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EXHIBIT 294

FOR PUBLICATION

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; MERRICK B. GARLAND, Attorney General; ANNE MILGRAM, Administrator, Drug Enforcement Administration, *Respondents*.	No. 20-71433 DEA No. DEA-427 OPINION

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On Petition for Review of an Order of the Drug Enforcement Agency

Argued and Submitted June 10, 2021
Seattle, Washington

Filed August 30, 2021

Before: William A. Fletcher, Paul J. Watford, and Daniel P. Collins, Circuit Judges.

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v.	DEA No. DEA-427
U.S. DRUG ENFORCEMENT ADMINISTRATION; MERRICK B. GARLAND, Attorney General; ANNE MILGRAM, Administrator, Drug Enforcement Administration, *Respondents*.	OPINION

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Opinion by Judge W. Fletcher;
Concurrence by Judge Watford;
Concurrence by Judge Collins

SUMMARY[*]

Exhaustion / Controlled Substances Act

The panel dismissed a petition for review of a Drug Enforcement Agency ("DEA") letter responding to a request that the DEA reschedule marijuana in all of its forms under the Controlled Substances Act ("CSA").

Stephen Zyszkiewicz, a California state prisoner, joined by Jeramy Bowers, a medical cannabis patient, submitted a one-page handwritten petition to the DEA, seeking to reschedule marijuana. The DEA responded by letter, denying the request. Petitioners in this case are Dr. Suzanne Sisley, Scottsdale Research Institute, LLC, Battlefield Foundation, and three veterans, who filed in this court a petition for review of the DEA's response.

The panel held that petitioners had Article III standing. The panel rejected the government's contention that petitioners lacked standing because they only asserted a generalized grievance. Rather, petitioners contended that they suffered direct and particularized harms due to the misclassification of cannabis.

[*] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

The panel held that petitioners failed to exhaust their administrative remedies with the DEA. Although the CSA does not, in terms, require exhaustion of administrative remedies, the panel agreed with the Second Circuit that the text and structure of the CSA show that Congress sought to favor administrative decisionmaking that required exhaustion under the CSA. Petitioners did not seek to join Zyszkiewicz's one-page petition or seek to intervene with respect to his petition to the DEA. In addition, petitioners did not raise the issue that Zyszkiewicz raised in his petition to the DEA, but instead raised two different arguments. The panel concluded that under the circumstances of this case petitioners had not exhausted their administrative remedies and had given no convincing reasons to excuse their failure to exhaust.

Judge Watford concurred. He wrote separately to note that in an appropriate case, the DEA may be obliged to initiate a reclassification proceeding for marijuana given the strength of petitioners' argument that the agency misinterpreted the CSA by concluding that marijuana has no currently accepted medical use in the United States.

Judge Collins concurred in Parts I, II(B), and III of the majority opinion. He did not join Part II(A), which concluded that petitioners had Article III standing to challenge the denial of Zyszkiewicz's handwritten petition to the DEA. Given that petitioners' failure to exhaust administrative remedies was dispositive here, there was no need to address petitioners' Article III standing.

COUNSEL

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OPINION

W. FLETCHER, Circuit Judge:

Stephen Zyszkiewicz, joined by Jeramy Bowers, filed a one-page, handwritten petition to the United States Drug Enforcement Administration ("DEA") seeking the rescheduling of marijuana in all of its forms under the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq*. The DEA wrote a letter in response, stating that Zyszkiewicz's letter was not in the proper format for a petition but that it welcomed the opportunity to respond to his concerns. The DEA's letter gave reasons for having denied an earlier rescheduling petition filed by Governors Lincoln Chafee of Rhode Island and Christine Gregoire of Washington State. Zyszkiewicz treated the DEA's answer as a denial of his petition and unsuccessfully sought judicial review.

Dr. Suzanne Sisley, Scottsdale Research Institute, LLC ("SRI"), Battlefield Foundation (the non-profit research arm of SRI), and three veterans (collectively, "Petitioners") seek judicial review of the DEA's response to Zyszkiewicz's petition. Petitioners did not seek to intervene in Zyszkiewicz's petition before the DEA, nor have they filed a petition of their own before the DEA. The arguments Petitioners now seek to raise were not made in Zyszkiewicz's petition.

The government challenges Petitioners' standing and argues that Petitioners failed to exhaust their claims before the DEA. We hold that Petitioners satisfy Article III's standing requirements, but that they have failed to exhaust their administrative remedies under the CSA. We therefore

do not reach the merits of Petitioners' arguments. We dismiss their petition for review.

I. Background

A. The Controlled Substances Act

The Controlled Substances Act of 1970 places federally regulated substances into one of five schedules depending on the substance's "potential for abuse," "medical use," "safety," and likelihood of physical or psychological "dependence." *See* 21 U.S.C. § 812(b). Schedule I is the most restrictive schedule. Marijuana is currently a Schedule I substance. To merit scheduling in Schedule I, a substance must have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use . . . under medical supervision." *Id.* § 812(b)(1)(A), (B), (C). Schedule II requires, *inter alia*, that a substance have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." *Id.* § 812(b)(2)(B). Schedules III through V each require, *inter alia*, "a currently accepted medical use in treatment in the United States." *Id.* § 812(b)(3)–(5).

The CSA authorizes the Attorney General through rulemaking proceedings to reclassify drugs by assigning them to less restrictive schedules, or to remove them from control entirely. 21 U.S.C. § 811(a). The Attorney General may initiate rulemaking proceedings "(1) on his own motion, (2) at the request of the [Department of Health and Human Services ("HHS")] Secretary, or (3) on the petition of any interested party." *Id.* The Attorney General has delegated this authority to the DEA Administrator.

Before initiating proceedings to control, reschedule, or remove a substance from control, the Attorney General must request (1) "a scientific and medical evaluation" and (2) a scheduling recommendation from the HHS Secretary. *Id.* § 811(b). "If control is required by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by subsection (a) of [section 811] or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of [section 811]." *Id.* § 811(d)(1).

"[A]ny person aggrieved by a final decision of the Attorney General [under this subchapter] may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision." *Id.* § 877.

B. Zyszkiewicz's Petition to the DEA

Stephen Zyszkiewicz, a prisoner in Soledad State Prison in California, joined by Jeramy Bowers, a "medical cannabis epilepsy patient," submitted a one-page, handwritten petition to the DEA, dated January 3, 2020, seeking to reschedule marijuana or to remove it from the schedules. Zyszkiewicz stated in his petition that he was in prison after a conviction for selling cannabis. Zyszkiewicz's petition read, in relevant part:

> I hereby petition the US AG, DOJ, ONDCP, DEA and Congress to remove or reschedule cannabis (marijuana) in all its forms . . . .
>
> Petitioner finds the current situation of cannabis in Schedule I completely untenable. Half the states allow for medical use and the FDA allows CBD and THC pharmaceuticals as well as IND Compassionate Use.
>
> Under the Constitution and 21 USCS 811, 812 the continued war on drugs (cannabis) must be corrected by removing or rescheduling cannabis.

The DEA responded by letter to Zyszkiewicz's petition on April 22, 2020. The letter stated:

> . . . Although your letter is not in the proper format of a petition as outlined in Section 811 of the Federal Criminal Code, DEA appreciates the opportunity to address your concerns.
>
> On August 12, 2016, the Federal Register addressed similar concerns from a petition submitted on November 30, 2011, from the Honorable Lincoln D. Chafee and the Honorable Christine O. Gregoire. The above [governors] petitioned DEA to initiate rulemaking proceedings under the rescheduling provisions of the [CSA]. Specifically, they petitioned DEA to have marijuana and "related items" removed from

schedule I of the CSA and rescheduled as medical cannabis in schedule II. They requested that DEA remove marijuana and related items from schedule I based on their assertion that: (1) Cannabis has accepted medical use in the United States; (2) Cannabis is safe for use under medical supervision; (3) Cannabis for medical purposes has a relatively low potential for abuse, especially in comparison with other schedule II drugs.

In accordance with the CSA rescheduling provisions, after gathering the necessary data, DEA requested a scientific and medical evaluation and scheduling recommendation from [HHS]. HHS concluded 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. Therefore, HHS recommended that marijuana remain in schedule I. The scientific and medical evaluation and scheduling recommendation that HHS submitted to DEA is enclosed with this letter.

Based on HHS's evaluation and all other relevant data, DEA has concluded that there is no substantial evidence that marijuana should be removed from schedule I. A document prepared by DEA addressing these materials in detail is also enclosed. In short, marijuana continues to meet the criteria for schedule I control under the CSA.

> In sum, DEA recognizes the possibility that drugs containing marijuana or its derivatives might, in the future, be proven to be safe and effective for the treatment of certain conditions and thus approved [] by the United States Food and Drug Administration for marketing. Until then, we will continue to identify opportunities to assist researchers in this area while never losing sight of the need to protect the public.

Zyszkiewicz petitioned for mandamus in the District Court for the District of Columbia. The district court denied mandamus, and the D.C. Circuit affirmed. *See Zyszkiewicz v. Barr*, No. CV 20-1599, 2020 WL 3572908 (D.D.C. June 30, 2020), *aff'd*, 831 F. App'x. 519 (D.C. Cir. 2020). Zyszkiewicz also petitioned for review directly to the D.C. Circuit, which denied the petition as untimely. Order, *Zyszkiewicz v. Barr*, No. 20-1308 (D.C. Cir. Jan. 25, 2021). Petitioners did not seek to join or to intervene in either of Zyszkiewicz's judicial petitions.

C. The Present Petition

On May 21, 2020, Petitioners filed in this court a petition for review of the DEA's response to Zyszkiewicz's petition. Petitioners argue (1) that the DEA's interpretation of "no currently accepted medical use" under 21 U.S.C. § 812(b)(1)(B) with respect to cannabis is arbitrary and capricious or otherwise contrary to law; and (2) that 21 U.S.C. § 811(d)(1) constitutes an unconstitutional delegation of legislative power. Neither of these arguments was made in Zyszkiewicz's petition.

The government moved to dismiss for failure to exhaust administrative remedies. A motions panel of this court denied the government's motion without prejudice to presenting the argument in its brief to the merits panel.

II. Discussion

The government makes two preliminary arguments: (1) that Petitioners lack standing under Article III and (2) that Petitioners have failed to exhaust their administrative remedies under the CSA. We conclude that Petitioners have Article III standing, but that they have failed to exhaust their administrative remedies. We therefore dismiss the petition without reaching the merits.

A. Article III Standing

Article III standing requires that a plaintiff demonstrate (1) an "injury in fact," (2) "a causal connection between the injury and the conduct complained of," and (3) a likelihood "that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (quotations omitted). "An injury in fact is an invasion of a legally protected interest that is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Novak v. United States*, 795 F.3d 1012, 1018 (9th Cir. 2015) (quotation marks and alteration omitted) (citing *Lujan*, 504 U.S. at 560). "Because a generalized grievance is not a particularized injury, a suit alleging only generalized grievances fails for lack of standing." *Id.* "The fact that a harm is widely shared does not necessarily render it a generalized grievance." *Ecological Rts. Found. v. Pac. Gas & Elec. Co.*, 874 F.3d 1083, 1093 (9th Cir. 2017) (alteration omitted) (quoting *Novak*, 795 F.3d at 1018). "Rather, a

grievance too ‘generalized’ for standing purposes is one characterized by its ‘abstract and indefinite nature—for example, harm to the common concern for obedience to law.’” *Id.* (quoting *Novak*, 795 F.3d at 1018).

The government argues that Petitioners lack Article III standing because they assert only a generalized grievance. Characterizing Petitioners’ challenge as based on an asserted interest in the Executive Branch following the law, the government argues that Petitioners lack standing because that interest is common to all who may wish to reschedule controlled substances. The government may be right that such an interest is too generalized to warrant Article III standing, but Petitioners do not assert only a generalized harm. Rather, they contend they suffer direct and particularized harms due to the misclassification of cannabis. Dr. Sisley and her associated institutions contend that the misclassification impedes their research efforts, and the veterans contend that it forecloses their access to medical treatment with cannabis through the Department of Veterans Affairs. The government also argues Petitioners’ claims rest “on the legal rights or interests of third parties.” While it is undoubtedly true that the interests of third parties would be affected by a rescheduling of cannabis, this fact does not diminish Petitioners’ direct and particularized interest in rescheduling. *See Americans for Safe Access v. DEA*, 706 F.3d 438, 445–49 (D.C. Cir. 2013).

We therefore conclude that Petitioners have Article III standing.

B. Failure to Exhaust

"The doctrine of exhaustion of administrative remedies is well established in the jurisprudence of administrative law." *Woodford v. Ngo*, 548 U.S. 81, 88 (2006) (quoting *McKart v. United States*, 395 U.S. 185, 193 (1969)); *see Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51 (1938). "[P]roper exhaustion of administrative remedies . . . means using all steps that the agency holds out, and doing so properly (so that the agency addresses the issues on the merits)." *Woodford*, 548 U.S. at 90 (quotations and emphasis omitted). "As a general rule . . . courts should not topple over administrative decisions unless the administrative body not only has erred, but has erred against objection made at the time appropriate under its practice." *Id.* (alteration adopted and emphasis omitted) (quoting *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952)).

Where Congress has not clearly required exhaustion, courts may impose it as an act of "sound judicial discretion." *McCarthy v. Madigan*, 503 U.S. 140, 144 (1992). Our discretion requires "appropriate deference to Congress' power to prescribe the basic procedural scheme under which a claim may be heard in a federal court." *Id.* Any "fashioning of exhaustion principles" must be made "in a manner consistent with congressional intent and any applicable statutory scheme." *Id.*

The CSA does not, in terms, require exhaustion of administrative remedies. However, we agree with the Second Circuit that the text and structure of the CSA "show[] that Congress sought to favor administrative decisionmaking" and that requiring exhaustion under the CSA "is consistent with

congressional intent." *Washington v. Barr*, 925 F.3d 109, 116, 118 (2d Cir. 2019). As stated by the Second Circuit:

> The exhaustion requirement under the CSA is . . . prudential, not jurisdictional. It is not mandated by the statute. Rather, it is a judicially-created administrative rule, applied by courts in their discretion.

Id. at 119.

Section 811(a) tasks the Attorney General with scheduling, rescheduling, or removing from the schedules drugs or other substances by rulemaking. As we noted above, such proceedings "may be initiated by the Attorney General (1) on his own motion, (2) at the request of the [HHS] Secretary, *or (3) on the petition of any interested party*." 21 U.S.C. § 811(a) (emphasis added). Congress thus expressly authorized individuals to petition the DEA—not the courts directly—to schedule, reschedule, or remove a substance. The CSA prescribes steps for the Attorney General to follow before initiating proceedings, § 811(b), and details factors to consider in so doing, § 811(c). In § 877, the CSA provides for judicial review of final agency action, not judicial decisionmaking in the first instance. To require interested individuals to petition the DEA before seeking judicial review is consistent with—indeed almost demanded by—this carefully established statutory process. *See United States v. Cal. Care Corp.*, 709 F.2d 1241, 1248–49 (9th Cir. 1983) (requiring exhaustion where to do otherwise "would encourage the deliberate bypass of the administrative scheme").

In the case before us, Petitioners ask us either to conclude that their administrative remedies have been exhausted by Zyszkiewicz's one-page petition or to excuse their failure to exhaust. The government has not argued to us that the DEA's response to Zyszkiewicz's petition was not a denial of the petition, or that its response was not final agency action within the meaning of the Administrative Procedure Act ("APA"). *See* 5 U.S.C. § 704. In light of the government's failure to make such arguments, we are willing to assume for present purposes that the DEA's response to Zyszkiewicz's petition was a denial of that petition and was final agency action under the APA, even though the DEA characterized its action as only an "opportunity to address [Zyszkiewicz's] concerns" rather than as a denial of the petition.

Petitioners did not seek to join Zyszkiewicz's one-page petition or seek to intervene with respect to his petition to the DEA. Zyszkiewicz advanced only one argument in his petition to the DEA. Petitioners ignore that argument; instead, they advance two different arguments. Petitioners were asked during oral argument before our court why they did not file their own petition with the DEA and then seek review if the DEA denied their petition. They responded that that process would take too long, even though Zyszkiewicz's petition was filed in January 2020, and the DEA responded to that petition in April 2020. Oral Argument at 31:54–33:19, *Sisley v. DEA*, No. 20-71433 (9th Cir. June 10, 2021).

Recognizing that administrative exhaustion under the CSA is judge-made law, "applied by courts in their discretion," *Washington*, 925 F.3d at 119, we hold, under the circumstances of this case, that Petitioners have not exhausted

their administrative remedies and have given no convincing reason to excuse their failure to exhaust. We are well aware that reclassification of cannabis is a matter of ongoing active debate. However, this is not an appropriate case in which to consider that issue.

III. Conclusion

Petitioners seek to bypass the normal administrative process by seeking review of the DEA's response to Zyszkiewicz's petition and then seeking to make arguments never advanced by Zyszkiewicz. Nothing prevents Petitioners from filing a petition of their own before the DEA, raising the arguments they seek to raise before us now. Because Petitioners have failed to exhaust their administrative remedies with the DEA, their petition for judicial review is

DISMISSED.

WATFORD, Circuit Judge, concurring:

I agree that the petitioners in this case failed to exhaust their administrative remedies and therefore join the court's opinion dismissing their petition for review. I write separately to note that, in an appropriate case, the Drug Enforcement Administration may well be obliged to initiate a reclassification proceeding for marijuana, given the strength of petitioners' arguments that the agency has misinterpreted the controlling statute by concluding that marijuana "has no

currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(1)(B).

COLLINS, Circuit Judge, concurring in part:

I concur in Parts I, II(B), and III of the majority opinion, which provide fully sufficient grounds for dismissing the petition in this case. I do not join Part II(A), which concludes that Petitioners have Article III standing to challenge the denial of Zyszkiewicz's handwritten petition to the U.S. Drug Enforcement Administration ("DEA"). I am skeptical that the particular injuries that Petitioners assert are "fairly traceable" to *that* decision of the DEA, *see Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (simplified), but I do not think that it is necessary to decide the point. Because exhaustion of administrative remedies "does not entail any assumption by the court of substantive 'law-declaring power,'" it raises the sort of threshold, non-merits issue that we may resolve first, without having to address subject matter jurisdiction. *See Sinochem Int'l Co. v. Malay. Int'l Shipping Corp.*, 549 U.S. 422, 433 (2007) (citation omitted); *see also id.* at 431 (noting that "a federal court has leeway 'to choose among threshold grounds for denying audience to a case on the merits'" (citation omitted)).[1] And

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[1] *See also Sarei v. Rio Tinto, PLC*, 550 F.3d 822, 824 & n.1 (9th Cir. 2008) (en banc) (plurality) (concluding that, under *Sinochem*, it was appropriate to direct the district court to consider whether to require exhaustion of local remedies in a suit under the Alien Tort Statute, 28 U.S.C. § 1350, despite the presence of unresolved jurisdictional issues); *id.* at 833–37 (Bea, J., concurring) (agreeing with the plurality's remand to consider exhaustion, while differing as to the source of the exhaustion requirement); *id.* at 840 & n.1 (Kleinfeld, J., concurring)

given that Petitioners' failure to exhaust administrative remedies is dispositive here, we have no need to address Petitioners' Article III standing, and I do not do so.[2]

(agreeing that, under *Sinochem*, a remand to consider exhaustion was appropriate, despite jurisdictional issues); *id*. at 837–38 (Ikuta, J., dissenting) (agreeing that, under *Sinochem*, "there is no mandatory sequencing of non-merits grounds for disposing of a case," but concluding that, under the circumstances of that case, the jurisdictional issue should be resolved first and was dispositive); *Valenzuela v. Silversmith*, 699 F.3d 1199, 1205 (10th Cir. 2012) (whether appellant "failed to exhaust tribal court remedies is . . . a threshold, nonmerits issue" that may be decided without resolving subject matter jurisdiction).

[2] I likewise express no view whatsoever on the merits of the claims.

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