UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HEMP INDUSTRIES ASSOCIATION, *et al.*, **Plaintiffs,** **v.** **UNITED STATES DRUG ENFORCEMENT ADMINISTRATION, *et al.*,** **Defendants.**	**Civil Action No. 20-2921 (JEB)**

MEMORANDUM OPINION

While the debate over marijuana legalization and enforcement consumes officials both in Washington and in various state capitals, this case focuses on its cousin: hemp. It principally involves a Drug Enforcement Administration rule issued in response to a recent round of statutory amendments to the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* As relevant here, the rule states that only hemp derivatives, extracts, and products exceeding 0.3% delta-9 tetrahydrocannabinol (THC) — the principal psychoactive component of the cannabis plant — shall be stringently regulated by the CSA. Plaintiffs seek 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. They likewise pursue an injunction preventing DEA from enforcing the CSA against such material.

Interesting as this question may be, the Court ultimately concludes that it is powerless to entertain the merits of Plaintiffs' entreaty. Congress has provided an exclusive pathway for

federal-court challenges to final DEA decisions such as the Interim Final Rule at issue here: namely, a petition for review filed in the court of appeals. See 21 U.S.C. § 877. As this lawsuit, in sum and substance, challenges an assertion of agency authority set out in the IFR, it falls squarely within the ambit of that exclusive-review provision. The Court, accordingly, will dismiss this action for lack of subject-matter jurisdiction.

I. Background

The Court begins with an overview of the relevant statutory and regulatory background, then offers a brief survey of the hemp-production process at the core of this suit, and concludes with a procedural history.

A. Legal Background

Passed in 1970 and enforced by DEA, the CSA creates a comprehensive regulatory regime that criminalizes the unauthorized manufacture, distribution, and dispensation of controlled substances. See 21 U.S.C. §§ 822, 841(a); see also 28 C.F.R. § 0.100(b) (Attorney General delegating regulatory authority under CSA to DEA). The CSA groups such substances into five "schedules" based on their potential for abuse, accepted medical uses, and accepted safety for use under medical supervision. See 21 U.S.C. § 812(a)–(b); see also id. § 811(a) (empowering DEA to add or remove substances from schedules). Substances in Schedule I — which have "no currently accepted medical use in treatment in the United States" — are subject to the most stringent controls. Id. § 812(a)–(b). For example, anyone who "manufactures," "distributes," or "dispenses" such a controlled substance is generally required to register with DEA. Id. § 822(a); see also id. § 823(a) (listing factors to be considered when registering manufacturers of Schedule I substances).

Both marijuana and tetrahydrocannabinols are classified under Schedule I. Id. § 812, Schedule I (c)(10), (17). Although Congress has long regulated these substances (the former since 1937), the Agriculture Improvement Act of 2018 ushered in a new regulatory framework for the plant *Cannabis sativa L.* and its various derivatives that have lower concentrations of delta-9 THC (a specific type of tetrahydrocannabinol). Specifically, the statute introduced a revised definition for "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.

7 U.S.C. § 1639*o*(1). With that definition in tow, the AIA then amended the CSA in two relevant ways. First, it clarified that "[t]he term [marijuana] does not include . . . hemp, as defined in [the AIA]." 21 U.S.C. § 802(16). Second, it carved out from Schedule I "tetrahydrocannabinols in hemp (as defined under [the AIA])." Id. § 812, Schedule I (c)(17). These changes thus exempted from the CSA's registration requirements the cultivation and processing of the cannabis plant under specified conditions. The AIA further granted the Department of Agriculture — subject to several exceptions not immediately relevant — "sole authority to promulgate Federal regulations and guidelines that relate to the production of hemp." 7 U.S.C. § 1639r(b); see also id. § 1639*o*(3). Notwithstanding that provision, the CSA continues to grant DEA general authority to promulgate and enforce regulations it deems necessary and appropriate to execute its functions under the CSA. See 21 U.S.C. §§ 821, 871(b); see also 21 C.F.R. §§ 1300–1317.

Invoking those rulemaking powers, DEA on August 21, 2020, published an interim final rule intended to "conform[] [its] regulations" to the AIA's statutory amendments. See

Implementation of the Agriculture Improvement Act of 2018, 85 Fed. Reg. 51,639, 51,639 (Aug. 21, 2020). Notwithstanding its oxymoronic-sounding title, the IFR became effective and binding upon regulated parties on the date of its publication and thus constitutes final agency action. Id. The rule altered the agency's Schedule I regulation to clarify that "[Marijuana] Extract" is limited to extracts "containing greater than 0.3% delta-9-[THC] on a dry weight basis," and that "Tetrahydrocannabinols" does not include "any material, compound, mixture, or preparation that falls within the [AIA's] definition of hemp." Id. at 51,640; see also 21 C.F.R. § 1308.11(d)(31), (58). The agency also specifically addressed products derived from hemp plants, stating that "[i]n 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-9]-THC limit." 85 Fed. Reg. at 51,641. In other words, according to DEA, "a cannabis derivative, extract, or product that exceeds the 0.3% [delta-9]-THC limit is a schedule I controlled substance, even if the plant from which it was derived contained 0.3% or less [delta-9]-THC on a dry weight basis." Id.; see also id. at 51,640–41 (similar). This determination is at the core of Plaintiffs' challenge here.

Finally, the CSA provides for original jurisdiction in the courts of appeals over "[a]ll final determinations, findings, and conclusions" made by DEA under the statute. See 21 U.S.C. § 877. Any person "aggrieved by a final decision" may obtain review thereof by filing a petition in the relevant court of appeals within thirty days. Id.

B. Factual Background

These statutory and regulatory developments occurred amidst an American hemp economy witnessing rapid and substantial growth. As of 2019, nearly 512,000 acres of land were licensed for hemp cultivation in the United States, and one survey the year after found more than 5,400 state-licensed hemp processors — both significant increases from years prior. See

ECF No. 29 (Am. Compl.), ¶¶ 22, 26. A wide array of hemp products, in turn, have flooded the consumer market; applications of the plant range from fabrics and textiles, to papermaking and oil absorbents, to foods and cosmetics, and beyond. Id., ¶ 16.

Among the ingredients for each of these products are extracts derived from hemp plants. Id., ¶ 29. In their final form, the extracts contain less than 0.3% delta-9 THC and are therefore not psychoactive or subject to the CSA. Id., ¶¶ 15, 29. The problem here for Plaintiffs lies in the hemp-extract production process. As a high-level understanding of that process is necessary to grasp the substantive issues underlying this action, the Court — with useful assistance from Plaintiffs — will briefly outline its key stages.

The journey begins with the cultivation and harvest of hemp plants, which are soon transferred to third-party processors for "milling" and "extraction." Id., ¶¶ 32–34. Deploying a series of complex procedures, the processors separate the hemp flower from the remainder of the plant, extract cannabinoids from raw flower material (the remains of which are then discarded), and evaporate the resulting oil in order to remove extraneous solvents, fats, and lipids. Id., ¶¶ 33–35. Evaporation generates two outputs of particular relevance here: intermediate hemp material and waste hemp material. Both substances "naturally (and unavoidably) exceed" 0.3% delta-9 THC concentration, as prior steps in the production process have stripped away the low-THC and THC-free parts of the hemp plant. Id., ¶¶ 35–37; see also id., ¶¶ 35–36 (explaining that IHM and WHM "contain[] concentrated levels of cannabinoids"). According to Plaintiffs, however, neither IHM nor WHM is added to or otherwise used as an ingredient in any consumer product. Id., ¶¶ 35–36. IHM, rather, is further refined into extracts or isolates containing less than 0.3% delta-9 THC, which are in turn used as ingredients in such consumer products. Id., ¶¶ 35, 38. Plaintiffs do not discuss what processors or businesses do with WHM.

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