No. 20-71433

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SUSAN SISLEY, et al.,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION, et al.,

Respondents.

On Petition for Review From An Order of the U.S. Drug Enforcement Administration

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ANSWERING BRIEF FOR THE FEDERAL RESPONDENTS

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STATEMENT OF JURISDICTION

On April 22, 2020, the U.S. Drug Enforcement Administration (DEA) denied a request by two individuals to initiate a rulemaking under 21 U.S.C. § 811(a). ER2-5. Petitioners in this case did not participate in that request for rulemaking and have not asked DEA to initiate rulemaking. Instead, petitioners ask this Court to review DEA's denial of a rulemaking petition filed by other people, citing 21 U.S.C. § 877. For the reasons explained *infra*, pp. 15-21, this Court lacks jurisdiction over the petition.

INTRODUCTION

This case concerns marijuana's status as a schedule I substance under the Controlled Substance Act. Under the Act, any citizen may petition DEA to move a schedule I substance to a different schedule, or to remove it from the schedules of controlled substances entirely. If DEA denies that petition, or issues an adverse order, the petitioner may seek judicial review.

In January 2020, two individuals—Stephen Zyszkiewicz and Jeramy Bowers—petitioned DEA to reschedule marijuana in a one-page petition. DEA denied that request. Zyszkiewicz has filed two separate lawsuits in the federal courts for the District of Columbia seeking review of DEA's decision. Neither those lawsuits are before this Court.

Petitioners here seek review of the denial of the Zyszkiewicz petition even though they were not involved in that request and have not asked DEA to reschedule

marijuana. Instead, petitioners ask this Court to reverse DEA's decision based on arguments that were never presented to the agency. If petitioners think marijuana should be rescheduled, they may petition DEA to do so and present their contentions to the agency. And if their petition is denied, they can then pursue those arguments in this Court. They may not, however, present an array of arguments in this Court that formed no part of a request for rulemaking filed by other people, not parties here.

Assuming that the petition is properly before the Court, its arguments fail on the merits. Petitioners contend that DEA's decision to retain marijuana on schedule I is arbitrary and capricious and that Congress has unconstitutionally granted DEA legislative authority. Those arguments are contrary to settled precedent and should be rejected if the Court were to reach them.

STATEMENT OF THE ISSUES

1. Whether petitioners have standing to challenge DEA's denial of another person's petition to reschedule a controlled substance.

2. Whether petitioners have failed to exhaust their administrative remedies because they have not asked DEA to reschedule marijuana.

3. On the merits, whether DEA's denial of the rescheduling petition violated the nondelegation principle or was arbitrary and capricious.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in the addendum to this brief.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY FRAMEWORK

The Controlled Substances Act, 21 U.S.C. §§ 801-971, establishes a comprehensive federal scheme to regulate the manufacture and distribution of controlled substances. The Act divides controlled substances into five schedules, based on their potential for abuse, medical uses, and risk of physical or psychological dependence. *Id.* § 812(a)-(b). Generally speaking, a schedule I substance has no accepted medical use and a high risk for abuse, while schedule II-V substances have accepted medical uses and decreasing risk of abuse and dependence. *Id.* Congress initially designated scores of substances under the schedules, *id.* § 812(c), and authorized the Attorney General to add, remove, or reschedule substances through rulemaking, *id.* § 811(a). The Attorney General, in turn, delegated this authority to the DEA Administrator. 28 C.F.R. § 0.100.[1]

Congress initially designated marijuana as a schedule I substance. *See* Pub. L. No. 91-513, title II, § 202(c) (schedule I(c)(10)), 84 Stat. 1242, 1249 (1970). Schedule I substances have "a high potential for abuse," have "no currently accepted medical use in treatment in the United States," and lack "accepted safety for use * * * under medical supervision." 21 U.S.C. § 812(b)(1). In a 1992 rulemaking, DEA set forth

[1] For simplicity, this brief refers to authority exercised by DEA whenever the Controlled Substances Act grants authority to the Attorney General and the Attorney General has in turn delegated that authority to the DEA Administrator.

five factors to consider in determining whether a substance has a currently accepted medical use:

1. Whether the substance's chemistry is known and reproducible;
2. Whether there are adequate safety studies;
3. Whether there are adequate and well-controlled studies proving efficacy;
4. Whether the substance is accepted by qualified experts; and
5. Whether the scientific evidence is widely available.

57 Fed. Reg. 10499, 10506 (Mar. 26, 1992). Under that rulemaking, DEA has required all five factors to be satisfied in order for a substance to "be deemed to have a currently accepted medical use." *Americans for Safe Access v. DEA*, 706 F.3d 438, 450 (D.C. Cir. 2013).

DEA can, if the evidence warrants, transfer a substance from one schedule to another by rulemaking. 21 U.S.C. § 811(a)(1). Such rulemaking proceedings "may be initiated" by the DEA Administrator "(1) on his own motion, (2) at the request of the Secretary [of Health and Human Services], or (3) on the petition of any interested party." *Id.* § 811(a). "[B]efore initiating [rulemaking] proceedings," DEA gathers all "necessary data" and obtains a written "scientific and medical evaluation" and a recommendation from the Secretary of Health and Human Services (HHS) as to whether a substance should be rescheduled. *Id.* § 811(b). The Secretary's recommendations on scientific and medical matters "shall be binding." *Id.* If DEA determines that substantial evidence supports moving the substance to a different schedule, then it "shall initiate proceedings for control or removal, as the case may be." *Id.*

"[A]ny person aggrieved by a final decision" regarding rescheduling may seek judicial review in the D.C. Circuit or the circuit in which their principal place of business is located. 21 U.S.C. § 877. Thus, a person who petitions DEA to reschedule a substance may seek judicial review if the Administrator denies that petition. *Americans for Safe Access*, 706 F.3d at 442.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. The Zyszkiewicz Petition For DEA Rulemaking

In January 2020, Stephen Zyszkiewicz and Jeramy Bowers filed a one-page, handwritten petition "to remove or reschedule cannabis (marijuana) in all its forms" under "21 USCS 811, 812." ER1. Zyszkiewicz and Bowers stated that "the current situation of cannabis in Schedule I [is] completely untenable" because "[h]alf the states allow for medical use and the FDA allows CBD and THC pharmaceuticals as well as IND compassionate use." ER1. Zyszkiewicz and Bowers offered no other argument for rescheduling marijuana, and provided no medical evidence regarding its use.

DEA responded in an April 2020 letter. ER2-5. DEA denied the petition for rulemaking, explaining that DEA had conducted an extensive analysis of the medical and scientific literature related to marijuana potential use in treatment in response to a different petition for rulemaking in 2016. ER2, ER7. As part of that 2016 analysis, the DEA Administrator had referred a petition to reschedule marijuana to the Secretary of HHS to obtain her findings and opinions on scientific and medical

matters, in accordance with 21 U.S.C. § 811(b). ER8. The Secretary, in turn, referred the petition to the Food and Drug Administration (FDA) to evaluate the scientific and medical data, assess whether marijuana has a currently accepted medical use, and provide a scheduling recommendation for marijuana. ER31-32. FDA conducted its scientific review, ER31-57, and referred the petition back to the Secretary, who issued a series of factual findings concerning marijuana's chemistry, its physiological effects, its potential medical use, and its potential for abuse, ER8-31. The Secretary concluded that "[m]arijuana does not meet any of the elements for having a 'currently accepted medical use.'" ER26. The Secretary then referred the petition back to DEA, which issued additional findings, ER58-85, and the DEA Administrator ultimately concluded that marijuana should remain a schedule I substance, ER7. For ease of reference, this brief generally refers to the findings and conclusions of this collaborative process as being DEA's.

In concluding that marijuana does not have a currently accepted medical use, DEA applied the five-factor test set out in the governing regulations, and concluded that none of the factors were met. ER26, 75-76.

1. *The substance's chemistry must be well known and reproducible.* DEA explained that marijuana samples come from a variety of cultivated strains, which can have "very different chemical constituents." ER11. In particular, each marijuana plant will possess approximately 100 cannabinoid chemical compounds, but the concentration of these compounds will vary across different strains. ER11, 17. This variation in

marijuana's chemical profile "complicate[s] the interpretation of clinical data using marijuana." ER17. For example, a 1-gram marijuana cigarette might have as little as 3 milligrams of THC (tetrahydrocannabinol, marijuana's principal psychoactive chemical) or as much as 150 milligrams of THC, thus making it difficult to evaluate studies that test the efficacy of smoking marijuana. ER17-18. In considering whether to reschedule marijuana, DEA concluded that it was not possible to reproduce a consistent, standardized dose for all of marijuana's potential strains. ER19 (noting that this might be possible for a particular marijuana strain if it was consistently cultivated under strict conditions).

2. *There must be adequate and well-controlled studies proving efficacy.* DEA reviewed the abstracts of 566 scientific articles, which contained terms indicating that they might be an adequate and well-controlled study of marijuana's efficacy. ER34 & n.30. Of these, only 11 studies were determined to be "randomized, double-blind, placebo-controlled clinical studies conducted with marijuana to assess marijuana's efficacy in any therapeutic indication." ER34; *see also* ER35 (explaining why other studies did not meet this criteria). DEA concluded that these 11 studies did not demonstrate efficacy, but were best understood as "[p]roof of concept studies" that can "provide preliminary evidence on a proposed hypothesis involving a drug's effect." ER20.

Five studies showed "positive results" for using marijuana as an analgesic for chronic neuropathic pain. ER41. But the subjects in these studies continued to use their preexisting analgesic drugs in addition to marijuana, making it difficult to

conclude if marijuana had effective analgesic properties on its own. ER36-39. The subjects also suffered from many different kinds of neuropathic pain, "making it difficult to identify whether a specific set of symptoms might be more responsive to the effects of marijuana." ER41. Some subjects also had to withdraw from the studies based on adverse effects from marijuana. ER37 (one subject "developed an intractable smoking-related cough" while the only "marijuana-naïve" subject "experienced an incident of acute cannabis-induced psychosis").

Two studies showed "positive results" for using both marijuana and dronabinol (synthetic THC) to increase appetite and weight gain in HIV-positive patients. ER41. However, all of the subjects in these studies were chronic marijuana users, and the doses of THC given to the subjects were several times greater than the typical doses for appetite stimulation. ER41. Thus, the studies did not address whether patients with little prior exposure to marijuana would be able to tolerate the high THC levels used in these studies, or whether marijuana would still show positive results with limited adverse effects for such patients. ER41.

One study showed some "positive results" for treating spasticity in multiple sclerosis patients with smoked marijuana. ER42. However, the patients continued to use their preexisting medication regime, and it was difficult to conclude marijuana's efficacy as a stand-alone treatment. ER42. Moreover, it was "concerning" that five out of thirty subjects withdrew from the study "because they were unable to tolerate the psychiatric [adverse events] induced by marijuana." ER40, 42.

While one study showed "positive results" for treating asthma patients with smoked marijuana, there was an obvious concern about administering "harmful and irritating substances" into the lungs of asthma patients by instructing them to smoke. ER42. Additionally, the patients smoked marijuana while they were at rest and not suffering bronchospasms, leaving it uncertain whether marijuana was effective at treating asthma attacks. ER42.

Two studies had shown "positive results" for treating glaucoma with marijuana, but "the effect is short-lasting, requires a high dose, and is associated with many [adverse events]. Thus, the potential harmful effects may outweigh any modest benefit of marijuana for this condition." ER42.

DEA noted a number of other complicating factors in these studies that limited their usefulness in determining marijuana's efficacy as a medical treatment. The treatment groups in these studies were small (ranging from 10 to 25 subjects) and were "statistically inadequate to support a showing of safety or efficacy." ER42. No study lasted longer than five days, although the purpose of the studies was to determine to demonstrate marijuana's efficacy for treating chronic medical conditions that could last a lifetime. ER43. And, as a general matter, it was "not recommended" to prescribe smoking as a medical treatment, because this would necessarily put smoke "into the lungs of individuals with a disease state * * * when their bodies may be physically compromised." ER43. Finally, all of these studies had an inherent difficulty in ensuring that the subjects were truly "blind," *i.e.*, that they did not know if

they were receiving marijuana or a placebo. ER43. Because marijuana has a "rapid onset of psychoactive effects," test subjects will likely know if they are receiving marijuana instead of a placebo, which could lead to an expectation bias that changes the subjects' "perceived responsivity to the therapeutic outcome." ER43.

3. DEA then determined that none of the remaining three factors supported a finding that marijuana had a currently accepted medical use. DEA concluded that there were no adequate safety studies for marijuana, because in order to determine whether marijuana could be safe for treatment, there needs to be a "risk-benefit analysis" for whether marijuana's side effects are outweighed by its "potential benefits for a particular indication." ER20. Because DEA concluded that marijuana has not been shown to be an effective treatment for any medical condition, it similarly could not be shown to be safe for treating such conditions. ER20.

Likewise, given the absence of any adequate, well-controlled studies, DEA concluded that there was "no evidence that there is a consensus among qualified experts that marijuana is safe and effective for use in treating a specific, recognized disorder." ER20.

Finally, DEA found that there was not widely available scientific evidence of a cultivated marijuana strain "that could produce standardized and reproducible doses." ER21.

Accordingly, DEA found that the current scientific evidence "has not progressed to the point where marijuana is considered to have a 'currently accepted

medical use' or a 'currently accepted medical use with severe restrictions,'" ER21, and it therefore must remain classified as a schedule I substance, ER7.[2]

B. Zyszkiewicz's Attempts to Seek Judicial Review

After receiving DEA's denial, Zyszkiewicz sought judicial review. He first filed suit in the District Court for the District of Columbia seeking to compel DEA to reschedule marijuana. Pet. for Declaratory Judgment, Writ of Mandamus, and Review at 2-3, *Zyszkiewicz v. Barr*, No. 20-1599 (D.D.C. May 29, 2020). The district court *sua sponte* dismissed Zyszkiewicz's lawsuit, noting that he could have—but had not—sought judicial review of DEA's denial in the D.C. Circuit under 21 U.S.C. § 877. *Zyszkiewicz v. Barr*, 2020 WL 3572908, at *1 (D.D.C. June 30, 2020). Zyszkiewicz appealed from that dismissal, and that appeal is pending in the D.C. Circuit. *Zyszkiewicz v. Barr*, No. 20-5213 (D.C. Cir.).

In August 2020, after appealing the adverse district court order, Zyszkiewicz separately sought judicial review of DEA's denial under 21 U.S.C. § 877 by filing a petition for judicial review in the D.C. Circuit. *Zyszkiewicz v. DEA*, No. 20-1308 (D.C. Cir.). DEA moved to dismiss that petition as untimely because it was filed outside the 30-day time limit prescribed by § 877. Mot. to Dismiss, *Zyszkiewicz v. DEA*, No. 20-

[2] DEA also found that marijuana poses health risks from acute use, including impaired psychomotor performance, dysphoria, and prolonged psychological distress, including prolonged anxiety reactions. ER23. DEA further found that marijuana has a widespread potential for abuse through non-medical use. ER62, 66, 80.

1308 (D.C. Cir. Oct. 5, 2020). Zyszkiewicz did not contest that his petition was untimely, Opp. at 1-2, *Zyszkiewicz v. DEA*, No. 20-1308 (D.C. Cir. Oct. 25, 2020), and the D.C. Circuit has not yet acted on the petition.[3]

C. This Petition For Judicial Review

Petitioners are Suzanne Sisley, Scottsdale Research Institute LLC, Battlefield Foundation, Lorenzo Sullivan, Kendrick Speagle, and Gary Hess. Their petition in this Court seeks "review of [DEA's] final determination denying Stephen Zyszkiewicz's January 3, 2020 petition to reschedule." Pet. at 6, Dkt. 1-6. Because none of these petitioners were a signatory to the Zyszkiewicz petition or had otherwise asked DEA to reschedule marijuana, DEA moved to dismiss the case because petitioners had failed to exhaust their administrative remedies. Dkt. 11. This Court entered an order that denied dismissal "without prejudice to renewing the arguments in the answering brief." Dkt. 17.

SUMMARY OF ARGUMENT

I. A. Petitioners have not filed a petition for rulemaking with DEA and have not had a petition denied. Their petition must therefore be dismissed at the threshold. Petitioners' contention that they were injured by the denial of the Zyszkiewicz petition for rulemaking states the kind of "generalized grievance against

[3] In his opposition, Zyszkiewicz stated that he has filed a new petition to reschedule marijuana with DEA, and that DEA has not yet acted on that subsequent petition. Opp. at 2, 6-7, *Zyszkiewicz v. DEA*, No. 20-1308 (D.C. Cir. Oct. 25, 2020).

governmental conduct" that is insufficient to support standing. *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018). Nor can petitioners assert third-party standing based on any harm to Zyszkiewicz or Bowers. Those third-parties are fully capable of defending their interests, and Zyszkiewicz has challenged the denial of his petition for rulemaking.

B. For related reasons, the petition should be dismissed because petitioners have failed to exhaust their administrative remedies. This Court has consistently required parties to exhaust their applicable administrative remedies before seeking judicial review, and those precedents apply with full force to the administrative remedies available under the Controlled Substances Act. *See Washington v. Barr*, 925 F.3d 109, 115-18 (2d Cir. 2019) (holding that plaintiffs may not sue over marijuana's placement on schedule I without first filing a rescheduling petition under 21 U.S.C. § 811(a)), *cert. denied*, --- S. Ct. ---, 2020 WL 6037234 (Oct. 13, 2020). The importance of that requirement is particularly evident here, where petitioners attack DEA's decision on grounds never presented to the agency.

II. A. If this petition were properly before the Court, its arguments should be rejected on the merits. DEA acted reasonably in denying a one-page petition to reschedule marijuana which presented no scientific evidence as to marijuana's safety or efficacy as a medical treatment and merely argued that rescheduling was warranted because many states had enacted medical marijuana laws. In denying the petition, DEA examined whether marijuana has a "currently accepted medical use in treatment

in the United States." 21 U.S.C. § 812(b)(1)(B). That statutory phrase is ambiguous, *see Grinspoon v. DEA*, 828 F.2d 881, 885 (1st Cir. 1987); *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991), and DEA has construed its meaning by promulgating a five-factor test that examines whether a substance is safe and effective way to treat specific medical conditions. That multi-factor test has been explicitly and repeatedly endorsed by the D.C. Circuit, *see e.g.*, *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013), and it a reasonable exercise of authority to construe an ambiguous statutory phrase. Under the framework laid out in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984), DEA's denial was a proper application of that reasonable interpretation.

B. Petitioners wrongly claim that DEA's denial constituted an impermissible exercise of legislative power. Congress placed marijuana on schedule I by statute, and DEA here denied rescheduling based on the statutory factors identified in 21 U.S.C. § 812(b), which this Court has explained do not offend the nondelegation doctrine. *See United States v. Kelly*, 874 F.3d 1037, 1047-48 (9th Cir. 2017).

STANDARD OF REVIEW

Whether petitioners have standing is a legal issue determined de novo. *Arakaki v. Lingle*, 477 F.3d 1048, 1056 (9th Cir. 2007). The Court also determines de novo whether petitioners have exhausted their administrative remedies. *Leorna v. U.S. Department of State*, 105 F.3d 548, 550 (9th Cir. 1997). The Court reviews DEA's decision not to initiate rulemaking proceedings to determine whether it was arbitrary,

capricious, and abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A).

ARGUMENT

I. THE COURT SHOULD DISMISS THE PETITION FOR REVIEW

Stephen Zyszkiewicz and Jeramy Bowers petitioned DEA to institute rulemaking about marijuana's designation as a schedule I controlled substance, and DEA declined to do so. Petitioners seek judicial review of DEA's decision. The fundamental problem with petitioners' suit is that neither Zyszkiewicz nor Bowers is a party to it. Petitioners do not seek relief for any action that DEA has taken against them—instead, they assert the rights of others and contend that DEA's decision must be set aside based on legal theories that neither Zyszkiewicz nor Bowers presented to the agency. The Court should dismiss petitioners' suit for two related reasons. First, petitioners lack standing to challenge DEA's denial of someone else's rulemaking petition. Second, petitioners have failed to exhaust their administrative remedies because they have never asked DEA to institute rulemaking proceedings themselves.

A. Petitioners Lack Standing Because Their Claims Rest On A Generalized Grievance And The Rights Of Third Parties

In order to have standing to bring suit, a plaintiff must establish that she has a concrete and particularized injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). A plaintiff fails to satisfy that requirement if she asserts only a "generalized grievance" that is "shared in substantially equal measure by all or a large class of

citizens," or if her claim rests "on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975).[4]

1. The Supreme Court has "consistently held" that a plaintiff cannot premise standing on "a generally available grievance about government—claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him than it does the public at large." *Lujan*, 504 U.S. at 573-74. Accordingly, plaintiffs lack standing when they assert an injury based on "the public interest in proper administration of the laws," including a federal agency's "observance of a particular, statutorily prescribed procedure." *Id.* at 576. That is true even when a statute purports to "permit[] all citizens (or, for that matter, a subclass of citizens who suffer no distinctive concrete harm) to sue." *Id.* at 576-77. *See also Whitmore v. Arkansas*, 495 U.S. 149, 160 (1990) ("This Court has repeatedly held that an asserted right to have the Government act in accordance with law is not sufficient, standing alone, to confer jurisdiction on a federal court.").

That principle has been applied in a variety of cases to hold that plaintiffs lack standing when they assert a generally applicable interest in ensuring the government's

[4] The requirement that a plaintiff must assert more than a generalize grievance is based on the constitutional requirements of Article III. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 n.3 (2014). The general prohibition on raising the rights of third parties is "harder to classify," and has at times been considered an element of prudential standing. *Id.*

compliance with the law. Thus, a petitioner lacks standing to challenge the appointment of a Supreme Court Justice when the asserted interest is shared by all "citizen[s]" and "member[s] of the bar of this Court." *Ex parte Levitt*, 302 U.S. 633, 633-34 (1937). Likewise, while a plaintiff has "the right, possessed by every citizen, to require that the government be administered according to law," that interest is insufficient to allow the plaintiff to challenge the adoption of a constitutional amendment based on asserted irregularities. *Fairchild v. Hughes*, 258 U.S. 126, 129-30 (1922). *See also United States v. Richardson*, 418 U.S. 166, 176-77 (1974) (plaintiffs asserted a generalized grievance in claiming that government acted unconstitutionally in failing to provide an accounting of expenditures for the Central Intelligence Agency); *Schlesinger v. Reservists Comm. to Stop the War,* 418 U.S. 208, 217 (1974) (plaintiffs asserted a generalized grievance in claiming that members of Congress were unconstitutionally serving as commissioned officers in the Armed Forces Reserves).

In *Lujan*, the Supreme Court considered the Endangered Species Act citizen suit provision, which permitted "any person" to "commence a civil suit on his own behalf" to enjoin the United States or any federal agency "who is alleged to be in violation" of the act. 504 U.S. at 571-72 (quoting 16 U.S.C. § 1540(g)). The *Lujan* plaintiffs sued under that provision, alleging that the Secretary of the Interior had violated the act by promulgating a rule without performing a statutorily required interagency consultation. *Id.* at 559, 572. The Supreme Court explained that the plaintiffs lacked standing, noting that "[t]his is not a case where plaintiffs are seeking

to enforce a procedural requirement the disregard of which could impair a separate concrete interest of theirs," like the "denial of their license application" or the construction of a federal facility next to their home. *Id.* at 572. Nor was it a case where "Congress has created a concrete private interest" for the plaintiffs obtain after a victorious suit, like a "cash bounty" for a relator in a False Claims Act case. *Id.* at 573.

Instead, the *Lujan* plaintiffs claimed standing based on a "congressional conferral upon *all* persons of an abstract, self-contained, noninstrumental 'right' to have the Executive observe the procedures required by law." *Lujan*, 505 U.S. at 573. The Supreme Court "reject[ed] this view" of standing, explaining that the plaintiffs sought relief "that no more directly and tangibly benefits [them] than it does the public at large," and failed to present "an Article III case or controversy." *Id.* at 573-74.

Petitioners lack standing for the same reason. They assert a right to challenge DEA's denial of someone else's petition for rulemaking, based on their theory that DEA's action is unlawful. But that general interest—common to the public and all citizens who may wish to reschedule certain controlled substances—is not a concrete and particularized injury, but a generalized grievance that is insufficient to support standing.

The standing concerns presented here parallel in key respects those identified by the Supreme Court in *Lance v. Coffman*, 549 U.S. 437 (2007). In *Lane*, the Colorado

Supreme Court decided in a case brought by the state's attorney general that Colorado was required to adopt a redistricting plan issued by a state court. *Id.* at 437-38. After that decision, "four Colorado citizens—none of whom had participated in" the Colorado Supreme Court case—filed a federal lawsuit arguing that the implementation of the redistricting plan was unconstitutional. *Id.* at 438. The Supreme Court held that plaintiffs lacked standing because their allegation "that the law—specifically the Elections Clause—has not been followed" was "precisely the kind of undifferentiated, generalized grievance about the conduct of government that we have refused to countenance in the past." *Id.* at 442. Because the plaintiffs had "no particularized stake in the litigation" they lacked standing. *Id.*

That reasoning applies here with full force. Petitioners were not parties to or involved in the Zyszkiewicz petition for rulemaking. They have no particularized stake in DEA's denial of that petition. Instead, they advance only a generalized grievance that DEA's denial of someone else's petition violates the nondelegation doctrine and is arbitrary and capricious. That is insufficient to confer standing. Petitioners are like a "plaintiff who complains of gerrymandering, but who does not live in a gerrymandered district," and thus "assert[s] only a generalized grievance against governmental conduct of which he or she does not approve." *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018) (quotation marks omitted).

The absence of standing is also illustrated by this Court's decision in *Smelt v. County of Orange*, 447 F.3d 673, 684 (9th Cir. 2006), which held that plaintiffs there

lacked standing to challenge the federal Defense of Marriage Act because they had not "applied for any federal benefits, much less been denied any." *See id.* (holding that plaintiffs presented a "generalized grievance[]" and that they "might someday * * * ask for some federal benefit which they are denied is not enough").[5]

2. Petitioners also cannot establish standing by asserting that they are acting to protect the rights of Zyszkiewicz and Bowers, the individuals who filed the petition for rulemaking with DEA. Petitioners "must assert [their] own legal rights and interests, and cannot rest [their] claim to relief on the legal rights or interests of third parties." *Mills v. United States*, 742 F.3d 400, 406 (9th Cir. 2014). This Court has recognized some exceptions to this rule, and permitted third-party standing "when (1) the party asserting the right has a close relationship with the person who possesses the right and (2) there is a hindrance to the possessor's ability to protect his own interests." *Id.* at 407 (quotation marks omitted). Neither condition is satisfied here, where petitioners have asserted no connection to Zyszkiewicz and Bowers, and where

[5] Petitioners suggest that they are injured because they cannot obtain the kind of marijuana that they would like to use in studies. Br. 37-39. But that alleged injury is not fairly traceable to the denial of the Zyszkiewicz petition. Indeed, petitioners may file applications with DEA to grow their own marijuana for research purposes, 21 U.S.C. § 823(a), and petitioner Scottsdale Research Institute has already filed such an application. *See* 84 Fed. Reg. 44920, 44923 (Aug. 27, 2019) (notice of Scottsdale Research Institute's application to grow marijuana); 84 Fed. Reg. 54926 (Oct. 11, 2019) (amended notice). If petitioners are ultimately aggrieved by a DEA decision on their applications to grow marijuana, they may seek judicial review of that decision under 21 U.S.C. § 877.

those third parties are obviously able to protect their own interests. Indeed, Zyszkiewicz has filed multiple suits to challenge DEA's denial of his petition, and has filed another petition with DEA to reschedule marijuana. *See Zyszkiewicz v. Barr*, 2020 WL 3572908 (D.D.C. June 30, 2020); *Zyszkiewicz v. Barr*, No. 20-5213 (D.C. Cir.); *Zyszkiewicz v. DEA*, No. 20-1308 (D.C. Cir.); Opp. at 2, 6-7, *Zyszkiewicz v. DEA*, No. 20-1308 (D.C. Cir. Oct. 25, 2020) (describing Zyszkiewicz's subsequent petition for rulemaking).

Thus, there is "[n]o relationship, other than an incidental congruity of interest," that connects petitioners to Zyszkiewicz and Bowers, and there is no indication that Zyszkiewicz and Bowers are "disabled from asserting their own right in a proper case." *Warth*, 422 U.S. at 510. And while petitioners' interests may be "essentially co-terminous with" the interests of Zyszkiewicz and Bowers, that is insufficient to confer standing. *Hollingsworth v. Perry*, 570 U.S. 693, 708 (2013) (holding that plaintiffs' lacked standing to appeal a decision invalidating a state statute that the state had chosen not to appeal). At bottom, no matter "how deeply committed petitioners may be" to rescheduling marijuana, or "how zealous [their] advocacy," petitioners lack "a particularized interest sufficient to create a case or controversy under Article III." *Id.* at 707 (quotation marks omitted).

B. Petitioners Have Not Exhausted Their Administrative Remedies, And May Not Challenge The Denial Of Another Person's Petition For Rulemaking

For related reasons, the Court should dismiss the petition because petitioners have not exhausted their administrative remedies.

Any of the petitioners may ask DEA to consider rescheduling marijuana under 21 U.S.C. § 811(a), as Zyszkiewicz and Bowers did. If they do so, petitioners would be able raise the arguments they have raised to this Court, and DEA would be able to consider those arguments in the first instance. Petitioners may also submit evidence regarding marijuana's efficacy, safety, and use in medical treatment, which DEA and HHS can evaluate. *Id.* § 811(b). But petitioners "have made no attempt to exhaust that process" and "until they do so, they are not entitled to the relief they seek in this lawsuit." *Agua Caliente Tribe of Cupeño Indians of Pala Reservation v. Sweeney*, 932 F.3d 1207, 1216, 1219 (9th Cir. 2019).

The requirement that plaintiffs exhaust their administrative remedies before seeking judicial review "is well established in the jurisprudence of administrative law." *Woodford v. Ngo*, 548 U.S. 81, 88-89 (2006). Administrative exhaustion "serves two main purposes." *Id.* at 89. First, by requiring plaintiffs to first present their claims to the agency, exhaustion provides agencies "an opportunity to correct its own mistakes with respect to the programs it administers before it is haled into federal court, and it discourages disregard of [the agency's] procedures." *Id.* (quotation marks omitted). Second, exhaustion "promotes efficiency" by permitting claims to "be resolved much

more quickly and economically in proceedings before an agency." *Id.* In this way, the agency proceedings may grant plaintiffs the relief they seek, or otherwise "convince the losing party not to pursue the matter in federal court." *Id.* And even if plaintiffs ultimately seek judicial review, the completed administrative proceedings "may produce a useful record for subsequent judicial consideration." *Id.* Thus, the "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." *United Sates v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952); *Woodford*, 548 U.S. at 90 (collecting cases).

Consistent with these principles, this Court has held that plaintiffs must exhaust the administrative remedies available before seeking judicial review. Thus, an Indian tribe seeking federal recognition must first exhaust the Department of the Interior's administrative procedures for federal recognition before seeking judicial review. *Agua Caliente Tribe*, 932 F.3d at 1216-19. Similarly, aliens who are in removal proceedings and seek an adjustment of status must first seek that relief "during their pending removal proceedings," and may not seek judicial review "[u]ntil they have exhausted this available administrative remedy." *Cabaccang v. U.S. Citizenship and Immigration Services*, 627 F.3d 1313, 1316-17 (9th Cir. 2010). And parents who seek damages because they believe their child should have received a different placement under the Individuals with Disabilities Education Act may not pursue that action if

they "failed to exhaust" their administrative remedies. *Paul G. by and through Steve G. v. Monterey Peninsula Unified School Dist.*, 933 F.3d 1096, 1098 (9th Cir. 2019); *id.* at 1102.

In similar circumstances, the Second Circuit has held that plaintiffs must first exhaust their administrative remedies under the Controlled Substances Act before seeking judicial review. *Washington v. Barr*, 925 F.3d 109, 115-18 (2d Cir. 2019), *cert. denied*, --- S. Ct. ---, 2020 WL 6037234 (Oct. 13, 2020). The plaintiffs in *Washington* sued in district court to challenge marijuana's status as a schedule I substance, "but did not first bring this challenge to" the DEA, which "has the authority to reschedule marijuana." 925 F.3d at 115. In light of the rulemaking provisions provided by 21 U.S.C. § 811, the court held that "[r]equiring would-be plaintiffs to exhaust that process before turning to the courts is consonant with" Congress's purpose in passing the Controlled Substances Act. *Id.* at 116. That rescheduling process could potentially obviate any need for judicial review, because plaintiffs could persuade DEA to reschedule marijuana. *Id.* at 117. And at a minimum, the rulemaking process would "generate a comprehensive record that would aid in eventual judicial review." *Id.* And a contrary rule—allowing petitioners to bypass DEA and seek judicial intervention on their claims in the first instance—would "undermine the text and structure of the [Controlled Substances Act]." *Id.* Accordingly, the Second Circuit held that the plaintiffs must first exhaust their administrative remedies in a DEA rescheduling proceeding before seeking judicial review. *Id.* at 122. *See also John Doe, Inc. v. DEA*, 484 F.3d 561, 570 (D.C. Cir. 2007) (plaintiff must complete DEA

administrative process and seek review under 21 U.S.C. § 877 rather than "'jump the gun' by going directly to" court "instead of exhausting their administrative remedies before the agency"). The same reasoning requires dismissal here.[6]

As noted earlier, DEA moved to dismiss the petition for failure to exhaust administrative remedies, and this Court denied the motion without prejudice to consideration of the arguments at this stage. In opposing the motion, petitioners argued that exhaustion is not required because they raise a purely legal issue over which DEA has no expertise. Dkt. 14 at 17-18. Petitioners' argument is difficult to fathom: they urge, among other things, that DEA acted arbitrarily and capriciously in construing and applying the Controlled Substances Act, which it administers. That kind of decision goes to the heart of the agency's expertise. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 214-15 (1994) (holding that plaintiff must exhaust administrative remedies before filing suit because, among other things, "'agency expertise [could] be brought to bear on' the statutory questions presented here").

[6] The *Washington* court retained jurisdiction over the case while permitting the plaintiffs to petition DEA to reschedule marijuana. 925 F.3d at 122. For the reasons Judge Jacobs explained in his dissent, the correct course would have been to affirm the district court's dismissal of the suit for failure to exhaust administrative remedies. *Id.* at 122-24 (Jacobs, J., dissenting). As this Court has explained, a plaintiff "may not maintain [an] action after he failed to" exhaust administrative remedies. *Paul G.*, 933 F.3d at 1102. The Second Circuit did ultimately affirm dismissal of the case when plaintiffs refused to exhaust their administrative remedies. Order, *Washington v. Barr*, No. 18-859 (2d Cir. Feb. 3, 2020) (affirming district court's judgment and dismissing case with prejudice).

Petitioners cannot circumvent the statutory process on the ground that they also assert a nondelegation argument. The Supreme Court has made clear that litigants cannot side-step statutory procedures even they present purely constitutional challenges that are not intertwined with the substance of the agency's determination. In *Elgin v. Department of Treasury*, 567 U.S. 1 (2012), the Court considered a suit by federal employees who had been fired for failing to register for the draft, and those employees sought to assert a facial constitutional challenge to the Selective Service Act. The Supreme Court held that the employees must first exhaust their remedies under the Civil Service Reform Act, which allowed them to seek administrative review of their firings. *Id.* at 5. The Court declined to create an exception for "facial constitutional challenges to statutes," *id.* at 15, and explained that the agency could apply its expertise by potentially deciding in the employees' favor on other grounds, *id.* at 22-23.

In arguing that exhaustion was nevertheless not required here, petitioners relied on *Darby v. Cisneros*, 509 U.S. 137 (1993), *see* Dkt. 14 at 7-8, a decision that only underscores the absence of any authority for their position. In *Darby*, the Department of Housing and Urban Development initiated administrative proceedings against the plaintiffs and imposed a sanctions order against them that became final. 509 U.S. at 141. Although the plaintiffs could have sought further review within the agency by appealing to the Secretary, they instead filed suit in district court to challenge the sanctions order. *Id.* at 141-42. The Supreme Court held that the plaintiffs did not

need to seek further administrative review before filing their district court suit because they were not required to do so by statute or regulation, and because they were challenging final agency action under the Administrative Procedure Act. *Id.* at 153-54. Here, by contrast, petitioners never participated in any administrative proceeding, and never petitioned DEA to reschedule marijuana.

Petitioner's reliance on *Pacific Maritime Ass'n v. NLRB*, 827 F.3d 1203 (9th Cir. 2016), is equally inapposite. In that case, the plaintiff trade association took advantage of the available administrative remedies by seeking to intervene in NLRB administrative proceedings and filing briefs in those proceedings. *Id.* at 1205-06. Although the NLRB ultimately denied its intervention attempts, this Court held that the plaintiff was "aggrieved" by the NLRB's denial of intervention and NLRB's order regarding a labor dispute that directly affected the employment contract for one of plaintiff's member businesses. *Id.* at 1206, 1211. Accordingly, the plaintiff could seek judicial review under the applicable statute. *Id.* at 1211. Here, in contrast, petitioners have made no attempt to avail themselves of any administrative remedies. They did not join Zyszkiewicz and Bowers in filing a petition, nor did they file an separate petition to set out their own arguments for DEA's consideration. And even assuming that petitioners could seek review of the denial of the Zyszkiewicz petition—notwithstanding their own failure to file a petition and the separate request for judicial

review made by Zyszkiewicz himself—they could not pursue a challenge based on arguments never presented to the agency.[7]

In short, there is no excuse for petitioners' failure to ask the agency in the first instance to consider their claims and to reschedule marijuana, as Congress provided for in 21 U.S.C. § 811(a). The Court should accordingly dismiss the petition. *Washington*, 925 F.3d at 115-18.

II. DEA APPROPRIATELY DENIED THE ZYSZKIEWICZ PETITION FOR RULEMAKING

If the Court were to address petitioners' challenge to DEA's denial of the Zyszkiewicz petition, it should reject petitioners' arguments on the merits.

A. DEA's Denial Was Reasonable And Appropriate

1. The action challenged here is DEA's denial of Zyszkiewicz and Bowers' one-page petition to reschedule marijuana. ER1. The petition noted that in 2016,

[7] *Bonds v. Tandy*, 457 F.3d 409 (5th Cir. 2006), and *PDK Laboratories Inc. v. DEA*, 362 F.3d 786 (D.C. Cir. 2004), also cited by petitioners, are similarly unavailing. The question in both cases was one of prudential standing, not administrative exhaustion. The petitioner in *PDK Laboratories* completed all administrative proceedings before seeking judicial review. 362 F.3d at 790-91. The petitioner in *Bonds* had been denied employment at a pharmacy under applicable DEA regulations because of a past criminal conviction. 457 F.3d at 411. Bonds' prospective employer sought a waiver from DEA, and when the waiver was denied, Bonds sought review of that order. *Id.* Petitioners appear to analogize their circumstances to those in *Bonds*, in that the employer, rather than Bonds himself, sought relief from DEA. But that analogy is inapt—unlike petitioners, Bonds was the subject of an application made to DEA, which could only be made by his employer, and the merits of that application had been presented to DEA. Even so, the Fifth Circuit held that Bonds lacked prudential standing because the waiver provision was not designed to protect his interests. *Id.* at 415-16.

California had passed the Adult Use of Marijuana Act to "insure a comprehensive regulatory system that take production and sales away from an illegal market." ER1. Based on that state law and petitioners' assertion that "[h]alf the states allow for medical use and the FDA allows CBD and THC pharmaceuticals was well as IND compassionate use," the petition argued that keeping marijuana "in schedule I [was] completely untenable." ER1. The petition presented no other argument for rescheduling marijuana or removing it from the list of controlled substances.

DEA appropriately denied that petition because it presented no basis for rescheduling. Individual states may pass laws that decriminalize marijuana under state law and provide for its use as a medical treatment. But those laws, standing by themselves, do not demonstrate that marijuana has an accepted medical use such that it can be rescheduled from schedule I. 21 U.S.C. § 812(b)(1)(B). That is a factual question, and the one-page petition presented no evidence on it. Nor did the petition argue that DEA should change its regulatory framework for determining whether a substance has an accepted medical use. Because the petition presented no plausible basis to reschedule marijuana, DEA acted reasonable in declining to institute rulemaking. *See Massachusetts v. EPA*, 549 U.S. 497, 527-28 (2007) (judicial review of an agency's refusal to promulgate a rule is "extremely limited" and "highly deferential"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must provide a "rational connection between the facts found and the choice made").

In this Court, petitioners press arguments that were not raised in Zyszkiewicz's petition for rulemaking and which DEA never had an opportunity to consider. Under basic principles of administrative law, the Court should decline to consider these arguments raised for the first time on judicial review. "A reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented," and "absent exceptional circumstances, a reviewing court will refuse to consider contentions not presented before the administrative proceeding at the appropriate time." *Getty Oil Co. v. Andrus*, 607 F.2d 253, 256 (9th Cir. 1979) (collecting cases). Plainly, DEA cannot have acted arbitrarily and capriciously by not addressing arguments and evidence not presented to it.

2. If the Court were to engage with petitioners' arguments, those arguments lack merit.

To determine whether a substance has a currently accepted medical use, DEA has promulgated a five-factor test to evaluate whether:

1. The substance's chemistry is known and reproducible;
2. There are adequate safety studies;
3. There are adequate and well-controlled studies proving efficacy;
4. The substance is accepted by qualified experts; and
5. The scientific evidence is widely available.

57 Fed. Reg. 10499, 10506 (Mar. 26, 1992). In denying the petition, DEA referenced its 2016 analysis of the medical and scientific literature on marijuana, which was conducted in conjunction with HHS in response to a petition to reschedule marijuana under 21 U.S.C. § 811(a). Under that process, DEA was required to defer to HHS's

findings and recommendations on "scientific and medical matters." 21 U.S.C. § 811(b).

As explained at length in the 2016 analysis, none of the five factors for establishing a "currently accepted medical use" were satisfied. ER19-21 (HHS evaluation of the five-factor test); ER33-44 (HHS review and summary of the scientific literature); ER74-75 (DEA application of HHS findings to the five-factor test). First, HHS explained that marijuana includes all existing strains of the cannabis plant, and therefore its chemistry "is not reproducible such that a standardized dose can be created," although it remains possible that this could be overcome is a specific cannabis strain were "cultivated and processed under controlled conditions." ER74. Second, HHS's scientific review indicated that "there are no adequate safety studies on marijuana." ER74. Third, HHS noted there were several marijuana studies that "could be used as proof of concept studies" to "provid[e] preliminary evidence" for possible treatment, but there "are no adequate or well-controlled studies that prove marijuana's efficacy" for treating a specific condition. ER74-75. Fourth, HHS concluded that "there is currently no evidence of a consensus among qualified experts that marijuana is safe and effective in treating a specific and recognized disorder," and that "state-level medical marijuana laws do not provide evidence of such a consensus among qualified experts." ER75. Fifth, HHS found that "the currently available data and information on marijuana is not sufficient to allow scientific scrutiny of the chemistry, pharmacology, toxicology, and effectiveness." ER75.

Petitioners do not challenge those factual findings, and do not point to any evidence or current studies that would contradict them.

Instead, petitioners argue that the phrase "currently accepted medical use in treatment in the United States" is so clear that DEA is statutorily prohibited from using its five-factor test. Br. 47 (arguing that "DEA's interpretation * * * cannot be squared with the ordinary meaning of the words of the statute"). In other words, petitioners argue that state marijuana laws preclude DEA from considering whether a drug has a reproducible chemistry, whether there are adequate studies demonstrating the drug's safety and efficacy, and whether the scientific evidence underlying the drug is widely available in determining whether *any* drug has a "currently accepted medical use." But Congress did not require DEA to accept the judgments of state legislatures regardless of whether or how a state evaluated relevant scientific evidence. Studies presented to state legislatures might provide a basis for urging DEA to review the pertinent scientific questions. But DEA is no more bound by the determinations of the states that have legalized marijuana for some or all uses than it is bound by the view of the states that have made marijuana illegal in all circumstances.

Petitioners note that DEA considers a drug to have an "accepted medical use" when approved by FDA, and they urge that it must therefore accept the determinations of several state legislatures in the same way. Br. 74 (citing ER59). When FDA approves a new drug application, FDA evaluates "full reports of investigations which have been made to show whether" the drug "is safe for use and

* * * effective in use," and FDA examines the "full list of articles used as components" in the drug and "the composition of" the drug. 21 U.S.C. § 355(b)(1). FDA approval often involves more than just these considerations, but approval does indicate that a drug is safe and effective and has been extensively studied. State laws concerning marijuana are not required to be premised on the same rigorous and extended scrutiny that precedes FDA's approval of a new drug application.

At bottom, petitioners contend that because several states have permitted doctors to prescribe marijuana, DEA cannot deny a petition to reschedule marijuana. That position is remarkable. There are a number of drugs besides marijuana currently listed in schedule I, including heroin[8] and methaqualone[9] (also known as Quaalude). In petitioners' view, if several states allowed for doctors to prescribe those drugs, then DEA would act unlawfully if it kept those drugs controlled under schedule I, even if there was extensive scientific evidence that those drugs are dangerous and fail to effectively treat any medical condition. There is no support for that position.

The cases on which petitioners seek to rely confirm that the statutory phrase "currently accepted medical use in treatment in the United States" does not require DEA to forgo evaluation of scientific and medical studies simply because state legislatures have legalized the use of marijuana. As the First Circuit explained in *Grinspoon v. DEA*, 828 F.2d 881, 885 (1st Cir. 1987), it is "undisputed that Congress

[8] 21 U.S.C. § 812(c), schedule I(b)(10).
[9] Pub. L. No. 89-329, 98 Stat. 280 (1984); 21 C.F.R. § 1308.11(e)(3).

has not directly spoken to the question at issue here, namely, the proper means of interpreting the second and third criteria of section 812(b)(1)," *i.e.*, whether a substance has a currently accepted medical use, and whether there is a lack of accepted safety for using the substance under medical supervision, 21 U.S.C. § 812(b)(1)(B)-(C). The fact that the statute uses "the term 'accepted' does not cure the statute's ambiguity," *Grinspoon*, 828 F.2d at 885, and there is "nothing to indicate how Congress affirmatively intended" the "ambiguous" phrase "currently accepted medical use" should be "construed and applied," *id.* at 892. Instead, "Congress has implicitly delegated to the [DEA] Administrator the authority to interpret these portions of the [Controlled Substances Act], and we must therefore refrain from imposing our own statutory interpretation upon the agency." *Id.* (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984)).

The D.C. Circuit is in accord with that analysis. That court has considered a number of challenges to marijuana's status as a schedule I substance, and explained that "neither the statute nor its legislative history precisely defines the term 'currently accepted medical use'; therefore, we are obliged to defer to the [DEA] Administrator's interpretation of that phrase if reasonable." *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991). And in interpreting "currently accepted medical use," DEA acts appropriately in examining "the lack of exact scientific knowledge as to the chemical effects of the drug's elements." *Id.* Accordingly, the D.C. Circuit has repeatedly approved of DEA's five-factor test for determining whether a substance a

currently accepted medical use. *Alliance for Cannabis Therapeutics v. DEA,* 15 F.3d 1131, 1134 (D.C. Cir. 1994) ("We noted the ambiguity of the phrase and the dearth of legislative history on point and deferred to the Administrator's interpretation as reasonable."); *Americans for Safe Access v. DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013) (explaining that the court "expressly approved" DEA's five-factor test); *Krumm v. DEA*, 739 F. App'x 655 (D.C. Cir. 2018) (per curiam) (same).

3. If necessary to determine whether DEA's denial of rulemaking was reasonable, it would be appropriate to defer to DEA's interpretation of the statutory phrase "currently accepted medical use in treatment" in 21 U.S.C. § 812(b)(1)(B). That phrase is subject to multiple reasonable interpretations and DEA has properly construed its meaning through rulemaking. This Court reviews DEA's construction of the Controlled Substances Act under the familiar *Chevron* framework, *see Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1015 (9th Cir. 2004); *United States v. Kelly*, 874 F.3d 1037, 1050-51 (9th Cir. 2017), and will sustain DEA's rule if it is "based on a permissible construction" of the statute, *Barnhart v. Walton,* 535 U.S. 212, 218 (2002). DEA's rule easily satisfies that test—it evaluates whether a substance's chemistry can be reproduced, whether it has been demonstrated to be safe and effective in studies, whether relevant medical experts accept its use in treatment, and whether the underlying data is widely available. 57 Fed. Reg. at 10506. Those are all reasonable factors to consider when determining whether a substance as a currently accepted

medical use, and petitioners identify nothing in the statute that prohibits DEA from considering those factors.

Petitioners argue that DEA must defer to state laws that permit marijuana to be prescribed for medical uses, relying on *Gonzales v. Oregon*, 546 U.S. 243 (2006). But *Oregon* did not concern whether DEA had correctly placed a substance on a controlled schedule. All parties agreed that the drugs at issue were correctly listed in schedule II and could be prescribed by a physician registered with DEA to dispense controlled substances. *Id.* at 250-51. The case instead concerned an Oregon law that permitted physicians to prescribe drugs to terminally ill patients who could then end their lives by ingesting a lethal dose of the prescribed drugs. *Id.* at 251-52. DEA did not determine that these drugs warranted rescheduling, and DEA did not determine that revocation of any physician's registration was warranted under 21 U.S.C. §§ 823-824. *Oregon*, 546 U.S. at 259-61. Rather, the Attorney General promulgated an interpretive rule stating "[a]ssisting suicide is not a 'legitimate medical purpose' * * * and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the Controlled Substances Act." *Id.* at 254. The Supreme Court held that this interpretive rule was without statutory support, explaining, *inter alia*, that the rule "was not issued [under] the required procedures for rules regarding scheduling." *Id.* at 260.

Here, by contrast, there is no doubt that there is statutory support for marijuana's placement on schedule I, because Congress put marijuana on schedule I.

21 U.S.C. § 812(c), schedule I(c)(10). And there is no doubt that DEA followed the required procedures for determining whether marijuana met the statutory criteria for continued placement on schedule I under 21 U.S.C. § 812(b)(1). *See* ER2, 8-80. Accordingly, DEA's denial of the Zyszkiewicz petition was appropriately based on the agency's conclusion that the petition failed to point to any evidence that marijuana had a "currently accepted medical use in treatment in the United States." DEA's interpretation of that ambiguous statutory phrase warrants deference, "not because [DEA] is better situated to interpret statutes," but because "Congress created gaps in the statutory scheme that cannot be filled through interpretation alone, but require the exercise of policymaking judgment." *Garfias-Rodriguez v. Holder*, 702 F.3d 504, 515 (9th Cir. 2012) (en banc) (citing *Chevron*). Thus, DEA's interpretation of what constitutes a currently accepted medical use "is not a once-and-for-always definition of what the statute means, but an act of interpretation in light of its policymaking responsibilities that may be reconsidered 'on a continuing basis.'" *Id.* at 515-16. A petitioner may urge DEA to revise its regulatory test, or DEA itself may reconsider whether a different test for determining accepted medical use should apply. But that authority rests with DEA, and the Court should not disturb DEA's reasonable inquiry into a substance's safety and efficacy in determining whether a substance meets the statutory criteria for placement on schedule I.

Petitioners err in suggesting that *Chevron* deference is inapplicable to the Controlled Substances Act because the Act has criminal applications. Br. 68-69. Any

concerns about fair notice of what the criminal law requires are absent here, where it is obvious from the Controlled Substances Act that marijuana is a schedule I substance. 21 U.S.C. § 812(c), schedule I(c)(10). And this Court has previously explained that it analyzes the Controlled Substances Act and DEA's scheduling decisions under the familiar *Chevron* framework. *Hemp Indus. Ass'n*, 357 F.3d at 1015; *Kelly*, 874 F.3d at 1050.

4. Petitioners raise several other contentions, none of which is availing. Petitioners contend that it is arbitrary and capricious to evaluate whether marijuana has a known and reproducible chemistry. Br. 71-72. DEA has explained that this is necessary to determine proper dosage levels for marijuana if it is used as a medical treatment, to further ensure that it can be administered safely and effectively. ER19. Moreover, this requirement is properly understood within the framework of DEA's five-factor test which is designed not just for marijuana, but for determining whether *any* controlled substance has a currently accepted medical use. And as DEA explained, this requirement of a known and reproducible chemistry can be satisfied if a specific cannabis strain can be cultivated under strictly controlled conditions. ER19. Alternatively, specific chemicals may be extracted from marijuana or otherwise synthesized, and those chemicals may satisfy this criteria. For example, dronabinol is a synthetic cannabinoid that is listed on schedules II and III, 21 C.F.R. §§ 1308.12(f)(2), 1308.13(g)(1), which can be used to treat nausea and vomiting in chemotherapy patients.

Petitioners assert that some FDA-approved drugs lack a known and reproducible chemistry, and argue that this demonstrates that DEA acted unreasonably in considering this factor. Br. 75. On this record, it is unclear whether petitioners are correct in their assertion that FDA-approved drugs lack a reproducible chemistry. If petitioners had asked DEA to reschedule marijuana and presented evidence on this point, DEA could have considered their claim and offered a response. Assuming that petitioners are correct in their factual assertion, petitioners present no evidence that marijuana satisfies any other portion of the five-part test such that it should be rescheduled. And in any event, petitioners have not demonstrated that this objection would entitle them to have marijuana rescheduled. Instead, assuming that petitioners were correct, DEA might determine that the proper course would be to require all substances—including FDA-approved drugs—to satisfy the five-part test to demonstrate a "currently accepted medical use" if such drugs have a high potential for abuse and would otherwise be subject to schedule I.

B. Petitioners' Nondelegation Argument Is Insubstantial

The Constitution vests the legislative power in Congress, U.S. Const. art. I, § 1, and that power may not be delegated to the Executive Branch. *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 472 (2001). Thus, to comply with the nondelegation principle, Congress must "lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform." *Id.* This is not a demanding standard. The Supreme Court has explained that Congress provides an

intelligible principle when it directs a federal agency to set air quality standards that are "requisite to protect the public health," *id.* at 473-74, or to temporarily schedule a drug as a controlled substance if it is "necessary to avoid an imminent hazard to public health," *Touby v. United States,* 500 U.S. 160, 163 (1991), or to set prices that "will be generally fair and equitable and will effectuate the purposes of this Act," *Yakus v. United States*, 321 U.S. 414, 420 (1944). And the Court has repeatedly upheld "various statutes authorizing regulation in the 'public interest.'" *American Trucking*, 531 U.S. at 474. Under this standard, the Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law." *Id.* at 474-75.

Under the Controlled Substances Act, Congress—not DEA—designated marijuana as a schedule I controlled substance. *See* Pub. L. No. 91-513, title II, § 202(c) (schedule I(c)(10)), 84 Stat. 1242, 1249 (1970) (codified at 21 U.S.C. § 812(c), schedule I(c)(10)). Thus, when DEA denied the Zyszkiewicz petition, it in no way altered Congress's statutory proclamation that marijuana was qualified to be controlled under schedule I, that it had no accepted medical use in the United States, and that it had a high potential for abuse. Because DEA's denial of rulemaking refused to alter Congress's placement of marijuana on schedule I, there is no way that DEA impermissible exercised Congress's legislative power.

Indeed, DEA explained in its denial why it was not initiating rulemaking based on Congress's directions for scheduling controlled substances, ER2, which are set

forth in 21 U.S.C. § 812(b). *See also* ER7 ("The statutory mandate of Title 21 United States Code, Section 812(b) * * * is dispositive"). Under that provision, a substance will be placed on schedule I if it has a "high potential for abuse," if it has "no currently accepted medical use in treatment in the United States," and if there "is a lack of accepted safety for use * * * under medical supervision." *Id.* § 812(b)(1). This Court has already explained that § 812(b) sets forth an intelligible principle to guide DEA's exercise of executive authority and does not offend the nondelegation principle. *Kelly*, 874 F.3d at 1047-48.

In *Kelly*, this Court considered a criminal defendant's nondelegation challenge temporary placement of a substance, as authorized under 21 U.S.C. § 811(h), onto schedule I, as authorized under 21 U.S.C. § 812(b). 874 F.3d at 1047. The Court explained that the requirements in § 812(b) for placing substances schedule I contained "specific restrictions on the [DEA]'s discretion" and "satisfy the constitutional requirements of the nondelegation doctrine." *Id.* (quoting *Touby*, 500 U.S. at 165); *id.* at 1048 ("Thus, by complying with §§ 811(h) and 812(b)'s 'specific restrictions on [its] discretion to define criminal conduct,' the DEA's temporary scheduling of ethylone did not amount to an exercise of legislative power in violation of the non-delegation doctrine.").

Petitioners assert that a different statutory provision, 21 U.S.C. § 811(d), implicates the nondelegation doctrine because it provides that the United States must consider information provided by the United Nations and the World Health

Organization. Br. 76-78. Under 21 U.S.C. § 811(d)(2), the Secretary of State may receive information from the United Nations and the World Health Organization that "may justify adding a drug or other substance to one of the schedules" or "transferring a drug" between schedules, or "deleting it from the schedules." If such information is received, the Secretary of State notifies the Secretary of Health and Human Services, who issues a notice in the Federal Register to "provide opportunity for interested persons to submit" comments about the substance. *Id.* The government may then determine to take further action, but it is not required to do so. Contrary to petitioners' suggestion, the statute does not delegate any legislative authority to the World Health Organization.

In any event, that statutory provision has no application here. DEA did not deny the petition for rulemaking based on any new information submitted to the Secretary of State under § 811(d)(2), and that provision has no bearing on the case.

Petitioners also contend that DEA's denial violates the nondelegation doctrine because 21 U.S.C. § 811(d)(1) grants the Attorney General authority to ensure that the United States complies with its international treaty obligations. Br. 79-80. Under § 811(d)(1), if control of a substance "is required by United States obligations under international treaties, conventions, or protocols in effect" as of October 1970, then 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" 21 U.S.C. §§ 811(a) and 812(b). As relevant to marijuana, that

provision is directed to ensure that the United States complies with its treaty obligations under the Single Convention on Narcotic Drugs, which was ratified by the Senate in 1967, *see* 18 U.S.T. 1407. The treaty requires signatories to "prohibit the production, manufacture" and "trade in, possession or use of" marijuana "except for amounts which may be necessary for medical and scientific research only." 18 U.S.T. 1407, art. 2.5(b) (requirements for drugs listed in the treaty's schedule IV).

As an initial matter, the direction Congress provided in 21 U.S.C. § 811(d)(1) to ensure compliance with treaty obligations is consistent with the nondelegation principles. Like a command to "effectuate the purposes of [an] Act," *Yakus*, 321 U.S. at 420, or to issue regulations "in the 'public interest,'" *American Trucking*, 531 U.S. at 474, Congress provided an intelligible principle in directing DEA to schedule substances under the Controlled Substances Act in order to "carry out such obligations" as provided in a ratified treaty, 21 U.S.C. § 811(d)(1).

Petitioners resist this conclusion, arguing that § 811(d)(1) must lack an intelligible principle because it allows the DEA to place substances in a schedule without regard to the statutory factors listed in § 812(b). Br. 80. But petitioners do not dispute that DEA did, in fact, consider the statutory factors listed in § 812(b), and explained 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." ER2. DEA supported that conclusion by referencing its exhaustive 2016 analysis of the medical and scientific literature on marijuana's use as a medical

treatment, in which it determined "that marijuana has no currently accepted medical use in treatment in the United States." ER8.[10] DEA made that determination in conjunction with a scientific review conducted by HHS, which explained that "[m]arijuana meets the three criteria for placing a substance in Schedule I of the [Controlled Substances Act] under 21 U.S.C. § 812(b)(1)." ER8. Throughout the 2016 decision, DEA consistently re-iterated that it was analyzing whether marijuana met the statutory factors in § 812(b) to be controlled under schedule I. *See, e.g.*, ER25-26 (walking through the statutory factors in § 812(b)(1)); ER33 (analyzing whether marijuana meets the § 812(b)(1) factors); ER58 (explaining that DEA "must determine whether there is substantial evidence to conclude that the drug meets the criteria for placement in another schedule based on the criteria set forth in 21 U.S.C. § 812(b)"); ER80 ("DEA finds that marijuana meets the three criteria for placing a substance in schedule I" under § 812(b)(1). As and this Court has already explained, those factors—including whether a substance has a "currently accepted medical use in treatment in the United States"—provide DEA with an intelligible principle to execute the law that Congress has duly enacted. *Kelly*, 874 F.3d at 1047-48.

[10] In its 2016 decision, DEA stated that it did not need to "evaluate the relative abuse potential of marijuana or the relative extent to which abuse of marijuana may lead to physical or psychological dependence," given the United States' obligation to control marijuana consistent with its treaty obligations and the statutory authority under 21 U.S.C. § 811(d). ER8. Petitioners do not contest that marijuana is subject to abuse by being used for non-medical purposes, or that it may lead to physical or psychological dependence.

CONCLUSION

The petition should be dismissed for lack of jurisdiction and for failure to exhaust administrative remedies. If the Court were to reach the merits, the petition should be denied.

Respectfully submitted.

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NOVEMBER 2020

STATEMENT OF RELATED CASES

Zyszkiewicz v. Barr, No. 20-1599 (D.D.C.). Plaintiff Zyszkiewicz filed this district court suit to challenge DEA's denial of his rulemaking petition, which petitioners also challenge in this case. The district court dismissed the suit on June 30, 2020. *Zyszkiewicz v. Barr*, 2020 WL 3572908 (D.D.C.). Zyszkiewicz filed an appeal, which is pending in the D.C. Circuit. *Zyszkiewicz v. Barr*, No. 20-5213 (D.C. Cir.).

Zyszkiewicz v. DEA, No. 20-1308 (D.C. Cir.). Petitioner Zyszkiewicz filed this petition in the court of appeals to challenge DEA's denial of his rulemaking petition, which petitioners also challenge in this case. The case is pending.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font. I further certify that this brief complies with the type-volume limitation of Circuit Rule 32-1(a) because it contains 11,280 words, excluding the parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word 2016.

/s/ Daniel Aguilar
Daniel Aguilar

ADDENDUM

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21 U.S.C. § 811. Authority and criteria for classification of substances.

(a) Rules and regulations of Attorney General; hearing

The Attorney General shall apply the provisions of this subchapter to the controlled substances listed in the schedules established by section 812 of this title and to any other drug or other substance added to such schedules under this subchapter. Except as provided in subsections (d) and (e), the Attorney General may by rule--

(1) add to such a schedule or transfer between such schedules any drug or other substance if he--

(A) finds that such drug or other substance has a potential for abuse, and

(B) makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed; or

(2) remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party.

(b) Evaluation of drugs and other substances

The Attorney General shall, before initiating proceedings under subsection (a) to control a drug or other substance or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation, and his recommendations, as to whether such drug or other substance should be so controlled or removed as a controlled substance. In making such evaluation and recommendations, the Secretary shall consider the factors listed in paragraphs (2), (3), (6), (7), and (8) of subsection (c) and any scientific or medical considerations involved in paragraphs (1), (4), and (5) of such subsection. The recommendations of the Secretary shall include recommendations with respect to the appropriate schedule, if any, under which such drug or other substance should be listed. The evaluation and the recommendations of the Secretary shall be made in writing and submitted to the Attorney General within a reasonable time. The recommendations of the Secretary to the Attorney General shall be binding on the

Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance. If the Attorney General determines that these facts and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or substantial evidence that the drug or other substance should be removed entirely from the schedules, he shall initiate proceedings for control or removal, as the case may be, under subsection (a).

(c) Factors determinative of control or removal from schedules

In making any finding under subsection (a) of this section or under subsection (b) of section 812 of this title, the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:

(1) Its actual or relative potential for abuse.

(2) Scientific evidence of its pharmacological effect, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

(d) International treaties, conventions, and protocols requiring control; procedures respecting changes in drug schedules of Convention on Psychotropic Substances

(1) 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 this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section.

(2) (A) Whenever the Secretary of State receives notification from the Secretary-General of the United Nations that information has been transmitted by or to the World Health Organization, pursuant to article 2 of the Convention on Psychotropic Substances, which may justify adding a drug or other substance to one of the schedules of the Convention, transferring a drug or substance from one schedule to another, or deleting it from the schedules, the Secretary of State shall immediately transmit the notice to the Secretary of Health and Human Services who shall publish it in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the scientific and medical evaluations which he is to prepare respecting such drug or substance. The Secretary of Health and Human Services shall prepare for transmission through the Secretary of State to the World Health Organization such medical and scientific evaluations as may be appropriate regarding the possible action that could be proposed by the World Health Organization respecting the drug or substance with respect to which a notice was transmitted under this subparagraph.

(B) Whenever the Secretary of State receives information that the Commission on Narcotic Drugs of the United Nations proposes to decide whether to add a drug or other substance to one of the schedules of the Convention, transfer a drug or substance from one schedule to another, or delete it from the schedules, the Secretary of State shall transmit timely notice to the Secretary of Health and Human Services of such information who shall publish a summary of such information in the Federal Register and provide opportunity to interested persons to submit to him comments respecting the recommendation which he is to furnish, pursuant to this subparagraph, respecting such proposal. The Secretary of Health and Human Services shall evaluate the proposal and furnish a recommendation to the Secretary of State which shall be binding on the representative of the United States in discussions and negotiations relating to the proposal.

(3) When the United States receives notification of a scheduling decision pursuant to article 2 of the Convention on Psychotropic Substances that a drug or other substance has been added or transferred to a schedule specified in the notification or receives notification (referred to in this subsection as a "schedule notice") that existing legal controls applicable under this subchapter to a drug or substance and the controls required by the Federal Food, Drug, and Cosmetic Act do not meet the requirements of the schedule of the Convention in which such drug or substance has been placed, the Secretary of Health and Human Services after consultation with the Attorney General, shall first determine whether existing legal controls under this subchapter applicable to the drug or substance and the controls

required by the Federal Food, Drug, and Cosmetic Act, meet the requirements of the schedule specified in the notification or schedule notice and shall take the following action:

(A) If such requirements are met by such existing controls but the Secretary of Health and Human Services nonetheless believes that more stringent controls should be applied to the drug or substance, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance, pursuant to subsections (a) and (b) of this section, to apply to such controls.

(B) If such requirements are not met by such existing controls and the Secretary of Health and Human Services concurs in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to subsections (a) and (b) of this section.

(C) If such requirements are not met by such existing controls and the Secretary of Health and Human Services does not concur in the scheduling decision or schedule notice transmitted by the notification, the Secretary shall--

(i) if he deems that additional controls are necessary to protect the public health and safety, recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to subsections (a) and (b) of this section, to apply such additional controls;

(ii) request the Secretary of State to transmit a notice of qualified acceptance, within the period specified in the Convention, pursuant to paragraph 7 of article 2 of the Convention, to the Secretary-General of the United Nations;

(iii) request the Secretary of State to transmit a notice of qualified acceptance as prescribed in clause (ii) and request the Secretary of State to ask for a review by the Economic and Social Council of the United Nations, in accordance with paragraph 8 of article 2 of the Convention, of the scheduling decision; or

(iv) in the case of a schedule notice, request the Secretary of State to take appropriate action under the Convention to initiate proceedings to remove the drug or substance from the schedules under the Convention or to

transfer the drug or substance to a schedule under the Convention different from the one specified in the schedule notice.

(4) (A) If the Attorney General determines, after consultation with the Secretary of Health and Human Services, that proceedings initiated under recommendations made under paragraph[1] (B) or (C)(i) of paragraph (3) will not be completed within the time period required by paragraph 7 of article 2 of the Convention, the Attorney General, after consultation with the Secretary and after providing interested persons opportunity to submit comments respecting the requirements of the temporary order to be issued under this sentence, shall issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. In the case of proceedings initiated under subparagraph (B) of paragraph (3), the Attorney General, concurrently with the issuance of such order, shall request the Secretary of State to transmit a notice of qualified acceptance to the Secretary-General of the United Nations pursuant to paragraph 7 of article 2 of the Convention. A temporary order issued under this subparagraph controlling a drug or other substance subject to proceedings initiated under subsections (a) and (b) of this section shall expire upon the effective date of the application to the drug or substance of the controls resulting from such proceedings.

(B) After a notice of qualified acceptance of a scheduling decision with respect to a drug or other substance is transmitted to the Secretary-General of the United Nations in accordance with clause (ii) or (iii) of paragraph (3)(C) or after a request has been made under clause (iv) of such paragraph with respect to a drug or substance described in a schedule notice, the Attorney General, after consultation with the Secretary of Health and Human Services and after providing interested persons opportunity to submit comments respecting the requirements of the order to be issued under this sentence, shall issue an order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention in the case of a drug or substance for which a notice of qualified acceptance was transmitted or whichever the Attorney General determines is appropriate in the case of a drug or substance described in a schedule notice. As a part of such order, the Attorney General shall, after consultation with the Secretary, except such drug or substance from

the application of any provision of part C of this subchapter which he finds is not required to carry out the United States obligations under paragraph 7 of article 2 of the Convention. If, as a result of a review under paragraph 8 of article 2 of the Convention of the scheduling decision with respect to which a notice of qualified acceptance was transmitted in accordance with clause (ii) or (iii) of paragraph (3)(C)--

(i) the decision is reversed, and

(ii) the drug or substance subject to such decision is not required to be controlled under schedule IV or V to carry out the minimum United States obligations under paragraph 7 of article 2 of the Convention,

the order issued under this subparagraph with respect to such drug or substance shall expire upon receipt by the United States of the review decision. If, as a result of action taken pursuant to action initiated under a request transmitted under clause (iv) of paragraph (3)(C), the drug or substance with respect to which such action was taken is not required to be controlled under schedule IV or V, the order issued under this paragraph with respect to such drug or substance shall expire upon receipt by the United States of a notice of the action taken with respect to such drug or substance under the Convention.

(C) An order issued under subparagraph (A) or (B) may be issued without regard to the findings required by subsection (a) of this section or by section 812(b) of this title and without regard to the procedures prescribed by subsection (a) or (b) of this section.

(5) Nothing in the amendments made by the Psychotropic Substances Act of 1978 or the regulations or orders promulgated thereunder shall be construed to preclude requests by the Secretary of Health and Human Services or the Attorney General through the Secretary of State, pursuant to article 2 or other applicable provisions of the Convention, for review of scheduling decisions under such Convention, based on new or additional information.

(e) Immediate precursors

The Attorney General may, without regard to the findings required by subsection (a) of this section or section 812(b) of this title and without regard to the procedures prescribed by subsections (a) and (b) of this section, place an immediate precursor in the same schedule in which the controlled substance of which it is an immediate precursor is placed or in any other schedule with a higher numerical designation. If the Attorney General designates a substance as an immediate precursor and places it

in a schedule, other substances shall not be placed in a schedule solely because they are its precursors.

(f) Abuse potential

If, at the time a new-drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

(g) Exclusion of non-narcotic substances sold over the counter without a prescription; dextromethorphan; exemption of substances lacking abuse potential

(1) The Attorney General shall by regulation exclude any non-narcotic drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(2) Dextromethorphan shall not be deemed to be included in any schedule by reason of enactment of this subchapter unless controlled after October 27, 1970 pursuant to the foregoing provisions of this section.

(3) The Attorney General may, by regulation, exempt any compound, mixture, or preparation containing a controlled substance from the application of all or any part of this subchapter if he finds such compound, mixture, or preparation meets the requirements of one of the following categories:

(A) A mixture, or preparation containing a nonnarcotic controlled substance, which mixture or preparation is approved for prescription use, and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

(B) A compound, mixture, or preparation which contains any controlled substance, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(C) Upon the recommendation of the Secretary of Health and Human Services, a compound, mixture, or preparation which contains any anabolic steroid, which is intended for administration to a human being or an animal,

and which, because of its concentration, preparation, formulation or delivery system, does not present any significant potential for abuse.

(h) Temporary scheduling to avoid imminent hazards to public safety

(1) If the Attorney General finds that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, he may, by order and without regard to the requirements of subsection (b) relating to the Secretary of Health and Human Services, schedule such substance in schedule I if the substance is not listed in any other schedule in section 812 of this title or if no exemption or approval is in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act. Such an order may not be issued before the expiration of thirty days from--

(A) the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued, and

(B) the date the Attorney General has transmitted the notice required by paragraph (4).

(2) The scheduling of a substance under this subsection shall expire at the end of 2 years from the date of the issuance of the order scheduling such substance, except that the Attorney General may, during the pendency of proceedings under subsection (a)(1) with respect to the substance, extend the temporary scheduling for up to 1 year.

(3) When issuing an order under paragraph (1), the Attorney General shall be required to consider, with respect to the finding of an imminent hazard to the public safety, only those factors set forth in paragraphs (4), (5), and (6) of subsection (c), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(4) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(5) An order issued under paragraph (1) with respect to a substance shall be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under subsection (a) with respect to such substance.

(6) An order issued under paragraph (1) is not subject to judicial review.

(i) Temporary and permanent scheduling of recently emerged anabolic steroids

(1) The Attorney General may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Attorney General finds that--

(A) the drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(B) adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(2) An order issued under paragraph (1) shall not take effect until 30 days after the date of the publication by the Attorney General of a notice in the Federal Register of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Attorney General may, during the pendency of proceedings under paragraph (6), extend the temporary scheduling order for up to 6 months.

(3) The Attorney General shall transmit notice of an order proposed to be issued under paragraph (1) to the Secretary of Health and Human Services. In issuing an order under paragraph (1), the Attorney General shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph.

(4) A temporary scheduling order issued under paragraph (1) shall be vacated upon the issuance of a permanent scheduling order under paragraph (6).

(5) An order issued under paragraph (1) is not subject to judicial review.

(6) The Attorney General may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid under section 802(41) of this title. Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (1).

(j) Interim final rule; date of issuance; procedure for final rule

(1) With respect to a drug referred to in subsection (f), if the Secretary of Health and Human Services recommends that the Attorney General control the drug in schedule II, III, IV, or V pursuant to subsections (a) and (b), the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule controlling the drug in accordance with such subsections and section 812(b) of this title using the procedures described in paragraph (3).

(2) The date described in this paragraph shall be the later of--

(A) the date on which the Attorney General receives the scientific and medical evaluation and the scheduling recommendation from the Secretary of Health and Human Services in accordance with subsection (b); or

(B) the date on which the Attorney General receives notification from the Secretary of Health and Human Services that the Secretary has approved an application under section 505(c), 512, or 571 of the Federal Food, Drug, and Cosmetic Act or section 262(a) of Title 42, or indexed a drug under section 572 of the Federal Food, Drug, and Cosmetic Act, with respect to the drug described in paragraph (1).

(3) A rule issued by the Attorney General under paragraph (1) shall become immediately effective as an interim final rule without requiring the Attorney General to demonstrate good cause therefor. The interim final rule shall give interested persons the opportunity to comment and to request a hearing. After the conclusion of such proceedings, the Attorney General shall issue a final rule in accordance with the scheduling criteria of subsections (b), (c), and (d) of this section and section 812(b) of this title.

21 U.S.C. § 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III--

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) Schedule V--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmathadol.

(4) Alphameprodine.

(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrorphan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

(19) Dioxaphetyl butyrate.

(20) Dipipanone.

(21) Ethylmethylthiambutene.

(22) Etonitazene.

(23) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacylmorphan.

(29) Morpheridine.

(30) Noracymethadol.

(31) Norlevorphanol.

(32) Normethadone.

(33) Norpipanone.

(34) Phenadoxone.

(35) Phenampromide.

(36) Phenomorphan.

(37) Phenoperidine.

(38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Racemoramide.

(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Etorphine.

(10) Heroin.

(11) Hydromorphinol.

(12) Methyldesorphine.

(13) Methylhydromorphine.

(14) Morphine methylbromide.

(15) Morphine methylsulfonate.

(16) Morphine-N-Oxide.

(17) Myrophine.

(18) Nicocodeine.

(19) Nicomorphine.

(20) Normorphine.

(21) Pholcodine.

(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.

(2) 5-methoxy-3,4-methylenedioxy amphetamine.

(3) 3,4,5-trimethoxy amphetamine.

(4) Bufotenine.

(5) Diethyltryptamine.

(6) Dimethyltryptamine.

(7) 4-methyl-2,5-dimethoxyamphetamine.

(8) Ibogaine.

(9) Lysergic acid diethylamide.

(10) Marihuana.

(11) Mescaline.

(12) Peyote.

(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.

(15) Psilocybin.

(16) Psilocyn.

(17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639*o* of Title 7).

(18) 4-methylmethcathinone (Mephedrone).

(19) 3,4-methylenedioxypyrovalerone (MDPV).

(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).

(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).

(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).

(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).

(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) In paragraph (1):

(A) The term "cannabimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes--

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

(v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);

(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and

(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

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21 U.S.C. § 877. Judicial Review

All final determinations, findings, and conclusions of the Attorney General under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the Attorney General 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. Findings of fact by the Attorney General, if supported by substantial evidence, shall be conclusive.