No. 21-5111

United States Court of Appeals for the District of Columbia Circuit

HEMP INDUSTRIES ASSOCIATION; RE BOTANICALS, INC.,

Plaintiffs-Appellants

v.

DRUG ENFORCEMENT ADMINISTRATION; ANNE MILGRAM, IN HER OFFICIAL CAPACITY AS ADMINISTRATOR OF THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Defendants-Appellees

On Appeal from the United States District Court
for the District of Columbia,
No. 1:20-cv-02921-JEB; Hon. James E. Boasberg, Judge Presiding

APPELLANTS' OPENING BRIEF

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

I. Parties

Plaintiffs-appellants ("Appellants") are Hemp Industries Association and RE Botanicals, Inc., who were both plaintiffs in the district court. Defendants-appellees (the "government") are the Drug Enforcement Administration ("DEA") and Anne Milgram, in her official capacity as DEA Administrator. No *amici curiae* appeared before the district court or have entered appearances before this Court.

II. Rulings Under Review

Appellants appeal from the May 3, 2021 order (ECF No. 35) of the district court (Boasberg, J.), granting the government's motion to dismiss and dismissing the case without prejudice. The district court's accompanying memorandum opinion (ECF No. 36) is not yet published, but it is available on Westlaw at 2021 WL 1734920.

III. Related Cases

This case has not previously been before the Court.

Hemp Industries Association v. DEA, No. 20-1376 (D.C. Cir.), which is also currently pending before this Court, is a related case within the meaning of D.C. Circuit Rule 28(a)(1)(C).

Sept. 28, 2021 /s/Matthew C. Zorn

CORPORATE DISCLOSURE STATEMENT

Hemp Industries Association is a non-profit trade group that represents hemp companies and researchers in the United States and Canada. It does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

RE Botanicals, Inc. is a privately held company and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

Sept. 28, 2021

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GLOSSARY

2018 Farm Bill	Agriculture Improvement Act of 2018
APA	Administrative Procedure Act
CSA	Controlled Substances Act
DEA	U.S. Drug Enforcement Administration
FAC	First Amended Complaint
FDA	Food and Drug Administration
HIA	Hemp Industries Association
IFR	Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020)
IHM	Intermediate Hemp Material
MTA	Marijuana Tax Act of 1937
MTD	Motion to Dismiss Amended Complaint, ECF 30-1
SOP	Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53,395 (Aug. 12, 2016)
THC	Delta-9 tetrahydrocannabinol
Op.	May 3, 2021, Memorandum Opinion
Resp.	Response to Motion to Dismiss Amended Complaint, ECF-33
USDA	U.S. Department of Agriculture
WHM	Waste Hemp Material

JURISDICTIONAL STATEMENT

On October 12, 2020, Appellants filed a complaint in the district court. A008. On January 21, 2021, Appellants filed an amended complaint, superseding the original complaint. A038 ("FAC"). On January 26, the government moved to dismiss the amended complaint. *Hemp Industries Association v. DEA*, 20-cv-02921-JEB, ECF No. 30-1 ("MTD").[1]

On May 3, 2021, the district court granted the government's motion to dismiss for lack of subject matter jurisdiction. A101. It issued a memorandum opinion accompanying the order. A102 ("Op."). On May 19, Appellants timely noticed an appeal. A127.

This Court has jurisdiction under 28 U.S.C. § 1291.

[1] References to "ECF No." refer to ECF filings before the district court.

INTRODUCTION AND STATEMENT OF THE ISSUES

On motions to dismiss, courts should construe complaints broadly and liberally in a light favorable to the plaintiff. In this case, however, the district court construed Appellants' allegations in favor of the government, accepted its view of the case, and dismissed for lack of subject matter jurisdiction.

This Court should reverse for two reasons.

First, contrary to what the district court concluded, in this case, Appellants do not seek to invalidate DEA's interim final rule, Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020) (the "IFR"). Rather, they claim that provisions of the Agriculture Improvement Act of 2018, Pub. L. No. 115-334, 132 Stat. 4490 (Dec. 20, 2018) ("2018 Farm Bill"), establish a statutory authorization or immunity from prosecution under the CSA allowing the manufacture and possession of in-process hemp materials during hemp production. This declaratory judgment non-liability claim does not challenge the IFR and does not seek APA relief consistent with a rule challenge. The district court erred in concluding otherwise.

Second, under the correct view of this case, the district court has exclusive original jurisdiction to adjudicate the claim. This immunity claim does not fall within the scope of the judicial review statute, 21 U.S.C. § 877,

that would otherwise preclude a district court action because Appellants do not challenge a final decision made by DEA under the Controlled Substances Act ("CSA"). In addition, applying *Thunder Basin*, this claim is not the type of claim Congress intended to channel into the CSA's administrative-review scheme. Indeed, it is the antithesis of such a claim, and forcing it into the CSA's exclusive-review scheme would defeat the purpose of the asserted immunity.

Therefore, the issues presented are:

1. Did the district court err in construing Appellants' claim as a challenge to the IFR where Appellants sought no relief from the IFR and instead sought a declaratory judgment that the Agricultural Improvement Act of 2018 authorizes the manufacture and possession of two in-process hemp byproducts made during hemp production? *Yes*.

2. Did the district court err in concluding, without addressing the two-part test in *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), that dismissal for lack of subject matter jurisdiction was required because the Controlled Substance's Act's judicial-review provision, 21 U.S.C. § 877, foreclosed district court review of Appellants' claim? *Yes*.

STATUTES AND REGULATIONS

Pertinent statutes and regulations are included in an Addendum.

STATEMENT OF THE CASE

I. Statutory and Regulatory Background

For as long as Congress has regulated the plant Cannabis sativa L. (cannabis) and related psychoactive substances, it has attempted to distinguish between psychoactive cannabis ("marijuana") with high-levels of delta-9 tetrahydrocannabinol ("THC"), and non-psychoactive cannabis ("hemp") with low-levels of THC.

Congress first regulated cannabis through the Marihuana Tax Act of 1937, Pub. L. No. 75-238, 50 Stat. 551 (Aug. 2, 1937) ("MTA"). Although the MTA required all growers, sellers, manufacturers, importers, and distributors of marijuana to register with the federal government, the statute carved out non-psychoactive parts of the cannabis plant, such as hemp seed and oil, from the MTA's reach. *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003) ("*HIA I*"). Technological limitations prevented differentiating between hemp and marijuana variants according to relative THC levels, as we do today. While the MTA did not prohibit hemp cultivation, these legal restrictions and technological limitations caused domestic hemp production to effectively disappear. *See* A043, FAC ¶¶ 19-20.

In 1970, Congress enacted the CSA as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970. *See Gonzales v. Oregon*, 546 U.S.

243, 250 (2006) (discussing legislative history). The CSA creates a comprehensive, closed regulatory regime that criminalizes the unauthorized manufacture, distribution, and possession of substances classified in any of its schedules. *See id*; *see also* 21 U.S.C. §§ 822, 823, 841(a) ("Except as authorized by this subchapter …"). Manufacturers and handlers of controlled substances can become authorized by registering with DEA to become part of the legitimate distribution chain. *See Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 542 (D.C. Cir. 2007). Also, Congress or DEA can authorize specific conduct with controlled substances by statute or regulation. *See, e.g.*, *United States v. Akinyoyenu*, 199 F. Supp. 3d 106, 112 (D.D.C. 2016) (Boasberg, J.).

Like the MTA, the CSA's definition of marijuana excluded non-psychoactive portions of the plant. *See* 21 U.S.C. § 802(16)(B)(ii); *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004) ("*HIA II*"). "Congress knew what it was doing" in the CSA and "its intent to exclude non-psychoactive hemp from regulation is entirely clear." *Id.* at 1018; *see also id.* ("Congress was aware of the presence of trace amounts of psychoactive agents (later identified as THC) … when it adopted the Tax Act marijuana definition in the CSA."). Although the CSA effectively banned hemp cultivation, it did not prohibit the importation, sale, and consumption of

cannabis products made from excluded parts of the plant, such as the mature stalks.

Nonetheless, as these legal non-psychoactive hemp products grew in popularity in the late 1990s, DEA attempted (unlawfully) to ban the THC naturally occurring in them. *See generally HIA II*, 357 F.3d at 1015-18. Bypassing notice-and-comment, DEA issued an interpretive rule in October 2001 that purported to interpret the CSA and DEA regulations, but in fact banned all products containing any amount of naturally occurring THC. *HIA I*, 333 F.3d at 1085. The Ninth Circuit invalidated that rule, concluding that DEA had attempted "to evade the time-consuming procedures of the APA by interpreting an existing regulation to cover naturally-occurring THC." *Id.* at 1091. "[T]o properly bring organic THC under the listing of THC," the court explained, "DEA must promulgate a legislative rule in accordance with the APA." *Id.*

Thereafter, following notice-and-comment, DEA issued a final rule banning naturally occurring THC. But the Ninth Circuit enjoined that second rule because DEA did not follow the statutory procedures under 21 U.S.C. §§ 811(a) and 812(b) to schedule non-psychoactive parts of the cannabis plant. *HIA II*, 357 F.3d 1017-18.

A. The 2014 Farm Bill.

The popularity of hemp products continued to grow in the 2000s. Notwithstanding federal law, several states passed laws permitting hemp cultivation subject to certain parameters. For example, in 1999, North Dakota legalized hemp cultivation by licensed and registered farmers. A080. Montana legalized hemp cultivation in 2001, and several other states, including Hawaii, Kentucky, Maine, Maryland, and West Virginia, adopted hemp cultivation and research programs in the early 2000s. *Id.*

These state hemp laws gave rise to numerous disputes between DEA and hemp cultivators around the country. *See, e.g., N.H. Hemp Council, Inc. v. Marshall*, 203 F.3d 1 (1st Cir. 2000); *United States v. White Plume*, 447 F.3d 1067 (8th Cir. 2006); *Monson v. DEA*, 589 F.3d 952 (8th Cir. 2009). Each time DEA took the position that the CSA banned hemp cultivation. And each time DEA prevailed.

So Congress changed federal law. In the Agricultural Act of 2014 (the "2014 Farm Bill"), Congress expressly authorized the domestic cultivation and marketing of industrial hemp as part of an agricultural pilot program or for research purposes. 7 U.S.C. § 5940(b). Rather than distinguish hemp based on the part of the plant as the MTA and CSA had, 7 U.S.C. § 5940(a)(2) distinguishes psychoactive marijuana from non-psychoactive "industrial

hemp" based on relative concentration of the main psychoactive component in cannabis, THC:

> 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.

But conflicts among DEA, Congress, and the hemp industry persisted. *See United States v. Mallory*, 372 F. Supp. 3d 377, 382 (S.D.W. Va. 2019). Congress first responded with the purse. In a 2016 appropriations rider, it barred the use of funds "to prohibit the transportation, processing, sale, or use of industrial hemp that is grown or cultivated in accordance with subsection section 7606 of the Agricultural Act of 2014, within or outside the State in which the industrial hemp is grown or cultivated." *Id.* at 382 (quoting Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, § 763, 129 Stat. 2242, 2285 (2015)). Congress renewed the rider in the Consolidated Appropriations Act of 2017. *Id.* (citing Pub. L. No. 115-31, § 773, 131 Stat. 135, 182 (2017)). And in the 2018 Consolidated Appropriations Act, it expanded the prohibition, adding the phrase "or seeds of such plant." *See id.* "[T]his language was included in the Spending Bills to clear up any doubt that Congress did not want these enforcement agencies from interfering with industrial hemp under the 2014 Farm Bill." *Mallory*, 372 F. Supp. 3d at 385.

Nevertheless, DEA, along with the United States Department of Agriculture ("USDA") and the United States Food and Drug Administration ("FDA"), issued a policy statement on August 12, 2016, entitled Statement of Principles on Industrial Hemp, 81 Fed. Reg. 53,395-01 (Aug. 12, 2016) ("SOP"). Among other provisions, the SOP (i) took the position that hemp plants and seeds grown in accordance with the 2014 Farm Bill could not be transported across state lines; and (ii) attempted to rewrite the definition of hemp, explaining that "[t]he term 'industrial hemp' includes the plant Cannabis sativa L. and any part or derivative of such plant, including seeds of such plant, whether growing or not, that is used exclusively for industrial purposes (fiber and seed) with a tetrahydrocannabinols concentration of not more than 0.3 percent on a dry weight basis." *Id.* at 53,395 (emph. added). *Compare with* 7 U.S.C. § 5940(a)(2) ("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.").

This SOP generated significant concern. For example, the members of Congress who drafted the 2014 Farm Bill stated in an amicus brief that the SOP contravened the 2014 Farm Bill by improperly narrowing the scope of legal hemp activity exclusively to industrial use. A084-A088.

B. The 2018 Farm Bill.

With the 2018 Farm Bill, Congress acted more forcefully: it erected a statutory fence designed to keep DEA out.

First, the 2018 Farm Bill defines "hemp" broadly to include "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers" of the plant:

> [Hemp is] 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. § 16390 of 2018 Farm Bill (emph. added). This definition expands the 2014 Farm Bill's definition of "industrial hemp" to facilitate the commercial cultivation, processing, and marketing of hemp.

Second, to prohibit DEA interference with hemp production, the 2018 Farm Bill grants USDA the "*sole authority* to promulgate Federal regulations and guidelines that *relate to the production* of hemp." 7 U.S.C. § 1639r(b) (emph. added). The 2018 Farm Bill also charges the USDA Secretary with administering and implementing hemp production plans, *id.* §§ 1639q & 1639p, a mandate that extends beyond cultivation, *see* A092 ("In Sec. [1639p], the Managers intend to authorize states and tribal Governments to

submit a state plan to the Secretary for approval to have primary regulatory authority over the growing and production of hemp.").

Third, although the 2018 Farm Bill preserves FDA's and the Department of Health and Human Services' preexisting authority under the Food, Drug, and Cosmetic Act ("FDCA") and Public Health Services Act, respectively, it does not preserve any authority for DEA, its Administrator, or the CSA. 7 U.S.C. § 1639r(c). The drafters confirmed that this omission was intentional: the 2018 Farm Bill was "carefully and deliberately crafted" to remove hemp production "from the purview of the DEA." A093.

Fourth, in a section entitled "Conforming Changes to Controlled Substances Act," the 2018 Farm Bill carves "hemp" out of the CSA's definition of marijuana and tetrahydrocannabinols. 132 Stat. 5018. Thus, per Congress, "hemp" and "tetrahydrocannabinols in hemp" are no longer scheduled. In the entire 2018 Farm Bill, DEA is not mentioned once. And the only time the CSA is mentioned is in the section removing hemp from the CSA schedules.

C. DEA Regulation of Hemp Production Under the 2018 Farm Bill

On October 31, 2019, USDA published the United States Domestic Hemp Production Program with comprehensive interim regulations to govern domestic hemp cultivation and production. Establishment of a

Domestic Hemp Production Program, 84 Fed. Reg. 58522 (Oct. 31, 2019) (the "USDA Interim Rule").

Months later, DEA released the IFR entitled Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639 (Aug. 21, 2020). The IFR purports to "merely conform[] DEA's regulations to the statutory amendments to the CSA that have already taken effect [through the 2018 Farm Bill]." The explanatory language accompanying the IFR states, "the definition of hemp [in Section 1639] does not automatically exempt [from Schedule I] any product derived from a hemp plant, regardless of the Δ9-THC content of the derivative" and that "a cannabis derivative, extract, or product that exceeds the 0.3% Δ9-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less Δ9-THC on a dry weight basis."

These developments caused members of Congress to again voice concerns that DEA overstepped its authority, contrary to express Congressional commands. In a letter dated October 22, 2020, Sens. Wyden and Merkley expressed "strong objections," stating:

- Congress "carefully and deliberately crafted the [2018 Farm Bill] to establish the right regulatory framework to grow and support hemp production."
- "The 2018 Farm Bill formally removed hemp, including…all 'derivatives, extracts, cannabinoids,'…from the purview of the

> DEA and placed the sole authority to promulgate federal regulations and guidelines that relate to the production of hemp, which includes its derivatives, extracts, and cannabinoids, with the Secretary of Agriculture."
>
> - Congress intended for USDA's authority to extend to in-process hemp materials such as intermediate- and waste- hemp material ("IHM" and "WHM"), because "when Congress passed the 2018 Farm Bill, we understood that intermediate stages of hemp processing can cause hemp extracts to temporarily exceed 0.3% THC."

A093.

In an October 20, 2020, letter, nine members of Congress expressed similar "concern":

- "Since the Farm Bill legalized hemp along with hemp derivatives, extracts and cannabinoids, it logically follows that the only viable methods for processing hemp into those derivatives, extracts, and cannabinoids would also be legal."
- DEA "ignored the clear legislative intent of the [2018] Farm Bill in making the processing of hemp into extracts, derivatives, and cannabinoids subject to DEA enforcement as a violation of the Controlled Substances Act."

A095-A097.

On January 19, 2021, USDA released its final rule governing hemp production, titled Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5596 (the "USDA Final Rule"). In it, USDA responded to comments about "in-process material," like IHM and WHM, stating:

> The 2018 Farm Bill directed USDA to establish a national regulatory framework for hemp production in the U.S., and the final rule outlines provisions for this mandate. The IFR and this

> final rule do not cover hemp or its products beyond production. Further, DEA has issued regulations covering some of these products or "in-process materials." Accordingly, this final rule does not address "in-process materials," processors, end-products, processing of CBD or other cannabinoids or anything that may contain hemp or hemp byproducts.

Id. at 5,649 (footnote removed).

II. Proceedings Below

On October 12, 2020, Appellants filed an original complaint for declaratory and injunctive relief in the district court. Summarizing much of the background in the previous section, Plaintiffs requested judicial determinations that (1) the definition of "hemp" as set forth in § 16390, includes IHM and WHM, and that IHM and WHM are not controlled substances, and (2) the THC in hemp, including THC in IHM and WHM, is not a Schedule I substance. A008. Appellants also brought a non-APA ultra vires claim, *see Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988), seeking a judicial determination that DEA lacks authority to regulate hemp production, including the production of IHM and WHM. A032-A033.

On December 31, the government moved to dismiss the original complaint on grounds that (1) 21 U.S.C. § 877 precluded review, (2) Appellants lack standing, (3) the dispute was not ripe, and (4) equitable factors favored declining jurisdiction. ECF No. 26-1.

On January 21, 2021, Appellants amended their complaint and clarified the relief sought. A038, FAC. Appellants no longer seek a determination that IHM and WHM are not controlled substances. Instead, Appellants request a judicial determination of non-liability under the CSA. A064-66, FAC ¶¶ 96-105. Specifically, Appellants request a determination that either (1) the definition of "hemp" as set forth in Section 16390, includes IHM and WHM, or (2) regardless of whether IHM and WHM are "hemp" as set forth in Section 16390, the 2018 Farm Bill authorizes and/or immunizes the possession and manufacture of IHM and WHM, and (3) in either case, the possession and manufacture of IHM and WHM during the hemp-production process do not require registration under the CSA. A067, FAC at Prayer (a) & (b).

Five days later, the government moved to dismiss the amended complaint, urging the same arguments that it had urged to dismiss the original complaint. ECF No. 30-1, MTD. Appellants opposed the motion, noted that the government's motion "confuse[d]" Appellants' challenge, and requested an oral hearing to clear up the confusion. ECF No. 33 ("Resp.") at 45.

On May 3, 2021, the district court granted the governments' motion to dismiss. A101. It did not hold an oral hearing. In the opinion accompanying

its decision, the district court agreed with the government and concluded that Appellants' lawsuit seeks "a declaration that two necessary byproducts of the hemp-production process — specifically, intermediate hemp material (IHM) and waste hemp material (WHM), both of which unavoidably exceed 0.3% delta-9 THC — do not qualify as controlled substances subject to the CSA's registration requirements" and pursues "an injunction preventing DEA from enforcing the CSA against such material." A102, Op. 1. "In sum and substance," the district court summarized, Appellants "challenged an assertion of agency authority set out in the IFR" and therefore, Appellants' claim falls squarely within the ambit of that exclusive-review provision. A103, Op. 2.

This appeal follows.

SUMMARY OF ARGUMENT

This Court should reverse the judgment below and remand the case for further proceedings for two reasons.

First, rather than treating Appellants' claim as pleaded, the district court recast Appellants' pleadings in favor of the government and dismissal. It concluded that Appellants' immunity claim was in substance a challenge seeking to set aside the IFR under 5 U.S.C. § 706. But Appellants did not seek to set aside the IFR. Rather, they sought a declaratory judgment that the

2018 Farm Bill authorizes the manufacture and possession of in-process hemp materials. This relief has no bearing on the validity or enforceability of the IFR. Had the district court permitted this action to proceed past the pleadings, the distinction between the actual claim and the government's mischaracterization would have been apparent.

Second, in the proper light, the district court has federal question jurisdiction to adjudicate these immunity claims. Appellants' immunity claim does not fall within the scope of the relevant judicial-review statute, nor does *Thunder Basin* preclude jurisdiction.

STANDARD OF REVIEW

This Court reviews *de novo* an order granting a motion to dismiss for lack of subject matter jurisdiction. *See Am. Fed'n of Gov't Emps., AFL-CIO v. Trump*, 929 F.3d 748, 754 (D.C. Cir. 2019); *Am. Nat. Ins. Co. v. F.D.I.C.*, 642 F.3d 1137, 1139 (D.C. Cir. 2011). In doing so, the Court "assume[s] the truth of all material factual allegations in the complaint," "construe[s] the complaint liberally," "grants[s] plaintiff the benefit of all inferences that can be derived from the facts alleged," and "upon such facts determine[s] jurisdictional questions." *Id.* (cleaned up).

ARGUMENT

I. The District Court Improperly Construed Appellants' Claim as a Challenge to the IFR.

A. Plaintiffs seek a declaratory judgment immunizing conduct, not a declaration that the IFR is invalid or that in-process hemp materials are not controlled substances.

Rather than accept Appellants' view of the case at the pleadings stage, the district court accepted the government's incorrect view and dismissed for lack of subject matter jurisdiction. In the first page of its opinion, for example, the district court characterizes Appellants' claim as seeking "a declaration that two necessary byproducts of the hemp-production process — specifically, intermediate hemp material (IHM) and waste hemp material (WHM), both of which unavoidably exceed 0.3% delta-9 THC — do not qualify as controlled substances subject to the CSA's registration requirements." A102, Op. 1.

Appellants made no such claims. In their Amended Complaint, Appellants sought a declaratory judgment of non-liability/authorization under the CSA and a declaration that because of that authorization, CSA registration is not required. Am Compl. ¶¶ 96-105. This non-liability flows either (a) the definition of "hemp" as set forth in Section 16390 of the 2018

Farm Bill or (b) from the fact that the 2018 Farm Bill authorizes and/or immunizes the possession and manufacture of IHM and WHM. *Id.* at ¶ 105.

Whether IHM and WHM "qualify as controlled substances" is another matter. Appellants' claim poses a question related to *conduct*: Regardless of whether IHM or WHM is controlled, is the manufacture or production of IHM or WHM during the hemp-production process authorized by the 2018 Farm Bill or otherwise immune from the CSA's registration and enforcement provisions? Under the CSA, some conduct with a controlled substance can be authorized (e.g., manufacture and possession) and other not (e.g., distribution and sale).

This distinction is apparent in the statutory scheme. Part B of the CSA is entitled "Authority to Control; Standards and Schedules" and relates to controlling drugs or substances. *See* 21 U.S.C. §§ 811-814. For example, § 812 contains the drug-control schedules, which list each controlled substance. Part D is entitled "Offenses and Penalties." It provides penalties and sanctions for unauthorized conduct involving controlled substances. 21 U.S.C. §§ 841-865. For example, 21 U.S.C. § 841 prohibits the manufacture, distribution, or dispensing of substances "[e]xcept as authorized by" the CSA. Then, Part C of the CSA, entitled "Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances," provides some

authorizations. 21 U.S.C. §§ 821-832. DEA regulations provide others. *See, e.g.*, 21 C.F.R. § 1307.11(a) (under specified circumstances, permitting distribution of controlled substances from one practitioner to another).

The IFR supposedly sorts out a "Part B" type question—what is controlled in the schedules after the 2018 Farm Bill? But Appellants urged a "Part D" type non-liability claim: Regardless of whether IHM and WHM are controlled (the "Part B" issue), is the *manufacture* and *possession* of IHM and WHM *during the hemp production process* authorized (a "Part D" authorization)?

For example, in a section entitled "Plaintiffs' Statutory Challenge," Appellants argued that "Congress drew the clear statutory lines that give rise to Plaintiffs' grievance and the authorization or immunity that Plaintiffs seek to vindicate in this action." ECF No. 33, Resp. at 19-20. Alternatively, citing the doctrine of implied repeal, Appellants argued that "the manufacture and possession of IHM and WHM must be exempt from the CSA and DEA regulation":

> On the merits, Plaintiffs will argue that the text of Section 1639r, coupled with the broad definition in Section 16390, displaces the Attorney General and DEA from regulating matters which "relate to the production of hemp," including the production of IHM and WHM—byproducts made during the production of hemp derivatives, extracts, and cannabinoids. Because of the broad delegation to USDA and other detailed provisions in the 2018

> Farm Bill, the manufacture and possession of IHM and WHM must be exempt from the CSA and DEA regulation. Reading the 2018 Farm Bill any other way would thwart the clear intent of Congress and frustrate whole swaths of the recently enacted statutory scheme. *See generally Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 285 (2007) (standard for implied repeal).

ECF No. 33, Resp. at 20. *See also id.* at 25 ("Plaintiffs … seek a declaration that the CSA cannot be enforced against the manufacture and possession of IHM and WHM during hemp production.").

This non-liability/authorization claim tracks a similar claim the district court recognized in its well-reasoned opinion in *United States v. Akinyoyenu*, 199 F. Supp. 3d 106, 112 (D.D.C. 2016) (Boasberg, J.). The defendant argued that "even if Fioricet is a controlled substance, distributing it without a prescription is not criminal conduct; instead, such conduct is 'authorized by this subchapter'—viz., the CSA—because 21 C.F.R. § 1308.32 exempted the drug from the Act's prescription requirement." *Id.* There, the district court agreed. Here, like in *Akinyoyenu*, Appellants argue that even if IHM and WHM meet the definition of "marihuana" (and thus are controlled) the 2018 Farm Bill authorizes their activities: the manufacture and possession of those materials during the hemp-production process.

Indeed, the contrary narrative urged by the government below does not make sense. IHM and WHM are neither "drugs" nor "substances." Coined by Appellants, these terms merely describe a cannabis-derived substance at a

certain point in the hemp-production process, i.e., *when* and *where* in the hemp-production process a cannabis extract is created and used. IHM is extract manufactured during the processing of hemp. WHM is extract manufactured during the processing of hemp that is discarded as waste. To say IHM and WHM are controlled substances is a misnomer because neither is a controlled drug or substance independent of marijuana or hemp.

Nonetheless, the district court concluded that "Plaintiffs' amended pleading attacks the very position that they claim DEA adopted in the IFR." A114-15, Op. 14-15. Certainly, the government said that. *Id.* (quoting government Reply at 6-7). But it is wrong. The IFR adopts no position on the question of whether the 2018 Farm Bill authorizes the manufacture and possession of IHM or WHM. Although the IFR has left many unsure of precisely what it means, this much is clear: nowhere does it mention the manufacture and possession of IHM and WHM. Considering this silence, it is hard to see how the district court correctly concluded that Appellants seek "a judicial pronouncement as to the validity of a substantive position adopted by DEA" in the IFR. A115, Op. 14. The only way Appellants are "shrewdly" challenging a "substantive position adopted by DEA," *id.*, is if the IFR substantively does something that it does not state. *See also* ECF No. 33, Resp. at 22 (explaining that new policy regulating manufacture and

possession of IFR would be "radically different from what DEA told the public in the Federal Register").

In accepting the government's view, the district court appears to have relied on matters other than the pleadings themselves. For example, its opinion identifies that Appellants had filed "a self-styled Emergency Motion for Expedited Discovery seeking an order compelling DEA to answer two interrogatories aimed at ascertaining whether IHM and WHM were controlled substances under the CSA." A108, Op. 7. This observation is irrelevant. Or that Appellants did not move "for a temporary restraining order or a preliminary injunction." A109, Op. 8. Also, irrelevant. In addition, the district court appears to have placed significant weight on the fact that Appellants first filed the challenge to the IFR in this Court, A107-08, Op. 6-7—a matter easily explained by § 877's short 30-day window for "person[s] aggrieved" by final DEA decisions to seek judicial review.

To the extent the district court relied on these procedural matters as indicating the true substantive nature of Appellants' claim, *see* A107-09, Op. 6-8, it erred. Although district courts may sometimes consider matters outside the pleadings to determine subject matter jurisdiction, *see In re Swine Flu Immunization Prod. Liab. Litig.*, 880 F.2d 1439, 1442 (D.C. Cir. 1989), Appellants are unaware of authority that permits courts to assess

jurisdiction based on its subjective sense of the motivations underlying a party's strategic decisions in litigation.

Finally, the relief Appellants seek is inconsistent with a claim seeking to invalidate agency action. Appellants do not seek any APA relief under 5 U.S.C. § 706. Rather, they seek a declaration that certain conduct—the manufacture and processing of IHM and WHM—does not require registration and is immune from prosecution. This relief is not just different and independent from APA relief, it is unavailable on direct review under § 877.

B. The legal arguments the district court did not consider.[2]

Had this action been allowed to proceed past a motion to dismiss, Appellants' arguments would have widened the divide between the claim authorization/immunity claim Appellants pleaded and the IFR challenge that the government foisted upon them. To illustrate the point, Appellants briefly explain two merits points below.

1. The manufacture and possession of IHM and WHM is a necessary predicate act

"The law has long recognized that the '[a]uthorization of an act also authorizes a necessary predicate act.'" *Luis v. United States*, 136 S. Ct. 1083,

[2] Because the district court dismissed Appellants' case on the pleadings, Appellants did not have an opportunity to develop these arguments below.

1097 (2016) (Thomas, J., concurring) (citing A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts 192 (2012)). Here, the definition of "hemp" in the 2018 Farm Bill authorizes the creation of all cannabis "derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers … with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Therefore, where the manufacture and possession of IHM and WHM is a necessary predicate act to the production of these uncontrolled hemp derivatives and extracts, the 2018 Farm Bill authorizes the predicate activity.

2. The 2018 Farm Bill impliedly repeals the CSA's coverage of "hemp production" activities

Beyond necessity, Appellants contend that the claimed immunity arises out of the doctrine of implied repeal. This doctrine, of course, is "not favored." *Branch v. Smith*, 538 U.S. 254, 273 (2003). It "will only be found where provisions in two statutes are in irreconcilable conflict, or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute." *Id.* (quot. omitted). And when two statutes are partially in conflict, "[r]epeal is to be regarded as implied only if necessary to make the [later enacted law] work, and even then only to the minimum extent necessary." *Silver v. New York Stock Exchange*, 373 U.S. 341, 357 (1963); *see also Lockhart v. United States*, 546 U.S. 142, 149 (2005) (Scalia, J.

concurring) ("When the plain import of a later statute directly conflicts with an earlier statute, the later enactment governs, regardless of its compliance with any earlier-enacted requirement of an express reference or other 'magical password.'").

The text and statutory history show that the 115th Congress unambiguously intended to make USDA the sole regulator of hemp production, with a defined exception only for FDA. The plain import of the 2018 Farm Bill must be to partially repeal DEA and CSA activities in the sphere of "relating to hemp production."

The Supreme Court in *Credit Suisse Secs. (USA) LLC v. Billing*, 551 U.S. 264 (2007) identified four "critical" factors relevant to this inquiry: (1) the existence of regulatory authority to supervise the activities in question; (2) evidence that the responsible regulatory entities exercise that authority; (3) a resulting risk that the application of both laws would produce conflicting guidance, requirements, duties, privileges, or standards of conduct; and (4) whether the possible conflict affected practices that lie squarely within an area of activity that the later law seeks to regulate. *Id.* at 275–76. Briefly, those factors are all present here.

First, the later enactment in this case provides USDA regulatory authority to supervise the activities in question in broad terms: USDA "shall

have sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp, including Federal regulations and guidelines that relate to the implementation of sections 1639p and 1639q of this title." 7 U.S.C. § 1639r(b). While § 1639r(c) makes exceptions for FDA and the FDCA, no exception is made for DEA and the CSA. That the statute requires USDA to "*consult* with the Attorney General on the promulgation of regulations and guidelines" to govern hemp production, 7 U.S.C. § 1639r(a) (emph. added), underscores that USDA and DEA regulate separate spheres of activity.

Second, USDA exercised its delegated authority. It published rules on the U.S. Domestic Hemp Production Program. *See* 86 Fed. Reg. 5,596 (Jan. 19, 2021). These rules provide the detailed and comprehensive regulations for hemp production in the United States that the 2018 Farm Bill expressly requires in Section VII entitled "Hemp Production."

Under § 1639q(a)(1), the "production of hemp shall be subject to a plan established by [USDA] to monitor and regulate that production in accordance with paragraph (2)." The USDA plan "shall include" the gamut of issues relating to hemp production, including "a procedure to comply with the enforcement procedures under subsection (c)(2)." Subsection (c)(2) requires USDA provide a procedure to provide for the effective disposal of

products from non-compliant plants, such as extracts and derivatives. And in Section § 1639q(a)(1), Congress delegated to USDA (not DEA) authority to monitor non-compliance of the procedure.

The statutory text thus shows Congress wanted USDA to occupy the entire space, including enforcement. And in turn, USDA's rules establish a "Domestic Hemp Production Program," which notes that the Agricultural Marketing Service ("AMS") "has been delegated authority to administer the U.S. Domestic Hemp Production Program" and "Section 297D of the AMA requires the Secretary to promulgate regulations and guidelines relating to the production of hemp under sections 297B and 297C."

Importantly, "related to hemp production" includes the manufacture and production of IHM and WHM. "Hemp" as defined in 7 U.S.C. § 16390 includes derivatives and extracts. And "production" is broader than *cultivation* or *propagation*. *See*, *e.g.*, 21 U.S.C. § 802 (CSA definition of manufacture including "the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin." It means "making." *See* https://www.merriam-webster.com/dictionary/produce. So "hemp production" means making (but not selling or distributing) anything that is hemp under 7 U.S.C. § 16390, including making hemp derivatives and

extracts. That scope encompasses the manufacture and possession of IHM and WHM—necessary byproducts in a hemp production process.

Third, applying both USDA regulations and the CSA results in conflicting guidance, requirements, and standards of conduct and upend the entire 2018 Farm Bill. Consider, as one example, 21 U.S.C. § 811(d)(1) of the CSA. This provision mandates that the Attorney General must control a drug if international treaties in effect on October 27, 1970, so require. The Single Convention, entered into force for the United States on June 24, 1967, requires parties to impose stringent controls on "cannabis," which the treaty defines as "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated." *See* Licensing Marijuana Cultivation in Compliance with the Single Convention on Narcotic Drugs, 42 O.L.C. Op. __ at 2 (June 6, 2018) (https://www.justice.gov/olc/file/1272131/download).

This treaty definition does not distinguish between low-THC cannabis (hemp) and high-THC cannabis (marijuana). It requires control of *cannabis*. Therefore, unless the 2018 Farm Bill impliedly repeals the CSA on hemp production, DEA *must* put cannabis (including hemp) back onto Schedule I or II by order under § 811(d)(1), and impose other regulatory requirements,

like quotas. Doing this, of course, would fly in the face of the 2018 Farm Bill, which is why implied repeal must address this plain repugnancy.

Fourth, the conflict here affects practices—hemp production and activities "related to hemp production"—that lie at the very heart of the activity that the 2018 Farm Bill sought to place in the hands of USDA.

Put simply, a degree of implied repeal is necessary to make the 2018 Farm Bill tick. That issue should be adjudicated by the district court in the first instance.

II. Because Appellants Do Not Challenge the IFR, Dismissal Was Improper.

Having disagreed with Plaintiffs' characterization of their claims, the district court determined that § 877 divested it of subject matter jurisdiction and did not apply *Thunder Basin*. But under *Thunder Basin*, the district court has original jurisdiction over Appellants' claims.

To determine whether an administrative-review process limits federal question jurisdiction, courts must consider (A) whether the statutory scheme at issue in fact provides an exclusive administrative review scheme, and (B) whether the claims at issue are of the type that Congress intended to fall within that scheme. *See Sturm, Ruger & Co. v. Chao*, 300 F.3d 867, 871, 874 (D.C. Cir. 2002). Here, the question Appellants raise does not fall within the

plain meaning of the text of § 877, and it certainly is not a question Congress intended to be handled through the CSA scheme.

A. Appellants' claims fall outside the administrative review scheme.

"Whether a statute is intended to preclude initial judicial review is determined from the statute's language, structure, and purpose, its legislative history, and whether the claims can be afforded meaningful review." *Thunder Basin*, 510 U.S. at 207 (internal cit. omitted).

Under § 877, courts of appeals have exclusive jurisdiction to review "final decision[s]" that result from "final determinations, findings, and conclusions under [the CSA]." The district court correctly observed that nothing about § 877 purports to be an exclusive review provision that sweeps so broadly as to cover any matter involving DEA or the CSA. A124, Op. 23. In fact, the text precludes review over nothing. Rather, it provides for direct review in the appeals courts of final decisions made by DEA under the CSA. Exclusive jurisdiction in courts of appeals for matters involving final DEA decisions is not rooted in the text § 877, but case law. *See Inv. Co. Inst. v. Bd. of Governors of Fed. Rsrv. Sys.*, 551 F.2d 1270, 1280 (D.C. Cir. 1977).

The text resolves this case at *Thunder Basin* step one. Appellants' assert that *Congress* created a non-liability immunity by *statute*. This claim breaks from the textual limits of § 877 in three ways: Appellants do not

challenge (1) a "final decision" (2) "under the [CSA]" (3) "of the Attorney General" or DEA.

General Elec. Co. v. EPA, 360 F.3d 188 (D.C. Cir. 2004) is instructive. There, the district court initially dismissed the complaint for lack of subject matter jurisdiction under CERCLA § 113(h), which (unlike § 877) bars district courts from reviewing "any challenges to removal or remedial actions…" This Court reversed, holding that the plaintiff's challenge was "not a challenge to the way in which EPA is administering the statute in any particular removal or remedial action or order, but rather it is a challenge to the CERCLA statute itself." *Id.* at 191. The district court had jurisdiction over the structural, pre-enforcement facial challenge because the plain text of § 113(h) "afford[ed] no indication that Congress intended to preclude all pre-enforcement review of constitutional challenges to the CERCLA statute." *Id.* at 191, 193-194.

Beyond the text of § 877, the scheme reinforces the notion that the exclusivity of the administrative process as to Appellants' challenge is not "fairly discernable," *Thunder Basin*, 510 U.S. 207, and pre-enforcement type challenges belong in district court. Boiled down, Appellants bring a mirror image of a § 882 action. *See Menominee Indian Tribe of Wisconsin v. DEA*, 190 F. Supp. 3d 843, 850 (E.D. Wis. 2016) ("This action is simply a mirror image of the Government's action in *White Plume*."). Unlike § 877, § 882 of

the CSA expressly grants *district courts* original jurisdiction over these types of enforcement actions seeking injunctive relief. Under the statutory scheme, pre-enforcement type challenges seeking injunctive remedies are not "final decisions" subject to § 877 direct review.[3]

The district court dismissed the relevance of § 882, explaining that the government's ability to "seek and obtain declaratory judgments under the CSA" and "enjoin violations of" the CSA, *see* 21 U.S.C. § 882, "has no bearing upon the preclusive effect of Section 877 when private litigants initiate an action that falls squarely in its teeth." A124, Op. 23. It cited no authority for this proposition. And according to *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 489 (2010), it is wrong.

Setting aside whether Appellants pursue an action that falls "squarely" within Section 877's teeth (they do not), under *Thunder Basin*, "[p]rovisions for agency review do not restrict judicial review unless the 'statutory scheme' displays a 'fairly discernible' intent to limit jurisdiction, and the claims at issue 'are of the type Congress intended to be reviewed within th[e] statutory

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[3] The Mine Safety and Health Act at issue in *Thunder Basin* was also facially silent as to pre-enforcement challenges. 510 U.S. at 208-09. Unlike the CSA and § 882, however, the scheme in *Thunder Basin* required the government to bring ordinary enforcement actions through the administrative scheme.

structure.'" *Id.* at 489 (quoting *Thunder Basin*, 510 U.S. at 207 (1994)). The statutory scheme not only displays no "fairly discernable" intent to limit district court jurisdiction for pre-enforcement type actions, § 882 affirmatively indicates otherwise. Whatever preclusive effect § 877 has, it does not cover a challenge in § 882's image or mirror image.

B. Appellants' immunity claim does not belong in the administrative review scheme.

At the second step of the *Thunder Basin* framework, courts "presume" Congress wants district courts to remain open to claims if (1) "a finding of preclusion could foreclose all meaningful judicial review"; (2) "the suit is wholly collateral to a statute's review provisions"; and (3) "the claims are outside the agency's expertise." *Free Enterprise*, 561 U.S. at 489-90 (quot. omitted). These considerations do not form "three distinct inputs into a strict mathematical formula." *Jarkesy,* 803 F.3d at 17. Rather, they serve as "general guideposts useful for channeling the inquiry into whether the particular claims at issue fall outside an overarching congressional design." *Am. Fed'n of Gov't Emps.,* 929 F.3d at 754 (quoting *Jarkesy*, 803 F.3d at 17).

Even if first step of the *Thunder Basin* framework is met (it is not), these three guideposts all weigh strongly against preclusion.

1. Meaningful judicial review: adjudicating the immunity in the administrative scheme deprives Appellants of the immunity

The gravamen of Appellants' grievance is that after decades of DEA interference, Congress divested DEA of regulatory authority over hemp production in all respects and gave USDA (and FDA) sole regulatory over all such matters. Taken as true, thrusting Appellants' pre-enforcement/immunity claim back into the CSA's administrative review scheme would deprive Appellants meaningful judicial review of the immunity.

The Supreme Court has repeatedly held that structural or systemic claims are not susceptible to adjudication in agency review processes. For example, in the issue-exhaustion context, the Court opined that "agency adjudications are generally ill suited to address structural constitutional challenges" and therefore it "is sometimes appropriate for courts to entertain constitutional challenges to statutes or other agency-wide policies even when those challenges were not raised in administrative proceedings." *Carr v. Saul*, 141 S. Ct. 1352, 1360 (2021). Or, in *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496 (1991), the Court held that objections to INS procedures escaped the administrative review scheme because if aliens had

to "voluntarily surrender themselves for deportation" to challenge the procedures, they would lose meaningful judicial review.

Appellants' objection fits this mold. They object to the existence of a DEA-run administrative process applied to issues central to hemp production and to being subjected to that DEA process. Forcing Plaintiffs to surrender to the scheme to test the merits of such a claim negates the immunity Appellants contend Congress created and effectively renders their structural challenge to what they claim are ultra vires DEA actions unreviewable.

These principles are well-established. Immunities provide defenses not only within proceedings but *to the proceedings themselves*. For this reason, legal determinations about immunities can be directly appealed under the collateral order doctrine. Take double jeopardy. A decision denying a right not to stand trial on double jeopardy grounds is directly appealable, for the immunity cannot be effectively vindicated after the trial has already occurred. *Mitchell v. Forsyth*, 472 U.S. 511, 525 (1985). So too with qualified immunity. The sine qua non of an immunity is not to have to answer for conduct at all. *Id.* at 425. Here, as well, Appellants contend they do not have to answer to DEA for their conduct. Forcing them to submit that

claim to the very administrative process from which they claim statutory protection strips the immunity of any meaning.

Rhode Island Dept. of Environmental Management v. United States, 304 F.3d 31 (1st Cir. 2002) is illustrative. There, the state and state agency brought a suit in district court to enjoin administrative proceedings on grounds that the proceedings infringed on state sovereign immunity. The court held that the district court had properly exercised non-statutory ultra vires review over agency action. *Id.* at 42 (citing *Dart*, 848 F.2d at 224 and *Leedom v. Kyne*, 358 U.S. 184 (1958)). Despite recognizing the narrow nature of non-statutory review, the First Circuit observed that it was "beyond cavil" that absent immediate judicial review, the agency's adverse immunity determination would "wholly deprive" the state of "a meaningful and adequate means of vindicating its … rights." *Id.* at 43. The state was not advocating a "mere defense from liability," it was "an immunity from being haled before [the] tribunal." *Id. See also, cf.*, *N.H. Hemp Council*, 203 F.3d at 5 (opining that it was "hard to see why" a party should be forced to apply for a license where the party urged that production of industrial products was not subject to the statute at all, whether as a prohibition or licensing scheme and citing *Leedom*, 358 U.S. at 188-89).

The district court here concluded that Appellants must wait for some DEA enforcement action regarding the legality of their essential activities, exhaust lengthy administrative proceedings, and only then, in the court of appeals, test the merits of their claim. But of course, courts normally do not require plaintiffs to "bet the farm … by taking the violative action" before "testing the validity of the law." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 129 (2007). This principle carries extra force with the CSA where both civil and criminal liability is at stake.

2. Wholly collateral: immunity questions DEA's authority

This Court has held that claims are not wholly collateral when they are the vehicle by which a party seek to reverse agency action. *Jarkesy*, 803 F.3d at 23. This consideration is "related" to whether "meaningful judicial review" is available, and the two considerations are sometimes analyzed in tandem. *Id.* at 22. Here, the analysis goes the same way.

Collateral claims are those that arise outside an agency's administrative enforcement scheme and essentially divorced from any action taken, or any determination made, in the context of agency proceedings. *See, e.g., Free Enterprise*, 561 U.S. at 490 (challenging the very existence of an administrative agency, not any proceeding before that agency). In contrast, challenges to agency actions in proceedings include attacks on the initiation

of proceedings involving the plaintiff, challenges to specific decisions that the agency made in the course of those proceedings, or any other attempt to use a federal lawsuit as "the 'vehicle by which' [the party] seeks to prevail in his administrative proceeding." *Jarkesy*, 803 F.3d at 23 (quoting *Elgin*, 567 U.S. 1, 22 (2012)). In essence, the inquiry focuses on whether the claims would impact ongoing administrative proceedings such that the plaintiff can be said to have made "an end run around" around the applicable statutory review scheme "by going directly to district court." *Sturm*, 300 F.3d at 876.

There are no ongoing administrative proceedings here, and Appellants' structural challenge is not about a substantive or procedural deficiency in an administrative proceeding against them. Neither do they take issue with a deficiency within a future administrative proceeding. Nor do they, in this case, challenge a substantive or procedural impropriety made in rulemaking. Rather, Appellants assert a non-liability defense to the existence of CSA proceedings based on an entirely different statute. It is a threshold jurisdictional-type objection: they should not be in this scheme.

The district court reasoned that if Appellants were permitted to bring their claim in district court,

> [L]itigants could routinely skirt Section 877's command that review of DEA's final decisions and determinations under the CSA be entrusted to the court of appeals simply by challenging

> the substance of such decisions and determinations in the district court while refraining from seeking their invalidation or reversal as a formal legal matter.

A117-18, Op. 16-17. Perhaps, if a proceeding were pending against Appellants (such as an ongoing adjudication or enforcement action), this notion might have more merit. Such was the case in *Elgin*, 567 U.S. at 22, where there was no dispute about whether the party should be in the scheme, and the party's constitutional challenge was the vehicle by which it sought to reverse a removal decision. But in this case, there is no adjudication and no administrative record. This case involves a pre-enforcement type challenge to confirm that certain conduct falls outside the CSA's grasp.

That is where this case departs from *Elgin* and converges with *Free Enterprise*. Appellants' immunity challenge attacks the legitimacy of DEA as a decisionmaker with respect to the issue at hand. In *Elgin*, the claim was a facial constitutional challenge, but it did not call into question the authority of the decisionmaker (the Merit Services Protection Board or ALJ) to render a decision. The claim was that 5 U.S.C. § 3328 discriminated based on gender and operated as a bill of attainder. 567 U.S. at 7-8. That claim did not call into question the legitimacy of the proceedings or of the decisionmaker's authority to pass judgment. But in *Free Enterprise*, that was precisely the problem. The collateral claim was that the Public Company Accounting

Oversight Board was *itself* unconstitutional, and therefore the Board had no authority to conduct proceedings or decide. It was a challenge "to the Board." 561 U.S. at 490.

The claim in this case falls on the *Free Enterprise* end of the continuum: it is not being asserted as a defense in a proceeding and is wholly collateral because it calls into question the validity of a proceeding or of the decisionmaker to conduct proceedings. *Cf. Rhode Island Dep't of Env't Mgmt.*, 304 F.3d at 43 (sovereign immunity claim was "wholly collateral" to a "a mechanism for facilitating judicial review of final determinations").

This distinction makes sense. Having an executive agency decide the threshold issue of whether it has jurisdiction to pass judgment on an immunity presupposes its authority. If it has authority, it can decide; but if it does not, it cannot decide the threshold question. Until decided by someone, this threshold question exists in a Schrödinger's Cat-like state. If the agency decides, it dictates the outcome, because in deciding, it necessarily uses authority (which ex ante, it may or may not have) to make that decision. Therefore, when an issue presents a jurisdictional question about whether a federal agency has statutory or constitutional authority to decide about an *immunity* to administrative enforcement, the decision must be made by a federal court in the first instance, or else the immunity

disappears before the ultra vires agency action threatening it can be judicially reviewed.

The collateral nature of Appellants' challenge also sounds in *McNary*, where the Court held said that plain language of § 210(e)(1)'s reference to "a determination" describes "a single act rather than a group of decisions or a practice or procedure employed in making decisions." *McNary*, 498 U.S. at 492. Here, no different than the statute in *McNary*, § 877 refers to judicial review of a single act: a "final decision." But Appellants do not challenge a final decision. Like a *McNary*-type claim, they level a broadside challenge.

The district court explained that Appellants "themselves have repeatedly maintained that the IFR embodies a specific assertion of regulatory authority that flouts the commands of Congress." A121, Op. 20. So what? The district court appears to have misunderstood Appellants' argument on this point. Appellants never made this point to argue that DEA acted "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C), in promulgating the IFR—a proposition irrelevant to their claim in this case. Rather, Appellants discussed § 1639r because it evidences the implied repeal.

Funneling a case like this through the administrative review scheme raises grave separations of powers problems. Assume Appellants' well-

pleaded allegations have merit: after decades of (sometimes unlawful, *e.g.*, *HIA II*, 357 F.3d 1012) DEA involvement in legal hemp product markets, Congress enacted legislation drawing clear boundaries, placing hemp production under the auspices of USDA. That law divested DEA of regulatory authority over hemp production and moved hemp production out of the CSA's administrative scheme.[4] But, by merely back-door promulgating a cryptic IFR—without even *informal* rulemaking's procedural safeguards—DEA asserts the unreviewable authority to re-route claims that DEA transgressed an immunity back into its own administrative review scheme.

It gets worse. In the Federal Register, DEA stated its rule did nothing more than conform regulations to statutory amendments that already took effect. If so, Appellants' claim could not possibly challenge any final DEA decision because DEA decided nothing. But to shield itself from judicial review, DEA switched horses in the district court and said something else: Appellants' non-liability claim challenged the IFR. For this latter statement

[4] To be clear, Appellants do not contend that DEA maintains no role in regulating marijuana or issues outside of hemp production. For example, DEA has a role in regulating and enforcing the CSA to police the unlawful sale of a controlled substance that would otherwise be characterized as IHM or WHM if it were in produced in hemp production.

to be true, the IFR must create some new right or obligation pertaining to IHM or WHM. One of these positions cannot be right.

3. DEA has no special expertise to offer on this problem

This factor is met when an agency's expertise can be "brought to bear" on the issues. *Jarkesy*, 803 F.3d at 29.

Here, the Court need not look farther than the 2018 Farm Bill. Congress wanted *USDA's* expertise brought to bear on this issue, in consultation with the Attorney General. As noted above, DEA is not mentioned anywhere in the 2018 Farm Bill, and the lone reference to the CSA is in the context of removing hemp from that statute's control schedules.

In addition, the legal issue is how the 2018 Farm Bill interfaces with the CSA. DEA has no special expertise in reconciling two federal statutes. To be sure, the statutory questions presented to this Court do require an analysis of the CSA. But whatever those questions may be, they are less "technical considerations of agency policy," *Free Enterprise*, 561 U.S. at 491 (quot. omitted), and more about statutory definitions and technology related to hemp production.

III. There Is a Ripe Case or Controversy.

The district court did not reach the government's ripeness arguments. A124, Op. 23. In the interest of judicial efficiency, the Court should dispose

them. *See Insurance Corp. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982) (appeals courts may address unresolved jurisdictional issues in the first instance).

Beyond what Appellants identified below, *see* ECF No. 33, Resp. at 37-45 (citing Trojan Declaration, A098-A100), the government's briefing illustrates that Appellants' claim arising out of the text of the 2018 Farm Bill is ripe. For example, DEA argued to the district court that the "[r]egulation of IHM and WHM raises numerous statutory, technical, and scientific issues" that "cry out for the exercise of DEA's relevant expertise." ECF No. 30-1, MTD at 21. But Appellants claim is that the 2018 Farm Bill discharges DEA of this burden. In this sphere, Congress did not want DEA to regulate or render its expertise. There is a concrete case and controversy over whether DEA can regulate the manufacture and possession IHM and WHM.

This case is like *New Hampshire Hemp Council* where DEA's position on an abstract question of statutory interpretation favored review due to possible criminal penalties:

> As for ripeness, the issue posed by Owen is an abstract one of statutory interpretation: whether the federal statute makes criminal the production of cannabis sativa for use in making industrial products. And the DEA's emphatic position equitably argues for review—not because there is anything wrong with the agency expressing its view but because, that view having been expressed, there ought to be a way to resolve the legal correctness

> of its position without subjecting an honest businessman to criminal penalties well known for their severity and inflexible administration.

N.H. Hemp Council, 203 F.3d at 5.

On equitable discretion, this Court applies the non-exclusive *Hanes* factors to determine the usefulness of a declaratory judgment, including (1) whether a declaratory judgment would finally settle the controversy between the parties; (2) whether other remedies are available or other proceedings are pending; (3) the convenience of the parties; (4) the equity of the declaratory judgment plaintiff; (5) prevention of procedural fencing; (6) the state of adverseness between the parties; and (7) the public importance of the case. *See Morgan Drexen, Inc. v. Consumer Fin. Prot. Bureau*, 785 F.3d 684, 697 (D.C. Cir. 2015). These factors weigh in favor of a declaratory judgment on Appellants' non-liability/immunity claim:

- A judicial determination that a CSA registration is not required to manufacture and possess such byproducts would end the controversy as to that issue between Appellants and the government.
- For the reasons discussed above, the relief Appellants seek is unavailable in other proceedings, including in Appellants APA-petition for review proceeding. Vacating and setting aside the IFR would not vindicate the asserted immunity.
- This dispute is being litigated in a convenient forum close to the government, and given the resources already put into the case, it would be more convenient and judicially efficient to proceed with this case in the district court upon remand.

- There has been no procedural fencing. The government questioned why Appellants proceeded with the district court action first. Appellants proceeded with the district court action because they do not believe this Court had original jurisdiction to adjudicate their immunity claim.

- The issues in this action are of exceptional public import and would provide clear regulatory lines—and provide clear guidance on potential criminal liability—for a growing billion-dollar hemp industry.

CONCLUSION

The district court misinterpreted Appellants' claims. Properly construed, the district court has jurisdiction because Appellants' claims (a) do not fall within the text of § 877 and (b) are not the type of claims Congress intended to be adjudicated through the CSA's administrative review scheme.

The judgment below should be reversed.

Dated: September 28, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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Date: September 28, 2021

Matthew C. Zorn
Matthew C. Zorn

CERTIFICATE OF SERVICE

I certify that this document was filed with the Court via the court's electronic filing system, on the 28th day of September, 2021, and an electronic copy of this document was served on all counsel of record, as listed below, via the court's electronic filing system on the same date:

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ADDENDUM

Appendix Table of Contents

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part E. Administrative and Enforcement Provisions

21 U.S.C.A. § 877

§ 877. Judicial review

Currentness

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.

CREDIT(S)

(Pub.L. 91-513, Title II, § 507, Oct. 27, 1970, 84 Stat. 1273.)

Notes of Decisions (15)

21 U.S.C.A. § 877, 21 USCA § 877
Current through PL 117-39.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)
Subchapter VII. Hemp Production

7 U.S.C.A. § 1639*o*

§ 1639*o*. Definitions

Effective: December 20, 2018
Currentness

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.

(2)Indian tribe

The term "Indian tribe" has the meaning given the term in section 5304 of Title 25.

(3)Secretary

The term "Secretary" means the Secretary of Agriculture.

(4)State

The term "State" means--

(A) a State;

(B) the District of Columbia;

(C) the Commonwealth of Puerto Rico; and

(D) any other territory or possession of the United States.

(5)State department of agriculture

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

(6)Tribal government

The term "Tribal government" means the governing body of an Indian tribe.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 297A, as added Pub.L. 115-334, Title X, § 10113, Dec. 20, 2018, 132 Stat. 4908.)

Notes of Decisions (1)

7 U.S.C.A. § 1639*o*, 7 USCA § 1639o
Current through PL 117-39.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)
Subchapter VII. Hemp Production

7 U.S.C.A. § 1639p

§ 1639p. State and Tribal plans

Effective: December 20, 2018
Currentness

(a) Submission

(1) In general

A State or Indian tribe desiring to have primary regulatory authority over the production of hemp in the State or territory of the Indian tribe shall submit to the Secretary, through the State department of agriculture (in consultation with the Governor and chief law enforcement officer of the State) or the Tribal government, as applicable, a plan under which the State or Indian tribe monitors and regulates that production as described in paragraph (2).

(2) Contents

A State or Tribal plan referred to in paragraph (1)--

(A) shall only be required to include--

(i) a practice to maintain relevant information regarding land on which hemp is produced in the State or territory of the Indian tribe, including a legal description of the land, for a period of not less than 3 calendar years;

(ii) a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe;

(iii) a procedure for the effective disposal of--

(I) plants, whether growing or not, that are produced in violation of this subchapter; and

(II) products derived from those plants;

(iv) a procedure to comply with the enforcement procedures under subsection (e);

(v) a procedure for conducting annual inspections of, at a minimum, a random sample of hemp producers to verify that hemp is not produced in violation of this subchapter;

(vi) a procedure for submitting the information described in section 1639q(d)(2) of this title, as applicable, to the Secretary not more than 30 days after the date on which the information is received; and

(vii) a certification that the State or Indian tribe has the resources and personnel to carry out the practices and procedures described in clauses (i) through (vi); and

(B) may include any other practice or procedure established by a State or Indian tribe, as applicable, to the extent that the practice or procedure is consistent with this subchapter.

(3) Relation to State and Tribal law

(A) No preemption

Nothing in this subsection preempts or limits any law of a State or Indian tribe that--

(i) regulates the production of hemp; and

(ii) is more stringent than this subchapter.

(B) References in plans

A State or Tribal plan referred to in paragraph (1) may include a reference to a law of the State or Indian tribe regulating the production of hemp, to the extent that law is consistent with this subchapter.

(b) Approval

(1) In general

Not later than 60 days after receipt of a State or Tribal plan under subsection (a), the Secretary shall--

(A) approve the State or Tribal plan if the State or Tribal plan complies with subsection (a); or

(B) disapprove the State or Tribal plan only if the State or Tribal plan does not comply with subsection (a).

(2) Amended plans

If the Secretary disapproves a State or Tribal plan under paragraph (1)(B), the State, through the State department of agriculture (in consultation with the Governor and chief law enforcement officer of the State) or the Tribal government, as applicable, may submit to the Secretary an amended State or Tribal plan that complies with subsection (a).

(3) Consultation

The Secretary shall consult with the Attorney General in carrying out this subsection.

(c) Audit of State compliance

(1) In general

The Secretary may conduct an audit of the compliance of a State or Indian tribe with a State or Tribal plan approved under subsection (b).

(2) Noncompliance

If the Secretary determines under an audit conducted under paragraph (1) that a State or Indian tribe is not materially in compliance with a State or Tribal plan--

(A) the Secretary shall collaborate with the State or Indian tribe to develop a corrective action plan in the case of a first instance of noncompliance; and

(B) the Secretary may revoke approval of the State or Tribal plan in the case of a second or subsequent instance of noncompliance.

(d) Technical assistance

The Secretary may provide technical assistance to a State or Indian tribe in the development of a State or Tribal plan under subsection (a).

(e) Violations

(1) In general

A violation of a State or Tribal plan approved under subsection (b) shall be subject to enforcement solely in accordance with this subsection.

(2) Negligent violation

(A) In general

A hemp producer in a State or the territory of an Indian tribe for which a State or Tribal plan is approved under subsection (b) shall be subject to subparagraph (B) of this paragraph if the State department of agriculture or Tribal government, as applicable, determines that the hemp producer has negligently violated the State or Tribal plan, including by negligently--

(i) failing to provide a legal description of land on which the producer produces hemp;

(ii) failing to obtain a license or other required authorization from the State department of agriculture or Tribal government, as applicable; or

(iii) producing Cannabis sativa L. with a delta-9 tetrahydrocannabinol concentration of more than 0.3 percent on a dry weight basis.

(B) Corrective action plan

A hemp producer described in subparagraph (A) shall comply with a plan established by the State department of agriculture or Tribal government, as applicable, to correct the negligent violation, including--

(i) a reasonable date by which the hemp producer shall correct the negligent violation; and

(ii) a requirement that the hemp producer shall periodically report to the State department of agriculture or Tribal government, as applicable, on the compliance of the hemp producer with the State or Tribal plan for a period of not less than the next 2 calendar years.

(C) Result of negligent violation

A hemp producer that negligently violates a State or Tribal plan under subparagraph (A) shall not as a result of that violation be subject to any criminal enforcement action by the Federal Government or any State government, Tribal government, or local government.

(D) Repeat violations

A hemp producer that negligently violates a State or Tribal plan under subparagraph (A) 3 times in a 5-year period shall be ineligible to produce hemp for a period of 5 years beginning on the date of the third violation.

(3) Other violations

(A) In general

If the State department of agriculture or Tribal government in a State or the territory of an Indian tribe for which a State or Tribal plan is approved under subsection (b), as applicable, determines that a hemp producer in the State or territory has violated the State or Tribal plan with a culpable mental state greater than negligence--

(i) the State department of agriculture or Tribal government, as applicable, shall immediately report the hemp producer to--

(I) the Attorney General; and

(II) the chief law enforcement officer of the State or Indian tribe, as applicable; and

(ii) paragraph (1) of this subsection shall not apply to the violation.

(B) Felony

(i) In general

Except as provided in clause (ii), any person convicted of a felony relating to a controlled substance under State or Federal law before, on, or after December 20, 2018, shall be ineligible, during the 10-year period following the date of the conviction--

(I) to participate in the program established under this section or section 1639q of this title; and

(II) to produce hemp under any regulations or guidelines issued under section 1639r(a) of this title.

(ii) Exception

Clause (i) shall not apply to any person growing hemp lawfully with a license, registration, or authorization under a pilot program authorized by section 5940 of this title before December 20, 2018.

(C) False statement

Any person who materially falsifies any information contained in an application to participate in the program established under this section shall be ineligible to participate in that program.

(f) Effect

Nothing in this section prohibits the production of hemp in a State or the territory of an Indian tribe--

(1) for which a State or Tribal plan is not approved under this section, if the production of hemp is in accordance with section 1639q of this title or other Federal laws (including regulations); and

(2) if the production of hemp is not otherwise prohibited by the State or Indian tribe.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 297B, as added Pub.L. 115-334, Title X, § 10113, Dec. 20, 2018, 132 Stat. 4909.)

Notes of Decisions (3)

7 U.S.C.A. § 1639p, 7 USCA § 1639p
Current through PL 117-39.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)
Subchapter VII. Hemp Production

7 U.S.C.A. § 1639q

§ 1639q. Department of Agriculture

Effective: December 20, 2018
Currentness

(a) Department of Agriculture plan

(1) In general

In the case of a State or Indian tribe for which a State or Tribal plan is not approved under section 1639p of this title, the production of hemp in that State or the territory of that Indian tribe shall be subject to a plan established by the Secretary to monitor and regulate that production in accordance with paragraph (2).

(2) Content

A plan established by the Secretary under paragraph (1) shall include--

(A) a practice to maintain relevant information regarding land on which hemp is produced in the State or territory of the Indian tribe, including a legal description of the land, for a period of not less than 3 calendar years;

(B) a procedure for testing, using post-decarboxylation or other similarly reliable methods, delta-9 tetrahydrocannabinol concentration levels of hemp produced in the State or territory of the Indian tribe;

(C) a procedure for the effective disposal of--

(i) plants, whether growing or not, that are produced in violation of this subchapter; and

(ii) products derived from those plants;

(D) a procedure to comply with the enforcement procedures under subsection (c)(2);

(E) a procedure for conducting annual inspections of, at a minimum, a random sample of hemp producers to verify that hemp is not produced in violation of this subchapter; and

(F) such other practices or procedures as the Secretary considers to be appropriate, to the extent that the practice or procedure is consistent with this subchapter.

(b) Licensing

The Secretary shall establish a procedure to issue licenses to hemp producers in accordance with a plan established under subsection (a).

(c) Violations

(1) In general

In the case of a State or Indian tribe for which a State or Tribal plan is not approved under section 1639p of this title, it shall be unlawful to produce hemp in that State or the territory of that Indian tribe without a license issued by the Secretary under subsection (b).

(2) Negligent and other violations

A violation of a plan established under subsection (a) shall be subject to enforcement in accordance with paragraphs (2) and (3) of section 1639p(e) of this title, except that the Secretary shall carry out that enforcement instead of a State department of agriculture or Tribal government.

(3) Reporting to Attorney General

In the case of a State or Indian tribe covered by paragraph (1), the Secretary shall report the production of hemp without a license issued by the Secretary under subsection (b) to the Attorney General.

(d) Information sharing for law enforcement

(1) In general

The Secretary shall--

(A) collect the information described in paragraph (2); and

(B) make the information collected under subparagraph (A) accessible in real time to Federal, State, territorial, and local law enforcement.

(2) Content

The information collected by the Secretary under paragraph (1) shall include--

(A) contact information for each hemp producer in a State or the territory of an Indian tribe for which--

(i) a State or Tribal plan is approved under section 1639p(b) of this title; or

(ii) a plan is established by the Secretary under this section;

(B) a legal description of the land on which hemp is grown by each hemp producer described in subparagraph (A); and

(C) for each hemp producer described in subparagraph (A)--

(i) the status of--

(I) a license or other required authorization from the State department of agriculture or Tribal government, as applicable; or

(II) a license from the Secretary; and

(ii) any changes to the status.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 297C, as added Pub.L. 115-334, Title X, § 10113, Dec. 20, 2018, 132 Stat. 4912.)

7 U.S.C.A. § 1639q, 7 USCA § 1639q
Current through PL 117-39.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)
Subchapter VII. Hemp Production

7 U.S.C.A. § 1639r

§ 1639r. Regulations and guidelines; effect on other law

Effective: December 20, 2018
Currentness

(a) Promulgation of regulations and guidelines; report

(1) Regulations and guidelines

(A) In general

The Secretary shall promulgate regulations and guidelines to implement this subchapter as expeditiously as practicable.

(B) Consultation with Attorney General

The Secretary shall consult with the Attorney General on the promulgation of regulations and guidelines under subparagraph (A).

(2) Report

The Secretary shall annually submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report containing updates on the implementation of this subchapter.

(b) Authority

Subject to subsection (c)(3)(B), the Secretary shall have sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp, including Federal regulations and guidelines that relate to the implementation of sections 1639p and 1639q of this title.

(c) Effect on other law

Nothing in this subchapter shall affect or modify--

(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

(2) section 262 of Title 42; or

(3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services--

(A) under--

(i) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(ii) section 262 of Title 42; or

(B) to promulgate Federal regulations and guidelines that relate to the production of hemp under the Act described in subparagraph (A)(i) or the section described in subparagraph (A)(ii).

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 297D, as added Pub.L. 115-334, Title X, § 10113, Dec. 20, 2018, 132 Stat. 4913.)

7 U.S.C.A. § 1639r, 7 USCA § 1639r
Current through PL 117-39.

End of Document

United States Code Annotated
Title 7. Agriculture (Refs & Annos)
Chapter 38. Distribution and Marketing of Agricultural Products (Refs & Annos)
Subchapter VII. Hemp Production

7 U.S.C.A. § 1639s

§ 1639s. Authorization of appropriations

Effective: December 20, 2018
Currentness

There are authorized to be appropriated such sums as are necessary to carry out this subchapter.

CREDIT(S)

(Aug. 14, 1946, c. 966, Title II, § 297E, as added Pub.L. 115-334, Title X, § 10113, Dec. 20, 2018, 132 Stat. 4914.)

7 U.S.C.A. § 1639s, 7 USCA § 1639s
Current through PL 117-39.

End of Document

85 FR 51639-01, 2020 WL 4893800(F.R.)
RULES and REGULATIONS
DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Parts 1308 and 1312
[Docket No. DEA-500]
RIN 1117-AB53

Implementation of the Agriculture Improvement Act of 2018

Friday, August 21, 2020

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

***51639** ACTION: Interim final rule with request for comments.

SUMMARY: The purpose of this interim final rule is to codify in the Drug Enforcement Administration (DEA) regulations the statutory amendments to the Controlled Substances Act (CSA) made by the Agriculture Improvement Act of 2018 (AIA), regarding the scope of regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents. This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations.

DATES: Effective August 21, 2020. Electronic comments must be submitted, and written comments must be postmarked, on or before October 20, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "RIN 1117-AB53/Docket No. DEA-500" on all correspondence, including any attachments.

***51640** • Electronic comments: The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on http://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

• Paper comments: Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-2596.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at http://www.regulations.gov.

Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to http://www.regulations.gov may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and the complete Economic Impact Analysis, to this interim final rule are available in their entirety under the tab "Supporting Documents" of the public docket of this action at http://www.regulations.gov under FDMS Docket ID: DEA-500 (RIN 1117-AB53/Docket Number DEA-500) for easy reference.

Executive Summary

The Agriculture Improvement Act of 2018, Public Law 115-334 (the AIA), was signed into law on December 20, 2018. It provided a new statutory definition of "hemp" and amended the definition of marihuana under 21 U.S.C. 802(16) and the listing of tetrahydrocannabinols under 21 U.S.C. 812(c). The AIA thereby amends the regulatory controls over marihuana, tetrahydrocannabinols, and other marihuana-related constituents in the Controlled Substances Act (CSA).

This rulemaking makes four conforming changes to DEA's existing regulations:

• It modifies 21 CFR 1308.11(d)(31) by adding language stating that the definition of "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***."

• It removes from control in schedule V under 21 CFR 1308.15(f) a "drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols."

• It also removes the import and export controls described in 21 CFR 1312.30(b) over those same substances.

• It modifies 21 CFR 1308.11(d)(58) by stating that the definition of "Marihuana Extract" is limited to extracts "containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis."

This interim final rule merely conforms DEA's regulations to the statutory amendments to the CSA that have already taken effect, and it does not add additional requirements to the regulations. Accordingly, there are no additional costs resulting from these regulatory changes. However, as discussed below, the changes reflected in this interim final rule are expected to result in annual cost savings for affected entities.

Changes to the Definition of Marihuana

The AIA amended the CSA's regulatory controls over marihuana by amending its definition under the CSA. Prior to the AIA, marihuana was defined in 21 U.S.C. 802(16) as follows:

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.

The AIA modified the foregoing definition by adding that the "term 'marihuana' does not include hemp, as defined in section 1639***o*** of Title 7." 21 U.S.C. 802(16)(B). Furthermore, the AIA added a definition of "hemp" to 7 U.S.C. 1639***o***, which reads as follows:

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.

Taken together, these two changes made by the AIA limit the definition of marihuana to only include cannabis or cannabis-derived material that contain more than 0.3% delta-9-tetrahydrocannabinol (also known as [Delta][FN9]-THC) on a dry weight basis. Thus, to fall within the current CSA definition of ***51641** marihuana, cannabis and cannabis-derived material must both fall within the pre-AIA CSA definition of marihuana and contain more than 0.3 percent [Delta][FN9]-THC on a dry weight basis. Pursuant to the AIA, unless specifically controlled elsewhere under the CSA, any material previously controlled under Controlled Substance Code Number 7360 (marihuana) or under Controlled Substance Code Number 7350 (marihuana extract), that contains 0.3% or less of [Delta][FN9]-THC on a dry weight basis—i.e., "hemp" as that term defined under the AIA—is not controlled. Conversely, any such material that contains greater than 0.3% of [Delta][FN9]-THC on a dry weight basis remains controlled in schedule I.

In order to meet the AIA's definition of hemp, and thus qualify for the exception in the definition of marihuana, a cannabis-derived product must itself contain 0.3% or less [Delta][FN9]-THC on a dry weight basis. It is not enough that a product is labeled or advertised as "hemp." The U.S. Food and Drug Administration (FDA) has recently found that many cannabis-derived products do not contain the levels of cannabinoids that they claim to contain on their labels.[FN1] Cannabis-derived products that exceed the 0.3% [Delta][FN9]-THC limit do not meet the statutory definition of "hemp" and are schedule I controlled substances, regardless of claims made to the contrary in the labeling or advertising of the products.

In addition, the definition of hemp does not automatically exempt any product derived from a hemp plant, regardless of the [Delta][FN9]-THC content of the derivative. In order to meet the definition of "hemp," and thus qualify for the exemption from schedule I, the derivative must not exceed the 0.3% [Delta][FN9]-THC limit. The definition of "marihuana" continues to state that "all parts of the plant Cannabis sativa L.," and "every compound, manufacture, salt, derivative, mixture, or preparation of such plant," are schedule I controlled substances unless they meet the definition of "hemp" (by falling below the 0.3% [Delta][FN9]-THC limit on a dry weight basis) or are from exempt parts of the plant (such as mature stalks or non-germinating seeds). See 21 U.S.C. 802(16) (emphasis added). As a result, a cannabis derivative, extract, or product that exceeds the 0.3% [Delta][FN9]-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less [Delta][FN9]-THC on a dry weight basis.

Finally, nothing in the AIA or in these implementing regulations affects or alters the requirements of the Food, Drug, & Cosmetic Act (FD&C Act). See 7 U.S.C. 1639r(c). Hemp products that fall within the jurisdiction of the FD&C Act must comply with its requirements. FDA has recently issued a statement regarding the agency's regulation of products containing cannabis and cannabis-derived compounds, and DEA refers interested parties to that statement, which can be found at https://www.fda.gov/newsevents/Newsroom/PressAnnouncements/ucm628988.htm.

Changes to the Definition of Tetrahydrocannabinols

The AIA also modified the listing for tetrahydrocannabinols under 21 U.S.C. 812(c) by stating that the term tetrahydrocannabinols does not include tetrahydrocannabinols in hemp. Specifically, 21 U.S.C. 812(c) Schedule I now lists as schedule I controlled substances: "Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639***o*** of Title 7)."

Therefore, the AIA limits the control of tetrahydrocannabinols (for Controlled Substance Code Number 7370). For tetrahydrocannabinols that are naturally occurring constituents of the plant material, Cannabis sativa L., any material that contains 0.3% or less of [Delta][FN9]-THC by dry weight is not controlled, unless specifically controlled elsewhere under the CSA. Conversely, for tetrahydrocannabinols that are naturally occurring constituents of Cannabis sativa L., any such material that contains greater than 0.3% of [Delta][FN9]-THC by dry weight remains a controlled substance in schedule I.

The AIA does not impact the control status of synthetically derived tetrahydrocannabinols (for Controlled Substance Code Number 7370) because the statutory definition of "hemp" is limited to materials that are derived from the plant Cannabis sativa L. For synthetically derived tetrahydrocannabinols, the concentration of [Delta][FN9]-THC is not a determining factor in whether the material is a controlled substance. All synthetically derived tetrahydrocannabinols remain schedule I controlled substances.

This rulemaking is modifying 21 CFR 1308.11(d)(31) to reflect this statutory change. By this rulemaking, 21 CFR 1308.11(d)(31) is being modified via the addition of subsection (ii), which reads: "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***."

Removal of Schedule V Control of FDA-Approved Products Containing Cannabidiol

Previously DEA, pursuant to 21 CFR 1308.15, separately controlled in Schedule V drug products in finished dosage formulations that have been approved by FDA and that contain cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols (under Controlled Substance Code Number 7367). The FDA-approved substances described under Drug Code 7367 are no longer controlled, by virtue of the AIA. As a result, DEA is removing the listing for "Approved cannabidiol drugs" under schedule V in 21 CFR 1308.15.

Note that CBD in a mixture with a [Delta][FN9]-THC concentration greater than 0.3% by dry weight is not exempted from the definition of "marihuana" or "tetrahydrocannabinols." Accordingly, all such mixtures exceeding the 0.3% limit remain controlled substances under schedule I.

Removal of Import/Export Provisions Involving FDA-Approved Products Containing CBD

Previously DEA, pursuant to 21 CFR 1312.30, required import and export permits pursuant to 21 U.S.C. 811(d)(1), 952(b)(2), and 953(e)(3) for the import and export of drug products in finished dosage formulations that have been approved by FDA and that contain CBD derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. Because such substances are no longer controlled substances, DEA is likewise removing the import and export permit requirement for these substances. The regulation is revised to delete § 1312.30(b).

Drug Code 7350 for Marihuana Extract

The current control status of marihuana-derived constituents depends upon the concentration of [Delta][FN9]-THC in the constituent. DEA is amending the scope of substances falling within the Controlled Substances Code Number for marihuana extract (7350) to conform to the amended definition of marihuana in the AIA. As amended, the Drug Code 7350 definition reads:

Marihuana Extract—meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight ***51642** basis, other than the separated resin (whether crude or purified) obtained from the plant.

21 CFR 1308.11(d)(58). The drug code 7350 became effective on January 13, 2017. 81 FR 90194.

Regulatory Analysis

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring the publication of a prior notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if such actions are determined to be unnecessary, impracticable, or contrary to the public interest.

DEA finds there is good cause within the meaning of the APA to issue these amendments as an interim final rule and to delay comment procedures to the post-publication period, because these amendments merely conform the implementing regulations to recent amendments to the CSA that have already taken effect. DEA has no discretion with respect to these amendments. This 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. See 5 U.S.C. 553(b)(B) (relating to notice and comment procedures). "[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary." Gray Panthers Advocacy Committee v. Sullivan, 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also United States v. Cain, 583 F.3d 408, 420 (6th Cir. 2009) (contrasting legislative rules, which require notice-and-comment procedures, "with regulations that merely restate or interpret statutory obligations," which do not); Komjathy v. Nat. Trans. Safety Bd., 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule "does no more than repeat, virtually verbatim, the statutory grant of authority" notice-and-comment procedures are not required).

In addition, because the statutory changes at issue have already been in effect since December 20, 2018, DEA finds good cause exists to make this rule effective immediately upon publication. See 5 U.S.C. 553(d). Therefore, DEA is issuing these amendments as an interim final rule, effective upon publication in the Federal Register.

Although publishing a notice of proposed rulemaking and soliciting public comment prior to publication are unnecessary in this instance because these regulations merely implement statutory changes over which the agency has no discretion, DEA is soliciting public comment on this rule following its publication. For that reason, DEA is publishing this rule as an interim final rule and is establishing a docket to receive public comment on this rule. To the extent required by law, DEA will consider and respond to any relevant comments received.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Cost)

This interim final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of

recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O.

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined and it has been determined that it is not a significant regulatory action under E.O. 12866 because it is a non-discretionary action that is dictated by the statutory amendments to the CSA enacted by the AIA. While not determined to be a significant regulatory action, this action has been reviewed by the OMB.

As explained above, DEA is obligated to issue this interim final rule to revise its regulations so that they are consistent with the provisions of the CSA that were amended by the AIA. In issuing this interim final rule, DEA has not gone beyond the statutory text enacted by Congress. Thus, DEA would have to issue this interim final rule regardless of the outcome of the agency's regulatory analysis. Nonetheless, DEA conducted this analysis as discussed below.

Summary of Benefits and Costs

This analysis is limited to the provisions of the AIA that are being directly implemented by this DEA interim final rule. DEA has reviewed these regulatory changes and their expected costs and benefits. Benefits, in the form of cost savings realized by DEA registrants handling previously controlled substances, will be generated as a direct result of the publication of this interim final rule. DEA does not expect there to be any costs associated with the promulgation of this interim final rule. The following is a summary; a detailed economic analysis of the interim final rule can be found in the rulemaking docket at http://www.regulations.gov.

The AIA's revised definitions of marihuana and tetrahydrocannabinols effectively decontrol hemp as defined under the AIA. DEA's regulatory authority over any plant with less than 0.3% THC content on a dry weight basis, and any of the plant's derivatives under the 0.3% THC content limit, is removed as a result. It is important to note, however, that this does not mean that hemp is not under federal regulatory oversight. The AIA directs the U.S. Department of Agriculture (USDA) to review and approve commercial hemp production plans developed by State, territory, and Indian tribal agencies and to develop its own production plan. 7 U.S.C. 1639p, 1639q. Until these regulations are finalized, State commercial hemp pilot programs authorized under the 2014 Farm Bill are still in effect and current participants may proceed with plans to grow hemp while new regulations are drafted.[FN2] DEA expects the USDA to assess the costs and benefits of this new regulatory apparatus once those rules are finalized. For these reasons, DEA considers any potential costs or benefits broadly related to changes in the domestic industrial hemp market due to the ***51643** decontrol of hemp, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. The removal of DEA's regulatory authority over hemp as defined under the AIA will impact only DEA registrants that currently import viable hemp seed intended for germination. Viable hemp seed was classified as a schedule I controlled substance prior to the amendments to the CSA enacted by the AIA. The importation and exportation of controlled substances requires an importer or exporter to first register with DEA, and then apply and obtain a permit to import or export controlled substances for each shipment.[FN3] The decontrol of hemp with this interim final rule means that viable hemp seed is no longer subject to those schedule I requirements, as long as the material contains less than the 0.3% limit.

Based on the number of import and export permits issued, DEA estimated the number of import and export permit applications that would no longer be needed. DEA reviewed internal data tracking the number of imports and exports for hemp seed over a three year period beginning January 1, 2016 and ending December 31, 2018.[FN4] During this three year period, there was an average of 88 import permits issued for hemp seed per year, and no exports. These import permits were issued only to participants in state commercial hemp pilot programs, including state departments of agriculture and higher education institutions, which are considered “fee exempt”, and do not pay the $1,523 annual importer registration fee.[FN5] However, fee-exempt institutions are still required to obtain a DEA registration and renew that registration annually by filling out and submitting DEA form

225a. DEA expects these institutions to relinquish their schedule I importer registrations as a result of the promulgation of this interim final rule.

DEA estimates the average annual cost savings attributable to the elimination of import permits for hemp seed, and the elimination of annual registration renewals for hemp seed importers to be $3,225.[FN6] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import permits and registration renewals being processed is negligible relative to the total amount of permits and renewals processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings		
Estimated hourly wage ($/hour): [7]		$45.54
Load for benefits (percent of labor rate): [8]	43%	
Loaded labor rate ($/hour): [9]		$65.06
Average hourly burden, per application:		0.25
Average annual # of import permit applications for hemp seed:		88
Average annual hemp seed import permit application labor costs: [10]		$1,431.32
Average annual mailing cost of hemp seed import permit applications: [11]		$1,579.50
Annual Registration Renewal Application (DEA Form 225a) Cost Savings		
Estimated hourly wage ($/hour): [12]		$59.56
Load for benefits (percent of labor rate): [13]	43%	
Loaded labor rate ($/hour): [14]		$85.09
# of Importers no longer requiring registration:		21
Average hourly burden, per application: [15]		0.12
Average annual registration renewal application labor cost: [16]		$214.43
Total Annual Cost Savings:		$3,225.25

This interim final rule removes FDA-approved products containing CBD from schedule V control, including controls over the importation and exportation of this class of drugs. There is currently only one drug that meets these criteria for decontrol.[FN17] To determine any cost savings resulting from this decontrol action, DEA analyzed its registration, import, and export data. DEA believes all entities that currently handle FDA-approved CBD products also handle other controlled substances. This means the decontrol of this product will not allow these DEA registrants to benefit from any registration-related cost savings. However, like importers of viable hemp seed, importers and exporters of FDA-approved CBD products will no longer be required to obtain import and export permits from DEA.

DEA analyzed its internal import and export data to identify the average ***51644** number of permits issued for FDA-approved CBD products over a three year period beginning January 1, 2016 and ending December 31, 2018. During this period there was an average of 52 import permits and one export permit issued per year, the elimination of which will result in an average annual cost savings of $1,814.[FN18] This cost savings is realized entirely by DEA registrants. Since the anticipated reduction in import and export permits being processed is negligible relative to the total number of permits processed by DEA annually, DEA is not expected to experience a measurable decrease in workflow or use of resources, and therefore, will incur no cost savings. The results of this analysis are summarized below:

Average Annual Import Permit Application (DEA Form 357) Cost Savings		
Estimated hourly wage ($/hour): [7]		$45.54
Load for benefits (percent of labor rate): [8]	43%	
Loaded labor rate ($/hour): [9]		$65.06
Average hourly burden, per application:		0.25
Average annual # of import permit applications for FDA-approved CBD:		52
Average annual FDA-approved CBD import permit application labor costs: [19]		$845.74
Average annual mailing cost for import permit applications: [11 20]		$916.50
Average Annual Export Permit Application (DEA Form 161) Cost Savings		
Estimated hourly wage ($/hour): [7]		$45.54
Load for benefits (percent of labor rate): [8]	43%	
Loaded labor rate ($/hour): [9]		$65.06
Average hourly burden, per collection:		0.5
Average annual # of export permit applications for FD-approved CBD:		1
Average annual FDA-approved CBD export permit application labor costs: [21]		$32.53
Average annual mailing cost of export permit applications: [11]		$19.50
Total Annual Cost Savings:		$1,814.27

This interim final rule amends the definition of marihuana extract to conform to the revised definitions of marihuana and tetrahydrocannabinols. This revised definition now includes the 0.3%-THC content limit for the extract, meaning hemp-derived extracts containing less than 0.3%-THC content are also decontrolled along with the plant itself. As discussed previously, the production of hemp and its extracts as defined under the AIA now falls under the same regulatory oversight shared between the States, territories, and Indian tribal agencies, and the USDA. The FDA also affirms its regulatory oversight over cannabis-derived compounds, such as CBD, whether or not these compounds are “classified as hemp under the 2018 Farm Bill.” [FN22] For these reasons, DEA considers any potential costs or benefits broadly related to changes in the markets for domestic hemp extracts due to their decontrol, including but not limited to the expansion in the number of producers, consumer products, and the impact on supply chains to be outside the scope of this analysis.

Like FDA-approved CBD products and viable hemp seeds, entities no longer require a DEA registration or import and export permits to handle hemp extract that does not exceed the statutory 0.3% THC limit. DEA's import and export data does capture a minimal number of instances of the importation and exportation of CBD; however, this data does not detail whether or not the CBD was derived from Cannabis sativa L. plants containing less than 0.3% THC content. For this reason, DEA does not have a good basis to estimate the annual number of imported or exported hemp-derived extracts that no longer require permits as a result of the promulgation of this interim final rule, but after reviewing its data, believes this number to be minimal. Therefore, DEA concludes that this provision of the interim final rule is likely to result in a minimal benefit to DEA registrants, but DEA does not have a good basis to quantify this amount.

As part of its core function, DEA's Diversion Control Division is responsible for managing over 1.8 million DEA registrations, processing new and renewal registration applications, processing registration modification requests, issuing certificates of registration, issuing import and export permits, issuing renewal notifications, conducting due diligence, maintaining and operating supporting information systems, etc. Therefore, DEA does not anticipate it will realize any measurable cost savings to the government as a result of the negligible decreases in registrant services resulting from the promulgation of this interim final rule.

As described above, DEA estimates the average annual benefit in the form of cost savings to DEA registrants as a result of the promulgation of this interim final rule to be $5,039.[FN23] DEA calculated the present value of this cost savings over a 20 year period at a 3 percent and 7 percent discount rate. At a 3 percent discount rate, the present value of benefits is $74,968, while the present value of costs is $0, making the net present value (NPV) $74,968. At a 7 percent discount rate, the present value of benefits is $53,383, the present value of costs is $0, making the NPV is $53,383.[FN24] The table below summarizes the present value and annualized benefit calculations.

Discount Rate	3%	7%
Annual benefit ($)	5,039	5,039
Present value of benefits ($)	74,968	53,383
Present value of costs ($)	0	0
Years	20	20
Net present value ($)	74,968	53,383

***51645** E.O. 13771 deregulatory actions are final actions that have totals costs less than zero. Also, under E.O. 13771, regulatory actions that expand production options, which are considered to be "enabling rules," generally qualify as E.O. 13771 deregulatory actions. This interim final rule decontrols hemp, hemp extracts and FDA-approved products containing CBD, and it results in cost savings to the public, as discussed above. Accordingly, DEA has determined that this interim final rule is an E.O. 13771 Deregulatory Action.

Executive Order 12988

This interim final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of E.O. 13132.

Executive Order 13175

This interim final rule is required by statute, and will not have tribal implications or impose substantial direct compliance costs on Indian tribal governments.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment under section 553(b) of the Administrative Procedure Act (5 U.S.C. 553). As explained in the interim final rule, DEA determined that there was good cause to exempt this interim final rule from pre-publication notice and comment. Consequently, the RFA does not apply to this interim final rule.

Paperwork Reduction Act of 1995

This interim final rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-21.

Unfunded Mandates Reform Act of 1995

This interim final rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. 2 U.S.C. 1532.

Congressional Review Act

This interim final rule is not a major rule as defined by the Congressional Review Act (CRA) (5 U.S.C. 804). DEA is submitting the required reports with a copy of this interim final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1308

Administrative practice and procedure; Drug traffic control; Reporting and recordkeeping requirements.

21 CFR Part 1312

Administrative practice and procedure; Drug traffic control; Exports; Imports; Reporting and recordkeeping requirements.

For the reasons set forth above, 21 CFR parts 1308 and 1312 are amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b).

21 CFR § 1308.11

2. In § 1308.11, paragraphs (d)(31) and (58) are revised to read as follows:

21 CFR § 1308.11

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(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. 1639*o*.

* * * * *

(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.

* * * * *21 CFR § 1308.15

§ 1308.15 [Amended]

21 CFR § 1308.15

3. In § 1308.15, paragraph (f) is removed.

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

4. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

21 CFR § 1312.30

§ 1312.30 [Amended]

21 CFR § 1312.30

5. In § 1312.30, paragraph (b) is removed and reserved.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020-17356 Filed 8-20-20; 8:45 am]

BILLING CODE 4410-09-P

Footnotes

1 See FDA, Warning Letters and Test Results for Cannabidiol-Related Products, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.

2 See USDA, Hemp Production Program Questions and Answers, https://www.ams.usda.gov/publications/content/hemp-production-program-questions-and-answers.

3 See 21 CFR 1312.11(a), 1312.21(a).

4 DEA import data is organized by drug code. Hemp seed falls within drug code "7360—Marihuana".

5 See 21 CFR 1301.21(a)(1).

6 Rounded down to the nearest whole dollar.

7 Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2018, 11-3071 Transportation, Storage, and Distribution Managers (http://www.bls.gov/oes/current/oes_nat.htm). The DEA considers this occupational category to be representative of the type of employee that is likely to fill out and submit import permits on behalf of a DEA registered importer.

8 Bureau of Labor Statistics, "Employer Costs for Employee Compensation—March 2019" (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

9 $45.54 x (1 + 0.4286) = $65.06.

10 ($65.06 x 0.25) x 88 = $1,431.32.

11 91% of import permits are submitted via paper form and delivered to DEA by an express carrier with respondent-paid means for return delivery. The estimated cost burden is $19.50 per response: 2 x $9.75 = $19.50. $9.75 is based on a major express carrier's national 3-day flat rate for envelopes. The DEA assumes that 91% of import permits submitted in any given year incur this mailing cost.

12 Estimates are based on the population of the regulated industry participating in these business activities. The DEA assumes that a general and operations manager (11-1021, 2018 Standard Occupational Classification) will complete the form on behalf of the applicant or registrant.

13 Bureau of Labor Statistics, "Employer Costs for Employee Compensation—March 2019" (ECEC) reports that average benefits for private industry is 30% of total compensation. The 30% of total compensation equates to 42.86% (30% / 70%) load on wages and salaries.

14 $59.56 x (1 + 0.4286) = $85.09.

15 The DEA assumes all forms are submitted online.

16 ($85.09 x 0.5) x 21 = $214.43.

17 See FDA, Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers, https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#approved.

18 Rounded down to the nearest whole number.

19 ($65.06 x 0.25) x 52 = $845.74.

20 52 x .91 = 47 (rounded down) permits mailed per year; 47 x $19.50 = $916.50.

21 ($65.06 x 0.5) x 1 = $32.53.

22 Ibid.

23 The total average annual cost savings resulting from the decontrol of viable hemp seed ($3,225) and FDA-approved CBD products ($1,814).

24 See Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A-4, Regulatory Analysis (2003). Figuresare rounded.

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