IN THE SUPREME COURT OF OHIO STATE OF OHIO EX REL. ATTORNEY GENERAL DAVE YOST	:	Case No. 2025-1510
Plaintiff-Appellant,	:	On Appeal from the Delaware County Court of Appeals,
v.	:	Fifth Appellate District
CENTRAL TOBACCO AND STUFF INC. D/B/A CENTRAL TOBACCO	:	Court of Appeals
Defendant-Appellee.	:	Case No. 24 CAE 11 0103

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH ORGANIZATIONS AND THE CITY OF COLUMBUS IN SUPPORT OF APPELLANT

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INTRODUCTION

As the U.S. Supreme Court has recognized, "the thousands of premature deaths that occur each year because of tobacco use" constitute "one of the most troubling public health problems facing our Nation . . . ." *FDA v. Brown & Williamson*, 529 U.S. 120, 125 (2000). Indeed, tobacco product use remains the leading cause of preventable death in the U.S., resulting in more than 490,000 deaths per year.[1] The tobacco industry has long understood that "young people are an important and often crucial segment of the tobacco market" since "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776, 1777-78 § 2(4) & (24) (2009) ("Tobacco Control Act" or "TCA") (codified at 21 U.S.C. § 387 note Findings at ¶¶ (4) & (24)). Today, youth tobacco use is largely fueled by e-cigarettes, particularly flavored disposables like the Blueberry Raspberry Gami- and Strawmelon-flavored products sold by Appellee Central Tobacco and Stuff Inc. ("Central Tobacco"). Compl. ¶¶ 21, 24.[2]

By enforcing Ohio's Consumer Sales Practices Act against the sale of these illegal, youth-appealing flavored disposable e-cigarettes that have been deceptively marketed as legal for sale in the U.S., the State has used its authority—expressly preserved in the Tobacco Control Act—to regulate the sale of tobacco products. Given the primary role states have historically played in tobacco regulation, there is a strong presumption that the State's actions here are not preempted by

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[1] U.S. Dep't of Health & Human Servs., *Eliminating Tobacco-Related Disease and Death: Addressing Disparities: A Report of the Surgeon General* 9 (2024), https://www.hhs.gov/sites/default/files/2024-sgr-tobacco-related-health-disparities-full-report.pdf.

[2] Eunice Park-Lee et al., *E-Cigarette and Nicotine Pouch Use Among Middle and High School Students – United States, 2024*, 73 Morbidity & Mortality Wkly. Rep. 774, 774 (2024), https://perma.cc/6XGR-L77M; Fatma Romeh M. Ali et al., *Trends in U.S. E-Cigarette Sales Measured in Milligrams of Nicotine, 2019-2024*, 68 Am J. Prev. Med. 1173 (2025), https://doi.org/10.1016/j.amepre.2025.02.007.

federal law. Far from evincing a clear congressional intent to preempt, which would be required to overcome the presumption, the federal Tobacco Control Act repeatedly confirms that states have the authority to regulate tobacco product sales. Rather than conflicting with federal law, the State's actions are entirely consistent with the Tobacco Control Act's regulatory scheme and with its objective of curbing youth tobacco use.

FDA has made clear that only 41 e-cigarettes are currently legal to sell under federal law—all tobacco- or menthol-flavored—and has identified those products on its website. Yet the market is dominated by disposable e-cigarettes available in a variety of kid-friendly flavors, unauthorized by the FDA and therefore illegal under federal law. *See infra* 14-15.[3] The State's actions to enforce the Consumer Sales Practices Act against Central Tobacco's flavored disposable e-cigarettes do not involve the State making its own judgments about what products are illegal under federal law. Rather, the Attorney General seeks to invoke the Ohio Consumer Sales Practices Act against deception involving products that are indisputably illegal to sell under federal law. Ohio's enforcement of its own statute against products also illegal under federal law, therefore, is fully consistent with the Tobacco Control Act's objective to ensure a well-regulated marketplace consisting exclusively of FDA-authorized products. The State's enforcement actions against the type of tobacco product most popular with youth (flavored disposable e-cigarettes) also directly advance a key objective of the Tobacco Control Act: curbing youth initiation and use of tobacco products. For all these reasons, the State's actions here are not preempted by federal law.

[3] Disposables are a type of e-cigarette that "come pre-filled" with nicotine-containing liquid and "are not designed to be refilled." Ctrs. for Disease Control and Prevention, *About E-Cigarettes (Vapes)* (Oct. 24, 2024), https://perma.cc/7BRH-JA8C.

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici are the City of Columbus and the following eleven public health and medical organizations: African American Tobacco Control Leadership Council; American Cancer Society Cancer Action Network; American Heart Association; American Lung Association; American Medical Association; Campaign for Tobacco-Free Kids; LGBTQIA+ Cancer Network; Ohio Chapter, American Academy of Pediatrics; Ohio State Medical Association; Parents Against Vaping E-Cigarettes; and Truth Initiative (collectively, "Public Health and Municipal *Amici*").

As is evident from the description of *Amici* included in the Addendum to this brief, these entities work daily to reduce the devastating harms of tobacco products, including e-cigarettes. *Amici* include organizations with formal programs urging users to quit, those representing physicians who counsel young patients and their families about the hazards of tobacco use, and groups representing parents and families struggling to free young people from nicotine addiction. *Amici* also include the City of Columbus, which has enacted and enforces a robust set of tobacco control laws, including a ban on the sale of flavored e-cigarettes and other tobacco products. Each of the *Amici* has a direct and immediate interest in curbing the sale of flavored disposable e-cigarettes as well as substantial expertise in the role these products play in enticing young people to use tobacco.

Many of the *Amici* also have a long-standing interest—and have played an active role—in defending the TCA's broad protection of state and local authority to take action to protect communities from the adverse effects of tobacco products on public health. For example, some of the *Amici* have made and joined *amicus* filings addressing the scope of the TCA's Preservation of State and local authority provision (21 U.S.C. § 387p) in the U.S. Supreme Court and U.S. Court

of Appeals for the First, Second, Eighth, and Ninth Circuits.[4] Thus, *Amici* are particularly well suited to inform the Court of the substantial public health benefits of protecting the State's actions here, and why such actions are not preempted by federal law.

STATEMENT OF THE CASE AND FACTS

The Public Health and Municipal *Amici* defer to the statement of the case and facts set forth in Appellant's merits brief.

ARGUMENT

Appellant's Proposition of Law:

> *Neither the federal Food, Drug, and Cosmetic Act, nor the federal Tobacco Control Act, preempts state-law claims alleging that the sale of illegal tobacco products violates Ohio's Consumer Sales Practices Act.*

I. The Tobacco Control Act Broadly Preserves the State's Authority to Regulate Sales of Tobacco Products.

In the Tobacco Control Act, "Congress made an 'explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco products.'" *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542, 550 (9th Cir. 2022) ("*L.A. County*") (quoting *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013)). It did so through the statute's "unique three-layered preservation provision," 21 U.S.C. § 387p. *Id.*

[4] Mot. for Leave and Br. of Pub. Health, Med., & Community Grps. as *Amici Curiae* in Opp. to Emergency App. for Inj., *R.J. Reynolds Tobacco Co. v. Bonta*, No. 22A474 (U.S. Dec. 6, 2022); Br. of Pub. Health & Med. Grps. as *Amici Curiae* in Supp. of Appellees (May 14, 2021), *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022) (No. 20-55930), ECF No. 29; Br. of *Amici Curiae* Pub. Health Law Ctr. et al. in Supp. of Defs.-Appelles and Affirmance (Dec. 2, 2020), *R.J. Reynolds Tobacco Co. v. City of Edina*, 60 F.4th 1170 (8th Cir. 2023) (No. 20-2852); *Amici Curiae* Br. in Supp. of Appellees (June 7, 2013), *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013) (No. 13-1053); Br. for *Amici Curiae* Tobacco Control Legal Consortium et al., in Supp. of Appellants (Apr. 19, 2011), *23-23 94th Grocery Corp. v. New York City Bd. Of Health*, 685 F.3d 174 (2d Cir. 2012) (No. 11-91-cv), ECF No. 82-2.

First, the Preservation Clause, 21 U.S.C. § 387p(a)(1), broadly preserves state authority to enact *any* regulation over tobacco products that is "in addition to, or more stringent than, requirements established under" the Tobacco Control Act.[5] "Essentially, the Preservation Clause tells us that there is no 'field preemption' for the TCA—states and cities are free to go above and beyond the requirements of the TCA to curb tobacco use." *R.J. Reynolds Tobacco Co. v. Edina*, 60 F.4th 1170, 1174 (8th Cir. 2023).

The "Preemption Clause," 21 U.S.C. § 387p(a)(2)(A), then "limits that general principle" by carving out particular areas in which states may not regulate. *Edina*, 60 F.4th at 1174. It provides that states may not "establish or continue in effect . . . any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A).[6]

However, the "Savings Clause then qualifies the Preemption Clause's scope." *Edina*, 60 F.4th at 1174. It states that the Preemption Clause "does not apply to requirements relating to the *sale*, distribution, possession, information reporting to the State, exposure to, access to, the

[5] 21 U.S.C. § 387p(a)(1) in full: "Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products."

[6] 21 U.S.C. § 387p(a)(2)(A) in full: "No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products."

advertising and promotion of, or use of, tobacco products by individuals of any age." 21 U.S.C. § 387p(a)(2)(B) (emphasis added).[7] Thus, as at least six federal courts, including four circuit courts, have held, states are fully empowered to regulate tobacco product sales. *Edina*, 60 F.4th at 1175-79 (8th Cir. 2023); *L.A. County*, 29 F.4th at 552-61 (9th Cir. 2022); *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 435-36 (2d Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 81-83 (1st Cir. 2013); *Utah Vapor Bus. Ass'n Inc. v. Utah*, 792 F. Supp. 3d 1226, 1230-1240 (D. Utah 2025); *Indeps. Gas & Serv. Stations Assn's, Inc. v. City of Chicago*, 112 F. Supp. 3d 749, 752-54 (N.D. Ill. 2015). Most recently, in rejecting the same type of preemption challenge as is at issue here, the Ninth District Court of Appeals reaffirmed that "federal law expressly *allows* states to enforce laws or measures with respect to tobacco products relating to the *sale* . . . of tobacco products." *State ex rel. Att'y Gen. Dave Yost v. Orrville Tobacco & Vape Shop, LLC*, 2026-Ohio-983, ¶ 27 (9th Dist.) (emphasis in original).

Below, the Fifth District majority held, with no analysis of the express preservation of state authority in the TCA, that the State's actions were impliedly preempted because "[t]he State's claim that the e-cigarettes are not in compliance with the FDCA [Food, Drug, and Cosmetic Act] is a claim that would not exist in the absence of the FDCA." *State ex rel. Att'y Gen. Dave Yost v. Central Tobacco & Stuff Inc.*, 2025-Ohio-4613, ¶ 41 (5th Dist.) ("App. Op."). In making this determination, the majority relied on two cases interpreting not the TCA, but the FDCA: *Buckman*

[7] 21 U.S.C. § 387p(a)(2)(B) in full: "Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of title 5 shall be treated as a trade secret and confidential information by the State."

Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001) and *Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576 (6th Cir. 2013). *Id.* at ¶¶ 37-41.

In both *Buckman* and *Loreto*, the courts held that plaintiffs' claims were impliedly preempted by 21 U.S.C. § 337, which provides that, except for certain actions related to foods, "all such proceedings for the enforcement, or to restrain violations of this chapter [the FDCA] shall be by and in the name of the United States." The U.S. Supreme Court in *Buckman* held that this language constituted "clear evidence that Congress intended that the MDA [the Medical Devices Amendments to the FDCA] be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Because the fraud-on-the-FDA claims at issue in *Buckman* "exist solely by virtue of the FDCA disclosure requirements," the Court held that such claims are impliedly preempted by 21 U.S.C. § 337. *Id.* at 353. Citing this section and *Buckman*, the Sixth Circuit in *Loreto* (an unpublished opinion that does not constitute binding authority within the Sixth Circuit)[8] deemed preempted a state tort law claim that alleged a drug manufacturer failed to tell consumers that its products' "labeling did not comply with the FDCA's requirements." *Loreto*, 515 Fed. App'x at 579. This theory of liability was impliedly preempted because it "depends entirely upon an FDCA violation." *Id.*

Although the Tobacco Control Act amended—and added a new chapter to—the FDCA, the courts in *Buckman* and *Loreto* neither interpreted nor applied 21 U.S.C. § 387p, the provision in the Tobacco Control Act that broadly preserves state authority over tobacco sales. The enactment of 21 U.S.C. § 387p makes this case fundamentally different from *Buckman* and *Loreto*. Those cases concerned federal regulation of devices and drugs, respectively, which are subject to

[8] *See Aleisa v. GOJO Industries, Inc.*, 538 F. Supp. 3d 764, 774 (N.D. Ohio 2021). ("[A]s an unpublished opinion, *Loreto* does not constitute binding authority within this Circuit.")

different statutory schemes than tobacco products. As one court recently held, when it comes to tobacco products, simply focusing on preemption under § 337 "ignores material differences in the relevant statutory language and context" for federal tobacco regulation and the device regulatory scheme at issue in *Buckman*. *Wisconsinites for Alternatives to Smoking & Tobacco, Inc. v. Casey*, No. 25-cv-552-wmc, 2025 WL 2582099, at *6 (W.D. Wis. Sept. 5, 2025).

For example, the FDCA provisions at issue in *Buckman* did not expressly reserve to private individuals (or states) any role in policing fraud against the FDA, the subject of the consumers' claims there. Similarly, the FDCA provisions at issue in *Loreto* did not expressly authorize private individuals (or states) to enforce the FDCA's labeling requirements. Here, in contrast, the State is attempting to regulate sales, specifically deceptive sales, of tobacco products. It is not attempting to "enforce an FDA decision or take regulatory action that is exclusive to the FDA." App. Opp. ¶ 76 (King, J., dissenting). The State is not alleging that Central Tobacco failed to comply with federal labeling requirements; nor is it seeking to change the label on the products.[9] Instead, it alleges that Central Tobacco, by choosing to sell products that are indisputably illegal under federal law, deceptively held out that its products are legal for sale, when in fact they are not. The State's authority to bring such a claim alleging deceptive sales of tobacco products is expressly preserved by 21 U.S.C. § 387p.

As one federal district court recently held, finding a state tobacco action preempted under § 337 simply because the action references a product's legal status under federal law "would render

[9] The Fifth District majority asserted that the FDCA requires all tobacco products, whether authorized or not, to affix the label, "sale only allowed in the United States." App. Op. ¶ 45. Even if true, this is beside the point. Ohio's enforcement action does not challenge Central Tobacco's application of that label, but rather alleges that Central Tobacco's decision to sell unauthorized products bearing that label is a deceptive act in violation of Ohio law. *See id.* at ¶ 65 King, J., dissenting) ("The Attorney General is seeking to prevent the sale of items that appear to be lawful e-cigarettes, but in fact are not.")

the [Tobacco Control Act's] Preservation and Savings Clauses a nullity." *Vapor Technology Ass'n v. Wooten*, No. 4:25-CV-00076-M-RJ, 2025 WL 1787420, at *5 (E.D.N.C. June 27, 2025). The court held:

> [W]hile Section 337(a) specifically requires that only the United States may initiate proceedings to enforce provisions of the []TCA, the Preservation Clause explicitly does not "limit the authority" of a State to enact and enforce laws with respect to the sale of tobacco products. § 387p(a)(l). Because Plaintiffs' reading of the statute would require this court to ignore that directive, the court declines to adopt it.

Id.

Thus, when properly considered within the context of 21 U.S.C. § 387p's broad preservation of state authority over tobacco product sales, the State's actions here are expressly preserved—not impliedly preempted—by federal law.

II. There Is a Strong Presumption Against Preemption Here that Cannot Be Overcome.

The Fifth District majority's preemption analysis was flawed from the start because it failed to apply—or even assess the applicability of—the presumption against federal preemption. As the U.S. Supreme Court has held, all preemption analyses must "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). The presumption is "particularly" strong when, as here, "Congress has 'legislated . . . in a field which the States have traditionally occupied.'" *Id.* (quoting *Rice*, 331 U.S. at 230).

The "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 719 (1985). And with respect to tobacco regulation specifically, "states and localities have historically played a primary role in regulating the sale of tobacco products." *L.A. County*, 29 F.4th at 555; *see also Austin v. Tennessee*, 179 U.S. 343, 348-49 (1900) ("[W]e think it within the province of the [State]

legislature to say how far [cigarettes] may be sold, or to prohibit their sale entirely . . . provided no discrimination be used . . . and there be no reason to doubt that the act in question is designed for the protection of the public health.").

The Tobacco Control Act, which was enacted in 2009 against this "historical backdrop," "effectively *carves out* federal power from a historical body of state and local authority by setting the floor for production and marketing standards, while still preserving states and localities' broad power over regulation of the sales of those products." *L.A. County*, 29 F.4th at 555 (emphasis in original) (internal quotations omitted). Thus, "because the TCA implicates the States' traditional use of its police power, we must assume that the TCA does not preempt that authority unless it was the 'clear and manifest purpose of Congress.'" *Edina*, 60 F.4th at 1178 (quoting *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008)). In other words, "if there is any ambiguity as to whether the local [or state] and federal laws can coexist, we must uphold the ordinance" against a preemption challenge. *U.S. Smokeless Mfg. Co.*, 708 F.3d 428 at 433.

Here, there is no such ambiguity. Rather than a clear Congressional intent to preempt—a finding that would be required to find preemption in this context—the Tobacco Control Act's "preservation and savings clauses . . . explicitly and repeatedly reiterate[] local authority over product sales." *L.A. County*, 29 F.4th at 558. Thus, the strong presumption against preemption has not been overcome here.

The applicability of the presumption against preemption also distinguishes this case from *Buckman* and *Loreto*, two cases in which the presumption was not applied. In *Buckman*, the U.S. Supreme Court found that "no presumption against pre-emption obtains in this case" because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied.'" *Id.* at 347-48 (quoting *Rice*, 331 U.S. at 230). As noted above, the opposite is true of

regulation of tobacco product sales—a longtime matter of primary state concern. The court in *Loreto*, like the majority below, erred by failing even to consider whether the presumption applied to plaintiffs' claims. *See Medtronic, Inc.*, 518 U.S. at 485. Whereas the presumption was not applied in either *Buckman* nor *Loreto*, here, in contrast, there is a strong presumption that must be applied, given states' primary and historic role in regulating tobacco product sales. When applied, the presumption cannot be overcome, particularly in light of the Tobacco Control Act's express preservation of state authority over tobacco sales.

III. The State's Actions Advance the Tobacco Control Act's Regulatory Scheme and Core Objective of Curbing Youth Tobacco Use.

In *Buckman*, the Supreme Court found implied preemption in part based on the Court's conclusion that allowing private litigants to bring fraud-on-the-FDA claims under state tort law would upset the FDA's "somewhat delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348. For example, the Court was concerned that these state law fraud-on-the-FDA claims could discourage would-be applicants from seeking "approval of medical devices with potentially beneficial off-label uses . . . despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine and even though off-label use is generally accepted." *Id.* at 350-51 (internal citation omitted). "Conversely," the Court was concerned that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court" thereby incentivizing applicants "to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." *Id.* at 351. Thus, allowing these fraud-on-the FDA claims "would exert an extraneous pull on the scheme established by Congress and is therefore pre-empted by that scheme." *Id.* at 353.

Here, in contrast, the State's actions to enforce its state consumer protection laws against the sale of youth-appealing unauthorized flavored disposable e-cigarettes advances—rather than upsets—the federal statutory scheme and objectives. When Congress enacted the Tobacco Control Act, it was particularly concerned with curbing youth initiation and use of tobacco products. "So as part of the legislation and so no confusion could exist, Congress made legislative findings of fact. Foremost among those factual findings, Congress determined that '[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions.…'" *Bidi Vapor v. FDA*, 47 F.4th 1191, 1210 (11th Cir. 2022) (quoting 21 U.S.C. 387 note Findings at ¶ (1)).

Congress reiterated its concern with youth tobacco use time and again in the Findings section. *See* 21 U.S.C. § 387 note Findings at ¶ (4) ("Virtually all new users of tobacco products are under the minimum legal age to purchase such products."); ¶ (14) ("Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs."); ¶ (15) ("Advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth."); ¶ (18) ("Tobacco product advertising is regularly seen by persons under the age of 18, and persons under the age of 18 are regularly exposed to tobacco product promotional efforts."); ¶ (20) ("Children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use, plays a role in leading young people to overestimate the prevalence of tobacco use, and increases the number of young people who begin to use tobacco."); ¶ (21) ("The use of tobacco products in motion pictures and other mass media glamorizes its use

for young people and encourages them to use tobacco products."); ¶ (22) ("Tobacco advertising expands the size of the tobacco market by increasing consumption of tobacco products including tobacco use by young people."); ¶ (24) ("Tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market. Children, who tend to be more price sensitive than adults, are influenced by advertising and promotion practices that result in drastically reduced cigarette prices.").

A key mechanism through which Congress chose to address this problem is the Act's premarket review requirement, which requires all tobacco products, including e-cigarettes, that were not commercially marketed before February 15, 2007 to receive FDA authorization prior to introduction. 21 U.S.C. § 387j(a); *see Bidi Vapor*, 47 F.4th at 1211 ("To address these problems, through the Act, Congress required manufacturers to submit all new tobacco products for FDA review and approval before they could be marketed in interstate commerce."). To receive authorization, e-cigarette manufacturers must demonstrate that the marketing of their products would be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). The manufacturers of the e-cigarettes sold by Central Tobacco did not do that. As detailed below, the State's efforts to invoke its consumer protection law against Central Tobacco's federally illegal, youth-appealing flavored e-cigarettes directly advances the Tobacco Control Act's objectives of curbing youth tobacco use through a well-regulated marketplace consisting entirely of FDA-authorized products. As the Ninth District properly found in its recent consideration of this issue, the "State's claims . . . do not conflict with, and are in fact consistent with Congress's intent [in the TCA] to protect the public health and Congress's express reservation of authority to the states" in 21 U.S.C. § 387p(a)(1). *Orrville Tobacco & Vape Shop, LLC*, 2026-Ohio-983, at ¶ 28 (9th Dist.).

A. The State's actions complement the federal tobacco regulatory scheme.

To date, FDA has authorized only 41 e-cigarette products, all of which are either tobacco- or menthol-flavored.[10] It has also denied authorization to millions of flavored e-cigarettes that have failed to demonstrate that they satisfy the "appropriate for the protection of the public health" statutory standard. *See FDA v. Wages & White Lions Invs., L.L.C.*, 604 U.S. 542, 562-63 (2025).[11] FDA has stated—explicitly and repeatedly—that the 41 authorized products "are the only e-cigarettes that may be lawfully sold in the United States."[12] It is uncontested that Central Tobacco sold products not among the 41 FDA authorized e-cigarettes. App. Op. ¶ 31. It therefore misrepresented the legality of its products in violation of Ohio's Consumer Sales Practices Act. Thus, rather than exerting the "extraneous pull" on the federal statutory scheme found in *Buckman*, the State's actions here complement the federal tobacco regulatory scheme established by Congress. If there were any doubt, the TCA's "own terms" make clear that "state regulation of tobacco sales neither frustrates nor prevents the []TCA's objectives." *Vapor Technology Ass'n*, 2025 WL 1787420, at *5.

The State's use of its consumer protection law is entirely consistent with federal efforts to curb the sale of illegal e-cigarettes. Although FDA and its federal enforcement partners have taken

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[10] *See* FDA, *E-Cigarettes, "Vapes" and Other Electronic Nicotine Delivery Systems (ENDS) Authorized by the FDA*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends-authorized-fda (last updated Mar. 12, 2026) ("FDA, *Authorized E-Cigarettes*").

[11] *See also* Brian King, Dir., FDA Ctr. for Tobacco Prods., *A Year in Review: FDA's Progress on Tobacco Product Regulation in 2024* (Jan. 14, 2025), https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2024.

[12] FDA, *Authorized E-Cigarettes*, *supra* note 10; *see also* FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Products*, https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products (last updated Mar. 12, 2026) ("To date, FDA has authorized 41 e-cigarettes. These are the only e-cigarette products that currently may be lawfully sold in the U.S.").

important enforcement actions against unauthorized flavored e-cigarettes, including through large-scale seizures, injunctions, and civil monetary penalties,[13] the e-cigarette market remains overrun with illegal products. The CDC Foundation recently estimated that during the 4-week period ending August 10, 2025, 68.2% of all e-cigarettes sold in tracked retailers had not been authorized by FDA.[14]

In addition, most of the illegal e-cigarettes are flavored disposables like those sold by Central Tobacco. A CDC Foundation analysis found that, during the 6-month period ending May 18, 2025, 7,066 unique e-cigarette brands were sold in the U.S., of which 6,593 (93.3%) were disposable.[15] And among these disposables, 94.7% were flavored.[16]

These unauthorized products, which have not met the required "appropriate for the protection of public health" standard, threaten youth, with the Office of the Surgeon General

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[13] *See, e.g.*, FDA, *Advisory and Enforcement Actions*, *supra* note 12; FDA News Release, *HHS, CBP Seize $86.5 Million Worth of Illegal E-Cigarettes in Largest-Ever Operation* (Sept. 10, 2025), https://www.fda.gov/news-events/press-announcements/hhs-cbp-seize-865-million-worth-illegal-e-cigarettes-largest-ever-operation; King, *Year in Review*, supra note 11.

[14] Varvara Schoute et al., *Sales Estimation and Challenges in Monitoring of E-Cigarettes with Marketing Granted Orders*, https://perma.cc/75BX-CMQ4 (accessed Mar. 13, 2026) (data from Circana). This is likely a significate underestimate because it only includes e-cigarette sales data from convenience stores, gas stations, and other retail store chains, but not internet and tobacco-specialty stores, including vape shops. *See* Alex Liber et al., *How Complete Are Tobacco Sales Data? Assessing the Comprehensiveness of US Tobacco Product Retail Sales Data Through Comparisons to Excise Tax Collections*, 26 Nicotine & Tobacco Res. 1103, 1103 (2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC11260888/pdf/ntad214.pdf (noting that "sales data do not include sales from online retailers, stores on Native American reservations, or specialty stores such as tobacconists and vape shops.").

[15] CDC Found., *Monitoring E-Cigarette Sales: National Trends* 1 (Aug. 2025), https://perma.cc/TW8Q-76WQ (data from Circana). This is also likely a significate underestimate for the same reason detailed in note 14.

[16] *Id.*

recently noting that "[m]any vaping products accessible to youth are not authorized by the FDA and are illegally marketed."[17]

Thus, the State's enforcement actions against deceptive sales of the types of products that dominate the illegal e-cigarette market (flavored disposables) provides important protection to Ohio's youth beyond that provided by FDA's enforcement efforts.

B. The State's actions advance the Tobacco Control Act's core objective of protecting youth from the health harms of tobacco use.

The State's actions to enforce the Consumer Sales Practices Act against Central Tobacco's flavored disposable e-cigarettes is entirely consistent with the Congressional intent expressed in the TCA to curb youth initiation and use of tobacco products. Flavored disposable e-cigarettes, like those sold by Central Tobacco, are highly attractive to, and widely used by, youth. They also pose serious risks of addiction and other health harms, particularly to young people. Thus, enforcement of state law against these products protects Ohio's youth and directly advances a key objective of the Tobacco Control Act.

E-cigarettes, like those sold by Central Tobacco, are the most popular tobacco product among youth.[18] Over 1.6 million youth nationwide, including 7.8% of high schoolers, reported current e-cigarette use in 2024.[19] Rates are significantly higher in Ohio. In 2023 (the most recent

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[17] Office of the Surgeon General, U.S. Dep't of Health & Human Servs., *Sound the Alarm: Youth Vaping Can Harm* 3 (2025), https://www.hhs.gov/sites/default/files/osg-youth-vaping-data-sheet.pdf.

[18] Ahmed Jamal et al., *Tobacco Product Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2024*, 73 Morbidity & Mortality Wkly. Rep. 917, 918 (2024), https://perma.cc/MR2L-Q5VB.

[19] Park-Lee et al., *supra* note 2, at 774.

year with available data), 18.8% of Ohio high schoolers, including 27.5% of 12th graders, were current e-cigarette users.[20]

Young people are not only experimenting with e-cigarettes—they are using them frequently. In 2024, 42.1% of U.S. high school e-cigarette users reported using them on at least 20 of the preceding 30 days, and even more alarming, 29.7% of U.S. high school e-cigarette users reported *daily* use, a strong indicator of nicotine addiction.[21] Roughly 430,000 U.S. middle and high school students are vaping on a daily basis.[22] In Ohio in 2023, 7.7% of *all* high schoolers, including 15.3% of 12th graders, reported using e-cigarettes on 20 of the preceding 30 days, and 5.5% of high schoolers, including more than one-in-ten 12th graders (10.2%), reported daily use.[23]

Flavored e-cigarettes, like the Lost Mary Blueberry Raspberry Gami- and Breeze Smoke Strawmelon-flavored products sold by Central Tobacco (Compl. ¶¶ 21, 24), are driving the high rates of youth use. As the Sixth Circuit and others have recognized, flavored e-cigarettes "especially appeal to children," *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 505 (6th Cir. 2021), and "lie at the heart of the problem" of youth e-cigarette use. *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11 (D.C. Cir. 2022). A 2020 Surgeon General's Report noted that "the role of flavors in promoting initiation of tobacco product use among youth is well established . . . and appealing flavor is cited

[20] Ohio Youth Surveys, *YRBS/YTS High School Tobacco and Electronic Vapor Product Use 2023*, at 13, https://youthsurveys.ohio.gov/reports-and-insights/yrbs-yts-reports/2023/yrbs-yts-high-school-tobacco-and-electronic-vapor-product-use-2023 (accessed Mar. 20, 2026); The Ohio survey uses the term "electronic vapor product" rather than the synonymous "e-cigarette." This brief uses the term "e-cigarette" throughout.

[21] Park-Lee et al., *supra* note 2, at 775 tbl.

[22] *Id.*

[23] Ohio Youth Surveys, *supra* note 20, at 15, 17.

by youth as one of the main reasons for using e-cigarettes."[24] In 2024, 87.6% of current U.S. middle and high school e-cigarette users reported using a flavored product.[25]

Moreover, the disposable e-cigarettes sold by Central Tobacco are the favorite device type among youth. In 2024, 55.6% of current U.S. youth e-cigarette users (870,000 students) reported use of a disposable device.[26]

Most e-cigarettes "contain high concentrations of nicotine,"[27] which is "among the most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). According to the U.S. Centers for Disease Control and Prevention, adolescent brains are particularly sensitive to nicotine, and exposure during this critical period can "harm the parts of an adolescent's brain that control attention, learning, mood, and impulse control."[28]

Many e-cigarettes also contain or produce other harmful chemicals. The Office of the Surgeon General recently noted that "[r]esearch has detected arsenic along with other toxic metals in vapes, e.g., chromium, antimony, nickel, lead, tin, and aluminum" and that "[i]norganic arsenic and antimony are classified as carcinogenic and can lead to an increased risk of cancer and disruption of hormones."[29] FDA also recently warned that illegal e-cigarettes "frequently contain

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[24] U.S. Dep't of Health & Human Servs., *Smoking Cessation: A Report of the Surgeon General* 611 (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf.

[25] Park-Lee et al., *supra* note 2, at 774.

[26] *Id.* at 775 tbl.

[27] Office of the Surgeon General, *Sound the Alarm*, *supra* note 17, at 2.

[28] Ctrs. for Disease Control and Prevention, *E-Cigarette Use Among Youth* (Oct. 17, 2024), https://perma.cc/79PC-GZ3Q.

[29] Office of the Surgeon General, *Sound the Alarm*, *supra* note 17, at 3.

chemicals such as formaldehyde, lead, and acrolein—materials more commonly found in industrial textiles and pesticides."[30]

Finally, there is little evidence that e-cigarettes, particularly flavored e-cigarettes, yield any public health benefit. The leading public health authorities in the U.S., including the Surgeon General, the U.S. Preventive Services Task Force, the Centers for Disease Control and Prevention, and the National Academies of Science, Engineering and Medicine, have all concluded that there is insufficient evidence to recommend any e-cigarettes for smoking cessation.[31] The FDA has also repeatedly found that there is little evidence that flavors in e-cigarettes aid smokers to stop smoking. For example, in upholding FDA marketing denial orders for flavored e-cigarettes, the U.S. Court of Appeals for the Fourth Circuit noted FDA's conclusion that the "literature was conflicting and inconclusive on whether flavors actually promoted switching [from cigarettes to e-cigarettes] or cessation by adult smokers." *Avail Vapor, LLC v. FDA*, 55 F. 4th 409, 421 (4th Cir. 2022).

Thus, the State's actions to enforce Ohio's Consumer Sales Practices Act against Central Tobacco's illegal flavored disposable e-cigarettes provides young Ohioans with much-needed protection from the addictive and other harmful effects of such products. That is fully consistent with the TCA's objective of curbing youth tobacco initiation and use.

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[30] FDA, *A Statement from FDA Commissioner Marty Makary, M.D., M.P.H.: Encouraging Retailers to Stop Selling Illegal Vapes* (Sept. 30, 2025), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-encouraging-retailers-stop-selling-illegal-vapes.

[31] U.S. Dep't of Health & Human Servs., *Smoking Cessation: A Report of the Surgeon General*, *supra* note 24 at 7; U.S. Preventive Servs. Task Force, *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: USPSTF Recommendation Statement*, 325 J. Am. Med. Ass'n 265 (2021), https://jamanetwork.com/journals/jama/fullarticle/2775287; Ctrs. for Disease Control & Prevention, *Adult Smoking Cessation – The Use of E-Cigarettes*, https://perma.cc/UZB4-2C6L (last visited Mar. 3, 2026); Nat'l Acads. of Sci., Eng'g & Med., *Public Health Consequences of E-Cigarettes* 10 (2018), https://perma.cc/AZZ8-LKXW.

CONCLUSION

For these reasons, and those presented by Appellants, we urge the Court to reverse the Fifth District's judgment and find no preemption.

ADDENDUM

1. African American Tobacco Control Leadership Council

The African American Tobacco Control Leadership Council is a national cadre of community activists and public health organizers dedicated to saving Black Lives through removing menthol and all flavored tobacco and nicotine products from the Black Community. Removing menthol and flavors is step one in removing all tobacco and nicotine products from the marketplace.

2. American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network ("ACS CAN") is committed to ensuring everyone has a fair and just opportunity to prevent, find, treat, and survive cancer. Our advocacy includes support for evidence-based tobacco control measures such as Ohio's authority to regulate the sale of tobacco products. ACS CAN currently has 1,941 tobacco control advocates in Ohio.

3. American Heart Association

The American Heart Association ("AHA") is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, the organization now includes more than 35 million volunteers, donors and supporters with offices nationwide. The Association funds innovative research, advocates for the public's health, and shares lifesaving resources. For more than 40 years AHA's volunteer advocates and staff have been active in policies promoting longer, healthier lives for all.

4. American Lung Association

The American Lung Association is the nation's oldest voluntary health organization working to save lives by improving lung health and preventing lung disease. The American Lung Association has long been active in research, education and public policy advocacy regarding the adverse

health effects caused by tobacco use. This includes supporting the rights of states to regulate tobacco product sales as allowed under the Family Smoking Prevention and Tobacco Control Act.

5. American Medical Association

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes.

6. Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from using tobacco products, help smokers quit, educate the public about the dangers of smoking and tobacco use, and protect everyone from secondhand smoke.

7. City of Columbus

The City of Columbus is the largest city in the State of Ohio with over 900,000 residents. It has a robust health department that enforces the city's tobacco ordinances including a ban on the sale of vapes and flavored tobacco.

8. LGBTQIA+ Cancer Network

The mission of the LGBTQIA+ Cancer Network is to improve the lives of LGBTQI+ individuals on the cancer journey and those at risk through educational, training, and advocacy initiatives. LGBTQIA+ communities are disproportionately impacted by flavored tobacco products, which in

turn impacts community rates of cancer. As such, LGBTQIA+ communities have a strong interest in responsible public health policy.

9. Ohio Chapter, American Academy of Pediatrics

The Ohio Chapter, American Academy of Pediatrics ("Ohio AAP") promotes the health, safety and well-being of children and adolescents so they may reach their full potential. The Ohio AAP accomplishes this by addressing the needs of children, their families, and their communities, and by supporting Chapter members through advocacy, education, research, service, and improving the systems through which they deliver pediatric care. The Ohio AAP works to curb tobacco exposure to children from infancy through adolescence with advocacy and programs on smoking dangers and cessation for family members, and works to promote the dangers of tobacco use on long term health.

10. Ohio State Medical Association

The Ohio State Medical Association ("OSMA") is a nonprofit professional association established in 1846 and is comprised of physicians, resident physicians, and medical students in Ohio. The majority of OSMA's membership includes Ohio physicians engaged in the private practice of medicine. The OSMA's purposes are to advocate for physicians and their patients, improve public health through education, encourage interchange of ideas among members, and maintain and advance the standards of practice.

11. Parents Against Vaping E-Cigarettes

Parents Against Vaping E-cigarettes was founded by three moms in 2018 as a grassroots response to the youth vaping epidemic. Parents Against Vaping, a volunteer-powered education and advocacy nonprofit, is the first and only national parent voice in the fight against youth tobacco

use and the predatory behavior of the tobacco industry. Parents Against Vaping educates parents across the country and supports ending the sale of all flavored tobacco products.

12. Truth Initiative

The Truth Initiative Foundation, d/b/a Truth Initiative, is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served this day, March 30, 2026, upon the following via electronic mail:

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