[ORAL ARGUMENT NOT SCHEDULED]

No. 20-1376

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

HEMP INDUSTRIES ASSOCIATION and RE BOTANICALS, INC.,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION and ANNE MILGRAM, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,

Respondents.

On Petition for Review from the
Drug Enforcement Administration

BRIEF FOR RESPONDENTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici

Petitioners are Hemp Industries Association and RE Botanicals, Inc. Respondents are the Drug Enforcement Administration (DEA) and Anne Milgram, in her official capacity as Administrator of DEA. No amici have entered appearances.

B. Rulings Under Review

Petitioners seek review of a DEA rule entitled Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020).

C. Related Cases

This case has not previously been before the Court. *Hemp Industries Ass'n v. DEA*, No. 21-5111 (D.C. Cir.), which is also pending before the Court, is a related case within the meaning of D.C. Circuit Rule 28(a)(1)(C). The Court has ordered that the cases be scheduled for oral argument on the same day and before the same panel, along with a third case, *St. Croix v. DEA*, No. 21-1116 (D.C. Cir.). *See* Order (July 27, 2021).

/s/ Sarah Carroll
Sarah Carroll

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GLOSSARY

APA	Administrative Procedure Act
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
FDA	Food and Drug Administration
THC	Tetrahydrocannabinols

STATEMENT OF JURISDICTION

The Drug Enforcement Administration (DEA) published its final rule on August 21, 2020. *See* JA 1. The petition for review, which invokes the Court's jurisdiction under 5 U.S.C. §§ 702 and 706 and 21 U.S.C. § 877, was timely filed on September 18, 2020. *See* 21 U.S.C. § 877; *infra* Argument Part I (addressing the petition's timeliness at the Court's direction).

STATEMENT OF THE ISSUES

In the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490 (Farm Bill or 2018 Farm Bill), Congress narrowed the definitions of marijuana and tetrahydrocannabinols (THC) in the Controlled Substances Act (CSA) to exclude substances that the Farm Bill defined as "hemp." *See* 2018 Farm Bill §§ 10113, 12619, 132 Stat. at 4908-09, 5018 (codified at 7 U.S.C. § 1639o(1), 21 U.S.C. §§ 802(16), 812(c)). DEA regulations list all of the substances that are scheduled under the CSA. 21 C.F.R. §§ 1308.11-.15. After Congress enacted the Farm Bill, DEA issued a rule to conform those regulations to the amended statute by removing hemp substances from the regulatory definitions of "marijuana extract" and THC. 81 Fed. Reg. 51,639 (Aug. 21, 2020). Relying on this Court's precedent, DEA determined that notice and comment were unnecessary

because the rule "merely conform[ed] [DEA's] regulations to recent amendments to the CSA that ha[d] already taken effect." *Id.* at 51,642.

Petitioners are a company that apparently operates in the cannabis industry and a trade association representing individuals and entities interested in hemp. They challenge the rule on procedural grounds and assert that the rule unlawfully lifts restrictions on a Food and Drug Administration (FDA)–approved drug derived from cannabis and unlawfully purports to control naturally derived THC that is not hemp but is outside the CSA definition of marijuana.

The questions presented are:

1. Whether the petition for review for should be dismissed as untimely or for lack of standing.

2. Whether the rule unlawfully removes restrictions on the FDA-approved drug or purports to control previously unscheduled substances.

3. Whether DEA was required to engage in notice and comment or conduct a CSA scheduling action before promulgating the rule.

4. Whether the rule is invalid under the Federal Vacancies Reform Act of 1998, 5 U.S.C § 3345 *et seq.* (Vacancies Reform Act).

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

Under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, it is generally unlawful to manufacture, distribute, or dispense a controlled substance without a registration from the Attorney General. *See id.* §§ 822, 841(a)(1). Under the statute's comprehensive scheme, a controlled substance is assigned to one of five schedules based on its abuse potential, currently accepted medical use, and accepted safety for use under medical supervision. *See id.* § 812(a), (b). Congress may enact legislation to add substances to the CSA's schedules, remove substances from the schedules, or transfer substances between schedules. *See id.* § 812. The CSA sets out procedures by which the Attorney General may make similar changes. *See id.* § 811.[1]

[1] The Attorney General has delegated relevant authorities under the CSA to DEA. *See* 21 U.S.C. § 871(a); 28 C.F.R. § 0.100(b).

A. The Statutory And Regulatory Framework Before The 2018 Farm Bill

1. Congress placed marijuana on Schedule I when it enacted the CSA in 1970. *See* 21 U.S.C. § 812(c) (Schedule I (c)(10)); Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 202(c), 84 Stat. 1236, 1249.[2] Before the 2018 Farm Bill, the CSA defined marijuana to include

> all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

21 U.S.C. § 802(16) (2012). As a practical matter, this definition precluded cultivation of the cannabis plant in the United States, absent special authorization for research or for other purposes.[3]

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[2] The CSA and relevant regulations spell the word "marihuana," but this brief uses the contemporary spelling outside of direct quotations.

[3] In 2014, Congress authorized "institution[s] of higher education" and "State department[s] of agriculture" to "grow or cultivate" what Congress defined as "industrial hemp" "for purposes of research" if permitted by state law, "[n]otwithstanding the Controlled Substances

Congress also placed "tetrahydrocannabinols" on Schedule I when it enacted the CSA. *See* 21 U.S.C. § 812(c) (Schedule I (c)(17)); Comprehensive Drug Abuse Prevention and Control Act of 1970, § 202(c), 84 Stat. at 1249. THC, which is not defined in the statute, is a psychoactive chemical substance that can be found in cannabis plants. *See* DEA, *Marijuana*, https://go.usa.gov/xe5Ea (last visited Nov. 29, 2021). THC can also be created synthetically. *See* DEA, *Spice/K2, Synthetic Marijuana*, https://go.usa.gov/xe5Er (last visited Nov. 29, 2021). THC and other chemicals in the cannabis plant are sometimes called "cannabinoids."

2. Congress has mandated that the Attorney General regularly update and republish the lists of substances that are scheduled under the CSA. *See* 21 U.S.C. § 812(a); *United States v. Eddy*, 549 F.2d 108, 111-13 (9th Cir. 1976) (describing this requirement). DEA regulations therefore list all of the substances that are currently included on each CSA schedule, assigning drug code numbers to facilitate administrative identification and providing definitions for some individual substances. *See* 21 C.F.R.

Act . . . or any other Federal law." Agricultural Act of 2014, Pub. L. No. 113-79, § 7606, 128 Stat. 649, 912 (codified at 7 U.S.C. § 5940).

§§ 1308.11-.15. DEA updates these regulations when either Congress or DEA changes a substance's status under the CSA.

Consistent with the CSA, DEA's regulations list marijuana as a Schedule I substance. *See* 21 C.F.R. § 1308.11(d)(23). DEA created a related drug code number in 2016 for "marijuana extract," a term encompassing a subset of substances within the statutory definition of "marijuana" that DEA defined to mean "an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant." *Id.* § 1308.11(d)(58) (2020); *see* 81 Fed. Reg. 90,194 (Dec. 14, 2016).

Before DEA issued the rule under review, DEA's regulations defined THC to include, in relevant part, THC "naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant." 21 C.F.R. § 1308.11(d)(31) (2020). When DEA promulgated this provision in 2003, DEA interpreted it to include trace amounts of THC that might be found in parts of the cannabis plant that Congress excluded from the statutory definition of marijuana. *See Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004). The Ninth Circuit held that that reading

swept too broadly and that, absent a scheduling action, "any THC occurring naturally within *Cannabis* is banned only if it falls within the Schedule I definition of 'marijuana.'" *Id.* at 1013. Since that ruling, DEA has repeatedly clarified that parts of the cannabis plant that are excluded from the marijuana definition are not subject to control under the CSA. *See, e.g.*, DEA, *DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant* (May 22, 2018), https://go.usa.gov/xe5E4 (Internal Directive). DEA has likewise made clear that its definition of "marijuana extract" includes only substances within the CSA definition of marijuana. *See, e.g.*, DEA, *Clarification of the New Drug Code (7350) for Marijuana Extract*, https://go.usa.gov/xe5E2 (Drug Code Clarification) (last visited Nov. 29, 2021).

B. The 2018 Farm Bill

In the 2018 Farm Bill, Congress narrowed the CSA definitions of marijuana and THC with the objective of facilitating commerce in cannabis plants and materials that have very low concentrations of a specific variant of THC called "delta-9 THC." The Farm Bill made three relevant changes. First, it defined a new statutory term—"hemp"—to "mean[] the plant Cannabis sativa L. and any part of that plant, including the seeds thereof

and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." 7 U.S.C. § 1639o(1). Second, the Farm Bill amended the CSA definition of "marijuana," specifying that the term "does not include . . . hemp, as defined in" 7 U.S.C. § 1639o. 21 U.S.C. § 802(16)(B)(i). Third, the Farm Bill amended Schedule I of the CSA so that it includes "Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under [7 U.S.C. § 1639o])." 21 U.S.C. § 812(c) (Schedule I (c)(17)).

The effect of the Farm Bill is to allow individuals and entities to produce and distribute cannabis plants and cannabis-derived materials that are very low in delta-9 THC without registering under the CSA. The U.S. Department of Agriculture, states, and tribes now have primary responsibility for regulating hemp. *See, e.g.*, 7 U.S.C. § 1639p (requiring the Secretary of Agriculture to oversee states' and tribes' plans for regulating hemp production); *id.* § 1639r(a)(1) (directing the Secretary of Agriculture to "promulgate regulations and guidelines to implement" the hemp provisions, in consultation with the Attorney General). The Commissioner

of Food and Drugs and the Secretary of Health and Human Services also have regulatory authority. *See id.* § 1639r(c).

C. The Rule Under Review

In 2020, DEA issued the challenged rule, which amends the regulations listing scheduled substances to reflect the Farm Bill's removal of hemp from CSA control. The rule made "four conforming changes to DEA's existing regulations," 85 Fed. Reg. at 51,640:

First, DEA modified the regulatory definition of "tetrahydrocannabinols" to state that the term "does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*." 85 Fed. Reg. at 51,645 (codified at 21 C.F.R. § 1308.11(d)(31)(ii)).

Second, DEA modified the regulatory definition of "marijuana extract" to include only substances that "contain[] greater than 0.3% delta-9 tetrahydrocannabinol on a dry weight basis." 85 Fed. Reg. at 51,645 (codified at 21 C.F.R. § 1308.11(d)(58)).

Third, DEA removed from its list of Schedule V substances a cannabis-derived drug called Epidiolex, which FDA has approved to treat

seizures under certain conditions. 85 Fed. Reg. at 51,641, 51,645.[4] DEA moved Epidiolex to Schedule V in 2018, explaining that it was within the statutory definition of "marijuana" but no longer satisfied the criteria for placement on Schedule I because FDA's approval meant it had an accepted medical use. 83 Fed. Reg. 48,950, 48,951-52 (Sept. 28, 2018); *see also* 21 U.S.C. § 812(b)(1)(B) (stating that a substance may be placed on Schedule I only if, among other things, it "has no currently accepted medical use in treatment in the United States"). In the rule under review, DEA explained that Epidiolex is "no longer controlled, by virtue of the" Farm Bill, because it contains less than 0.1% THC and is therefore hemp. 85 Fed. Reg. at 51,641.

Fourth, DEA removed a regulatory provision that had required permits for the import and export of Epidiolex, reiterating that Epidiolex is "no longer [a] controlled substance[]" after the Farm Bill. 85 Fed. Reg. at 51,641, 51,645.

[4] DEA's rule applies to Epidiolex and any drugs sharing its relevant characteristics, but this brief refers only to Epidiolex for purposes of brevity.

DEA stated that there was "good cause" to exempt the rule from the notice-and-comment requirements of the Administrative Procedure Act (APA). *See* 5 U.S.C. § 553(b)(B). DEA explained that the rule "merely conform[s] the implementing regulations to recent amendments to the CSA that have already taken effect"; the rule "does no more than incorporate the statutory amendments into DEA's regulations, and publishing a notice of proposed rulemaking or soliciting public comment prior to publication is unnecessary." 85 Fed. Reg. at 51,642.[5]

SUMMARY OF ARGUMENT

In the 2018 Farm Bill, Congress exempted "hemp" from regulation under the Controlled Substances Act, amending the CSA definitions of "marijuana" and "THC" to exclude substances within that term's meaning. In the rule under review, DEA amended its regulations to conform to those changes, removing "hemp" from regulatory definitions of controlled substances and acknowledging that a particular FDA-approved drug was

[5] Despite DEA's conclusion that it was unnecessary to conduct notice and comment "because these regulations merely implement statutory changes over which the agency has no discretion," DEA solicited post-publication comments on the rule. 85 Fed. Reg. at 51,642. DEA stated that it would "consider and respond to any relevant comments received" "[t]o the extent required by law." *Id.*

no longer subject to CSA control because it qualifies as hemp under the statute. All of petitioners' challenges to the rule fail.

I. The Court directed the parties to address whether the petition for review is timely under 21 U.S.C. § 877, which requires that a petition be filed "within thirty days after notice of the decision" under review. The petition here was filed 28 days after the challenged rule was published in the Federal Register, rendering it timely. Although questions might arise in other cases about what constitutes "notice" within the meaning of § 877, it is unnecessary to resolve those issues here, as the government is not aware of alternative means by which petitioners could have obtained notice of the rule more than 30 days before they filed their petition.

II. Petitioners' challenges to the rule fail for lack of standing and on the merits.

A. Petitioners assert that the rule unlawfully removes a cannabis-derived drug called Epidiolex from the list of Schedule V substances in DEA's regulations. But petitioners make no effort to explain why the lifting of CSA controls on Epidiolex injures them; they have no apparent connection to the drug. On the merits, petitioners do not dispute that DEA is bound by the changes Congress makes to the CSA's schedules, at least

absent a scheduling action; they do not dispute that Epidiolex is "hemp" under the Farm Bill; and they do not identify any alternative action that they believe DEA could have taken to conform its regulations to the statute. They accordingly do not state a claim that the rule's treatment of Epidiolex is contrary to law.

B. Petitioners also err in contending that the rule unlawfully purports to control naturally occurring THC that does not qualify as hemp but is nonetheless outside the CSA definition of marijuana. *See* 21 U.S.C. § 802(16). Petitioners provide no evidence that they handle substances fitting this description, and in any event, DEA has made clear in the rule and in preexisting guidance that such substances are not subject to CSA control, which precludes both standing and success on the merits.

III. A. DEA correctly concluded that the APA did not require it to conduct notice and comment before issuing the rule. As DEA explained, the rule merely conforms DEA's regulations to preexisting statutory amendments. Notice and comment were therefore unnecessary under the APA's "good cause" provision, and they also were not required because the rule is interpretive. Although petitioners suggest that an interpretive

rule can do no more than parrot the language of an underlying statute, this Court has squarely rejected that proposition.

B. DEA likewise was not required to conduct a scheduling action under the CSA before issuing the rule. *See* 21 U.S.C. § 811(a)-(c). The CSA's administrative scheduling procedures apply when the Attorney General "add[s]" a substance to a schedule, "transfer[s]" a substance between schedules, or "remove[s]" a substance from a schedule. *Id.* § 811(a). Here, Congress removed hemp from Schedule I, and DEA merely adjusted its regulations to conform to the changes Congress had already made.

IV. Petitioners are also mistaken to contend that the rule is invalid because Acting DEA Administrator Timothy J. Shea, who issued the rule, was allegedly serving in violation of the Federal Vacancies Reform Act. The Vacancies Reform Act does not provide the exclusive means for designating an acting official where another statute "expressly . . . authorizes the President, a court, or the head of an Executive department, to designate an officer or employee to perform the functions and duties of a specified office temporarily in an acting capacity." 5 U.S.C. § 3347(a)(1). Shea was designated pursuant to a provision that expressly authorizes the

Attorney General to "designate" any "official of the Department of Justice" to serve as Acting Administrator when there is a vacancy in that office. Reorganization Plan No. 2 of 1973 § 5(c), 38 Fed. Reg. 15,932, 15,933 (June 19, 1973), *as amended by* Pub. L. No. 93-253, 88 Stat. 50 (1974), *reprinted in* 28 U.S.C. § 509 app., *and in* 87 Stat. 1091 (1973).

STANDARD OF REVIEW

A court may set aside DEA's final action only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001).

ARGUMENT

I. The Petition For Review Is Timely

The Court has ordered the parties to address "whether the petition for review was timely filed 'within thirty days after notice of the decision'" under review. Order (July 27, 2021) (quoting 21 U.S.C. § 877). The government believes the petition for review was timely (although it should be dismissed for lack of Article III standing, *see infra* Part II).

21 U.S.C. § 877 authorizes "any person aggrieved by a final decision of the Attorney General" under the CSA to obtain judicial review by filing

a petition for review "within thirty days after notice of the decision." 21 U.S.C. § 877; *see also* Fed. R. App. P. 15(a)(1) (requiring that a petition for review be filed "within the time prescribed by law"). Although questions might arise in other cases about when the 30-day period for filing a petition for review begins to run, the government believes the petition for review in this case is timely under any potential reading of § 877.

Section 877's 30-day period begins running when the petitioner receives "notice of the decision" under review. 21 U.S.C. § 877. As petitioners acknowledge, Br. 17, publication in the Federal Register suffices to provide the public with "notice" and trigger § 877's time limit. *See, e.g.*, *Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384-85 (1947) ("Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the Federal Register gives legal notice of their contents."); *see also Fry v. DEA*, 353 F.3d 1041, 1044 (9th Cir. 2003) (describing Federal Register publication as "the affirmative act that begins the running of the thirty-day time limit"). The rule at issue here was published in the Federal Register on August 21, 2020, and petitioners filed their petition for review 28 days later, on September 18, 2020.

It is possible that the 30-day period for filing a petition for review under § 877 would begin running earlier if a petitioner obtained actual notice of a final decision before it was published—for example, if DEA served a copy of its decision on an affected individual before publishing the decision.[6] We are not aware of cases in which courts have been required to confront that issue. The petitioner in *Fry v. DEA*, a Ninth Circuit case, filed her petition for review 32 days after the order revoking her CSA registration was published in the Federal Register, 353 F.3d at 1044; the petition was therefore untimely regardless of whether she received actual notice even earlier and whether actual notice would have triggered § 877's time limit. *Cf. id.* at 1042-43 (stating that DEA issued its order seven days before it was published but not making clear whether the petitioner was notified of the order prior to publication). Similarly, the

[6] *Cf. City of Chicago v. U.S. Dep't of Labor*, 737 F.2d 1466, 1470 (7th Cir. 1984) (holding, in construing a provision similar to § 877, that "one has 'notice' under Section 817(a) when he or she actually knows or has reason to know of the Secretary's final action"); *Kessler v. FCC*, 326 F.2d 673, 690 (D.C. Cir. 1963) ("[P]etitioners are bound by the actual knowledge they had of the freeze order, including knowledge of its effective date, and . . . they are not privileged to claim that it was ineffective as to them because their applications were tendered before the document was filed for publication.").

petitioner in *Nutt v. DEA*, 916 F.2d 202 (5th Cir. 1990), filed his petition for review "60 days after receiving constructive notice in the Federal Register, and 57 days after receiving actual notice by mail," so it was untimely by any potential measure. *Id.* at 203.

It is likewise unnecessary to decide here whether actual notice of a DEA decision can trigger § 877's time limit before the decision is published, as the government is not aware of any means by which petitioners could have gained notice of DEA's rule more than 30 days before they filed the petition for review. The rule was released for public inspection on August 20, 2020, the day before it was published in the Federal Register. *See* National Archives, Federal Register, *08/20/2020 Public Inspection Issue*, https://go.usa.gov/xe5Eb (updated Aug. 20, 2020). Even assuming that triggered § 877's time limit,[7] the petition for review was filed 29 days later, which means it would remain timely in any event.

[7] *But see id.* ("Only official editions of the Federal Register provide legal notice to the public and judicial notice to the courts under 44 U.S.C. 1503 & 1507." (emphasis omitted)).

II. Petitioners' Substantive Challenges To The Rule Fail On The Merits And For Lack Of Standing

A. The Rule's Treatment Of Epidiolex Is Consistent With Law And Does Not Injure Petitioners

Petitioners assert that the rule unlawfully removes a cannabis-derived drug called Epidiolex from the list of Schedule V substances, contending in particular that that action violates the United States' obligations under the Single Convention on Narcotic Drugs. *See* Br. 35-45. Petitioners lack standing to bring this challenge, as well as to challenge the rule more generally. To establish standing, a party seeking direct review of administrative action in this Court must satisfy the same burden of production as would "a plaintiff moving for summary judgment in the district court," "support[ing] each element of its claim to standing 'by affidavit or other evidence.'" *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)); *see also id.* at 900 (emphasizing that evidence of standing should be submitted "at the first appropriate point in the review proceeding," such as in an opening brief). Petitioners provide no evidence of their standing, instead asserting that the standing of petitioner Hemp Industries Association "is self-evident" (while making no similar claim about RE Botanicals, the other

petitioner). Br. 34. But standing is far from self-evident, particularly given that the rule merely amends DEA's regulations to conform to the Farm Bill's removal of hemp from CSA control, thus reflecting that individuals and entities engaged in activity involving hemp (as it is defined in the Farm Bill) are no longer subject to regulatory obligations under the CSA.[8]

Petitioners likewise make no effort to establish that they have standing to bring their claim regarding Epidiolex. *See Competitive Enter. Inst. v. FCC*, 970 F.3d 372, 382 (D.C. Cir. 2020) (explaining that parties "must separately prove standing for each claim that they seek to press" and that the Court "must therefore separately assess their standing to challenge each of the disputed conditions" embodied in an agency action (quotation marks omitted)). Petitioners claim that the removal of Epidiolex from Schedule V violates the Single Convention, which is a multilateral

[8] Petitioners' opening brief describes Hemp Industries Association as "a non-profit trade group representing hemp companies, researchers, and supporters" that "advocate[s] for the fair treatment and regulation of industrial hemp." Br. 34. Hemp Industries Association does not specify whether it asserts standing on its own behalf or on behalf of its members, *see, e.g.*, *Electronic Privacy Info. Ctr. v. U.S. Dep't of Commerce*, 928 F.3d 95, 100 (D.C. Cir. 2019) (explaining that an organization "can assert standing on its own behalf, as an organization, or on behalf of its members, as associational standing"), but it has not demonstrated standing under either framework.

agreement aimed at coordinating international action against drug abuse. *See* Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 204 (Single Convention). "Like the CSA, the Single Convention establishes several classifications or 'schedules' of substances, to which varying regimes of control attach." *National Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 739 (D.C. Cir. 1977). "Cannabis" and "cannabis resin" are Schedule I substances under the Convention, and the Convention calls for signatory nations to impose various controls on them. *See, e.g.*, Single Convention arts. 2(1), (6), (7). The Convention does not, however, "apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes." *Id.* art. 28(2). Congress has implemented the Single Convention through the CSA, and various CSA provisions therefore reflect obligations under the Convention. *See, e.g.*, 21 U.S.C. §§ 801(7), 811(d), 958(a).

In 2018, before Congress enacted the Farm Bill, FDA approved Epidiolex to treat seizures under specified conditions. *See* 83 Fed. Reg. at 48,951. After FDA acted, DEA concluded that Epidiolex no longer met the criteria for placement on Schedule I because it had an "accepted medical

use." *Id.*; *see also* 21 U.S.C. § 812(b)(1)(B) (specifying that a drug may be placed on Schedule I only if, among other things, it "has no currently accepted medical use in treatment in the United States"). DEA determined that Epidiolex should be moved to Schedule V, rather than removed from CSA regulation altogether, because the Administrator deemed Schedule V placement "most appropriate to carry out the United States' obligations under the Single Convention." 83 Fed. Reg. at 48,951-52 (citing 21 U.S.C. § 811(d)(1)).

In the rule under review, DEA determined that Epidiolex is "no longer controlled, by virtue of the" Farm Bill, because it contains "no more than 0.1 percent (w/w) residual tetrahydrocannabinols" and is therefore within the statutory definition of "hemp." 85 Fed. Reg. at 51,641. Petitioners claim that DEA's conclusion on this point contravenes the Single Convention, but they make no effort whatsoever to establish that they are injured by Epidiolex's removal from Schedule V. Nothing in the record suggests that petitioners are involved in the production of Epidiolex or engaged in any other activities related to that drug, and even assuming that some such connection existed, it is not apparent how they would be injured by a rule that removes regulatory burdens. Petitioners have

similarly failed to provide any basis for "competitor standing," which can exist in some cases where "agencies lift regulatory restrictions on [plaintiffs'] competitors or otherwise allow increased competition against them." *Sherley v. Sebelius*, 610 F.3d 69, 72 (D.C. Cir. 2010) (quotation marks omitted). Petitioners have cited no evidence that they compete against the manufacturer of Epidiolex or are otherwise harmed by the loosening of restrictions surrounding the drug. If petitioners believe they are injured by the removal of Epidiolex from the list of Schedule V substances, it was incumbent on them to explain that injury in their opening brief.[9]

Petitioners' argument also fails on the merits. Petitioners do not dispute that DEA is bound by the schedules Congress establishes, at least absent a scheduling action. *See* 21 U.S.C. § 812(c) (specifying that the CSA schedules set out by statute govern "unless and until" the Attorney General conducts a scheduling action to change a particular substance's

[9] To the extent that petitioners' argument regarding Epidiolex implies more broadly that the Single Convention calls for hemp to remain subject to CSA control, that argument—and the "relief" petitioners would obtain if they prevailed on it—is directly contrary to petitioners' stated interest in precluding DEA from regulating hemp. *See, e.g.*, Br. 31 (explaining that petitioners' parallel district court lawsuit "challenge[s] DEA's authority to regulate the production of hemp at all").

status). They also acknowledge that Congress removed hemp from CSA control and recognize that, accordingly, "DEA may no longer assert authority over hemp unless and until it undertakes the procedures required by 21 U.S.C. § 811 to place a substance on the Controlled Substances Act's schedules." Br. 46.

Petitioners observe that the 2018 Farm Bill does not specifically mention Epidiolex, Br. 50, but they do not dispute that the drug, which contains "no more than 0.1 percent (w/w) residual tetrahydrocannabinols," 85 Fed. Reg. at 51,641, qualifies as "hemp" under the Farm Bill. They suggest that Congress did not require DEA to remove the drug from Schedule V, *see* Br. 50, and devote long passages of their brief to the standards for evaluating whether a statute abrogates a treaty, *see* Br. 36-42. But they identify no way in which DEA could have continued to classify Epidiolex as a scheduled substance while complying with the Farm Bill, which unambiguously removed hemp from CSA control. Accordingly, even if petitioners had standing, they would not have a

plausible claim that the rule's treatment of Epidiolex contravened the governing statute, whose validity they do not challenge.[10]

Petitioners are relatedly mistaken to claim that the rule reflects an unexplained change in DEA's position with respect to Epidiolex. As petitioners note, DEA moved Epidiolex from Schedule I to Schedule V in 2018. *See* Br. 42-45. The preamble to the rule under review clearly explains why DEA took a different approach here: DEA explained that the drug is "no longer controlled, by virtue of the" Farm Bill. 85 Fed. Reg. at 51,641. DEA's treatment of Epidiolex therefore does not reflect an arbitrary and capricious, unexplained change in policy, but a recognition that Congress fundamentally altered the drug's regulatory status.

[10] Petitioners note that 21 U.S.C. § 811(d)(1) directs the Attorney General to "issue an order controlling [a] drug under the schedule he deems most appropriate to carry out" "United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970." *See* Br. 38. The purpose of the rule under review was to conform DEA's regulatory list of scheduled substances to the changes Congress made in the Farm Bill; a section 811(d)(1) action would be a separate matter. For the reasons discussed, petitioners have no apparent interest in DEA's issuance of an order pursuant to section 811(d)(1) to reestablish CSA controls over Epidiolex and other hemp substances. *See supra* pp. 22-23 & n.9.

B. Petitioners' Claim That The Rule Purports To Schedule Naturally Occurring THC That Is Not Within The CSA Definition Of "Marijuana" Likewise Fails

Petitioners' other substantive argument—that the rule unlawfully "asserts" the "power[]" to regulate naturally derived THC that is outside the CSA definition of marijuana, Br. 45—likewise fails for lack of standing and lack of merit.

The CSA definition of marijuana, as amended by the Farm Bill, exempts "hemp," 21 U.S.C. § 802(16)(B)(i), and also exempts "the mature stalks of [the cannabis] plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination," *id.* § 802(16)(B)(ii). Petitioners appear to contend that DEA's rule seeks to regulate substances that are not hemp but are within the provision exempting particular parts of the cannabis plant. *See* Br. 45-48.

As an initial matter, petitioners do not explain why this claim is relevant to their activities and why they would have standing to assert it. They cite no evidence that, for example, they or their members

manufacture or sell substances that contain THC, do not qualify as hemp, and are nonetheless outside the statutory definition of marijuana, much less that DEA has threatened them with prosecution for such conduct.

In any event, petitioners fundamentally misread the rule in claiming that it "asserts" the "power[]" to control cannabis-derived substances that are not within the CSA definition of "marijuana." Br. 45. To the contrary, the rule acknowledges that the Farm Bill narrowed DEA's authority over cannabis-derived materials, and it therefore amends DEA's regulations to state that the term "tetrahydrocannabinols" "does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*," 85 Fed. Reg. at 51,645 (codified at 21 C.F.R. § 1308.11(d)(31)), and that "marijuana extract" is limited to substances "containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis," *id.* (codified at 21 C.F.R. § 1308.11(d)(58)).

The rule's preamble confirms that the rule does not purport to control substances outside the CSA definition of marijuana. The preamble explains that, "to fall within the current CSA definition of marihuana, cannabis and cannabis-derived material must both *fall within the pre-[Farm Bill] CSA definition of marihuana* and contain more than 0.3 percent [delta-9 THC] on a

dry weight basis." 85 Fed. Reg. at 51,640-41 (emphasis added). DEA similarly explained that cannabis-derived substances "are schedule I controlled substances unless they meet the definition of 'hemp' . . . *or* are from exempt parts of the plant (such as mature stalks or non-germinating seeds)." *Id.* at 51,641 (emphasis added) (citing 21 U.S.C. § 802(16)). Petitioners' assertions that the rule purports to control exempt parts of the cannabis plant are therefore irreconcilable with the rule's actual content.

DEA's statements in the rule are consistent with the agency's longstanding recognition that preexisting language in the regulatory definitions of THC and marijuana extract does not apply to substances outside the statutory definition of marijuana. In the early 2000s, DEA interpreted its THC definition to include naturally occurring THC that was derived from an exempt part of the cannabis plant containing trace amounts of the psychoactive substance. In holding that interpretation to be invalid, the Ninth Circuit concluded "that any THC occurring naturally within *Cannabis* is banned only if it falls within the Schedule I definition of 'marijuana.'" *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1013 (9th Cir. 2004); *see also id.* at 1013 n.2, 1019 ("enjoin[ing] enforcement" of DEA regulations "with respect to" substances outside the marijuana definition).

Since that decision, DEA has not sought to control cannabis-derived THC or other cannabis substances that are outside the statutory definition of marijuana. In 2018, for example, after receiving inquiries on the subject, DEA issued an internal directive reminding its personnel that DEA "does not enforce" the regulatory definition of THC as to "products that are excluded from the definition of marijuana in the Controlled Substances Act." *Internal Directive*, *supra*. "The mere presence of" THC or other "cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance falls within the CSA definition of marijuana." *Id.*

DEA has similarly made clear that its regulation defining "marijuana extract" "does not include materials or products that are excluded from the definition of marijuana set forth in the Controlled Substances Act." *Drug Code Clarification*, *supra*. "[I]f a product . . . consisted solely of parts of the cannabis plant excluded from the CSA definition of marijuana, such product would not be included in the" drug code for marijuana extract or marijuana, "even if it contained trace amounts of cannabinoids." *Id.*; *see also Internal Directive*, *supra* (reiterating that "the drug code for marijuana extract extends no further than the CSA does, and it thus does not apply to

materials outside the CSA definition of marijuana"). Petitioners identify nothing in the rule that backtracks from that consistent position.

These points establish both that petitioners lack standing to bring this claim and that the claim fails on the merits. Petitioners lack standing because DEA's rule does not impose controls on substances outside the CSA definition of marijuana and because DEA "has shown no intention of enforcing" its regulations against such substances. *Matthew A. Goldstein, PLLC. v. U.S. Dep't of State*, 851 F.3d 1, 5 (D.C. Cir. 2017); *see also Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (dismissing a case for lack of informational standing where the plaintiff was "seeking to enforce a statutory deadline provision that by its terms does not require the public disclosure of information"). The rule, DEA's preexisting guidance, and its statements in this brief "demonstrate that, in [DEA's] view," those substances are "*not* subject to regulation," and petitioners therefore do not "face[] a meaningful risk" of enforcement for conduct involving them. *Matthew A. Goldstein*, 851 F.3d at 6. And if the Court concluded that these arguments were better viewed as addressing the merits, they would demonstrate that petitioners' claims fail because the rule does not, in fact, "add natural tetrahydrocannabinols to schedule I." Br. 47.

III. Petitioners' Procedural Challenges To The Rule Lack Merit

A. DEA Was Not Required To Conduct Notice And Comment

DEA did not conduct notice and comment before it promulgated the rule, explaining that the rule "merely conform[s] [DEA's] regulations to recent amendments to the CSA that have already taken effect." 85 Fed. Reg. at 51,642. DEA correctly concluded that notice and comment were not required.

DEA explained in the preamble that there was "good cause" to exempt the rule from the APA's notice-and-comment requirements. *See* 85 Fed. Reg. at 51,642. Notice and comment are not required when an "agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). As particularly relevant here, DEA cited decisions holding that notice and comment were not required because the rules at issue were interpretive. *See* 85 Fed. Reg. at 51,642 (citing *Gray Panthers Advocacy Comm. v. Sullivan*, 936 F.2d 1284, 1291 (D.C. Cir. 1991); *Komjathy v. NTSB*, 832 F.2d 1294, 1296 (D.C. Cir. 1987); and *United States v.*

Cain, 583 F.3d 408, 420 (6th Cir. 2009)). The rule at issue here merely adjusts the list of controlled substances in DEA's regulations to reflect Congress's prior judgment that hemp should no longer be controlled. *See, e.g.*, 85 Fed. Reg. at 51,642 (explaining that the rule "does no more than incorporate the statutory amendments into DEA's regulations"). And in that sense it was also "a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public," the standard for concluding that notice and comment are "unnecessary" under the APA's good cause provision. *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 94 (D.C. Cir. 2012).

In any event, the rule is plainly interpretive and not an exercise of delegated authority to issue "legislative" rules, which provides a second reason that notice and comment were not required. *See* 5 U.S.C. § 553(b)(A) (specifying that the APA's notice-and-comment requirements do not apply "to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice"). The rule "merely track[s] preexisting requirements and explain[s] something the statute or regulation already required," rather than "effect[ing] a substantive change in existing law or policy." *POET Biorefining, LLC v. EPA*, 970 F.3d 392, 407

(D.C. Cir. 2020) (quotation marks omitted). Rather than reflecting an exercise of "delegated legislative power," the rule "derive[s] a proposition from an existing document"—the Farm Bill—"whose meaning compels or logically justifies the proposition." *Natural Res. Def. Council v. Wheeler*, 955 F.3d 68, 83 (D.C. Cir. 2020) (alteration in original) (quotation marks omitted). The rule therefore does not "creat[e] legal effects" but merely "puts the public on notice of *pre-existing* legal obligations or rights," *id.*, by adjusting DEA's regulations to reflect Congress's removal of hemp from CSA control. *Cf.* 21 U.S.C. § 812(a) (requiring that the CSA schedules "be updated and republished on an annual basis").

It "could hardly be clearer" that DEA's rule simply revises DEA's regulations to reflect preexisting statutory amendments. *POET*, 970 F.3d at 407. The preamble explains that the rule "merely conform[s] the implementing regulations to recent amendments to the CSA that have already taken effect" and states that "DEA has no discretion with respect to these amendments." 85 Fed. Reg. at 51,642. "The legal norm is" therefore "one that Congress has devised," and DEA "does not purport to modify that norm." *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997). Indeed, DEA's disclaimer of authority to engage in substantive regulation

on the matters at issue is further evidence that the rule is not legislative. *See American Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 401 (D.C. Cir. 2013) (holding a rule to be interpretive where the parties "agree[d] that OSHA ha[d] no authority to determine" the matter addressed and the rule instead merely "'advise[d] the public of the agency's construction of the statute it administers'" (quoting Edwards, Elliott & Levy, *Federal Standards of Review* 160 (2d ed. 2013))).

Petitioners acknowledge that, if a rule simply gives effect to a statute, it is "a mere interpretive rule and thus exempt from the APA's notice-and-comment rulemaking requirements." Br. 57. But petitioners mistakenly contend that an interpretive rule must "simply parrot[] the language of the" governing statute. *Id.* To the contrary, this Court has "squarely rejected" the notion that an interpretive rule is "confined to parroting the" authority it interprets. *POET*, 970 F.3d at 408 (quotation marks omitted); *see also Central Tex. Telephone Coop., Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) ("[A]n interpretive rule does not have to parrot statutory or regulatory language . . . . "). That the rule does not merely cite the language of the Farm Bill is beside the point. The changes made by the rule follow directly from Congress's amendments to relevant statutory

provisions and do not reflect an exercise of DEA's policymaking discretion. *Cf. Central Tex.*, 402 F.3d at 214 ("[A]n agency may use an interpretive rule to transform a vague statutory duty or right into a sharply delineated duty or right.") (quotation marks omitted).

Petitioners urge that DEA's actions related to Epidiolex are legislative because the Farm Bill "never mentions" that drug. Br. 57. As discussed above, however, petitioners do not dispute that Epidiolex is "hemp," and they do not explain how DEA could have read the Farm Bill to allow it to regulate a hemp substance. *See* Br. 46-47 (asserting that Congress did not "preserv[e] DEA's pre-2018 Farm Bill authority over hemp in any way"). DEA correctly explained that the changes made in the rule were compelled by the Farm Bill and did not constitute an exercise of delegated authority. *See* 85 Fed. Reg. at 51,641 (explaining that Epidiolex must be removed from the list of Schedule V substances because it is "no longer controlled, by virtue of the [Farm Bill]"); *see also, e.g.*, *United Techs. Corp. v. U.S. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987) ("If the rule is based on specific statutory provisions, and its validity stands or falls on the correctness of the agency's interpretation of those provisions, it is an interpretive rule."). Petitioners likewise err in asserting that the rule is legislative because the Farm Bill did

not affect "the divide between natural and synthetic" THC, Br. 57; as explained, the rule makes no change to DEA's regulations in that regard, *see supra* Part II.B.

For similar reasons, petitioners are mistaken to contend that DEA was required to show "good cause" to make the rule immediately effective on publication. Br. 58-59. Although the APA generally specifies that "[t]he required publication or service of a substantive rule shall be made not less than 30 days before its effective date," 5 U.S.C. § 553(d), that requirement does not apply to "interpretative rules and statements of policy," *id.* § 553(d)(2), or to "a substantive rule which grants or recognizes an exemption or relieves a restriction," *id.* § 553(d)(1). As explained, the rule is interpretive, and even if it were substantive, it recognizes Congress's decision to lift the restrictions the CSA had imposed on hemp. DEA therefore was not required to make a good cause finding for the rule to be effective on publication.

B. DEA Was Not Required To Conduct A Scheduling Action

Petitioners similarly err in contending that the rule is invalid because DEA did not follow the statutory procedures for adding substances to or

removing substances from the CSA's schedules. *See* Br. 50-52. Either Congress or the Attorney General may change the status of a substance under the CSA. *See* 21 U.S.C. §§ 811, 812. If the Attorney General wishes to "add," "transfer," or "remove" a substance from the CSA's schedules, he must typically issue a rule "made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5," *id.* § 811(a); obtain a recommendation from the Secretary of Health and Human Services, *id.* § 811(b); and consider particular factors outlined in the statute, *id.* § 811(c).

By contrast, if Congress changes the status of a substance under the CSA, it amends the statute, which states that "Schedules I, II, III, IV, and V shall, unless and until amended [through an administrative scheduling action], consist of the following drugs or other substances," followed by a list. 21 U.S.C. § 812(c). When Congress changes a substance's status, DEA updates its regulations to reflect the change but does not conduct a scheduling action (because Congress has already changed the substance's schedule). *See, e.g.*, Synthetic Drug Abuse Prevention Act of 2012, Pub. L. No. 112-144, tit. XI, subtit. D, 126 Stat. 1130-32 (2012) (adding "cannabimimetic agents" to Schedule I); 78 Fed. Reg. 664 (Jan. 4, 2013)

(amending DEA's regulations to reflect Congress's action and create drug code numbers for the newly scheduled substances).

A scheduling action was not required here because Congress—not DEA—removed "hemp" from Schedule I. Indeed, petitioners elsewhere recognize that Congress, in the Farm Bill, "exempt[ed] specific material from schedule I control." Br. 46. Although petitioners assert that DEA independently removed Epidiolex from the CSA's schedules, *see* Br. 50-51, and added natural THC to Schedule I, *see* Br. 51-52, those assertions are wrong, as already explained. *See supra* Part II. Far from reflecting DEA's exercise of judgment about which schedules were best suited for particular substances, the rule merely adjusted DEA's regulations to reflect scheduling decisions Congress had already made.

IV. Petitioners' Challenge Under The Federal Vacancies Reform Act Lacks Merit

Petitioners are also mistaken to contend that the rule is invalid because it was issued by former Acting DEA Administrator Timothy J. Shea, who, petitioners contend, was serving in violation of the Federal

Vacancies Reform Act. *See* Br. 59-63.[11] That contention fails because the Vacancies Reform Act does not provide the exclusive means for designating an Acting Administrator, and Shea was designated pursuant to an office-specific provision that does not include the restrictions on which petitioners rely.

The Vacancies Reform Act often provides "the exclusive means for temporarily authorizing an acting official to perform the functions and duties of any office of an Executive agency . . . for which appointment is required to be made by the President, by and with the advice and consent of the Senate." 5 U.S.C. § 3347(a). That rule is subject to various exceptions, however, including cases in which "a statutory provision expressly . . . authorizes the President, a court, or the head of an Executive department, to designate an officer or employee to perform the functions and duties of a specified office temporarily in an acting capacity." *Id.* § 3347(a)(1).

[11] The Senate confirmed Anne Milgram as DEA Administrator on June 24, 2021. *See* Press Release, DEA, *Anne Milgram Sworn in as DEA Administrator* (June 29, 2021), https://go.usa.gov/xe5EK.

Acting Administrator Shea was designated pursuant to an office-specific provision that Congress has expressly recognized as an alternative to the Vacancies Reform Act for the office of DEA Administrator. *See* Add. 8 (order of Attorney General William Barr designating Shea). Reorganization Plan No. 2 of 1973 specifies that, although the Administrator is to be "appointed by the President by and with the advice and consent of the Senate," "[t]he Deputy Administrator or such other official of the Department of Justice as the Attorney General shall from time to time designate shall act as Administrator during the absence or disability of the Administrator or in the event of a vacancy in the office of Administrator." Reorganization Plan No. 2 of 1973 § 5(a), (c), 38 Fed. Reg. 15,932, 15,933 (June 19, 1973), *as amended by* Pub. L. No. 93-253, 88 Stat. 50 (1974), *reprinted in* 28 U.S.C. § 509 app., *and in* 87 Stat. 1091.[12] Shea was an eligible "official of the Department of Justice," serving as Interim U.S. Attorney for the District of Columbia, when the Attorney General designated him pursuant to that provision in 2020. *See* Press Release, DEA, *Attorney General Barr Announces Timothy J. Shea as New Acting Administrator*

[12] Congress "ratifie[d] and affirm[ed]" this Reorganization Plan "as law" in 1984. Pub. L. No. 98-532, § 1, 98 Stat. 2705, 2705 (1984).

of Drug Enforcement Administration (May 19, 2020), https://go.usa.gov/xe5ED. Although petitioners claim that Shea's designation violated limitations that the Vacancies Reform Act imposes on the permissible duration of a vacancy and who may serve as an acting official, *see* Br. 59-61, the DEA-specific vacancy provision does not include those restrictions.

The legislative history eliminates any possible doubt on this question. The Senate Report on the bill that became the Vacancies Reform Act explains that the Act "retain[ed] existing statutes that [we]re in effect on the date of [its] enactment . . . that expressly authorize the President, or the head of an executive department[,] to designate" an acting officer. S. Rep. No. 105-250, at 15 (1998). The report notes Congress's "aware[ness] of the existence of statutes specifically governing a vacancy in 41 specific offices, 40 of which would be retained by th[e] bill," and acknowledges that many of these statutes do not incorporate restrictions like those imposed by the Vacancies Reform Act. *See id.* at 16-17. Indeed, the first such statute that Congress listed is "Administrator, Drug Enforcement Administration (5 U.S.C. Reorg. Plan No. 2 of 1973)." *Id.* at 16. Shea's designation complied with that DEA-specific provision and was therefore lawful.

CONCLUSION

For the foregoing reasons, the petition for review should be dismissed for lack of standing or denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8456 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

/s/ Sarah Carroll
Sarah Carroll

ADDENDUM

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5 U.S.C. § 3347

§ 3347. Exclusivity

(a) Sections 3345 and 3346 are the exclusive means for temporarily authorizing an acting official to perform the functions and duties of any office of an Executive agency (including the Executive Office of the President, and other than the Government Accountability Office) for which appointment is required to be made by the President, by and with the advice and consent of the Senate, unless—

(1) a statutory provision expressly—

(A) authorizes the President, a court, or the head of an Executive department, to designate an officer or employee to perform the functions and duties of a specified office temporarily in an acting capacity; or

(B) designates an officer or employee to perform the functions and duties of a specified office temporarily in an acting capacity; or

(2) the President makes an appointment to fill a vacancy in such office during the recess of the Senate pursuant to clause 3 of section 2 of article II of the United States Constitution.

. . . .

7 U.S.C. § 1639o

§ 1639o. Definitions

In this subchapter:

(1) Hemp

The term "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

. . . .

21 U.S.C. § 802

§ 802. Definitions

As used in this subchapter:

. . . .

(16)(A) Subject to subparagraph (B), the term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.

(B) The term "marihuana" does not include—

(i) hemp, as defined in section 1639o of Title 7; or

(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

. . . .

21 U.S.C. § 811

§ 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.

. . . .

21 U.S.C. § 812

§ 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.

. . . .

(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

. . .

(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:

. . .

(10) Marihuana.

. . .

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

. . .

21 U.S.C. § 877

§ 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.

28 U.S.C. § 509 app. (Reorganization Plan No. 2 of 1973)

LAW ENFORCEMENT IN ILLICIT DRUG ACTIVITIES

. . . .

Sec. 4. Drug Enforcement Administration.

There is established in the Department of Justice an agency which shall be known as the Drug Enforcement Administration, hereinafter referred to as "the Administration."

Sec. 5. Officers of the Administration.

(a) There shall be at the head of the Administration the Administrator of Drug Enforcement, hereinafter referred to as "the Administrator." The Administrator shall be appointed by the President by and with the advice and consent of the Senate, and shall receive compensation at the rate now or hereafter prescribed by law for positions of level III of the Executive Schedule Pay Rates (5 U.S.C. 5314). He shall perform such functions as the Attorney General shall from time to time direct.

(b) There shall be in the Administration a Deputy Administrator of the Drug Enforcement Administration, hereinafter referred to as "the Deputy Administrator," who shall be appointed by the President by and with the advice and consent of the Senate, shall perform such functions as the Attorney General may from time to time direct, and shall receive compensation at the rate now or hereafter prescribed by law for positions of level V of the Executive Schedule Pay Rates (5 U.S.C. 5316).

(c) The Deputy Administrator or such other official of the Department of Justice as the Attorney General shall from time to time designate shall act as Administrator during the absence or disability of the Administrator or in the event of a vacancy in the office of Administrator.

. . . .

21 C.F.R. § 1308.11

§ 1308.11. Schedule I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

. . . .

(d) Hallucinogenic substances. 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 its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this paragraph only, the term "isomer" includes the optical, position and geometric isomers):

. . .

(23) Marihuana……7360

. . .

(31) Tetrahydrocannabinols……7370

(i) Meaning tetrahydrocannabinols, except as in paragraph (d)(31)(ii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

1 cis or trans tetrahydrocannabinol, and their optical isomers

6 cis or trans tetrahydrocannabinol, and their optical isomers

3, 4 cis or trans tetrahydrocannabinol, and its optical isomers

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered.)

(ii) Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639o.

. . .

(58) Marihuana Extract……7350

Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3% delta–9–tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.

. . . .

Office of the Attorney General
Washington, D. C. 20530

ORDER NO. 4699-2020

DESIGNATION OF TIMOTHY J. SHEA AS
ACTING ADMINISTRATOR OF DRUG ENFORCEMENT

By virtue of the authority vested in the Attorney General by law, including 28 U.S.C. §§ 509 and 510, and section 5(c) of Reorganization Plan No. 2 of 1973, I hereby designate Timothy J. Shea to perform the functions and duties of, and to act as, Administrator of Drug Enforcement.

MAY 18, 2020
Date

William P. Barr
Attorney General