioners contend that the earlier rule exceeded the agency's statutory and constitutional authority, so the agency lacked authority to take the recent action. In denying the Petition, the agency plainly applied the 2016 Denial and the 1992 Rule. Under this Court's precedents, Petitioners may therefore challenge their renewed application here. *See also California Sea Urchin Comm'n v. Bean*, 828 F.3d 1046, 1051 (9th Cir. 2016).

Third, notwithstanding *Wind River*, review of the statute's meaning and the constitutional issue is proper if not required under the APA's plain text. The meaning and constitutionality of the statutory provisions raised by review of the denial are "necessary to decision" and "presented" to the Court to review. 5 U.S.C. § 706.

Fourth, the § 811(a) petition process isn't adversarial. It lacks any of the hallmarks of adversarial-ness: no cross examination, no representation by counsel, no trial-like proceedings, etc. Nor is there notice-and-comment. *See Krumm v. Drug Enforcement Admin.*, 739 F. App'x 655 (D.C. Cir. 2018).[3] As a result, under *Sims*,

[3] The *Krumm* petitioner directly challenged the five-part test. The agency rejected that challenge and stated it would be "an extremely inefficient use of the agencies' resources" to conduct analysis based on a petition that puts forward "a cursory claim for rescheduling" and "plainly fails to materially alter the prior agencies' determination" under the test. Ex. 7. Non-statutory exhaustion is not

issue exhaustion doesn't apply. 530 U.S. at 107; *see also Alaska Survival v. Surface Transp. Bd.*, 705 F.3d 1073, 1080 (9th Cir. 2013) (no issue exhaustion with "informal" and "inquisitorial rather than adversarial" proceedings).

iii. The record is complete and squarely presents the issues.

The government also suggests that a slim administrative record is a reason to dismiss this case. Not so.

"Concern over the lack of a comprehensive administrative record is not sufficient cause to narrow the scope of 21 U.S.C. § 877." *John Doe, Inc. v. Drug Enforcement Admin.*, 484 F.3d 561, 569 (D.C. Cir. 2007). In *John Doe*, for example, the "meager" administrative record consisted of a permit denial. That allowed review in the Court of Appeals because "[t]he limited administrative record … establishe[d] sufficient facts to squarely present the critical legal issue." *Id.* at 570.

So too here. While the government implies this case would benefit from a more fulsome petition, *e.g.*, Mot. 4, in fact, the opposite is true. Petitioners raise matters of statutory interpretation and a separation of powers based facial challenge to § 811(d). No facts are disputed. The government does not and cannot explain how another petition supplemented with "evidence regarding marijuana's efficacy [or] safety," *see* Mot. 5, would assist this Court in deciding pure issues of law.

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required where the agency has not only predetermined the issue before it, but recently stated it would be an inefficient use of resources for it to analyze Petitioners' core claims. *See McCarthy v. Madigan*, 503 U.S. 140, 148 (1992).

The facts necessary to answer the legal questions presented are in the record: the Petition, the 2020 Denial, and the 2016 Denial. This is the ideal record for review.

III. Even if exhaustion were required, it should be excused.

While numerous exceptions to exhaustion arguably apply, *see, e.g.*, *supra* n. 3 (futility), Petitioners focus on two: the lack of special expertise to apply, and the undue prejudice that would result from foreclosing timely judicial review.[4]

i. The agency has no special expertise to apply.

The questions presented don't involve factual issues that implicate the agency's "special expertise." This is not a situation, for example, where the science is being challenged. Rather, the purely legal questions here concern the statutory requirements of the CSA. Accordingly, they are suited to judicial determination.

First, Petitioners raise a plausible, facial constitutional challenge to § 811(d) based on separation of powers. Pet. 15-16. Not once does the government address this claim, but it is important. Section 811(d) is part of the core logic underlying the 2016 Denial. This issue is in the administrative record and ripe for review.

"[E]xhaustion is generally inappropriate where a claim serves to vindicate structural constitutional claims … which implicate both individual constitutional rights and the structural imperative of separation of powers." *Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 153 (3d Cir. 2020) (citing *Glidden Co. v. Zdanok*, 370 U.S.

[4] If the Court has doubt, Petitioners request deferring ruling on the Motion until the merits, where a more fulsome background will provide more support.

530 (1962)). Of course, neither DEA nor the Attorney General can declare a statute they administer as facially violating separation of powers. *See Johnson v. Robison*, 415 U.S. 361, 368 (1974). The government not only has no expertise to apply to this claim, it is powerless to grant the relief Petitioners seek, making exhaustion inapplicable. *See McCarthy*, 503 U.S. at 147.

The statutory issues are also "purely legal" and thus do not require exhaustion. *Meridian Land & Mineral Co. v. Hodel*, 843 F.2d 340, 342 (9th Cir. 1988). To be sure, after *Chevron*, the pure statutory interpretation exception may, as a general matter, carry less force. But not here, because in *Gonzales v. Oregon*, 546 U.S. 243, 266 (2006), the Court held that Congress delegated authority to determine medical matters under the CSA *away* from Respondents. That includes the key question presented here: the meaning of "no currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B). Any authority or special expertise Respondents may claim in interpreting the statute is "incongruous with the statutory purposes and design." *Oregon*, 546 U.S. at 267.

ii. Requiring Petitioners to submit a rescheduling petition would cause undue prejudice.

Courts also excuse prudential exhaustion where pursuing agency review would subject a party to undue prejudice. *See Washington*, 925 F.3d at 119. "Such prejudice may result, for example, from an unreasonable or indefinite timeframe for administrative action." *McCarthy*, 503 U.S. at 147. Delay is particularly important

when public health is at stake. *See League of United Latin Am. Citizens v. Wheeler*, 899 F.3d 814, 828 (9th Cir. 2018).

The government (in a footnote) disputes the propriety of the *Washington* court's decision to retain supervisory jurisdiction, Mot. 8 n.2, but fails to explain why it took that unusual step: "the average delay in deciding petitions to reclassify drugs under the CSA is approximately ***nine years***." *Washington*, 925 F.3d at 120 (emph. added). There is no timeframe for DEA to act on a rescheduling petition, so the court retained jurisdiction "to encourage prompt decisionmaking." *Id.* at 121. DEA's swift denial of the handwritten Petition is anomalous.

Despite these delays, the *Washington* court required exhaustion because the existing classificatory scheme had not prevented the plaintiffs from obtaining marijuana. *Id.* at 119. Here, by contrast, the existing scheme prevents Petitioners Sisley, SRI, and other scientists from obtaining marijuana suitable for the safety and efficacy research that they are ready to do right now and in fact, have been trying to do for years. *See* Ex. 6, Tyler Kingkade, "One doctor vs. the DEA: Inside the battle to study marijuana in America," NBCNews (Apr. 29, 2020). Adding years more delay, *see id*., would cause significant prejudice, not just to Petitioners, but to the public health.

CONCLUSION

The Motion should be denied.

Dated: July 27, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that this document was filed with the Court via the court's electronic filing system, on the 27th day of July, 2020, and copy was served on all counsel of record, as listed below, via the Court's electronic filing system:

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I hereby certify that this document complies with the requirements of Federal Rule of Appellate Procedure 27(d)(1)(E), 32(a)(5), and 32(a)(6) because it has been prepared in 14-point font. I further certify that this motion complies with the 20-page limitation of Circuit Rule 27-1(1)(d).

/s/ Matthew C. Zorn
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