

No. 23-2192

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UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT

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**NORTHERN VIRGINIA HEMP AND AGRICULTURE,  
LLC, ET AL.,**  
*Plaintiffs-Appellants*

v.

**THE COMMONWEALTH OF VIRGINIA, ET AL.,**  
*Defendants-Appellees*

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On Appeal from the United States District Court for  
the Eastern District of Virginia

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**BRIEF OF AMICUS CURIAE AMERICAN TRADE  
ASSOCIATION FOR CANNABIS AND HEMP IN SUPPORT  
OF DEFENDANTS-APPELLEES AND AFFIRMANCE**

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## INTRODUCTION

Senate Bill 903 (“SB 903”) prevents Plaintiffs from producing and selling products containing highly intoxicating substances—“hemp-synthesized intoxicants,” or “HSIs”—synthesized from hemp through chemical processes. Virginia enacted this legislation in response to a public health crisis, with numerous reports of children becoming ill after consuming adulterated products containing delta-8 THC and other HSIs. (JA743.)

Against this backdrop, the district court rightly rejected Plaintiffs’ efforts to enjoin Virginia from enforcing SB 903. It properly deferred to the Commonwealth’s “political and social welfare judgments” as to how best to protect the public (JA766), and it correctly reasoned that the 2018 Farm Bill does not preempt SB 903. Plaintiffs now ask this Court to hold otherwise, an invitation the Court should reject for two reasons.

First, Plaintiffs’ preemption analysis gets congressional intent exactly backwards. Congress did not intend to legalize intoxicating substances for consumption in the 2018 Farm Bill, so 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, the 2018 Farm Bill explicitly allows states to continue regulating the production and sale of hemp derivatives within their borders. That is precisely—and only—what Virginia has done. This express statutory protection for state regulation operates as an important safety valve on the federal legalization of hemp, protecting the ability of states to establish state-level regulatory frameworks for hemp, on the one hand, and for adult-use and/or medical marijuana, on the other.

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 Virginia’s police power to regulate them. Enjoining SB 903 would produce an illogical result, allowing the Commonwealth to regulate marijuana—which is federally unlawful due to its intoxicating properties—while preventing it from regulating dangerous and potentially more intoxicating HSIs because they are purportedly derived from hemp. The district court rightly rejected this outcome by denying Plaintiffs’ motion for a preliminary injunction.

## 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. ATACH firmly believes that arguments against the ability of states to have regulatory authority over intoxicating products anywhere do so at the expense of cannabis and hemp industry regulation everywhere. The ability of states to establish regulatory frameworks for cannabis and hemp is a foundational principle of legalization, and this fundamental state right must be protected as a matter of law.<sup>1</sup>

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<sup>1</sup> The amicus curiae states (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). All parties have consented to the filing of this brief. *Id.* 29(a)(2).

## 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 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. § 1639o(1). As discussed below, the 0.3% threshold is intended to demarcate non-intoxicating cannabis, *i.e.*, hemp, from intoxicating cannabis, *i.e.*, marijuana. 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, Virginia passed SB 903. This law provides that hemp products must have “a total tetrahydrocannabinol concentration of no greater than 0.3 percent” and “contain[] either no more than two milligrams of total tetrahydrocannabinol per

package or an amount of cannabidiol that is no less than 25 times greater than the amount of total tetrahydrocannabinol per package.” Va. Code Ann. § 3.2-4112. This “Total THC Standard” is based on the sum of “any naturally occurring or synthetic tetrahydrocannabinol” present in a product (*i.e.*, not just delta-9), *id.*, and products that do not meet this standard are deemed unlawful marijuana, *see* Va. Code Ann. § 4.1-600. SB 903 also prohibits “processor[s from] sell[ing] industrial hemp or a substance containing an industrial hemp extract . . . to a person if the processor knows or has reason to know that such person will use the industrial hemp or substance containing an industrial hemp extract in a substance that” exceeds the Total THC Standard. Va. Code Ann. § 3.2-4116(C).

Here, the district court found that the 2018 Farm Bill does not preempt SB 903. For the reasons below, this Court should affirm that result.

**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).<sup>2</sup> 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).<sup>3</sup> 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).<sup>4</sup>

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 with innocuous amounts of the chemical qualify. *See* 7 U.S.C. §

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

<sup>3</sup> Available at: <https://www.webmd.com/pain-management/cbd-thc-difference>.

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

1639o(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  $\Delta^9$ -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<sup>5</sup> 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

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<sup>5</sup> ATACH treats cannabis as “one plant” and promotes establishing proper categories for hemp cannabinoids by regulating Intoxicating Hemp-Derived Cannabinoids and supporting nomenclature—Hemp Phytocannabinoids, Chemically Converted Cannabinoids, and Heavily Processed Synthetic Novel Cannabinoids (HSIs)—which would protect consumers and provide for a regulated industry.

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”).<sup>6</sup> 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,<sup>7</sup> 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*

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<sup>6</sup> Available at: <https://atach.org/wp-content/uploads/2023/06/ATACH-Paper-Toward-Normalized-Cannabinoid-Regulationd.pdf>.

<sup>7</sup> This is true of the products on Plaintiffs’ “Banned Products” list, which contain HSIs. (See JA231-248.)



*Tetrahydrocannabinol (THC): A Controversy in the Scientific Literature*, 8 *Toxics*, art. 41, June 2020, at 1, 4 (discussing how non-psychoactive CBD can be converted into THC and reviewing 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 an analysis of synthetic delta 8-THC,<sup>8</sup> one of the HSIs subject to SB 903, 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  $\Delta^8$ -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

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<sup>8</sup> Contrary to Plaintiffs’ statement that “[d]elta-8 THC is not synthetic” (Appellants’ Br. at 5), it is clear that the delta-8 in Plaintiffs’ products was chemically synthesized. (See JA353.)

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).<sup>9</sup> 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

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<sup>9</sup> Available at: <https://cen.acs.org/biological-chemistry/natural-products/Delta-8-THC-craze-concerns/99/i31>.

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.

**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, 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. § 1639o(1) (emphasis added). Plaintiffs’ entire argument turns on whether the HSIs present in their products are legal hemp “derivatives” within the meaning of the Farm Bill. (See Appellants’ Br. 7, 21, 27; JA671-674, JA726-728.) 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—“extracts, cannabinoids, isomers, acids, salts, and salts of isomers”—indicates that “derivatives” should be construed in a technical sense.

This is precisely how the D.C. Circuit and the Drug Enforcement Administration (“DEA”) 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 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. *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 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 analysis shows that the HSIs in Plaintiffs’ products 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 are vastly different from the effects that CBD and other organic hemp cannabinoids provide. HSIs are intoxicating, while hemp is not. Appreciating these “real-world effects,” as the court put it 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 analogous to the “high” produced by the 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”); 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”).

**C. The 2018 Farm Bill does not preempt SB 903 because Congress intended to legalize hemp as an agricultural commodity, not the consumption of psychoactive HSIs.**

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); *United States v. Bernstein*, 179 F.2d 105, 110 (4th Cir. 1949). “[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. *Lee v. Norfolk S. Ry. Co.*, 802 F.3d 626, 631 (4th Cir. 2015); *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* Leslie A. King, Istvan Ujvary & Simon D. Brandt, *Drug Laws and the ‘Derivative’ Problem*, 6 *Drug Testing & Analysis* 879, 879-81 (2014) (discussing different scientific definitions of “derivative,” noting that the proper meaning “depends on the topic and context”); *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 understand better what Congress intended when it redefined and legalized “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 . . .”). 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 recognition or endorsement of hemp as an intoxicating substance, much less one for recreational consumption.

To the contrary, legislators’ remarks indicate that the 0.3% delta-9 THC threshold in the definition of “hemp” was intended to distinguish 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.”<sup>10</sup>

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).<sup>11</sup> 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

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<sup>10</sup> Available at:

[https://www.richmondregister.com/opinion/mcconnell-growing-kentucky-s-economy-with-hemp/article\\_8c446f7c-4758-11e8-aea2-5fddfd73e0bc.html](https://www.richmondregister.com/opinion/mcconnell-growing-kentucky-s-economy-with-hemp/article_8c446f7c-4758-11e8-aea2-5fddfd73e0bc.html).

<sup>11</sup> Available at:

<https://www.warner.senate.gov/public/index.cfm/2018/5/warner-kaine-join-bipartisan-bil-to-legalize-hemp>.

marijuana . . . .”) (quoting Rep. Morgan Griffith (R-VA));<sup>12</sup> 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)).<sup>13</sup> 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

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<sup>12</sup> Available at:

<https://morgangriffith.house.gov/news/documentsingle.aspx?DocumentID=398984>.

<sup>13</sup> Available at:

<https://grothman.house.gov/news/documentsingle.aspx?DocumentID=419>.

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);<sup>14</sup> rather, this policy is driven by an overarching concern with psychoactivity and the dangers posed by intoxicating cannabis substances writ large. *See id.*; *United States v. Sanapaw*, 366 F.3d 492, 495 (7th Cir. 2004) (“[T]he purpose of banning marijuana was to ban the euphoric effects produced by THC.”). 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,

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<sup>14</sup> 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.

which has resulted in 38 states legalizing marijuana for medical purposes 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).<sup>15</sup> 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. *Statement from President Biden on Marijuana Reform*, White House (Oct. 6, 2022).<sup>16</sup>

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.

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

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

*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.<sup>17</sup>

By contrast, Plaintiffs read the 2018 Farm Bill as reflecting an intent to legalize any and all intoxicating cannabinoids in the cannabis plant (including synthetics converted therefrom) except delta 9-THC. (*See* Appellants' Br. 12, 14, 16.) In their view, states may regulate federally 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. The whole point of the

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<sup>17</sup> Virginia heavily regulates marijuana. While it has been decriminalized in Virginia, it has not been legalized for commercial sale. *See Frequently Asked Questions*, Va. Cannabis Control Auth. (last visited Jan. 26, 2024), <https://www.cca.virginia.gov/faqs#panel-2>. Thus, like federal policy, Virginia clearly distinguishes between non-intoxicating hemp and intoxicating marijuana by allowing the commercial sale of one (hemp), but not the other (marijuana). SB 903 is consistent with that policy, preventing products containing HSIs that are just as intoxicating as marijuana from being sold commercially based on the false premise that they are hemp.

Farm Bill's 0.3% threshold 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 then combined with other forms of THC (e.g., synthetic delta-10 and delta-8), raising the total intoxicating effect. (*See* JA742 ("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.")) And 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).<sup>18</sup>

This development flies in the face of Congress’s intent to legalize hemp as an *agricultural* commodity. The “loophole” here is not that Virginia is “ban[ning] a substance Congress had intended to be protected in interstate commerce” (Appellants’ Br. 18 n.5); the loophole is Plaintiffs’ erroneous reading of the Farm Bill as legalizing intoxicating substances that Congress did not intend to define as “hemp” in the first place.<sup>19</sup> The Court should not construe the terms of the Farm Bill such that HSIs escape regulation. *See Haggard Co. v. Helvering*, 308 U.S. 389, 394 (1940) (“All statutes must be construed in the light of their purpose . . . .”); *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 571 (1982) (“[I]n rare cases the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters, and those intentions must be controlling.”).

Because Congress only intended to legalize the production of non-intoxicating hemp, the Farm Bill does not preempt Virginia’s

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<sup>18</sup> Available at: <https://floridastatecannabis.org/thc/delta-thc>.

<sup>19</sup> Plaintiffs essentially argue that so long as their products contain no more than 0.3% *delta-9* THC, they are free to sell products that *also* contain other forms of THC (*e.g.*, delta-8, THC-P, and THC-X)—even though this results in products that are often significantly more intoxicating than the 0.3% threshold was designed to permit.

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). HSIs fall outside the scope of the Farm Bill, and far from “stand[ing] as an obstacle to the . . . purposes and objectives of Congress,” *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 248 (1984), SB 903’s restrictions actually further Congress’s intent to treat intoxicating and non-intoxicating cannabinoids differently. (See JA743 (noting task force that helped develop SB 903 was charged with “advis[ing] the General Assembly on the best way to distinguish between legal, non-intoxicating hemp products and illegal, intoxicating cannabis products”) (citation and internal quotation marks omitted).)

**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 derivatives of hemp, Virginia 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,” 7 U.S.C. § 1639p(a)(3)(A),

and it *only* expressly precludes them from imposing restrictions on the interstate “transportation or shipment of hemp or hemp products,” Pub. L. No. 115-334, § 10114. Accordingly, the Farm Bill “does not preempt state regulation of other aspects of industrial hemp” like commercial sale (JA742), and the district court properly “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” (JA751 (citing *C.Y. Wholesale*, 965 F.3d at 547; *Duke’s Invs.*, 2022 WL 17128976, at \*7)). *See also AK Indus. Hemp Ass’n, Inc. v. Alaska Dep’t of Nat. Res.*, No. 3:23-cv-00253, 2023 WL 8935020, at \*5 (D. Alaska Dec. 27, 2023) (rejecting preemption challenge).

A court’s interpretation of an express preemption provision hinges on “a fair understanding of congressional purpose” and a presumption that Congress does not intend to supersede a state’s historic police powers “unless that was [its] clear and manifest purpose.” *Omega World Travel, Inc. v. Mummagraphics, Inc.*, 469 F.3d 348, 352 (4th Cir. 2006) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-86 (1996)). As the district court observed, “[e]xpress 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 delta-8 or other delta variants.” (JA751-752.) Further, public health and safety are within states’ historic police powers, *see Recht v. Morrissey*, 32 F.4th 398, 413 (4th Cir. 2022), 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 SB 903 is not preempted by the 2018 Farm Bill. In passing the Farm Bill, Congress sought to promote the cultivation of hemp as an agricultural commodity, not the sale of dangerous psychoactive substances. 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 iterations of them) within their borders “more stringent[ly]” than the Farm Bill provides. That is exactly what Virginia 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).

But HSIIs are a different story. Given their high psychoactive potential, the sale and deceptive marketing of these intoxicants as purportedly harmless “hemp” present significant public health and safety risks. And these risks 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 HSIIs. 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 HSIIs 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, issues which SB 903 addresses. *See* Va. Code Ann. § 3.2-4123. 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.)).<sup>20</sup> 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).<sup>21</sup>

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<sup>20</sup> Available at: <https://www.wyden.senate.gov/news/press-releases/paul-wyden-polis-and-massie-defend-hemp>.

<sup>21</sup> Available at: <https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc>.

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).<sup>22</sup> The FDA blamed much of this on HSIIs 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 “for illegally selling copycat food products” and using HSIIs as unapproved food additives in violation of the Food, Drug, and Cosmetic Act. *See, e.g.*, U.S. Food & Drug Admin., *GCHNC LLC dba Hemp XR/Gate City Hemp dba Hemp XR/Allaziya*

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<sup>22</sup> Available at: <https://www.fda.gov/consumers/consumer-updates/5-things-know-about-delta-8-tetrahydrocannabinol-delta-8-thc>.

*Enterprises, LLC dba Hemp XR*, FDA (Sept. 28, 2023);<sup>23</sup> U.S. Food & Drug Admin., *FDA, FTC Warn Six Companies for Illegally Selling Copycat Food Products Containing Delta-8 THC*, FDA (July 6, 2023).<sup>24</sup> These violations further contradict any notion that the HSIs at issue here are 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”).

Fundamentally, the district court’s decision in this case protects consumers by letting Virginia exercise its police powers to curb the sale of harmful HSIs throughout the Commonwealth. HSI manufacturers should not be permitted to put consumers at risk by circumventing regulation through a definitional sleight of hand that passes off highly intoxicating HSIs as legal, non-psychoactive “hemp.”

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<sup>23</sup> Available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gchnc-llc-dba-hemp-xrgate-city-hemp-dba-hemp-xrallaziya-enterprises-llc-dba-hemp-xr-656057-09282023>.

<sup>24</sup> Available at: <https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-six-companies-illegally-selling-copycat-food-products-containing-delta-8-thc>.



## CONCLUSION

For the foregoing reasons, the Court should affirm the district court's denial of a preliminary injunction.

Respectfully submitted,

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February 2, 2024

### CERTIFICATE OF COMPLIANCE

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 6,498 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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**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 February 2, 2024.

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