**No. 17-70162**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

HEMP INDUSTRIES ASSOCIATION; CENTURIA NATURAL FOODS, INC; RMH HOLDINGS, LLC,

Petitioners,

v.

U.S. DRUG ENFORCEMENT ADMINISTRATION; CHUCK ROSENBERG, as Acting Administrator, Drug Enforcement Administration,

Respondents.

On Petition for Review of a Final Rule of the Drug Enforcement Administration

# BRIEF FOR RESPONDENTS

CHAD A. READLER
*Acting Assistant Attorney General*

MARK B. STERN
SARAH CARROLL
*Attorneys, Appellate Staff*
*Civil Division, Room 7511*
*U.S. Department of Justice*
*950 Pennsylvania Avenue NW*
*Washington, DC 20530*
*(202) 514-4027*

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## INTRODUCTION

"[F]or purposes of identification," the Drug Enforcement Administration (DEA) assigns an "Administration Controlled Substances Code Number" to each substance that is subject to federal control under the Controlled Substances Act (CSA). 21 C.F.R. § 1308.03(a). DEA uses these code numbers for administrative purposes, to identify and distinguish between various controlled substances that it may register persons to handle. *See id.* Petitioners challenge a final rule in which DEA established a new code number for "marijuana extract," a subclass of the materials that the CSA defines as "marijuana," a Schedule I substance, *see* 21 U.S.C. § 812(c).[1] By creating a separate code number for marijuana extract, DEA's rule allows the government and the public to identify those materials more precisely on agency paperwork, helping the United States record accurate data for reporting to international bodies, as required by multilateral agreements to which the United States is a party.

Petitioners mistakenly assert that, by creating the new code number, DEA implicitly subjected new substances to control under the CSA, purported to override statutes addressing "industrial hemp," and violated various procedural obligations. Petitioners' claims fail on multiple grounds. First, despite an opportunity to do so, petitioners did not participate in DEA's rulemaking proceeding. Neither petitioners

[1] The CSA uses the term "marihuana," but this brief uses the contemporary spelling except in direct quotations.

nor anyone else commented on the issues that petitioners raise here, and petitioners' claims are therefore waived. Petitioners also lack standing to challenge the rule, which inflicts no injury on them but instead simply adjusts DEA's administrative methods for tracking substances that the federal government has long controlled. Finally, the rule is well within DEA's authority: Congress directed the Attorney General to control the substances listed in the CSA, *see* 21 U.S.C. § 811, and gave him broad discretion to promulgate regulations "which he may deem necessary and appropriate for the efficient execution of his functions," *id.* § 871(b). The new code number refines the method by which DEA satisfies its statutory obligations but makes no substantive change to the government's control of any substance.

## STATEMENT OF JURISDICTION

Petitioners seek review of a final rule that DEA issued on December 14, 2016. Petitioners filed a petition for review on January 13, 2017, and they filed an amended petition for review on January 27, 2017. Petitioners invoke the Court's jurisdiction under 21 U.S.C. § 877.

## STATEMENT OF THE ISSUES

The federal government has assigned an Administration Controlled Substances Code Number to each substance that is controlled under the Controlled Substances Act. The government and the public use these code numbers to identify the substances on paperwork and for similar administrative purposes. Petitioners challenge a final rule in which DEA transferred some of the substances within the

CSA definition of "marijuana" to a new code number for "marijuana extract." The issues presented are:

1. Whether petitioners waived their challenge to the rule by failing to participate in the rulemaking proceeding.

2. Whether petitioners have standing to challenge the rule.

3. Whether the rule is a valid exercise of DEA's rulemaking power.

## PERTINENT STATUTES AND REGULATIONS

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

## STATEMENT OF THE CASE

### A. Statutory And Regulatory Background

**1.** Congress enacted the Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, as a comprehensive regime to combat drug abuse and control drug traffic. *See Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). The CSA divides all controlled substances into five schedules. *See* 21 U.S.C. § 812(a). Schedule I substances are subject to the most stringent controls, reflecting a judgment that they have (1) "a high potential for abuse," (2) "no currently accepted medical use in treatment in the United States," and (3) "a lack of accepted safety for use . . . under medical supervision." *Id.* § 812(b)(1). It violates federal law to manufacture, distribute, or dispense a Schedule I controlled substance without a DEA registration. *See id.* §§ 822, 823, 841(a).

Congress placed marijuana in Schedule I when it enacted the CSA, and it has remained there ever since. *See* 21 U.S.C. § 812(c); *see also Americans for Safe Access v.*

*DEA*, 706 F.3d 438, 449 (D.C. Cir. 2013) (holding that substantial evidence supported DEA's determination that marijuana continued to meet the statutory criteria for placement in Schedule I). The CSA defines "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." 21 U.S.C. § 802(16).[2] The statutory definition expressly excludes "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.*

"[F]or purposes of identification," DEA has assigned an Administration Controlled Substances Code Number to each substance that is controlled under the CSA. 21 C.F.R. § 1308.03(a). DEA and the public use these code numbers to identify the substances for various administrative purposes. For example, when DEA issues a certificate of registration permitting someone to manufacture a controlled substance, the certificate must identify the substance that the person is authorized to manufacture. *See* 21 U.S.C. § 823(c) (stating that a registrant may not "manufacture or

[2] This Court held in *United States v. Kelly*, 527 F.2d 961, 963-64 (9th Cir. 1976), that, notwithstanding the CSA's specific reference to "Cannabis sativa L.," Congress in fact "intended to outlaw all plants popularly known as marihuana to the extent that those plants possessed THC."

distribute controlled substances in schedule I or II other than those specified in the registration"). DEA uses the substance's code number to identify the substance on the certificate of registration. *See* 21 C.F.R. § 1308.03(a). Applicants for import and export permits and procurement or manufacturing quotas likewise include the relevant code numbers on their application forms to identify the substances they wish to import, export, procure, or manufacture. *Id.* "[N]o applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose" other than those listed in 21 C.F.R. § 1308.03(a). *Id.* § 1308.03(b).

DEA regulations list the code numbers that DEA has assigned to all of the substances that are controlled under the CSA. *See* 21 C.F.R. §§ 1308.11-.15. Until DEA issued the challenged rule in 2016, there was no drug code specifically dedicated to marijuana extracts (as opposed to marijuana generally).

**2.** As the CSA recognizes, *see, e.g.*, 21 U.S.C. § 811(d), the United States is a party to international agreements related to controlled substances. In particular, "[i]n 1948, in order to simplify existing treaties and international administrative machinery, members of the United Nations undertook codification of a single convention on international narcotics control." *National Org. for Reform of Marijuana Laws (NORML) v. DEA*, 559 F.2d 735, 739 (D.C. Cir. 1977). The result was the Single Convention on Narcotic Drugs, a multilateral agreement that was opened for signature in 1961 and that the United States ratified in 1967. *See* Single Convention on Narcotic Drugs, 1961, Mar. 30, 1961, 18 U.S.T. 1407, 520 U.N.T.S. 204 (Single Convention).

A primary purpose of the Single Convention is to coordinate international action against drug abuse. *See* Single Convention pmbl. The Convention accordingly "bind[s] . . . all signatories to control persons and enterprises engaged in the manufacture, trade and distribution of specified drugs." *United States v. Rodriquez-Camacho*, 468 F.2d 1220, 1222 (9th Cir. 1972); *see also* Single Convention art. 4 (requiring signatories to "take such legislative and administrative measures as may be necessary . . . [t]o give effect to and carry out the provisions of [the] Convention within their own territories"). Among other obligations, signatories must provide the International Narcotics Control Board with statistics regarding the quantities of controlled substances that people in their territories have imported, exported, produced, consumed, and used for various purposes. Single Convention arts. 19-20. The Board compiles this information into reports, which it publicly disseminates. *See, e.g.*, Int'l Narcotics Control Bd., *Report 2016*, U.N. Doc. E/INCB/2016/1, (Mar. 2017), https://www.incb.org/documents/Publications/AnnualReports/AR2016/English/AR2016_E_ebook.pdf. The Board's reports include statistics regarding individual substances. *See, e.g.*, Int'l Narcotics Control Bd., *Narcotic Drugs: Estimated World Requirements for 2017, Statistics for 2015*, U.N. Doc. E/INCB/2016/2, (2016), https://www.incb.org/documents/Narcotic-Drugs/Technical-Publications/2016/Narcotic_Drugs_Publication_2016.pdf.

Because of these control and reporting obligations, it is useful if a signatory nation can track substances using the same classifications that the Single Convention

uses. The Single Convention and the CSA classify substances according to somewhat different systems, however. Like the CSA, the Single Convention assigns drugs to schedules, *see* Single Convention art. 2, but the schedules do not correspond to those of the CSA. Among other things, the drugs that the Single Convention assigns to its Schedule IV (the most restrictive) also appear on its Schedule I (the second most restrictive). *Id.*

The Single Convention and the CSA also classify substances derived from the cannabis plant differently. Like the CSA, the Single Convention imposes controls on cannabis-derived substances. Unlike the CSA, however, "the Single Convention prescribes different controls for various parts of the cannabis plant." *NORML*, 559 F.2d at 739. "Cannabis" and "cannabis resin" appear on both Schedule I and Schedule IV, and they are therefore subject to the controls that accompany both designations. However, the Single Convention places "extracts and tinctures of cannabis" only on Schedule I. The International Narcotics Control Board also instructs signatories to distinguish between these categories of cannabis-derived substances for certain statistical reporting purposes. *See, e.g.*, Int'l Narcotics Control Bd., *Form A: Quarterly Statistics of Imports and Exports of Narcotic Drugs*, 2 ¶ 10, https://www.incb.org/documents/Narcotic-Drugs/Forms/Form_A/15th_Edition/Form_A_English_15thedition.pdf (directing reporting entities to multiply "[t]he weight of extracts of cannabis imported or exported . . . by seven" when calculating "the quantities of cannabis to be included in these statistics") (emphasis omitted).

### B. Procedural Background

**1.** DEA issued a notice of proposed rulemaking in 2011, proposing to create a new code number to identify "marijuana extract." ER 9. The notice explained that DEA had long used the code number for "marijuana" to refer to extracts of marijuana, as such extracts fall within the CSA's definition of marijuana. ER 10; *see also* 21 U.S.C. § 802(16) (defining "marihuana" to include "every compound, manufacture, salt, derivative, mixture, or preparation of [the Cannabis sativa L.] plant, its seeds or resin," subject to certain exceptions).

DEA explained that establishing a separate code number for marijuana extract would help the United States comply with the Single Convention. ER 10. As noted above, the Single Convention requires that the United States and other signatories compile and report statistics regarding controlled substances. Because the Single Convention "treat[s] extracts from the cannabis plant differently than marihuana or tetrahydrocannabinols," DEA explained, establishing a separate code number for marijuana extract would facilitate "more appropriate accounting of such materials consistent with treaty provisions." *Id.* DEA proposed to define "marihuana extract" to include "extracts that have been derived from any plant of the genus cannabis and which contain cannabinols and cannabidiols," *id.*, which are chemical substances that are present in controlled parts of the cannabis plant. DEA clarified that materials defined as marijuana extract would "remain in schedule I," notwithstanding the proposed change to their code number. *Id.*

DEA received six comments on the proposed rule. Three of the comments argued generally in favor of legalizing various substances and did not address the proposed drug code. ER 19; Supp. ER 1, 2. A fourth comment requested clarification about the scope of the proposed code number's application. ER 20. A fifth comment supported the prospect of establishing a new code number but suggested that DEA adjust its definition of "marihuana extract" to make it more precise. ER 15. The sixth comment corrected an error in the fifth comment. Supp. ER 3. Petitioners did not comment on the proposed rule, nor did any of the comments that were submitted address the issues that petitioners raise here.

**2.** DEA issued its final rule on December 14, 2016. *See* ER 12. The rule amends DEA's regulations to create a new identification code for marijuana extract, which the rule defines as "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.* Like the notice of proposed rulemaking, the final rule explained that the CSA's definition of marijuana includes "both derivatives and preparations of marihuana" and that DEA had therefore previously "used drug code 7360 for extracts of marihuana," as well as for other substances within the CSA's "marijuana" definition. *Id.* DEA reiterated that establishing a separate code number for marijuana extract, a subset of the materials that the CSA defines as marijuana, would "allow[] for more appropriate accounting of such materials consistent with treaty provisions." ER 13-14.

The final rule made clear that DEA was not subjecting new substances to federal control. Like the notice of proposed rulemaking, the final rule stated that the substances subject to the new code number would "remain in Schedule I." ER 13-14. DEA explained:

> This rule establishes a new drug code for marihuana extracts. DEA already registers persons handling marihuana extracts but within another already-established drug code. Thus, persons who handle these marihuana extracts have already met DEA's registration, security, and other statutory and regulatory requirements. The only direct effect to registrants who handle marihuana extracts will be the requirement to add the new drug code to their registration.

ER 14. The rule went into effect on January 13, 2017. ER 12.

**3.** On March 9, 2017, after petitioners initiated this proceeding but before they filed their opening brief, DEA issued guidance further clarifying the application of the new code number for marijuana extract. *See* DEA, Diversion Control Division, *Clarification of the New Drug Code (7350) for Marijuana Extract*, https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html (*Clarification*).[3] In response to questions that DEA had received, the guidance stated that "[t]he new drug code (7350) established in the Final Rule does not include materials or products that are excluded from the definition of marijuana set forth in the Controlled Substances Act." *Id.* DEA stated that "[t]he new drug code includes only those extracts that fall within the CSA definition of marijuana" and further

[3] Government counsel promptly notified petitioners' counsel of the guidance.

clarified that, "[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 new drug code (7350) or in the drug code for marijuana (7360)." *Id.* The guidance also reiterated that the purpose of the new code number is simply "to give DEA more precise accounting to assist the agency in carrying out its obligations to provide certain reports required by U.S. treaty obligations." *Id.*

The guidance cited scientific literature supporting the conclusion that the new code number does not apply to substances outside the CSA definition of "marijuana." *See Clarification*. As noted above, the rule defines "marijuana extract" as "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." ER 13. DEA's guidance explained that cannabinoids, which are chemicals in the cannabis plant, "are found in the parts of the cannabis plant that fall *within* the CSA definition of marijuana, such as the flowering tops, resin, and leaves." *Clarification* (emphasis added) (citing H. Mölleken & H. Husmann, *Cannabinoids in Seed Extracts of Cannabis Sativa Cultivars*, 4 J. Int'l Hemp Ass'n 73 (1997)). The parts of the cannabis plant that are exempt from the CSA definition of marijuana contain, at most, only "trace amounts (typically, only parts per million)" of cannabinoids. *Id.* (citing Mölleken & Husmann, *supra*; S.A. Ross et al., *GC-MS Analysis of the Total Delta9-THC Content of Both Drug- and Fiber-Type Cannabis Seeds*, 24 J. Analytical Toxicology 715 (2000)). "[I]f a product . . . consisted solely of parts of the cannabis plant excluded

from the CSA definition of marijuana," DEA clarified, "such product would not be included in the new drug code (7350) or in the drug code for marijuana (7360) even if it contained trace amounts of cannabinoids." *Id.*

## SUMMARY OF ARGUMENT

Congress directed the Attorney General to implement the Controlled Substances Act and broadly authorized him to promulgate regulations "which he may deem necessary and appropriate for the efficient execution of his functions." 21 U.S.C. § 871(b). DEA, to which the Attorney General has delegated the relevant authority under the CSA, promulgated a final rule assigning a new identification number to "marijuana extract," a subset of the substances that the CSA has always regulated as "marijuana." As DEA explained in its rule, assigning a separate identification number to marijuana extract helps the United States to satisfy more efficiently and precisely its recordkeeping and reporting obligations under international agreements.

Petitioners' challenge to the rule fails on several grounds. First, petitioners waived their challenge by failing to participate in DEA's rulemaking proceeding. "[A] party's failure to make an argument before the administrative agency in comments on a proposed rule bar[s] it from raising that argument on judicial review." *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004). DEA's proposed rule gave petitioners ample notice of the matters DEA was considering, but neither petitioners nor any other member of the public submitted a comment on the issues

petitioners raise here. Petitioners "offer[] no compelling reason" that they could not have participated in the rulemaking, *id.* at 1021, and DEA "cannot be faulted for failing to address . . . issues that were not raised," *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001).

Second, petitioners lack standing to challenge the rule, which does not restrict their activities or attach new penalties to any conduct. As the rule and DEA's subsequent guidance make clear, the new identification number does not apply to any substance that the CSA did not previously control as "marijuana." It simply requires that persons handling a subset of the materials defined as "marijuana" write a different identification number on their administrative paperwork. Petitioners "cannot . . . create a justiciable case or controversy simply by misreading [the rule] and claiming as injury fears born of their own error." *Western Mining Council v. Watt*, 643 F.2d 618, 626 (9th Cir. 1981).

Third, if petitioners' claims were properly before the Court, they would fail on the merits. No basis exists for petitioners' contention that DEA was required to proceed through a scheduling action. The rule does not impose new controls on any substance but instead applies only to extracts within the CSA definition of "marijuana." Petitioners likewise err in claiming that the rule conflicts with a section of the Agricultural Act of 2014. That provision, which created a limited authorization to cultivate what the statute defines as "industrial hemp," expressly applies

"[n]otwithstanding the Controlled Substances Act." 7 U.S.C. § 5940(a). Nothing in DEA's regulation conflicts with that statute.

Petitioners' claims under the Information Quality Act, Regulatory Flexibility Act, and Congressional Review Act also lack merit. Petitioners identify no statement in the rule that they believe requires correction under the Information Quality Act, nor do they allege that they ever invoked the administrative mechanisms at that statute's core. DEA satisfied its procedural obligations under the Regulatory Flexibility Act, explaining that the rule would have no significant economic impact on small entities because it simply requires that persons handling marijuana extract include a new code number on their registration forms. The Congressional Review Act expressly precludes judicial review, *see* 5 U.S.C. § 805, and DEA correctly determined in any event that its rule assigning a new identification number to marijuana extract was not a "major" one requiring a special alert to Congress.

## STANDARD OF REVIEW

A court may set aside DEA's final action only if the action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A); *see also Fry v. DEA*, 353 F.3d 1041, 1043 (9th Cir. 2003). Review under that standard is narrow, and a reviewing court may not substitute its judgment for that of the agency. *See Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 858 (9th Cir. 2005). The Court must simply determine "whether the agency articulated a rational connection between the facts found and the choice made."

*Arizona Cattle Growers Ass'n v. U.S. Fish & Wildlife Serv.*, 273 F.3d 1229, 1236 (9th Cir. 2001). So long as the agency's decision was "based on a consideration of relevant factors and there is no clear error of judgment," the agency's action is not arbitrary and capricious. *Fry*, 353 F.3d at 1043.

Pursuant to 21 U.S.C. § 877, DEA's findings of fact are "conclusive if supported by substantial evidence." *Ruben v. DEA*, 617 F. App'x 837, 838 (9th Cir. 2015). This Court applies the principles of deference articulated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984), to an agency's interpretation and application of the statute it administers. *See, e.g.*, *Sharemaster v. U.S. SEC*, 847 F.3d 1059, 1066-68 (9th Cir. 2017).

## ARGUMENT

### I. Petitioners Waived Their Claims By Failing To Raise Them In The Rulemaking Proceeding

"It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review." *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004). That principle applies with full force where a litigant challenges a rule promulgated after notice and comment: "a party's failure to make an argument before the administrative agency in comments on a proposed rule bar[s] it from raising that argument on judicial review." *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004) (citing *Exxon Mobil Corp. v. U.S. EPA*, 217 F.3d 1246, 1249 (9th Cir. 2000)); *see*

*also id.* at 1020 (describing this Court's rule as "consistent with the decisions of every other circuit to have addressed the issue of waiver in notice-and-comment rulemaking"). It is "black-letter administrative law that [a]bsent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue." *Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1036 (D.C. Cir. 2001) (alteration in original; quotation marks omitted).

This waiver principle applies to both legal and factual claims. *See, e.g.*, *Exxon Mobil*, 217 F.3d at 1249 (holding that petitioners had waived their challenge to an agency's construction of the governing statute); *see also National Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002) (per curiam) ("[T]here is a near absolute bar against raising new issues—factual or legal—on appeal in the administrative context."). This bar protects "the agency's interests in applying its expertise, correcting its own errors, making a proper record, enjoying appropriate independence of decision and maintaining an administrative process free from deliberate flouting." *Universal Health*, 363 F.3d at 1021. As the Supreme Court has explained in the adjudication context, a contrary system would "usurp[] the agency's function" and "deprive[] the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action." *Unemployment Compensation Comm'n of Alaska v. Aragon*, 329 U.S. 143, 155 (1946).

Petitioners did not participate in DEA's rulemaking proceeding. None of them submitted a comment regarding DEA's proposed rule (even though one of the

petitioners is a trade association that appears to monitor developments that may affect its members' interests). Nor did the six comments that DEA received from other members of the public address any of the issues that petitioners raise here. Three of the comments argued generally in favor of legalizing various substances. ER 19; Supp. ER 1, 2. A fourth comment requested clarification regarding the scope of the proposed code number. ER 20. The final two comments, from a single entity, endorsed the establishment of a separate code number for marijuana extract but suggested, in the interest of precision, that DEA adjust the definition it had proposed. ER 15; Supp. ER 3. No comment suggested that DEA's proposed rule was invalid for the reasons that petitioners offer in their brief to this Court.

Although courts occasionally excuse failure to participate in a rulemaking proceeding where "exceptional circumstances" exist, *see Exxon Mobil*, 217 F.3d at 1249, there are no exceptional circumstances here. Petitioners have not explained why they failed to raise their objections with DEA. The notice of proposed rulemaking was "clearly sufficient to provide [petitioners] with the incentive to make their arguments and the factual data on which to base them." *Universal Health*, 363 F.3d at 1021. It thoroughly outlined the matters that DEA was considering, and it closely resembles the final rule.

The final rule's modification of the definition of "marijuana extract" in response to comments from other members of the public does not excuse petitioners' failure to submit a comment. The proposed rule would have defined "marijuana

extract" by reference to the presence of "cannabinols and cannabidiols," which are specific types of cannabinoid, while the final rule refers to cannabinoids more generally. *See* ER 10 (proposed rule); ER 13 (final rule). Petitioners' brief makes clear, however, that they would object equally, and on the same grounds, to a definition that referred to either "cannabinols and cannabidiols" or "cannabinoids." *See, e.g.*, Br. 20 (asserting that DEA's "misconceptions" arose from its decision to define marijuana extract by reference to "cannabinoids generally, cannabidiol (CBD), . . . cannabinol (CBN) or any other individual cannabinoids other than [tetrahydrocannabinols (THC)]"). If petitioners were concerned about these issues, they should have commented on the proposed rule. They "offer[] no compelling reason" that they could not have done so, and they cannot make their arguments for the first time in a brief to this Court. *Universal Health*, 363 F.3d at 1021.[4]

Petitioners mistakenly suggest that DEA's rule "favor[s]" a company that submitted a comment on the rule. Br. 58. But DEA would have given equal

[4] One of petitioners' claims is that the rule contravenes the Agricultural Act of 2014, which established a limited authorization for institutions of higher education and state departments of agriculture to grow and cultivate what Congress defined as "industrial hemp." *See* 7 U.S.C. § 5940. Congress enacted the Agricultural Act after DEA issued its notice of proposed rulemaking, but before DEA promulgated the final rule. Because the rule does not purport to affect the regulation of "industrial hemp" under the Agricultural Act, however, *see infra* Pts. II, III.B.2, DEA's interests in "applying its expertise, correcting its own errors, making a proper record, enjoying appropriate independence of decision and maintaining an administrative process free from deliberate flouting" far outweigh petitioners' asserted "interest[] . . . in finding adequate redress for" their meritless claim under the Agricultural Act. *Universal Health*, 363 F.3d at 1021.

consideration to petitioners' views if petitioners had chosen to participate in the process. Had petitioners submitted comments on the issues they now raise, DEA's final rule could have explained even more clearly that the new code number for marijuana extract applies only to substances within the scope of the CSA, that the new code number does not interfere with other federal law, and that the rule facilitates the United States' recordkeeping and reporting activities. Petitioners failed to communicate any of their concerns during the rulemaking process, and the agency "cannot be faulted for failing to address . . . issues that were not raised." *Appalachian Power Co.*, 251 F.3d at 1036.

## II. Petitioners Lack Standing To Challenge DEA's Rule

Dismissal of the petition is also required because petitioners lack standing to maintain their challenge.[5] Article III of the Constitution permits litigants to bring suit only if they have suffered an injury that is "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1147 (2013) (quotation marks omitted). A party seeking direct review of administrative action in a court of appeals bears the same burden of production as would "a plaintiff moving for summary judgment in the district court": the petitioner "must support each element of its claim

[5] This Court could dismiss the petition for review on the basis of either waiver or standing, as "a federal court has leeway to choose among threshold grounds for denying audience to a case on the merits." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007) (quotation marks omitted).

to standing 'by affidavit or other evidence.'" *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)); *see also Crane v. U.S. Nuclear Regulatory Comm'n*, 344 F. App'x 316, 317 (9th Cir. 2009) (dismissing a petition for review for lack of standing because "[t]he record [did] not include any affidavit or medical record to demonstrate" the petitioner's injury).

**A.** DEA's rule does not cause petitioners to suffer any "concrete, particularized, and actual or imminent" injury. *Clapper*, 133 S. Ct. at 1147. The rule does not restrict petitioners' activity or attach new penalties to any conduct: it simply changes the identification number that people handling certain controlled substances must print on administrative paperwork.

The rule makes this clear, explaining that "DEA already registers persons handling marihuana extracts but within another already-established drug code." ER 14. "[P]ersons who handle these marihuana extracts have" therefore "already met DEA's registration, security, and other statutory and regulatory requirements." *Id.* The rule thus explains that "[t]he only direct effect to registrants who handle marihuana extracts [is] the requirement to add the new drug code to their registration." *Id.* DEA's subsequent guidance makes the point even more explicit, explaining that "[t]he new drug code (7350) . . . does not include materials or products that are excluded from the definition of marijuana set forth in the" CSA. *See Clarification*. The rule does not obligate anyone to register with DEA who was not already required to do so.

Because the code number extends no further than the CSA does, it has no relevance to petitioners if their activities involve only materials outside the CSA's definition of "marijuana," for which no code number is required. *See California Tow Truck Ass'n v. City & Cty. of S.F.*, 693 F.3d 847, 865-66 (9th Cir. 2012) (holding that truck operators lacked standing to argue that they could not be required to obtain permits to pass through San Francisco, as the city did not require permits in that circumstance); *Valley Outdoor, Inc. v. City of Riverside*, 446 F.3d 948, 952-53 (9th Cir. 2006) (dismissing a challenge for lack of standing because the challenged restrictions did not apply to the plaintiff's activity). Petitioners also do not need to use the code number if they engage in activities involving "industrial hemp" that fall within the parameters of the Agricultural Act of 2014 (Agricultural Act). As explained at greater length in Part III.B.2, the code number is part of the system for implementing the CSA, but the Agricultural Act expressly permits activities within its scope, "[n]otwithstanding the [CSA]." 7 U.S.C. § 5940(a).

If, on the other hand, petitioners' activities involve "marijuana" as defined in the CSA and are not within the scope of the Agricultural Act, petitioners have always been required to use code numbers to identify the substances they handle. *See* 21 C.F.R. § 1308.03(a) (stating that DEA has assigned a code number to "[e]ach controlled substance" under the CSA); *see also id.* § 1308.11(d)(23) (code number for "marihuana"). Petitioners can identify no injury resulting from creation of an additional identification number. *See Takhar v. Kessler*, 76 F.3d 995, 1001 (9th Cir.

1996) (dismissing a challenge to agency guidance interpreting a statute because "[t]he cause of any injury . . . is not the [guidance] but the [statute] itself"); *see also, e.g.*, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court . . . . ").

**B.** Although petitioners' opening brief does not address standing, it suggests in passing that DEA's rule might "chill the . . . legal hemp industry through confusion, misinterpretation and misapplication of law." Br. 9. Petitioners apparently speculate that industry participants might misunderstand the rule to impose new restrictions on substances that the federal government did not previously regulate. But petitioners "cannot . . . create a justiciable case or controversy simply by misreading [DEA's rule] and claiming as injury fears born of their own error." *Western Mining Council v. Watt*, 643 F.2d 618, 626 (9th Cir. 1981). The rule states explicitly that the new code number applies only to substances that have always been "in Schedule I," ER 13-14, and DEA's subsequent guidance eliminates any conceivable doubt on that point.

Petitioners have standing to challenge DEA's rule only if they "face 'a realistic danger of sustaining a direct injury as a result of [its] operation or enforcement.'" *Thomas v. Anchorage Equal Rights Comm'n*, 220 F.3d 1134, 1139 (9th Cir. 2000) (en banc) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). "[T]here must be a 'genuine threat of imminent prosecution'"; a risk of injury that is merely "imaginary" or "speculative" does not suffice. *Id.* (quoting *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1126 (9th Cir. 1996)); *see also Clapper*, 133 S. Ct. at

1150 n.5 (requiring that an alleged injury be "clearly impending" or that there be a "'substantial risk' that the harm will occur"). As explained above, there is no reasonable basis to think petitioners will need to use the new code number in connection with activities that federal law did not previously control. *See Lopez v. Candaele*, 630 F.3d 775, 788 (9th Cir. 2010) (explaining that plaintiffs lack standing "where the enforcing authority expressly interpret[s] the challenged law as not applying to the plaintiffs' activities"). Any contrary fears that petitioners might claim would be far too "imaginary" and "speculative" to support jurisdiction. *California Tow Truck Ass'n*, 693 F.3d at 866.

## III. The Rule Is A Valid Exercise Of DEA's Rulemaking Authority

If petitioners' claims were properly before the Court, they would appropriately be dismissed on the merits. All of petitioners' claims turn on the mistaken notion that DEA's rule imposes new restrictions on substances that were not previously controlled. But the rule simply adjusts DEA's methods for tracking substances that Congress placed in Schedule I when it enacted the CSA. The rule does not purport to control any substance that federal law did not previously control, nor has DEA violated any of the procedural statutes that petitioners cite.

### A. The Rule Is A Reasonable Means Of Facilitating The United States' Reporting Of Accurate Data To International Bodies

Since the federal government first promulgated regulations implementing the CSA, four-digit code numbers have been used to identify individual controlled

substances. *See* Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 Fed. Reg. 7776, 7803 (Apr. 24, 1971) (promulgating 21 C.F.R. § 308.03 (1972), the direct predecessor of today's 21 C.F.R. § 1308.03, which explained that each controlled substance had been assigned a code number "for purposes of identification"). These code numbers are necessary when the government authorizes people to engage in activities involving controlled substances, as those authorizations are substance-specific. *See, e.g.*, 21 U.S.C. § 958(a) (directing the Attorney General to "register an applicant to import or export" Schedule I and II controlled substances under certain circumstances); *id.* § 958(b) (stating that a registrant's export and import authority is limited to the substances "specified in the registration").

DEA's code numbers are useful for the additional purpose of compiling information for reporting to international regulatory bodies. The Single Convention on Narcotic Drugs requires signatories, including the United States, to take various actions related to controlled substances. Among other things, signatories must provide the International Narcotics Control Board with "[a]n annual report on the working of the Convention within each of their territories," Single Convention art. 18(1)(a); annual estimates of the quantities of drugs to be consumed for various purposes, *id.* art. 19; and annual "statistical returns" regarding production, manufacture, utilization, consumption, imports, exports, seizures, and stocks of drugs, *id.* art. 20.

While the CSA defines all regulated parts of the cannabis plant as "marijuana," "the Single Convention prescribes different controls for various parts of the cannabis plant." *NORML v. DEA*, 559 F.2d 735, 739 (D.C. Cir. 1977). Under the Single Convention, "cannabis" and "cannabis resin" are subject to the most restrictive controls, while "extracts and tinctures of cannabis" are treated somewhat less restrictively. The International Narcotics Control Board also distinguishes between those substances for statistical reporting purposes. *See, e.g.*, Int'l Narcotics Control Bd., *Form A: Quarterly Statistics of Imports and Exports of Narcotic Drugs*, 2 ¶ 10, https://www.incb.org/documents/Narcotic-Drugs/Forms/Form_A/15th_Edition/Form_A_English_15thedition.pdf (instructing signatories to multiply "the weight of extracts of cannabis imported or exported . . . by seven" for purposes of reporting cannabis quantities) (emphasis omitted). As the rule explains, tracking "marijuana" and "marijuana extract" separately "allows for more appropriate accounting of such materials consistent with treaty provisions." ER 13.[6]

[6] Petitioners' observation that the relevant international agreements do not "*per se* control[]" cannabinoids other than THC, Br. 42, is beside the point. DEA's rule does not control cannabinoids in their own right; it simply helps DEA satisfy its recordkeeping and reporting obligations as to cannabis and cannabis extract, which petitioners acknowledge that the Single Convention controls. *See* Br. 35-36.

### B. Petitioners' Contrary Arguments Lack Merit

#### 1. The Rule Is Consistent With The Controlled Substances Act

Petitioners mistakenly contend, *see* Br. 14-17, 44-51, that the rule contravenes the Controlled Substances Act by adding new substances to Schedule I without following the requisite procedures. *See* 21 U.S.C. § 812(b) (describing the findings that the government generally must make before "plac[ing]" a drug or any other substance "in any schedule"); *id.* § 811(a) (describing the procedures that the government generally must follow in those circumstances). But the rule does not place any new substance in Schedule I; it simply changes the code number used to identify certain substances that Congress assigned to Schedule I when it enacted the CSA. Because DEA did not "place[]" any "drug or other substance" in a new schedule, DEA was not required to make the findings set out in 21 U.S.C. § 812(b).

The new code number applies to "extract[s] containing one or more cannabinoids that ha[ve] been derived from any plant of the genus Cannabis, other than the separated resin . . . obtained from the plant." ER 13. As DEA's March 2017 guidance explained, cannabinoids "are found in the parts of the cannabis plant that fall within the CSA definition of marijuana." *Clarification*. "[C]annabinoids are not found in the parts of the cannabis plant that are excluded from the CSA definition of marijuana, except for trace amounts (typically, only parts per million) that may be found where small quantities of resin adhere to the surface of seeds and mature stalk."

*Id.* (footnote omitted). To the extent that a product consisting solely of exempt parts of the cannabis plant contained trace amounts of cannabinoids, "such product would not be included in the new drug code." *Id.*; *see also Auer v. Robbins*, 519 U.S. 452, 461 (1997) (agency's interpretation of its own regulation is "controlling unless plainly erroneous or inconsistent with the regulation") (quotation marks omitted). No scheduling action was required to assign a new code number to "those extracts that fall within the CSA definition of marijuana," *Clarification*, as they were already Schedule I substances.

Petitioners assert that cannabinoids can be found in parts of the cannabis plant that the CSA exempts from its definition of "marijuana." Br. 23. DEA cited evidence in its March 2017 guidance, however, to support its conclusion that only the controlled parts of the plant contain non-trace amounts of cannabinoids. *See Clarification* (citing H. Mölleken & H. Husmann, *Cannabinoids in Seed Extracts of Cannabis Sativa Cultivars*, 4 J. Int'l Hemp Ass'n 73 (1997); S.A. Ross et al., *GC-MS Analysis of the Total Delta9-THC Content of Both Drug- and Fiber-Type Cannabis Seeds*, 24 J. Analytical Toxicology 715 (2000)). Petitioners had ample opportunity during the rulemaking proceeding to submit any contrary evidence they might have thought they had. They did not do so, however, and the Court's review must be "limited . . . to

evidence within the administrative record," *Black Constr. Corp. v. INS*, 746 F.2d 503, 505 (9th Cir. 1984).[7]

Petitioners further contend that, with the exception of THC, *see* 21 U.S.C. § 812(c)(17), cannabinoids are not independently scheduled as controlled substances. *See* Br. 21-24. But the rule refers to cannabinoids simply to identify extracts that come from the controlled parts of the cannabis plant and are thus themselves controlled. *See Clarification*. As petitioners concede, *see, e.g.*, Br. 13, cannabinoids are controlled to the extent that they are found in non-exempt parts of the cannabis plant.

Petitioners also suggest that cannabinoids can be found in "several plant species besides cannabis," like coneflower, electric daisy, and liverwort. Br. 7 & n.3. That observation is of limited relevance even if true, as the new code number applies only to extracts derived from a "plant of the genus Cannabis." ER 13. If anything, the suggestion undermines petitioners' contention that DEA's rule seeks to "schedule[] cannabinoids." Br. 7. Petitioners do not claim that DEA has sought to

[7] This Court's decision in *Hemp Industries Association v. DEA*, 357 F.3d 1012 (9th Cir. 2004), and the regulations at issue in that case, assumed that "trace amounts" of THC, a cannabinoid, could be found in parts of the cannabis plant outside the CSA definition of marijuana. *See id.* at 1014. Consistent with the Court's 2004 ruling, DEA's March 2017 guidance makes clear that the code number for marijuana extract does not apply to products that consist solely of those parts of the plant, even if the products "contain[] trace amounts of cannabinoids." *Clarification*; *see also Hemp Indus.*, 357 F.3d at 1018 (noting that, "when Congress excluded from the definition of marijuana 'mature stalks of [the cannabis] plant, fiber . . . , [and] oil or cake made from the seeds,' it also made an exception to the exception, and included 'resin extracted from' the excepted parts of the plant in the definition of marijuana, despite the stalks and seed exception").

restrict activity related to coneflower, electric daisy, or liverwort, which it presumably would do if those plants contained cannabinoids and if DEA truly sought to control cannabinoids themselves.

Petitioners also cite the 2015 congressional testimony of a DEA official, which they assert shows that a particular cannabinoid called "cannabidiol" is not a controlled substance. *See* Br. 39-40. The testimony instead supports the rule's validity, however: the DEA official explained to Congress that cannabidiol and other cannabinoids derive from the controlled parts of the cannabis plant and that "[cannabidiol] derived from the cannabis plant is controlled under Schedule I of the CSA because it is a naturally occurring constituent of marijuana." Joseph T. Rannazzisi, Deputy Assistant Adm'r, DEA, *Cannabidiol: Barriers to Research and Potential Medical Benefits* 1 (2015) (statement before the Caucus on International Narcotics Control, United States Senate), https://www.dea.gov/pr/speeches-testimony/2015t/062415t.pdf. The excerpt that petitioners quote addressed whether the government might consider moving cannabidiol from Schedule I to a less restrictive schedule because of its claimed medical uses. *Id.* at 2.

Petitioners further contend that cannabinoids would not independently meet the statutory requirements for inclusion in Schedule I of the CSA, outside their capacity as a component of marijuana. *See* Br. 44-51. This is again beside the point, as DEA is not seeking to schedule cannabinoids, and Congress already made the required findings with respect to marijuana, the only substance to which DEA's rule

applies. In any event, contrary to petitioners' claim, the government has not "admit[ted]" anything about the effects, abuse potential, or potential medical use of products containing cannabinoids. Br. 47. It is true that certain products containing cannabinoids are the subject of medical research, but petitioners are mistaken to imply that the U.S. Food and Drug Administration (FDA) has approved those products. *See* Br. 49-50. The FDA has instead affirmatively warned consumers that "it is a prohibited act to introduce or deliver for introduction into interstate commerce any food . . . to which cannabidiol has been added" and that "the use of untested drugs can have unpredictable and unintended consequences." U.S. Food & Drug Admin., *FDA and Marijuana: Questions and Answers*, ¶¶ 8, 19 (Feb. 28, 2017), https://www.fda.gov/newsevents/publichealthfocus/ucm421168.htm#children; *see also* U.S. Food & Drug Admin., *2016 Warning Letters and Test Results for Cannabidiol-Related Products* (Aug. 31, 2016), https://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm (FDA warning letters issued to firms "market[ing] unapproved new drugs that allegedly contain cannabidiol").

Petitioners also suggest that DEA's rule is not entitled to deference under *Chevron U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984), *see* Br. 42-44, but they do not identify statutory language, ambiguous or otherwise, that DEA has misconstrued. They assert that Congress exempted parts of the cannabis plant from the CSA definition of "marijuana" and has authorized growth and cultivation of "industrial hemp" under certain circumstances, Br. 44, but neither observation undermines the

rule. *See Clarification* (explaining that the code number does not apply to extracts that consist solely of the exempt parts of the cannabis plant); Part III.B.2 (explaining that the code number does not purport to override the section of the Agricultural Act of 2014 that addresses "industrial hemp"). Petitioners imply that deference is inappropriate absent a clear delegation of authority, Br. 42, but here Congress has expressly delegated broad authority to the Attorney General. *See, e.g.*, 21 U.S.C. §§ 821, 871(b). And the Court should likewise reject petitioners' suggestion, Br. 43, based on concurring opinions of two members of other courts of appeals and a bill that Congress has not enacted, that "*Chevron* deference is no longer judicial canon." *See, e.g.*, *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (applying *Chevron* in the ordinary course); *Yazzie v. U.S. EPA*, 851 F.3d 960, 968 (9th Cir. 2017) (same).

### 2. The Rule Is Consistent With The Agricultural Act Of 2014 And The Related Appropriations Provision

Petitioners also mistakenly contend that the rule conflicts with the Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 649. Under certain circumstances, the Agricultural Act authorizes "institution[s] of higher education" and "State department[s] of agriculture" to "grow or cultivate" what the statute defines as "industrial hemp," "[n]otwithstanding the Controlled Substances Act . . . or any other Federal law." 7 U.S.C. § 5940(a). The Agricultural Act defines "industrial hemp" as "the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry

weight basis." *Id.* § 5940(b)(2). Although petitioners repeatedly suggest that the Agricultural Act "universally" authorized activities involving industrial hemp, *see, e.g.*, Br. 26, that suggestion is incorrect: the authorization to grow industrial hemp applies (1) to "institution[s] of higher education" and "State department[s] of agriculture"[8] that (2) "grow[] or cultivate[]" industrial hemp "for purposes of research conducted under an agricultural pilot program or other agricultural or academic research," and (3) only if state law permits the activity. 7 U.S.C. § 5940(a). Unless all of those criteria are satisfied, the Agricultural Act's limited authorization does not apply, and the "industrial hemp plant . . . may not be grown in the United States." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1085 n.2 (9th Cir. 2003).

DEA's rule implements the CSA and does not purport to override the Agricultural Act. The code number for marijuana extract appears alongside the code numbers for all other substances controlled under the CSA. *See* 21 C.F.R. § 1308.01 ("Schedules of controlled substances established by section 202 of the [Controlled Substances] Act (21 U.S.C. 812) . . . are set forth in this part."); *id.* § 1308.11 (list of substances and code numbers titled "Schedule I"). Where the Agricultural Act provision applies, it expressly overrides contrary provisions of the CSA. *See* 7 U.S.C.

[8] *See also* Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53,395, 53,395 (Aug. 12, 2016) (stating that the authorization applies to "State departments of agriculture, and persons licensed, registered, or otherwise authorized by them to conduct research under an agricultural pilot program in accordance with section 7606, and institutions of higher education . . . , or persons employed by or under a production contract or lease with them to conduct such research").

§ 5940(a) (stating that the industrial-hemp provision applies "[n]otwithstanding the Controlled Substances Act . . . or any other Federal law"). Petitioners appear to agree, *see* Br. 28, that "the use of such a 'notwithstanding' clause clearly signals the drafter's intention that the provisions of the 'notwithstanding' section override conflicting provisions of any other section." *Cisneros v. Alpine Ridge Grp.*, 508 U.S. 10, 18 (1993). It is thus not necessary for each DEA regulation implementing the CSA to carve out an exception for conduct authorized by the Agricultural Act, just as Congress did not need to amend the CSA itself for that purpose.

For the same reason, petitioners are mistaken in their claim that DEA's rulemaking violated a temporary appropriations rider forbidding the use of appropriated funds "in contravention of section 7606 of the Agricultural Act of 2014" or to restrict certain activities related to "industrial hemp that is grown or cultivated in accordance with . . . section 7606." *See* Br. 26-31 (citing Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 763, 129 Stat. 2242, 2285).[9] The materials to which the appropriations restriction applies are only those properly within the scope of Section 7606, and the rule establishing a new code number for marijuana extract does not purport to affect those materials.

[9] The two cases that petitioners claim "confirmed the validity of these prohibitions on funding," Br. 29, actually addressed an entirely different appropriations provision that does not relate to industrial hemp. *See United States v. McIntosh*, 833 F.3d 1163 (9th Cir. 2016) (interpreting a temporary appropriations rider related to medical marijuana); *United States v. Marin All. for Med. Marijuana*, 139 F. Supp. 3d 1039 (N.D. Cal. 2015) (same).

### 3. Petitioners Have No Valid Claim Under The Information Quality Act, The Regulatory Flexibility Act, Or The Congressional Review Act

Petitioners are also mistaken in their suggestions that DEA's rulemaking proceeding contravened the Information Quality Act, the Regulatory Flexibility Act, and the Congressional Review Act.

**a.** The Information Quality Act (which petitioners call the "Data Quality Act") is codified as a note to the Paperwork Reduction Act. *See* 44 U.S.C. § 3516 note. Enacted in appropriations legislation for fiscal year 2001, the Information Quality Act directed the Office of Management and Budget (OMB) to issue "guidelines" providing "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information" that the agencies disseminate. *Id.*; *see also Harkonen v. U.S. Dep't of Justice*, 800 F.3d 1143, 1145 (9th Cir. 2015). Congress also required that OMB's guidelines instruct other agencies, in turn, to create their own guidelines for maximizing the quality of their information and for creating "administrative mechanisms allowing affected persons to seek and obtain correction of information." 44 U.S.C. § 3516 note (b)(2)(B); *see also* 67 Fed. Reg. 8452 (Feb. 22, 2002) (OMB guidelines); U.S. Dep't of Justice, *Information Quality: DOJ Information Quality Guidelines* (2016), https://www.justice.gov/iqpr/information-quality (*DOJ Guidelines*).

Petitioners suggest that "DEA has violated the letter, if not the spirit, of the" Information Quality Act "by consistently misstating the law and facts regarding

industrial hemp generally, and [cannabidiol] in particular." Br. 51. This claim has several fundamental flaws. For one, petitioners make no attempt to connect their assertion that DEA has made misstatements about "industrial hemp" and cannabidiol to the rule that they are challenging in this proceeding. DEA's rule assigns a new identification code to a subset of the materials that the CSA has always controlled as "marijuana"; the rule makes no statements about industrial hemp, cannabidiol, or the legitimacy of petitioners' activities.

Furthermore, petitioners fail to allege that they ever sought to invoke the administrative mechanisms for information correction that are at the Information Quality Act's core. *See, e.g.*, *DOJ Guidelines*. Petitioners also make no effort to establish that the information at issue is within the scope of the Act or its implementing guidelines. They claim to be concerned about statements "by DEA's . . . spokespeople" and "contained within DEA's own publications and publicly available content," Br. 51-52, but the guidelines implementing the Act expressly exclude "press releases[,] fact sheets, press conferences[,] [and] similar communications." *DOJ Guidelines*; *see also Harkonen*, 800 F.3d at 1149-50 (approving the exclusion of press releases). Finally, most courts to address the issue have held that the Information Quality Act does not create a private right of action. *See, e.g.*, *Salt*

*Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006); *Harkonen v. U.S. Dep't of Justice*, No. 12-629, 2012 WL 6019571, at *11 (N.D. Cal. Dec. 3, 2012) (collecting cases).[10]

**b.** Petitioners' claim under the Regulatory Flexibility Act (RFA), 5 U.S.C. § 601 *et seq.*, is also mistaken. The RFA requires an agency promulgating a rule to analyze the rule's likely economic impact on small entities, *see* 5 U.S.C. §§ 603, 604, unless the "head of the agency certifies that the rule will not . . . have a significant economic impact on a substantial number of small entities," *id.* § 605(b). "The RFA imposes no substantive requirements on an agency; rather, its requirements are 'purely procedural' in nature." *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric.*, 415 F.3d 1078, 1101 (9th Cir. 2005). "To satisfy the RFA, an agency must only demonstrate a 'reasonable, good-faith effort' to fulfill its requirements." *Id.*

DEA satisfied that procedural mandate, certifying that its rule establishing a new code number for marijuana extract would not significantly affect small businesses. *See* ER 14. DEA explained that it "already registers persons handling marihuana extracts but within another already-established drug code." *Id.* "[P]ersons who handle these marihuana extracts have" therefore "already met DEA's registration, security, and other statutory and regulatory requirements," and "[t]he only direct effect" of the rule is "the requirement to add the new drug code to their registration." *Id.*

[10] This Court has not yet resolved that question. *See Harkonen*, 800 F.3d at 1148.

Petitioners' RFA claim is premised on the same mistaken understanding as the rest of their claims. Ignoring the text of the rule and DEA's clarifying guidance, petitioners assert that the new code number for marijuana extract silently extends a registration requirement to substances that federal law did not previously control, thus imposing costs on small entities that DEA failed to address in its rulemaking. *See* Br. 54-55. But as DEA has explained at length in the rule, in its guidance, and elsewhere in this brief, the new code number applies only to substances that the CSA has always regulated as "marijuana." It creates no obligations as to previously unregulated substances. Petitioners do not contend that significant costs would flow from a mere change to the code number used to identify already-controlled substances, and their RFA claim therefore fails with its mistaken premise.

**c.** Petitioners also mistakenly claim that the rule violates section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act. The Congressional Review Act imposes some procedural requirements on federal agencies, *see* 5 U.S.C. § 801, and outlines a procedure by which Congress can formally disapprove of a rule, *id.* § 802. But the Act also expressly precludes judicial review. *See id.* § 805 ("No determination, finding, action, or omission under this chapter shall be subject to judicial review."); *see also Montanans for Multiple Use v. Barbouletos*, 568 F.3d 225, 229 (D.C. Cir. 2009) (holding that section 805 "denies courts the power to void rules on the basis of agency noncompliance with the Act"); *Via Christi Reg'l Med. Ctr., Inc. v. Leavitt*, 509 F.3d 1259, 1271 n.11 (10th Cir.

2007) ("The Congressional Review Act specifically precludes judicial review of an agency's compliance with its terms."). This Court thus lacks jurisdiction to review the adequacy of the report that DEA provided to Congress regarding the rule.

Even if the Court had jurisdiction, petitioners' Congressional Review Act claim would fail for the same reason their other claims do. An agency is required to notify Congress when it issues a "major rule," which the statute defines as a rule that will have "an annual effect on the economy of $100,000,000 or more," will cause "a major increase in costs or prices," or will have "significant adverse effects" on various macroeconomic factors. 5 U.S.C. § 804. This rule merely changes the code number used to identify certain controlled substances on administrative paperwork. DEA correctly determined that the rule was not a "major" one requiring a special notification to Congress. *See* ER 14.

## CONCLUSION

For the foregoing reasons, the petition for review should be dismissed.

Respectfully submitted,

CHAD A. READLER
*Acting Assistant Attorney General*

MARK B. STERN

*s/ Sarah Carroll*
SARAH CARROLL
*Attorneys, Appellate Staff*
*Civil Division, Room 7511*
*U.S. Department of Justice*
*950 Pennsylvania Avenue NW*
*Washington, DC 20530*
*(202) 514-4027*
*sarah.w.carroll@usdoj.gov*

JUNE 2017

## STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, respondents state that they know of no related case pending in this Court.

*s/ Sarah Carroll*
Sarah Carroll

## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a). This brief contains 9549 words and was prepared in 14-point Garamond, a proportionally spaced font.

*s/ Sarah Carroll*
Sarah Carroll

## CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2017, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system, except for the following, who will be served via United States mail:

Robert Thomas Hoban
Hoban Law Group
730 17th Street
Suite 420
Denver, CO 80202

*s/ Sarah Carroll*
Sarah Carroll

# ADDENDUM

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**7 U.S.C. § 5940**

## § 5940. Legitimacy of industrial hemp research

### (a) In general

Notwithstanding the Controlled Substances Act (21 U.S.C. 801 et seq.), chapter 81 of Title 41, or any other Federal law, an institution of higher education (as defined in section 1001 of Title 20) or a State department of agriculture may grow or cultivate industrial hemp if—

**(1)** the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and

**(2)** the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or State department of agriculture is located and such research occurs.

### (b) Definitions

In this section:

#### (1) Agricultural pilot program

The term "agricultural pilot program" means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

**(A)** in States that permit the growth or cultivation of industrial hemp under the laws of the State; and

**(B)** in a manner that—

**(i)** ensures that only institutions of higher education and State departments of agriculture are used to grow or cultivate industrial hemp;

**(ii)** requires that sites used for growing or cultivating industrial hemp in a State be certified by, and registered with, the State department of agriculture; and

**(iii)** authorizes State departments of agriculture to promulgate regulations to carry out the pilot program in the States in accordance with the purposes of this section.

#### (2) Industrial hemp

The term "industrial hemp" means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

**(3) State department of agriculture**

The term "State department of agriculture" means the agency, commission, or department of a State government responsible for agriculture within the State.

**21 U.S.C. § 802**

**§ 802. Definitions**

As used in this subchapter:

. . . .

**(16)** 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. 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 C.F.R. § 1308.03**

**§ 1308.03. Administration Controlled Substances Code Number**

(a) Each controlled substance, or basic class thereof, has been assigned an "Administration Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to § 1301.35 of this chapter and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance

Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.