

**UNITED STATES DISTRICT COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

BLUESTAR OPERATIONS, LLC,

Petitioner,

v.

US DRUG ENFORCEMENT
ADMINISTRATION; TERRANCE
C. COLE, in his official capacity as
Administrator of the U.S. Drug
Enforcement Administration;
TODD BLANCHE, in his official
capacity as Acting Attorney
General,

Respondents.

No. 26-1691

**BRIEF OF AMICUS CURIAE
AMERICAN TRADE ASSOCIATION FOR CANNABIS AND
HEMP IN SUPPORT OF RESPONDENTS' OPPOSITION TO
PETITIONER'S MOTION TO STAY**

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INTRODUCTION

Since 1970, marijuana and tetrahydrocannabinols (THC) have been Schedule I controlled substances under the Controlled Substances Act (CSA), covering both naturally occurring THC and synthetic equivalents, derivatives, and related substances. The 2018 Farm Bill exempted “hemp” — cannabis with a delta-9 (D9) THC concentration at or below 0.3% — legalizing it as an agricultural commodity, not a consumer intoxicant. However, that threshold created an opening that opportunistic manufacturers operating outside state-regulated cannabis markets quickly exploited by marketing laboratory-synthesized intoxicants as Farm Bill-exempt hemp products. In 2025, Congress confirmed what the Farm Bill's text always required: hemp's exemption does not extend to substances synthesized outside the plant.

Hexahydrocannabinol (HHC) is precisely such a substance. It is manufactured by applying chemicals to THC that comes from outside the plant. That makes HHC a derivative of a controlled substance, not hemp, falling squarely within Schedule I— which expressly covers synthetic equivalents and derivatives of THC — and outside the Farm Bill's exemption, which reaches only THC in hemp. HHC can be just as intoxicating as D9, but it is not D9. This Court should uphold the DEA's final rule because HHC is and always has been a Schedule 1 substance.

STATEMENT OF INTEREST

The American Trade Association for Cannabis and Hemp (“ATACH”) is a 501(c)(6) trade organization registered in Washington, D.C., that promotes the expansion, protection, and preservation of businesses engaged in the legal trade of industrial, medical, and recreational cannabis and hemp-based products. ATACH supports a thriving, lawfully regulated hemp industry — and it is for that reason, ATACH supports the DEA's rule. ATACH has a direct interest in this case: the DEA’s rule curbs the unregulated marketing and sale of potentially harmful synthetic tetrahydrocannabinols, protecting public health and the integrity of the cannabis industry as a whole and those—like the members of ATACH—who are subject to its regulations.¹

ARGUMENT

HHC IS AN UNLAWFUL CONTROLLED SUBSTANCE THAT FALLS OUTSIDE THE SCOPE OF THE FARM BILL.

To protect public safety, the Controlled Substances Act of 1970 (CSA) places drugs and other substances on schedules based on their potential for abuse, accepted medical use, and safety

¹ The amicus curiae states that (i) no party’s counsel authored this brief in whole or in part; (ii) no party or party’s counsel contributed money that was intended to fund preparing or submitting this brief; and (iii) no other person contributed money that was intended to fund preparing or submitting this brief other than the amici and their counsel. See Fed. R. App. P. 29(a)(4)(E).

profile. 21 U.S.C. § 812(b). Schedule I — the most restrictive — is reserved for substances that have a high potential for abuse, no currently accepted medical use, and lack accepted safety for use even under medical supervision. *Id.* § 812(b)(1). Since 1970, both marijuana and THC have been listed independently on Schedule I. See *id.* § 812(c), Sched. I(c)(10) & (17). The Ninth Circuit has twice confirmed that the Schedule I THC listing covers "synthetic THC of any kind." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1089-90 (9th Cir. 2003) (Hemp I); *Hemp Indus. Ass'n v. DEA*, 357 F.3d 1012, 1018 (9th Cir. 2004) (Hemp II).

In 1973, the DEA promulgated regulations defining THC under Schedule I classification to include "synthetic equivalents of the substances contained in the plant, or in the resinous extractives of *Cannabis*" and "synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity." 21 C.F.R. § 1308.11(d)(31); see 38 Fed. Reg. 8254, 8256 (Mar. 30, 1973). That same definition remains today. See 21 C.F.R. § 1308.11(d)(31) (2025).

In 2018, Congress enacted the Farm Bill, legalizing the regulated production of hemp as an agricultural commodity — not as a consumer intoxicant. The Farm Bill amended the CSA by excluding “hemp” from the definition of marijuana, Pub. L. 115-334, § 12619(a), and “tetrahydrocannabinols in hemp from

Schedule I classification," *id.* § 12619(b). It defined "hemp" as the plant *Cannabis sativa* L. and its parts, derivatives, extracts, and cannabinoids, provided the delta-9 THC concentration does not exceed 0.3 percent on a dry weight basis. 7 U.S.C. § 1639o(1).

The only question before this Court is whether HHC — a synthetic hydrogenated derivative of THC, manufactured in a laboratory, and virtually pharmacologically indistinguishable from D9 — qualifies as a "tetrahydrocannabinol in hemp" exempt from Schedule I. It does not.

A. HHC is an Unnatural Substance with a Chemical Structure and Psychoactive Effects that Differ from non-Intoxicating Hemp

The plant *Cannabis sativa* L. contains more than one hundred chemical compounds, also known as cannabinoids — the two main cannabinoids being D9 and CBD. Ctrs. for Disease Control & Prevention, What We Know About Marijuana, CDC (Sept. 9, 2021).² D9 elicits a 'high' in those who consume it; CBD does not — because whereas THC contains a cyclic ring, CBD contains a hydroxyl group, and that structural difference gives the two compounds entirely different pharmacological properties. Jack Rudd, CBD vs THC — What are the Main Differences?, Analytical

² Available at: <https://www.cdc.gov/marijuana/what-we-know.html>.

Cannabis (Jan. 27, 2023).³ That distinction is why the Farm Bill defined "hemp" as cannabis by measuring D9 concentration specifically — freeing the plant, its derivatives, and cannabinoids like CBD for commercial production while preserving Schedule I status for intoxicating THC. *See* § 1639o(1).

Manufacturers operating outside regulated channels have exploited that framework by extracting CBD and other non-intoxicating cannabinoids from compliant hemp plants and converting them into new intoxicating substances, which are sometimes more potent than marijuana, through semi-synthetic processes involving heavy metals, volatile solvents, and other chemical agents. American Trade Ass'n for Cannabis & Hemp, *Toward Normalized Cannabinoid Regulation: The Regulation of Hemp-Synthesized Intoxicants 6-7* (2023) (ATACH 2023 Whitepaper);⁴ *see also* Patricia Golombek et al., *Conversion of Cannabidiol (CBD) into Psychotropic Cannabinoids Including Tetrahydrocannabinol (THC): A Controversy in the Scientific Literature*, 8 *Toxics*, art. 41, June 2020, at 5.

³ Available at: <https://www.analyticalcannabis.com/articles/cbd-vs-thc-what-are-the-main-differences-297486>.

⁴ Available at: <https://atach.org/wp-content/uploads/2023/06/ATACH-Paper-Toward-Normalized-Cannabinoid-Regulationd.pdf>

HHC does not occur in hemp in any commercially meaningful quantity and is not biosynthesized by the plant. European Monitoring Ctr. for Drugs & Drug Addiction, *Hexahydrocannabinol (HHC) and Related Substances 22* (2023)(EMCDDA Report); see also Anders Helander et al., *Appearance of Hexahydrocannabinols as Recreational Drugs and Implications for Cannabis Drug Testing*, 84 *Scandinavian J. Clinical & Lab. Investigation* 125, 126 (2024) (HHC "may not occur naturally or in only trace amounts in the cannabis plant"). It first emerged on the drug market in the United States in late 2021, when manufacturers began converting a legal hemp product, CBD, into synthetic intoxicants. EMCDDA Report at 8. HHC is not a derivative of the hemp plant — it is a derivative of a Schedule I controlled substance. EMCDDA Report at 34.

Commercial HHC production proceeds through one of two manufacturing methods: isomerization or functionalization. Isomerization — the more common commercial route — involves extracting CBD from raw hemp plant material, dissolving it in a solvent, and exposing it to an acidic catalyst and heat, which changes the bonds in CBD, creating new intoxicating molecules — primarily D8 and D9 — before hydrogenation of that intermediate yields HHC. EMCDDA Report at 35-36 ("CBD is a 'pre-precursor' with Δ 8-THC being the immediate precursor to HHC"); Fabio

Russo et al., *Synthesis and Pharmacological Activity of the Epimers of Hexahydrocannabinol (HHC)*, 13 Sci. Rep. 11061, at 3 (2023) (acid-catalyzed cyclization of CBD produces " Δ 9-THC or Δ 8-THC as reaction intermediates" before hydrogenation yields HHC); *see also* Golombek at 5. Functionalization begins with THC rather than CBD and applies different chemical processes to alter the cannabinoid's surface chemistry adding new functions or properties. ATACH 2023 Whitepaper at 15; American Trade Ass'n for Cannabis & Hemp, Hemp Intoxicants Report 6 (2026) (ATACH 2026 Report).⁵

The pharmacological evidence confirms that HHC's structural similarity to D9 determines its effects — but that parallel should not obscure a critical distinction. HHC is not the plant's own D9 THC; it is a synthetic conversion product manufactured in a laboratory. That pharmacological parity does not justify treating it as hemp; it confirms that HHC is in Schedule I. In laboratory tests directly comparing how strongly HHC and D9 each bind to and activate the CB1 receptor — the brain receptor that produces cannabis intoxication — the more active HHC form performed essentially identical to D9, leading

⁵ Available at

https://www.atach.org/insights?utm_source=MM&utm_medium=banner&utm_campaign=apr-2026-hemp-report

researchers to conclude that its activity "nearly matches that of [D]9-THC." Daniel J. Nasrallah & Neil K. Garg, *Studies Pertaining to the Emerging Cannabinoid Hexahydrocannabinol (HHC)*, 18 ACS Chem. Biol. 2023, 2027 (2023). After HHC emerged in Sweden, false positive screening tests for THC rose—because HHC cross-reacts with the same antibodies as D9. Helander at 127. Germany's Federal Institute for Risk Assessment reached the same conclusion: the commercially dominant form of HHC "has psychoactive potential" with "effects . . . similar to those of Δ 9-THC"—a finding the agency supported with reference to clinical case reports of HHC-associated psychosis. Bundesinstitut für Risikobewertung (BfR), *Psychoactive Effects to Be Expected Following Consumption of Products Containing Hexahydrocannabinol (HHC)*, BfR Opinion No. 019/2025, at 3-4 (June 4, 2025).

B. Because of its different chemical makeup and intoxicating effects, HHC is not a “derivative” of hemp and falls within Schedule I’s THC Class.

The Farm Bill defines hemp as "any part of" the cannabis plant, "including . . . all derivatives, extracts, cannabinoids, isomers,. . . with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent." § 1639o(1). HHC does not fall within that definition — it falls within Schedule I's THC class — which differs from the scientific definition, and covers THC "naturally

contained in a plant of the genus Cannabis . . . 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." 21 C.F.R. § 1308.11(d)(31)(i) (promulgated pursuant to 21 U.S.C. § 811). The class definition does contain a hemp carve-out, expressly excluding "any material, compound, mixture, or preparation that falls within the definition of hemp set forth in § 1639o." *Id.* § 1308.11(d)(31)(ii).

Although the Farm Bill does not define "derivatives," the surrounding statutory language — "cannabinoids, isomers, acids" — signals that the term bears a technical, scientific meaning.

Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 69 (2012) (statutory terms should be understood in their "ordinary, everyday meanings — unless the context indicates that they bear a technical sense"). Courts construing identical language in controlled substances statutes have agreed: "the term 'derivative' is a scientific term, definable only by reference to scientific dictionaries." *People v. Derror*, 715 N.W.2d 822, 828 (Mich. 2006), overruled on other grounds by *People v. Feezel*, 783 N.W.2d 67 (Mich. 2010). In *Reckitt & Colman, Ltd. v. Drug Enforcement Administration*, 788 F.2d 22

(D.C. Cir. 1986), the D.C. Circuit upheld the DEA's classification of a pharmaceutical compound as a narcotic derivative based on three factors: (1) whether the substance was prepared from the parent substance, (2) whether it chemically resembles that substance, and (3) whether it shares some of its adverse effects, cautioning that anything less would sweep in any downstream substance regardless of its chemical or pharmacological relationship to the source. *Id.* at 24-25 (reasoning that "[g]iven [the CSA's] overarching purpose of controlling the distribution of harmful drugs," it was reasonable to confirm chemical similarity "by examining [a substance's] real-world effects").⁶

HHC is therefore a derivative of THC, not of hemp, and falls within Schedule I's THC class regardless of its D-9 concentration — a conclusion the statute's text compels and, as Section C demonstrates, Congress's stated purpose confirms.

The Fourth Circuit has twice addressed hemp-derived product questions post-*AK Futures* without reaching the predicate question at issue here: whether a synthetic substance falls within Schedule I's THC class as a derivative of THC. In *Anderson v.*

⁶ The *Reckitt* court further noted that assessing chemical resemblance by whether "the nucleus or skeleton of the parent substance exists" in the derivative was "consistent with that employed by chemists." *Id.* at 25 & n.4 (citing *Van Nostrand's Scientific Encyclopedia* (5th ed. 1976)).

Diamondback Inv. Grp., LLC, 117 F.4th 165 (4th Cir. 2024), this Court adopted the Ninth Circuit’s source-not-method-of-manufacture test — the dispositive question being what a substance comes from, not how it is made. *Id.* at 188 (adopting *AK Futures LLC v. Boyd Street Distro, LLC*, 35 F.4th 682, 692 (9th Cir. 2022)). Under that standard, the source is what matters — and the source here is THC, a Schedule I substance. *Anderson* was resolved on other grounds. Its passing footnote grouping HHC with hemp-derived compounds, *id.* at 187 n.11, assumed without analysis the THC precursor qualifies as hemp; it does not. Judge Richardson declined to join the adoption of *AK Future’s* reasoning, noting that "whether synthetic derivatives . . . count as excepted hemp is a difficult question" the Ninth Circuit had not "fully considered." *Id.* at 193 (Richardson, J., concurring). This Court’s subsequent decision in *Northern Virginia Hemp & Agriculture, LLC v. Virginia*, 125 F.4th 472 (4th Cir. 2025), acknowledged *AK Futures* but declined to address “the outer contours of the hemp exclusion.” *Id.* at 485 n.6. That question remains open in this Circuit and is squarely presented here.

AK Futures — persuasive authority only, not binding on this Court — is where the Schedule I inquiry was first bypassed. The court held that D8, a conversion product derived from hemp CBD, qualifies as hemp under the Farm Bill’s D9 concentration

threshold, 35 F.4th at 690–91, but never asked whether D8 independently falls within Schedule I's THC class under § 1308.11(d)(31) — the inquiry this case requires. Treating the Farm Bill's D9 test as the only relevant question, *AK Futures* assumed its conclusion. *Anderson* adopted that reasoning, *id.* at 188, carrying the gap into this Circuit. Neither decision resolves the question before this Court.⁷

The practical stakes of that doctrinal gap are not theoretical. Manufacturers are currently doing what has always been prohibited: chemically converting hemp CBD into synthetic intoxicants and selling them to consumers across the country — all misleadingly under the 'hemp' label — exposing unsuspecting consumers to an unregulated Schedule I intoxicant. They have done so in reliance on decisions like *AK Futures* that never reached the question this case presents.

⁷ HHC also independently qualifies as a controlled substance analogue under 21 U.S.C. §§ 802(32)(A) and 813. It has a chemical structure substantially similar to D9 — differing by two hydrogen atoms — produces pharmacologically similar intoxicating effects and is sold for human consumption. See *United States v. Washam*, 312 F.3d 926, 930 (8th Cir. 2002) ("substantially similar" does not require identical chemical structure); *United States v. Galecki*, 89 F.4th 713, 730 (9th Cir. 2023) (same).

C. Congress Intended the Farm Bill to Legalize Hemp as an Agricultural Commodity — Not to Deregulate Synthetic Intoxicants.

The legislative history confirms what the text requires: legislators who spoke to the hemp provisions described the same purpose — legalizing hemp as an agricultural commodity and industrial crop, not a vehicle for consumer intoxication. *See, e.g.*, 164 Cong. Rec. H10142-03, H10145 (2018) (Rep. Comer) ("particularly glad to see industrial hemp de-scheduled"); 164 Cong. Rec. S7425-02, S7426 (2018) (Sen. Leahy) (Farm Bill would "legaliz[e] the growth and sale of hemp as an agricultural commodity"). The Congressional Research Service confirms: "The 2018 farm bill addressed hemp cultivation only and did not directly address . . . consumer products containing hemp or hemp ingredients." Renée Johnson, Cong. Rsch. Serv., IF12278, Farm Bill Primer 2 (2023). Senator McConnell, the bill's primary sponsor, emphasized that hemp contains only negligible levels of THC and that the legislation legalizes only cannabis at or below a 0.3% THC concentration. Mitch McConnell, *Growing Kentucky's Economy with Hemp*, Rich. Reg. (Apr. 20, 2018). Reading the Farm Bill exemption to cover HHC — a substance that binds the brain's cannabis receptor with essentially the same potency as Schedule I THC and has precipitated diagnosed psychotic illness — renders that threshold meaningless. The 0.3% threshold exists to separate

intoxicating cannabis from non-intoxicating hemp — not to create a loophole for laboratory-manufactured intoxicants whose intoxicating molecule carries a different chemical prefix.

Congress confirmed this understanding in Pub. L. 119-37, enacted November 12, 2025, which expressly excludes from the definition of hemp any cannabinoid product containing cannabinoids "synthesized or manufactured outside the plant." Pub. L. 119-37, div. B, title VII, § 781(2) (amending § 1639o) (effective Nov. 12, 2026). P.L. 119-37 closed no genuine statutory gap. Manufacturers had exploited the absence of express synthetic intoxicant language to claim Farm Bill protection for laboratory-synthesized products that the statute's structure and purpose never contemplated. In making its original intent explicit on the face of the statute, Congress reaffirmed — rather than created — the prohibition. HHC — manufactured through laboratory synthesis from THC and incapable of occurring in the cannabis plant in commercially meaningful quantities — falls squarely within that exclusion.

CONCLUSION

For the foregoing reasons, amicus curiae ATACH respectfully urges this Court to uphold DEA Docket No. DEA-1632 and affirm that hexahydrocannabinol falls within Schedule I's

tetrahydrocannabinols class regardless of its delta-9 THC concentration.

Respectfully submitted,

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Party Name Sean Mac

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