No. 23-3237

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BIO GEN, LLC, ET AL.,
Plaintiffs-Appellees

v.

SARAH HUCKABEE SANDERS, ET AL.,
Defendants-Appellants

On Appeal from the United States District Court for the Eastern District of Arkansas
Case No. 4:23-cv-718 (Hon. Billy Roy Wilson)

BRIEF OF AMICUS CURIAE AMERICAN TRADE ASSOCIATION FOR CANNABIS AND HEMP IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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United States Court of Appeals for the Eighth Circuit

CORPORATE DISCLOSURE STATEMENT AND STATEMENT OF FINANCIAL INTEREST

NO. 23-3237

BIO GEN LLC, ET AL.

v.

SARAH HUCKABEE SANDERS, ET AL.

Pursuant to Rule 26.1 and Eighth Circuit LAR 26.1A, the amicus curiae, the American Trade Association for Cannabis and Hemp, makes the following disclosure:

1) For non-governmental corporate parties please list all parent corporations:

None.

2) For non-governmental corporate parties please list all publicly held companies that hold 10% or more of the party's stock:

None.

3) If there is a publicly held corporation which is not a party to the proceeding before this Court but which has a financial interest in the outcome of the proceeding, please identify all such parties and specify the nature of the financial interest or interests:

None.

4) In all bankruptcy appeals counsel for the debtor or trustee of the bankruptcy estate must list: 1) the debtor, if not identified in the case caption; 2) the members of the creditors' committee or the top 20 unsecured creditors; and, 3) any entity not named in the caption which is an active participant in the bankruptcy proceeding. If the debtor or trustee is not participating in the appeal, this information must be provided by appellant.

None.

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INTRODUCTION

The district court's preliminary injunction prohibits the State of Arkansas from regulating highly intoxicating substances—"hemp-synthesized intoxicants," or "HSIs"—synthesized from hemp through chemical processes. The illogical result of that decision is that the State may regulate marijuana, which is federally unlawful due to its intoxicating properties, but it cannot regulate dangerous and potentially more intoxicating HSIs because they are purportedly derived from hemp.

The district court based its injunction on a preemption analysis that gets congressional intent exactly backwards. According to the district court, in the 2018 Farm Bill, Congress legalized all "downstream products and substances" made from hemp, including HSIs, "if their Delta-9 THC concentration does not exceed the statutory threshold" of 0.3 percent. (Order at 13.) This conclusion was wrong in two critical ways.

First, Congress did not intend to legalize intoxicating substances for consumption in the 2018 Farm Bill. Accordingly, HSIs are not "derivatives" of hemp within the meaning of the Farm Bill. They are controlled substances that are often more potent than marijuana, with chemical structures and psychoactive effects that differ from non-intoxicating hemp and its organic compounds.

Second, even if HSIs are "derivatives" of hemp, as the district court held, the 2018 Farm Bill plainly allows states to continue regulating the production and sale of hemp derivatives *within their borders*. That is precisely—and only—what Arkansas has done. This explicit statutory protection for state regulation operates as an important safety valve on the federal deregulation of hemp, but also protects the ability of states to establish state-level marijuana programs and regulatory frameworks.

The stakes of this debate are considerable. HSIs raise significant public health and safety concerns. Absent clear and unambiguous congressional direction to the contrary, it is squarely within Arkansas's police power to regulate them. But rather than deferring to the State's judgment about how best to protect the public, the district court's decision creates a two-tiered cannabis industry in Arkansas—a highly regulated market for medical marijuana, and a completely unregulated market for often more intoxicating HSIs. The Court should vacate the preliminary injunction that prevents the State from regulating HSIs within its borders.

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. To that end, ATACH provides a place for leaders in the cannabis and hemp industry to work toward the implementation of regulations and standards that advance the industry's business objectives while safeguarding public health and safety. ATACH has an interest in cases, such as this one, that affect the regulation of cannabis products. The district court's injunction in this case permits the unregulated marketing and sale of potentially harmful synthetic tetrahydrocannabinols, an outcome that not only threatens consumers of cannabis products but also undermines the cannabis industry as a whole and those—like the members of ATACH—who are subject to its regulations.[1]

ARGUMENT

I. HSIs are unlawful controlled substances that fall outside the scope of the 2018 Farm Bill.

Through the 2018 Farm Bill, Congress legalized the regulated production of hemp. Congress defined "hemp" as "the plant Cannabis sativa L. and any part of that plant, including the

[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).

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). The Farm Bill precludes any State from preventing "the transportation or shipment of hemp or hemp products . . . through the State." Agriculture Improvement Act of 2018, Pub. L. No. 115-334, § 10114, Dec. 20, 2018, 132 Stat. 4490. But Congress also provided that "[n]othing 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." 7 U.S.C. § 1639p(a)(3)(A).

In 2023, Arkansas passed Act 629, which bans the sale of all hemp products "produced as a result of a synthetic chemical process" and "[a]ny other psychoactive substance derived therein." Ark. Code Ann. §§ 5-64-215(a)(5)(A)(i)(i)-(j). The district court enjoined the enforcement of Act 629 on the ground that it is preempted by the 2018 Farm Bill. For the reasons discussed below, this injunction subverts congressional intent.

A. HSIs are unnatural substances 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, or cannabinoids. Ctrs. for Disease

Control & Prevention, *What We Know About Marijuana*, CDC (Sept. 9, 2021).[2] The two main cannabinoids found in the plant are delta 9-tetrahydrocannabinol ("delta 9-THC") and cannabidiol ("CBD"). *See id.* While delta 9-THC and CBD have the same molecular formula—21 carbon atoms, 30 hydrogen atoms, and two oxygen atoms—they differ in how the atoms are arranged. Mary Jo DiLonardo & Jennifer Walker-Journey, *CBD vs. THC: What's the Difference?*, WebMD (Oct. 31, 2023).[3] This structural difference matters. It is the reason why delta 9-THC can elicit a "high" in those who consume it, while CBD cannot. *See* Jack Rudd, *CBD vs THC – What are the Main Differences?*, Analytical Cannabis (Jan. 27, 2023) ("Structurally, however, there is one important difference. Where THC contains a cyclic ring . . . CBD contains a hydroxyl group. It is this seemingly small difference in molecular structure that gives the two compounds *entirely different pharmacological properties*.") (emphasis added).[4]

The 2018 Farm Bill defines "hemp" using a low threshold of 0.3% delta 9-THC so that only those parts of the cannabis plant

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

[3] Available at: https://www.webmd.com/pain-management/cbd-thc-difference.

[4] Available at: https://www.analyticalcannabis.com/articles/cbd-vs-thc-what-are-the-main-differences-297486.

with innocuous amounts of the chemical qualify. *See* 7 U.S.C. § 1639*o*(1). Cannabis with a higher delta 9-THC level is considered "marijuana." *See* 21 U.S.C. § 802(16). Manufacturers of HSIs game the definition of hemp by extracting CBD or other non-intoxicating cannabinoids from compliant hemp plants and converting those organic materials into new chemical substances that are sometimes significantly more intoxicating than any currently found in legal cannabis markets. *See generally* E. Dale Hart et al., *Conversion of Water-Soluble CBD to* Δ^9*-THC in Synthetic Gastric Fluid – An Unlikely Cause of Positive Drug Tests*, 47 J. Analytical Toxicology 632, 632 (2023) (noting that it is "well known" that CBD can be synthetically converted into intoxicating cannabinoids). This synthetic conversion process is what makes HSIs so different from hemp.

Generally speaking, HSIs are manufactured in two ways: isomerization and functionalization. Isomerization involves modifying an existing molecule—usually CBD—by extracting it from hemp biomass, dissolving it in a solvent, and then exposing it to an acidic catalyst and heat. Am. Trade Ass'n for Cannabis & Hemp, *Toward Normalized Cannabinoid Regulation: The Regulation of Hemp-Synthesized Intoxicants* 15 (2023) ("ATACH

Whitepaper").[5] This process changes the bonds in CBD, creating new intoxicating molecules (*e.g.*, delta-8 THC, delta-9 THC, and many others) that have a significantly different psychoactive effect. *Id.* Functionalization involves the use of different chemical processes to change the surface chemistry of a cannabinoid to add new functions or properties. *Id.*

Under either approach, the resulting compounds have a different chemical composition from the non-intoxicating hemp extracts used to make them,[6] resulting in drastically different effects on those who consume HSIs. *See* Malgorzata Smiarowska, Monika Bialecka & Anna Machoy-Mokrzynska, *Cannabis and Cannabinoids: Pharmacology and Therapeutic Potential*, 56 Polish J. Neurology & Neurosurgery 4, 5, 8 (2022) (noting that synthetic cannabinoids have "different chemical structures" from "naturally-derived cannabinoids"); 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 1, 4 (discussing how non-psychotropic CBD can be converted into THC and reviewing

[5] Available at: https://atach.org/wp-content/uploads/2023/06/ATACH-Paper-Toward-Normalized-Cannabinoid-Regulationd.pdf.

[6] This is true of each of the HSIs banned under Act 629.

research on their "different binding characteristics," which account "for their different physiological effects").

Recent scientific research and commentary confirm that HSIs are structurally different substances that produce significantly different—and more dangerous—effects than those produced by hemp. In one analysis of a popular HSI, synthetically derived delta 8-THC, the researchers stressed that the "subtle" molecular difference between delta 8-THC and hemp-derived CBD nonetheless "confers major pharmacological differences." Michael Geci, Mark Scialdone & Jordan Tishler, *The Dark Side of Cannabidiol: The Unanticipated Social and Clinical Implications of Synthetic* Δ^8*-THC*, 8 Cannabis & Cannabinoid Rsch. 270, 275 (2023). They further noted that because synthetic delta 8-THC is effectively a "'designer drug' synthesized from hemp-derived CBD and not extracted from naturally grown *C. sativa* material," many commercial products containing it have chemical "byproducts and degradants" that pose safety risks to consumers. *Id.* at 276, 279 ("In the case of [synthetic delta 8-THC], depending on the [chemical] reaction conditions, numerous additional THC isomers are formed with unknown pharmacological and safety profiles in humans.").

Little is known about these impurities and reaction byproducts found in HSIs, with one scientist remarking that after

analyzing thousands of synthetic delta-8 products, he found "'some delta-8 in there, but there's very frequently up to 30 [chromatographic] peaks that I can't identify.'" Britt E. Erickson, *Delta-8-THC Craze Concerns Chemists*, 99 Chem. & Eng'g News (Aug. 30, 2021) (alteration in original).[7] Recent research tends to show that many of these chemical reaction byproducts do not occur naturally in the hemp plant. *See, e.g.*, Lee Johnson et al., *Potency and Safety Analysis of Hemp Delta-9 Products: The Hemp vs. Cannabis Demarcation Problem*, 5 J. Cannabis Rsch., no. 1, art. 29, 2023, at 1, 4 (discussing how an unnatural chemical byproduct can be produced during the CBD to THC conversion process); Paola Marzullo et al., *Cannabidiol as the Substrate in Acid-Catalyzed Intramolecular Cyclization*, 83 J. Nat. Prods. 2894, 2894-2896 (2020) (finding that delta-8-iso THC is an unnatural chemical product that can be produced during CBD to THC conversion).

The prevalence of chemical byproducts and impurities, coupled with a chemical structure that gives rise to intoxicating effects that are often more significant than marijuana, demonstrate that HSIs cannot be considered just another form of hemp. They are different, and dangerously so.

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[7] Available at: https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31.

B. Because of their different chemical makeup and intoxicating effects, HSIs are not "derivatives" of hemp under the 2018 Farm Bill.

The 2018 Farm Bill defines hemp as "any part of" the cannabis plant, "including . . . all *derivatives*, extracts, cannabinoids, isomers, acids, salts, and salts of isomers . . . with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent." 7 U.S.C. § 1639*o*(1) (emphasis added). Plaintiffs' entire argument turns on whether the hemp-*synthesized* intoxicants proscribed by Act 629 are "hemp-*derived* cannabinoids" within the meaning of the Farm Bill. (*See* Plaintiffs' Complaint for Declaratory and Injunctive Relief at ¶¶ 1, 5-6, 72-73, 77-78, 84, 86, 96-98 (emphasis added).) They are not.

While the Farm Bill does not define "derivatives," statutory terms "are to be understood in their ordinary, everyday meanings—unless the context indicates that they bear a technical sense." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 69 (2012). Here, the surrounding statutory language—"cannabinoids, isomers, acids, salts"—indicates that "derivatives" should be construed in a technical sense. *See 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) (finding, in the context of a state controlled

substances statute, that "the term 'derivative' is a scientific term").

This is precisely how the D.C. Circuit analyzed the term in *Reckitt & Colman, Ltd. v. DEA*, 788 F.2d 22 (D.C. Cir. 1986). In that case, a distributor of buprenorphine complained that the Drug Enforcement Administration ("DEA") incorrectly deemed the drug a derivative of opium and, therefore, a narcotic under the Controlled Substances Act. *Id.* at 23-24. The court found that the DEA's interpretation of "derivative," an "undefined and potentially ambiguous statutory term," was reasonable and entitled to deference. *Id.* at 25. In so doing, the court first noted "that the derivative status of a substance is a more complicated and uncertain matter" than one might think. *Id.* at 24. Indeed, given "modern technological methods," it would be wrong to think that *anything* "prepared from" a substance necessarily qualifies as a derivative. *Id.* ("[I]t is possible to prepare aspirin, acetaminophen (Tylenol), and, apparently, even water from [the opiate at issue]."). "[A] more refined" definition of "derivative" is required. *Id.*

After referencing a scientific encyclopedia, the DEA defined a "derivative" as "any substance (1) prepared from that drug, (2) which chemically resembles that drug, and (3) which has some of the adverse effects of that drug." *Id.* at 24-25 (citing Drug Enf't Admin., Schedules of Controlled Substances; Rescheduling of

Buprenorphine from Schedule II to Schedule V of the Controlled Substances Act, 50 Fed. Reg. 8,104, 8,107 (Feb. 28, 1985)). As to the second prong, the court found it reasonable to consider the "overall chemical similarity of the product to its parent" because doing so was consistent with the definitional approach employed by chemists.[8] *Id.* at 25 & n.4 (citing the DEA's reliance on *Van Nostrand's Scientific Encyclopedia* (5th ed. 1976)). As to the third prong, the court found it reasonable to "consider[] a substance's pharmacological effects as an aspect of the definition of 'derivative,'" rejecting the argument that the determination of a derivative "is solely a question of . . . two substance[s'] chemical relationship." *Id.* at 25. "Given the [Controlled Substances] Act's overarching purpose of controlling the distribution of harmful

[8] More recent scientific dictionaries confirm that scientists still generally use this approach. *See, e.g.*, *Stedman's Medical Dictionary* (Nov. 2014) (defining derivative as "a chemical compound that may be produced from another compound of similar structure in one or more steps"); *Merriam-Webster Online Dictionary*, https://www.merriam-webster.com/dictionary/derivative#:~:text=1%20of%202-,noun,a%20word%20formed%20by%20derivation (last visited Dec. 4, 2023) (defining derivative scientifically as "a chemical substance related structurally to another substance and theoretically derivable from it"). However, other definitional approaches exist in the scientific literature, with the precise meaning of the term "depend[ent] on the topic and context." Leslie A. King, Istvan Ujvary & Simon D. Brandt, *Drug Laws and the 'Derivative' Problem*, 6 Drug Testing & Analysis 879, 879 (2014).

drugs," it made sense that the DEA "sought to confirm the theoretical chemical similarity of buprenorphine to [opium] by examining its real-world effects." *Id.*

Applying *Reckitt & Colman*'s three-step framework shows that HSIs are not "derivatives" of hemp. While HSIs are sourced or "prepared from" CBD and other non-intoxicating cannabinoids found in hemp, that does not end the inquiry. Otherwise, the definition of "derivative" would be overly broad and encompass *any* "downstream" substance, regardless of its psychoactive effect. *Contra Bio Gen, LLC v. Sanders*, No. 4:23-cv-00718, 2023 WL 5804185, at *6 (E.D. Ark. Sept. 7, 2023) (failing to discuss the meaning of the term "derivatives" and incorrectly finding that they encompass all "downstream products and substances"); *AK Futures LLC v. Boyd Street Distro, LLC*, 35 F.4th 682, 691 (9th Cir. 2022) (adopting an overly broad view of "derivatives" that "seemingly extends to downstream products and substances, so long as their delta-9 THC concentration does not exceed the statutory threshold"). Second, HSIs do not "chemically resemble" compounds found in hemp because, even though they are molecularly identical, the chemical synthesis process by which they are created results in substances that are structurally different in important ways and are often tainted by chemical byproducts and unknown chemical impurities. *See supra* Part I.A.

But even if their chemical structures resemble each other, the pharmacological effects of HSIs—the third and most important factor in the *Reckitt & Colman* inquiry—are vastly different from the effects that CBD and other organic hemp cannabinoids provide. *See id.* HSIs are intoxicating, while hemp is not. Appreciating these "real-world effects," as the court did in *Reckitt & Colman*, shows the vast difference between HSIs and hemp. And given this difference, it is wrong to characterize synthetically created, highly intoxicating substances as hemp "derivatives." They are controlled substances, with psychoactive effects that are analogous to the "high" produced by delta-9 THC found in federally unlawful marijuana; they are the functional equivalent of marijuana. *See* 21 C.F.R. § 1308.11(d)(31)(i) (listing as a Schedule I controlled substance "synthetic equivalents of the substances contained in the cannabis plant . . . and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant"); *see also* Andrew Fels, *Voiding the Federal Analogue Act*, 100 Neb. L. Rev. 577, 625-26 (2022) (arguing that HSIs "are very vulnerable to Analog Act prosecution" given their "effects and potency").

C. The 2018 Farm Bill does not preempt Act 629 because Congress intended to legalize hemp for agricultural and industrial purposes, not psychoactive HSIs for recreational consumption.

The purpose of statutory interpretation is to ascertain legislative intent. *United States v. N.E. Rosenblum Truck Lines, Inc.*, 315 U.S. 50, 53 (1942); *Sternberg Dredging Co. v. Walling*, 158 F.2d 678, 681 (8th Cir. 1946). "[W]hile the clear meaning of statutory language is not to be ignored, 'words are inexact tools at best,' . . . and hence it is essential [to] place the words of a statute in their proper context by resort[ing] to . . . legislative history." *Tidewater Oil Co. v. United States*, 409 U.S. 151, 157 (1972) (quoting *Harrison v. N. Trust Co.*, 317 U.S. 476, 479 (1943)). Legislative history is particularly useful when a statute contains undefined terms or ambiguous language. *Estate of Farnam v. C.I.R.*, 583 F.3d 581, 584 (8th Cir. 2009); *see also United States v. Markwood*, 48 F.3d 969, 975 n.7 (6th Cir. 1995) ("[W]hen there is an ambiguous term in a statute, or when a term is undefined or its meaning unclear from the context of the statute, it is [a court's] duty to examine the legislative history in order to render an interpretation that gives effect to Congress's intent.").

The 2018 Farm Bill's definition of hemp is ambiguous because it does not define "derivatives," and that term is potentially susceptible to different definitions in the scientific

literature. *See* King et al., *supra* note 7, at 879-81 (discussing different scientific definitions of "derivative," noting that the proper meaning "depends on the topic and context," and stating that "[a]lthough a number of definitions of derivative can be found in the chemical literature, no single definition is adequate to describe all situations where it occurs in legislation"); *Reckitt & Colman*, 788 F.2d at 25 (acknowledging the "potentially ambiguous" nature of the term). It is therefore appropriate to resort to legislative history to better understand what Congress intended when it redefined and deregulated "hemp" and its "derivatives." This legislative history sends a clear and uniform message—Congress intended to promote the cultivation of hemp as an agricultural commodity, and it most certainly did *not* intend to legalize a host of psychoactive designer drugs in the process.

Congressional records show that Congress legalized the agricultural production of hemp to allow farmers across the nation to produce a new commodity with many potential opportunities for industrial value. The purpose of this policy change was always *agricultural* and *industrial* in nature. *See, e.g.*, Renée Johnson, Cong. Rsch. Serv., IF12278, *Farm Bill Primer: Selected Hemp Industry Issues* 2 (2023) ("The 2018 farm bill addressed hemp *cultivation* only and did not directly address . . . consumer products containing hemp or hemp ingredients subject to FDA

regulation.") (emphasis added). Indeed, the only pertinent references in the Congressional record speak of "industrial hemp" and hemp as an "agricultural commodity."

For example, Congressman James Comer (R-KY) stated that he was "particularly glad to see industrial hemp de-scheduled from the controlled substances list." 164 Cong. Rec. H10142-03, H10145 (2018). Senator Patrick Leahy (D-VT) expressed similar enthusiasm, asserting that the Farm Bill would help Vermont farmers "diversify and remain viable . . . [by] legaliz[ing] the growth and sale of hemp as an agricultural commodity." 164 Cong. Rec. S7425-02, S7426 (2018). In addition, Congressman Pete Sessions (R-TX) stated that hemp was added to the Farm Bill because "[i]t is an important agricultural product and will aid and help very much . . . not only a marketplace, but farmers in Kentucky and other places." 164 Cong. Rec. H10115-04, H10123 (2018). Congressman Peter Welch (D-VT) observed that "this legislation legalizes industrial hemp production . . . [and] is going to be a boost for local agriculture in Vermont and other parts of our country," *id.* at H10121, and Congresswoman Suzanne Bonamici (D-OR) stressed the "bipartisan" nature of efforts "to legalize industrial hemp and define it as an agricultural commodity," 164 Cong. Rec. E690-04, E691 (2018). Conspicuously absent from these remarks is any mention of hemp as a product

for human consumption, much less endorsement of its use as a psychoactive designer drug.

Quite the contrary, legislators' remarks indicate that the 0.3% delta-9 THC threshold in the definition of "hemp" was intended to delineate intoxicating cannabis (illegal marijuana) from non-intoxicating cannabis (legal hemp). For instance, in the lead-up to the 2018 Farm Bill's enactment, Senator Mitch McConnell (R-KY) criticized "outdated Federal regulations [for] not sufficiently distinguish[ing] this industrial crop [i.e., hemp] from its illicit cousin." 164 Cong. Rec. S4689-07, S4690 (2018). Senator McConnell made clear that the crux of the distinction, reflected in the bill's THC threshold, was hemp's non-intoxicating effects. *See* Mitch McConnell, *Growing Kentucky's Economy with Hemp*, Rich. Reg. (Apr. 20, 2018) ("[B]ecause hemp only has negligible levels of THC, which is the compound which produces the 'high' associated with marijuana, the two plants are actually quite different . . . . This legislation only legalizes hemp with a THC concentration of 0.3 percent or less, far below the THC concentration in marijuana.").[9]

[9] Available at: https://www.richmondregister.com/opinion/mcconnell-growing-kentucky-s-economy-with-hemp/article_8c446f7c-4758-11e8-aea2-5fddfd73e0bc.html.

Senators Mark Warner and Tim Kaine (both D-VA) echoed these sentiments, issuing a joint press release stating, "Hemp is distinct from marijuana in that it has a miniscule concentration of tetrahydrocannabinol (THC), and thus *no narcotic capability*." *Warner & Kaine Join Bipartisan Bill to Legalize Hemp*, Mark R. Warner: U.S. Sen. from the Commonwealth of Va. (May 23, 2018) (emphasis added).[10] Other legislators issued similar statements. *See, e.g.*, Kevin Baird, *The Farm Bill: Supporting Farming for Food and Industry*, U.S. Congressman Morgan Griffith (Aug. 20, 2018) ("[H]emp cultivated for industrial use lacks the potency of marijuana . . . .") (quoting Rep. Morgan Griffith (R-VA));[11] Bernadette Green, *Grothman Cosponsors Bill to Legalize Industrial Hemp*, Glenn Grothman: U.S. Rep. (Sept. 29, 2017) ("*Non-narcotic* industrial hemp makes our economy stronger by providing an additional revenue stream for farmers . . . .") (emphasis added) (quoting Rep. Glenn Grothman (R-WI)).[12]

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[10] Available at: https://www.warner.senate.gov/public/index.cfm/2018/5/warner-kaine-join-bipartisan-bil-to-legalize-hemp.

[11] Available at: https://morgangriffith.house.gov/news/documentsingle.aspx?DocumentID=398984.

[12] Available at: https://grothman.house.gov/news/documentsingle.aspx?DocumentID=419.

Reading the 2018 Farm Bill as legalizing substances that are just as intoxicating as delta-9 THC, if not more so, effectively renders meaningless the 0.3% delta-9 THC threshold in the definition of hemp, which clearly was intended to demarcate psychoactive cannabis from non-psychoactive cannabis.

Indeed, federal policy toward intoxicating cannabis has been crystal clear since Congress passed the Controlled Substances Act in 1970—it is federally unlawful. *See* Peter Reuter, *Why Has US Drug Policy Changed So Little Over 30 Years?*, 42 Crime & Just. 75, 81, 118 (2013) (noting that Congress has taken seriously the regulation of psychoactive cannabinoids since it passed the Controlled Substances Act and stressing that "the development of new psychoactive substances" has "long been a concern"). The concerns driving this policy are not limited to specific chemical substances (*e.g.*, delta 8-THC, delta 9-THC, delta-10 THC);[13] rather, this policy is driven by an overarching concern with

[13] Recognizing that THCA, a non-intoxicating hemp cannabinoid, can be converted into intoxicating delta-9 THC when heated, the U.S. Department of Agriculture's laboratory testing requirements for hemp expressly mandate that "*total* THC" levels, *i.e.*, THCA plus delta-9 THC, "be reported and used for purposes of determining the THC content of a hemp sample." Dep't of Agric., Establishment of a Domestic Hemp Production Program, 86 Fed. Reg. 5,596, 5,602 (Jan. 19, 2021) (emphasis added). Plaintiffs ignore these implementing regulations that prevent the abuse of high THCA content in hemp.

psychoactivity and the dangers posed by intoxicating cannabis substances writ large. *See id.* The 2018 Farm Bill, which merely sought to legalize a non-intoxicating agricultural commodity, did nothing to alter this longstanding policy.

The fact that Congress did not intend to deregulate intoxicating cannabis through the Farm Bill's definition of hemp is further confirmed by the federal government's recent push to reschedule marijuana as a controlled substance. Current federal policy permits states to regulate federally unlawful marijuana, which has resulted in 38 states legalizing marijuana for medical purposes[14] and 24 states legalizing marijuana for adult recreational use. Alex Leeds Matthews & Christopher Hickey, *More US States are Regulating Marijuana. See Where It's Legal Across the Country*, CNN (Nov. 7, 2023).[15] This policy has continued to evolve since October 2022, when President Biden directed the Department of Health and Human Services ("HHS") to study whether marijuana has health benefits that warrant a change to its status as a Schedule I controlled substance.

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[14] Arkansas legalized marijuana for medical use after passing the Arkansas Medical Marijuana Amendment of 2016. *See* Ark. Const. amend. 98.

[15] Available at: https://www.cnn.com/us/us-states-where-marijuana-is-legal-dg/index.html.

Statement from President Biden on Marijuana Reform, White House (Oct. 6, 2022).[16]

HHS completed its study in August 2023, recommending that the DEA reschedule marijuana as a federally lawful drug subject to Food and Drug Administration ("FDA") approval. *See* Lisa N. Sacco & Hassan Z. Sheikh, Cong. Rsch. Serv., IN12240, *Department of Health and Human Services Recommendation to Reschedule Marijuana: Implications for Federal Policy* 1 (2023). The DEA is currently evaluating HHS's recommendation and is expected to issue rules rescheduling marijuana to Schedule III in 2024. *See id.* at 2. Schedule III drugs must be approved by the FDA to be legal under federal law. *See* 21 U.S.C. § 355(a). Collectively, these developments show that intoxicating cannabis remains unlawful under federal law and, far from being de-scheduled, will be subject to federal regulatory approval before being marketed for human consumption.

By contrast, Plaintiffs read the 2018 Farm Bill as reflecting an intent to deregulate any and all intoxicating cannabinoids in the cannabis plant (and synthetics converted therefrom) except delta 9-THC. In their view, states may regulate federally

[16] Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform/.

unlawful marijuana, but they cannot regulate purported hemp "derivatives" that are just as intoxicating (if not more so). But there is simply no reason to think that Congress intended for the Farm Bill to preclude states' regulation of novel HSIs or any other intoxicating substance that can be chemically processed from hemp.

Given the extensive evidence of legislative intent, the district court wrongly reasoned that the synthetic "THC substances listed [in Act 629] are likely legal under the 2018 Farm Bill" because the definition of hemp covers all "downstream products and substances" so long as their delta 9-THC level is below 0.3%. *Bio Gen*, 2023 WL 5804185, at *5-6. The whole point of this 0.3% requirement is to prevent products and substances with substantial psychoactive effects from escaping regulatory oversight under the veneer of "hemp." *See Hemp Indus. Ass'n v. DEA*, 36 F.4th 278, 281 (D.C. Cir. 2022) (noting hemp's status as "a non-psychoactive variant" of cannabis); *Lundy v. Commonwealth*, 511 S.W.3d 398, 404 (Ky. Ct. App. 2017) ("[W]hile marijuana has historically been used for its psychoactive effect, hemp has been used in industrial products since as early as the 1600s.").

But opportunistic HSI manufacturers are doing just that, rolling out products for consumption with low *delta 9*-THC

concentrations that are combined with synthetic THC (*e.g.*, synthetic delta-10 and delta-8), thereby raising the total intoxicating effect. *See, e.g.*, *N. Va. Hemp & Agric. LLC v. Virginia*, No. 1:23-cv-1177, 2023 WL 7130853, at *2 (E.D. Va. Oct. 30, 2023) ("Both the Centers for Disease Control and Prevention and the Food and Drug Administration have raised concerns about the elevated levels of delta-8 THC in hemp products, which can result in a product that is more intoxicating when combined with delta-9 THC."). Many of these other forms of THC are significantly more intoxicating than delta-9 THC. *See, e.g.*, *Is Delta THC Legal in Florida?*, Fla. Cannabis Info. (last visited Dec. 4, 2023) (noting that THC-O acetate and THC-P, both of which are HSIs, are three times and thirty times more intoxicating than delta-9 THC, respectively).[17]

This development flies in the face of Congress's intent to legalize hemp for agricultural and industrial purposes only. The Court should not construe the terms of the Farm Bill such that HSIs altogether escape regulation. *See Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940) ("All statutes must be construed in the light of their purpose . . . .").

[17] Available at: https://floridastatecannabis.org/thc/delta-thc.

Because Congress only intended to legalize the production of non-intoxicating hemp, the Farm Bill does not preempt Arkansas's regulation of psychoactive HSIs. *See C.Y. Wholesale, Inc. v. Holcomb*, 965 F.3d 541, 548 (7th Cir. 2020) (finding that "Congress's silence on [psychoactive] drugs does not, through conflict preemption, preclude their proscription, nor does the 2018 Farm Bill's lenience toward industrial hemp"); *Duke's Invs. LLC v. Char*, No. 22-00385, 2022 WL 17128976, at *5-6 (D. Haw. Nov. 22, 2022) (same). Psychoactive HSIs fall outside the scope of the Farm Bill. And rather than "stand[ing] as an obstacle to the . . . purposes and objectives of Congress," *N. Nat. Gas Co. v. Iowa Utils. Bd.*, 377 F.3d 817, 821 (8th Cir. 2004) (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984)), Act 629's restrictions on psychoactive HSIs actually further Congress's intent in the 2018 Farm Bill to treat intoxicating and non-intoxicating cannabinoids differently.

D. Even if HSIs are derivatives of hemp, the 2018 Farm Bill allows states to regulate them more stringently in the interests of public health and safety.

Even assuming HSIs are "hemp-derived" cannabinoids, Arkansas is still well within its rights to regulate them inside its borders. The 2018 Farm Bill expressly permits states to enact "more stringent" regulations on "the production of hemp." *See* 7

U.S.C. § 1639p(a)(3)(A). Accordingly, multiple courts have "refused to read the Farm Act's express preemption provision as to production so broadly as to usurp all authority from the states to regulate the sale and possession of hemp products within a state in a manner that is more stringent than that provided under federal law." *N. Va. Hemp*, 2023 WL 7130853, at *6 (citing *C.Y. Wholesale*, 965 F.3d at 547; *Duke's Invs.*, 2022 WL 17128976, at *7).

A court's interpretation of an express preemption provision "'must rest primarily on a fair understanding of congressional purpose'" and a presumption "that Congress does not intend preemption of historic police powers of the States 'unless that was [its] clear and manifest purpose.'" *Cellco P'ship v. Hatch*, 431 F.3d 1077, 1080 (8th Cir. 2005) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996)). "Express preemption turns on the precise language of the statute, and the Farm Act does not prohibit state regulation of the production, manufacture, sale, or consumption of industrial hemp, including hemp composed of [synthetic] variants." *N. Va. Hemp*, 2023 WL 7130853, at *6. In addition, public health and safety are within states' historic police powers, *see Frye v. Kansas City Mo. Police Dep't*, 375 F.3d 785, 791 (8th Cir. 2004), and HSIs raise public health and safety concerns

that states presumptively should be able to regulate, *see Duke's Invs.*, 2022 WL17128976, at *5-6, *9; *infra* Part II.

Here, "a fair understanding of congressional purpose" leads to the ineluctable conclusion that Act 629 is not preempted by the 2018 Farm Bill. In passing the Farm Bill, Congress sought to promote the cultivation of hemp for agricultural and industrial purposes, not the sale of dangerous psychoactive substances for unregulated consumption. In light of this purpose, the Farm Bill's express preemption provision operates as a safety valve, giving states the flexibility to regulate harmful substances (such as HSIs and new versions of them as they are developed) within their borders "more stringent[ly]" than the Farm Bill provides. That is exactly what Arkansas did here.

II. The unregulated marketing and sale of HSIs to consumers threaten public health and safety and undermine cannabis regulation.

The hallmark of industrial hemp is its lack of psychoactive effects, which ensures that "there simply is no probability of abuse or [public] health hazard." Christine A. Kolosov, *Evaluating the Public Interest: Regulation of Industrial Hemp Under the Controlled Substances Act*, 57 UCLA L. Rev. 237, 263-64 (2009). HSIs, however, are a different story. Given their high psychoactive potential, the deceptive marketing and sale of these intoxicants as purportedly harmless "hemp" present significant

public health and safety risks. And these risks, many of which have come to fruition, undercut the legitimacy of the cannabis industry and regulation of that industry more broadly.

Start with the health and safety concerns raised by the sheer potency of HSIs. The Farm Bill's 0.3% THC threshold is designed to apply to plant material "on a dry weight basis," not non-plant consumer products such as edibles, beverages, tinctures, and vaporized products. ATACH Whitepaper at 17. "These products are often measured in grams, while the presence of delta-9 THC is measured in thousandths of a gram, or milligrams." *Id.* By improperly characterizing their products as "hemp" or "hemp-derived cannabinoid products," bad actors are able to sell HSI products that "far exceed[] potency limits found in regulated marijuana programs." *Id.* For example, most marijuana programs in the United States limit the presence of delta-9 THC to 5 or 10 milligrams per serving. *Id.* However, in the case of a 0.5 ounce gummy under the "less than 0.3% dry weight" approach, "it would take over 43 mg of THC to exceed the weight limit, over 4 times the serving size of a regulated marijuana product." *Id.* It is inconceivable that Congress would have intended HSIs to be within the scope of the Farm Bill and subject to this calculation, opening the floodgates to a host of substances more intoxicating than marijuana.

These potency concerns are exacerbated by deceptive labeling and a lack of appropriate testing. As one congressman put it prior to the passage of the 2018 Farm Bill, "[i]t is a joke" to consider non-intoxicating hemp a Schedule I drug—after all, it is found in everyday products like the "ice cream we give our kids." *Paul, Wyden, Polis, and Massie Defend Hemp*, Ron Wyden: U.S. Sen. for Or. (Jan. 17, 2018) (quoting Rep. Jared Polis (D-Colo.)).[18] The irony today is that dangerous HSIs are now being passed off as legal "hemp" edibles in packaging that is "appeal[ing] to children and may be easily mistaken for popular, well-recognized foods." U.S. Food & Drug Admin., *FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC*, FDA (June 16, 2022) (providing examples of THC-laced products, including Cap'n Crunch cereal and Nerds candy).[19] Tragically, one case of accidental delta-8 overconsumption resulted in the death of a four-year-old boy last year. Nathan

[18] Available at: https://www.wyden.senate.gov/news/press-releases/paul-wyden-polis-and-massie-defend-hemp.

[19] Available at: https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.

Baca, *Virginia Mom Charged in 4-Year-Old Son's Overdose Death Won't Face a Jury, Takes Plea Deal*, WUSA9 (June 12, 2023).[20]

In a recent consumer update, the FDA noted that it had "received 104 reports of adverse events in patients who consumed delta-8 THC products between December 1, 2020, and February 28, 2022," and "[n]ational poison centers [had] received 2,362 exposure cases of delta-8 THC products between January 1, 2021 . . . and February 28, 2022." U.S. Food & Drug Admin., *5 Things to Know About Delta-8 Tetrahydrocannabinol – Delta-8 THC*, FDA (May 4, 2022).[21] The FDA blamed much of this on HSIs being "labeled simply as 'hemp products,' which may mislead consumers who associate 'hemp' with 'non-psychoactive.'" *Id.* The agency also stressed that these products "have not been evaluated or approved by the FDA for safe use in any context," with many of them manufactured "in uncontrolled or unsanitary settings" using "potentially unsafe household chemicals." *Id.* For these reasons, the FDA has recently issued warning letters chastising companies

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[20] Available at: https://www.wusa9.com/article/news/investigations/dorothy-clements-plea-deal-delta-8-death-4-year-old-child/65-4cab3737-ac0a-4422-a4d4-2062ba13dab1.

[21] Available at: https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc.

"for illegally selling copycat food products" and using HSIs as "unapproved food additives" in violation of the Food, Drug, and Cosmetic Act. *See, e.g.*, U.S. Food & Drug Admin., *FDA, FTC Warn Six Companies for Illegally Selling Copycat Food Products Containing Delta-8 THC*, FDA (July 6, 2023);[22] U.S. Food & Drug Admin., *FDA Issues Warning Letters to Companies Illegally Selling CBD and Delta-8 THC Products*, FDA (May 4, 2022).[23] These violations further contradict the district court's finding that HSIs are "likely legal" under the Farm Bill. *See* 7 U.S.C. § 1639r(c) (stating that "[n]othing in this subchapter shall affect or modify . . . the Federal Food, Drug, and Cosmetic Act").

The district court's decision to short-circuit Arkansas's perfectly legal efforts to curb the marketing and sale of harmful HSIs endangers consumers. The legal cannabis market is subject to stringent regulations that aim to promote public health and safety. HSI manufacturers should not be permitted to circumvent these safeguards through a definitional sleight of hand that passes off highly intoxicating HSIs as legal, non-psychoactive

[22] Available at: https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-six-companies-illegally-selling-copycat-food-products-containing-delta-8-thc.

[23] Available at: https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-companies-illegally-selling-cbd-and-delta-8-thc-products.

"hemp." Allowing them to do so not only harms consumers; it undercuts the highly regulated medical marijuana industry in Arkansas, where law-abiding industry actors have been putting public safety first.

CONCLUSION

For the foregoing reasons, the Court should reverse the district court's grant of a preliminary injunction preventing the enforcement of Act 629.

Respectfully submitted,

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COMBINED CERTIFICATIONS

CERTIFICATE OF COMPLIANCE with RULE 32(a) and RULE 29(a)(5)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7) and Fed. R. App. P. 29(a)(5) because it contains 6,292 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in 14 pt. Century Schoolbook, a proportionally spaced typeface, using Microsoft Office Word 2016.

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I certify that an electronic version of this brief, in PDF format, was filed; that the text of the electronic version is identical to the text in the paper copies; and that the Crowdstrike version 4.14.7702 antivirus protection program was run on the PDF version and no virus was detected.

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CERTIFICATE OF SERVICE

I certify that I served the foregoing brief on counsel of record for all parties through the Court's Electronic Case Filing system on December 6, 2023.

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