No. 20-2852

In the
United States Court of Appeals for the Eighth Circuit

R.J. REYNOLDS TOBACCO COMPANY, ET AL.
Plaintiffs-Appellants,
v.
CITY OF EDINA, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of Minnesota, No. 0:20-cv-1403 (Hon. Patrick Schiltz)

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH LAW CENTER, ACTION ON SMOKING AND HEALTH, AFRICAN AMERICAN TOBACCO CONTROL LEADERSHIP COUNCIL, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, AMERICAN PUBLIC HEALTH ASSOCIATION, AMERICAN THORACIC SOCIETY, AMERICANS FOR NONSMOKERS' RIGHTS, ASIAN PACIFIC PARTNERS FOR EMPOWERMENT, ADVOCACY AND LEADERSHIP, ASSOCIATION FOR NONSMOKERS—MINNESOTA, BLUE CROSS BLUE SHIELD OF MINNESOTA, CAMPAIGN FOR TOBACCO-FREE KIDS, CENTER FOR BLACK HEALTH AND EQUITY, CHANGELAB SOLUTIONS, CLEARWAY℠, MASSACHUSETTS ASSOCIATION OF HEALTH BOARDS, MINNESOTA MEDICAL ASSOCIATION, NATIONAL LGBT CANCER NETWORK, NATIONAL NATIVE NETWORK, PARENTS AGAINST VAPING E-CIGARETTES, PUBLIC HEALTH ADVOCACY INSTITUTE, PUBLIC HEALTH AND TOBACCO POLICY CENTER, AND TRUTH INITIATIVE IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

Rachel Bloomekatz
1148 Neil Avenue
Columbus, Ohio 43201
(614) 259-7611
rachel@bloomekatzlaw.com
Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

No publicly held corporation owns 10% or more of the stock in any amici curiae. Nor is any amicus curiae a subsidiary of any parent company.

/s/ Rachel Bloomekatz
Rachel Bloomekatz
Counsel for Amici Curiae

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INTRODUCTION[1]

Edina's Ordinance does one thing—it prohibits tobacco *retailers* from selling flavored tobacco products within the City's borders. As the lower court found, it does not require a tobacco *manufacturer* "to change anything about the ingredients that it uses or anything else about the way it manufacturers its products." Add. 16. Tobacco companies can still make their products with whatever manufacturing processes, ingredients, components, filters, and other properties they choose, so long as they are complying with federal regulations. No special cigarette, cigar, vape product, or chew tobacco has to be made for Edina. Instead, what the City has mandated is that of all tobacco products that exist on the market, some—those imparting a distinct non-tobacco taste or aroma—cannot be sold within its borders. That's it. Edina does not even prohibit the possession or use of flavored tobacco products within the City. It is, therefore, a measure "relating to or prohibiting the sale" of tobacco products—which the Tobacco Control Act (TCA) explicitly says states and local governments can adopt—not a "product standard," which Congress said was primarily reserved to the Food and Drug Administration (FDA). *See* 21 U.S.C. § 387g, p.

[1] All parties consent to the filing of this brief, and no counsel for any party authored it in whole or part or paid money to fund the brief's preparation and submission.

The City of Edina determined that this Ordinance was necessary to reduce youth access to flavored tobacco products. As the extensive record developed by the City reflects, and the Surgeon General has reported, many youth initiate tobacco use with flavored products. *See* DHHS, *Preventing Tobacco Use Among Youth and Young Adults: A Rep't of the Surgeon Gen.* 537–38 (2012), https://perma.cc/6EEU-PHH5 ("SG Rep't"). They get them hooked on nicotine, leading to deleterious and fatal health consequences. The tobacco companies want this Court to believe that, given what they characterize (at 10) as their "longstanding efforts to keep tobacco products away from youth," such measures are unnecessary. But the evidence shows just the opposite. Tobacco companies have long used flavors to attract youth and get new generations addicted to their products. SG Rep't at 538. So the City did what localities in the United States have had authority to do for over a century: it prohibited the sale of certain tobacco products. *See Austin v. Tennessee*, 179 U.S. 343, 362 (1900). Edina joined 300 local jurisdictions across the country and two states that have banned or restricted the sale of flavored tobacco products in order to curb youth use and protect the health and safety of their residents. CTFK, Fact Sheet (Oct. 23, 2020), https://perma.cc/JGX3-3VZP. No court in the country has held that any of these regulations is preempted by the TCA. Neither should this Court.

Unsurprisingly, then, the lower court held that the TCA does not preempt Edina's Ordinance. The TCA's provision on "preservation of state and local authority" contains three separate clauses: (1) a "preservation" clause, that clarifies local authority left undisturbed by the TCA, including the authority to regulate or "prohibit[] the sale . . . of tobacco products"; (2) a "preemption" clause, that reserves restrictions on manufacturers, including "product standards," to the federal government; and (3) a "savings" or "exception" clause, allowing local "requirements relating to the sale, . . . access to, . . . or use of, tobacco products by individuals of any age" even if they are otherwise covered by the preemption clause. Because all Edina's Ordinance does is place a "requirement[] relating to the sale" of tobacco products, the district court properly held that it falls within the savings clause. Amici adopt the City's arguments as to the savings clause and urge affirmance of the court's interpretation of that clause.

The district court, however, was wrong that the Ordinance fell within the preemption clause and needed to be "saved." Amici submit this brief to explain why Edina's regulation is not a "product standard"—as the district court erroneously construed it—and, hence, why it is not preempted even without resorting to the savings clause. Under the TCA, a "product standard" is a restriction on the manufacturer; for example, specifying the ingredients the manufacturer may use. Just like every other category mentioned in the TCA's

preemption clause, it is directed to manufacturers, and not to retail sales bans, which are explicitly reserved to local governments. Accordingly, no court in the country, except for the lower court here, has ever concluded that a state or local government's prohibition on flavored tobacco sales is a "product standard."

This Court should depart from the district court by following this unbroken line of authority and conclude that the Ordinance is not a "product standard." Affirming the lower court's view that the Ordinance is a product standard would part ways with every sister circuit and other court to reach the issue. And it would enlarge the scope of the TCA's preemption clause in ways that could upend the historic power of local governments to regulate tobacco sales. The Court should not, and need not, reach such a result.[2]

Furthermore, this Court should reject the plaintiffs' implied preemption argument. The tobacco industry relies on the FDA's inaction as to a nationwide ban on menthol to argue that a local government's decision to ban flavored product sales poses an "obstacle" to the national scheme. Not so. The TCA provides a framework for shared federal and local regulation of tobacco products,

[2] The district court's discussion of whether Edina's Ordinance is a "product standard" was dicta, as it was not necessary for the court's decision given that it upheld the Ordinance under the savings clause. It is still wrong and this Court should not split with every other circuit and district court on this issue, especially if it concludes (due to the savings clause) that reaching this issue is not necessary for the outcome of the case.

and local power cannot be displaced by the FDA's inaction. Adopting the plaintiffs' argument would expand obstacle preemption beyond its narrow moorings, threatening local authority not just as to tobacco restrictions, but also in other areas of public health.

INTEREST OF AMICI CURIAE

Amici curiae are twenty-five of the nation's leading nonprofit public health organizations. They are committed to supporting policies that educate the public about, and protect the public from, the devastating health consequences of tobacco.[3] Tobacco use remains the leading preventable cause of death nationally, killing more than 480,000 Americans annually. DHHS, *The Health Consequences of Smoking—50 Years of Progress: A Rep't of the Surgeon Gen.* 678 (2014), https://perma.cc/L4P8-SGVP. Flavored tobacco products—especially menthol—have played a key role in this epidemic because flavored products provide a gateway for youth to initiate tobacco use, getting each new generation addicted. SG Rep't (2012) at 537–539. The tobacco companies know that—that is why they fight so hard even against small municipalities that are trying to protect their constituents from these deadly products.

Amici are not just experts in public health, but in public health law. They have worked with governments at every level—Tribal, federal, state, and local—to

[3] A further description of each amicus is included as an addendum.

implement policies to protect health. Many of the amici were involved in the crafting of the TCA. Therefore, they are particularly well suited to address the role that state and local governments have historically played in tobacco control and how the TCA preserved that prominent role going forward.

ARGUMENT

I. The TCA preserved long-established state and local government authority over tobacco product sales within their borders.

State and local governments have a long and robust history of regulating and even prohibiting tobacco product sales, stretching back more than a century. The Supreme Court, in upholding Tennessee's ban on the sale of cigarettes in 1900, held that states were not "bound to furnish a market" for cigarettes, and instead could exercise their police powers to protect the health and welfare of their citizens, particularly youth, from the "deleterious" effects of smoking. *Austin*, 179 U.S. at 346, 348. The Court found it untenable to "force [cigarettes] into the markets of a state, against its will." *Id.* at 362. Fast forward 120 years and local jurisdictions are again prohibiting or limiting the sale of tobacco products to protect the health of their citizens, particularly youth. *See, e.g.*, Beverly Hills, Cal., Mun. Code 4-2-2101 *et seq.*; Manhattan Beach, Cal., Ordinance 20-0007. In the past decades, state and local governments have passed countless laws restricting and prohibiting the sale of tobacco products in various ways—prohibiting sales in vending machines, prohibiting sales near schools, prohibiting sales to those under 21 (even before the

federal statute), and, as Edina has done, restricting sales of flavored tobacco products. *See Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1190–91 (11th Cir. 2017) (en banc) (discussing historic and recent state and local tobacco restrictions). The history of tobacco regulation is, indeed, largely one of state and local action, as the FDA lacked authority to regulate tobacco products until Congress enacted the TCA in 2009.

The TCA, while it finally gave the FDA authority to regulate tobacco products, did not strip state and local governments of their historic police power to prohibit and restrict tobacco sales. "[T]he historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)) (alteration in original). Thus, to the extent there is any ambiguity in the scope of the TCA's preemption, the Court should "accept the reading that disfavors pre-emption." *Id.* (quoting *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)); *see Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

A. The TCA expressly preserves local government authority over tobacco retail sales.

The text of the TCA explicitly states that it is "preserving" for the states this historic power to adopt measures "relating to or prohibiting the sale" of tobacco

products, and it establishes only a narrow scope of preemption that does not infringe upon such power.

Section 916 of the TCA delineates the relationship between state and federal authority over tobacco products through three separate clauses. *First*, the "preservation clause" makes clear that the FDA does not have exclusive authority, or even have "primary" authority, as plaintiffs assert (at 3), in the area of tobacco control. Instead, the federal government sets the floor, and state and local governments can adopt their own regulations "with respect to tobacco products that [are] in addition to, or more stringent than," the FDA's rules, "including . . . [any] 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." 21 U.S.C. § 387p(a)(1).

Second, the preemption clause carves out eight limited exceptions to the preservation clause and reserves them to the FDA. These issues are of unique federal concern because they address the manufacture of tobacco products: "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." *Id.* § 387p(a)(2)(A).

Third, the savings clause provides an exception to the preemption clause, returning some authority to local governments even when they reach the eight

preempted areas. The preemption clause, it says, does "not apply to requirements relating to the sale . . . [of] tobacco products by individuals of any age." *Id.* § 387p(a)(2)(B).

The upshot: while the TCA gave the FDA authority to set national standards for tobacco products (something it previously had no authority over), it expressly codified that state and local governments are still free to be more protective than the national standard and—critical here—even restrict or prohibit tobacco sales within their jurisdictions. *Berger v. Philip Morris USA, Inc.*, 185 F. Supp. 3d 1324, 1335 (M.D. Fla. 2016), *aff'd sub nom. Cote v. R.J. Reynolds Tobacco Co.*, 909 F.3d 1094 (11th Cir. 2018) ("Although the federal government has chosen to regulate aspects of the cigarette industry while stopping *itself* short of banning cigarettes, it did not intend to force *the states* to accept that cigarettes must remain on *their* markets.").

Congress considered in earlier drafts of the TCA a more expansive preemption provision that would have invalidated local flavor prohibitions. But Congress rejected that approach. Instead, it decided to allow states and local governments to ban tobacco sales, either fully or as to certain products. As the Second Circuit detailed: "Earlier versions of § 907 would have expressly reserved to the federal government authority to ban the sale of entire categories of tobacco products." *See U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433 n.1 (2d Cir. 2013) (citing five previous drafts). "These draft versions of the

provision that ultimately became § 907(d)(3) were eventually rewritten to deny such power only to the FDA, and as enacted into law, this provision of the []TCA does not forbid such bans by state and local governments." *Id.*

Thus, the TCA did not overturn the historic power of local governments to eliminate tobacco product sales in their entirety or to restrict particular types of tobacco sales. Quite the opposite: the TCA expressly preserved that power.

B. The TCA only preempted local regulations that would force manufacturers to change their processes for each local jurisdiction.

The TCA's preemption clause bars state regulation of tobacco products only "narrowly," and focuses on one regulated entity—manufacturers. *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82 (1st Cir. 2013). As the text, structure, and purpose of the statute all demonstrate, the TCA "reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry." *U.S. Smokeless Tobacco Mfg. Co.*, 7087 F.3d at 434.

Congress was concerned about localities placing various and conflicting standards on manufacturers, which would require tobacco companies to make individualized products, apply separate labels, or follow unique processes for each jurisdiction that enacted a law. Accordingly, one of the articulated purposes of the TCA is "to authorize the [FDA] to set *national standards* controlling the *manufacture* of

tobacco products and the identity, public disclosure, and amount of ingredients used in such products." 21 U.S.C. § 387 note (emphasis added).

Looking to the text of the preemption clause, it is clear that each of the eight enumerated categories addresses the manufacture of tobacco products, not their sale at retail. For example, "premarket review" requires manufacturers to submit applications for new products, and requires the FDA to review "the components, ingredients, additives, and properties," as well as "the methods used in . . . the manufacture . . . of, [new] tobacco product[s]." 21 U.S.C. § 387j(b)(1). Similarly, "registration" is directed at persons who own or operate "any establishment . . . engaged in the manufacture, preparation, compounding, or processing of a tobacco product." *Id.* § 387e(b). The plaintiffs point to "labeling" (at 28), but that too is a component of manufacturing because a tobacco product includes its packaging. *See* 21 C.F.R. § 1140.3 (defining "manufacturer" as including one who "labels a finished tobacco product"); *id.* § 1143.3(a)(1) (making it "unlawful for any person to manufacture . . . such product unless the tobacco product package bears the . . . required warning statement on the package label."). "Adulteration" also targets manufacturers and the conditions where they make tobacco products. A tobacco product is "adulterated" if, among other things, "it has been prepared, packed, or held under insanitary conditions . . . ." *Id.* § 387b(2). The preemption of

"good manufacturing standards" speaks for itself—it also targets the manufacturers of tobacco products, not retail sellers.

This balance—between exclusive nationwide manufacturing standards and local sales control—is consistent with all of Congress's previous tobacco legislation that preceded the TCA. In previous acts, such as the Federal Cigarette Labeling and Advertising Act, Congress balanced strong local control with protecting manufacturers from having to redo their labels or revise their advertisements to comply with each local jurisdiction's proscription. And these previous enactments otherwise left intact local government authority to restrict and even fully prohibit tobacco sales. *See Graham*, 857 F.3d at 1187–88 (reviewing the six congressional statutes that preceded the TCA). Indeed, when the U.S. Supreme Court struck down one local government's decision to prohibit tobacco advertisements near schools—without requiring the manufacturer to change the content of the advertisements—Congress responded by clarifying that such local regulations were acceptable. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 80 (explaining that 15 U.S.C. § 1334(c) "was enacted in response to a portion of the *Lorillard* Supreme Court decision."). As long as such an ordinance does not force manufacturers to make new ads for every jurisdiction, it is not preempted. So too here. While the FDA is given exclusive authority to standardize manufacturing regulations

nationwide, consumer-retail sales provisions are still within state and local power. *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 434.

II. Edina's restriction on the sale of flavored tobacco products is not a "product standard" preempted by the TCA.

The district court improperly concluded that Edina's Ordinance amounts to a "product standard." Because the Ordinance only regulates sales and does not require manufacturers to create tobacco products in any specific way, it is not a "product standard."

A. The Ordinance is not a "product standard" because it does not require manufacturers to create tobacco products in any particular way.

Alongside the other categories of manufacturing regulations that the TCA preempts (discussed *supra*), the TCA bars state and local governments from establishing "product standards." 21 U.S.C. § 387p(a)(2)(A). The TCA does not specifically define what a "product standard" is but the text of § 907—describing existing and future product standards—as well as the structure of the TCA's preemption provisions, make plain that sales restrictions like Edina's Ordinance are not "product standards."

Consider the two "product standards" that Congress set forth in § 907 of the TCA—they are both "standards" that manufacturers have to meet in making their "product[s]." The first product standard states "a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not *contain*, as a constituent

(including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice." *Id.* § 387g(a)(1)(A) (emphasis added). This regulates the contents of cigarettes by dictating what manufacturers can put in cigarettes. The second product standard provides that a "tobacco product *manufacturer* shall not use tobacco . . . that *contains* a pesticide chemical residue that is" greater than a specific level. *Id.* § 387g(a)(1)(B) (emphasis added). Both of these can only be violated by the manufacturer.

In considering future "product standards," Congress directed the FDA to consider whether it was appropriate for public health to "require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because . . . the additive, constituent, or other component is or may be harmful." *Id.* § 387g(a)(3)(B)(ii). The focus, again, is on the ingredients a manufacturer is allowed to use in making the product. *See also id.* § 387g(a)(4)(A) (describing the "content" of product standards as including "the reduction or elimination of other constituents"). The preemption of local "product standards" therefore prevents local mandates that require manufacturers to create particular products or follow particular processes, not local decisions to prohibit sales of any existing products.

The tobacco industry, however, argues that sales restrictions like Edina's, if permitted, would allow localities to do an end-run around the TCA's preemption

of tobacco product standards. They argue that localities can in effect dictate product standards by banning sales of products with particular characteristics, even if they do not directly regulate the manufacturing process. RJR Br. at 32, 38. This argument, however, improperly conflates manufacturing and sale, which § 916 treats distinctly. *See U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 435 (rejecting industry's argument that sales bans are a "backdoor" to product standards because it would "collapse[] the distinction" between sales and product standards in § 916). To be sure, local sales regulations of all types may "have some effect on manufacturers' production decisions," but that does not convert them into "product standards." *Id.* A manufacturer's decision to change production in response to localities' sales restrictions is its choice; it is not a regulation (or "product standard") it must follow. *See id.*; *Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 83 n.11 ("Given Congress' decision to exempt sales regulations from preemption, whether those regulations have an impact on manufacturing is irrelevant."). "[T]o run afoul of the preemption clause, the ordinance must 'function[] as a command to tobacco manufacturers to structure their operations in accordance with local prescribed standards.'" *Independents Gas & Serv. Stations Ass'n v. Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill., 2015) (quoting *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 434).

The industry's argument also ignores that Congress explicitly preserved the right of local governments to enact measures "relating to or prohibiting the sale" of

tobacco products. 21 U.S.C. § 387p(a)(1). That language cannot be read out of the statute. As the Second Circuit concluded, the industry's "broad reading of the preemption clause . . . would render superfluous § 916's three-part structure, and in particular would vitiate the preservation clause's instruction that the Act not be 'construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any . . . measure . . . prohibiting the sale . . . of tobacco products.'" *U.S. Smokeless Mfg.*, 708 F.3d at 434 (quoting 21 U.S.C. § 387p(a)(1)). Congress could have allowed states and localities only time, place, and manner "requirements related to the sale" of tobacco products, as the industry argues is allowed. RJR Br. at 41. In other parts of the statute (e.g., respecting advertising) Congress allowed only time, place, and manner restrictions. *See* 15 U.S.C. § 1334(c). It did not do that with respect to sales. Its decision to explicitly preserve sales bans and restrictions must be honored.

Reading all the parts of the statute harmoniously, as a court must if possible, the resulting scheme is akin to a menu. The FDA regulates manufacturers, establishing the menu of products allowed to be sold on the market—including their ingredients, how they are made, and their labeling. Localities can't change the menu—they cannot mandate the chef make any substitutions or alterations—but nor are they required to order every item. While manufacturers are allowed to make any products permitted by federal regulations, including the FDA's product

standards, localities get to choose which of those products go on the shelves of its stores to be sold to its citizenry.

Edina's Ordinance, therefore, cannot be characterized as a "product standard." As the district court concluded, Edina's Ordinance "does not impose any manufacturing requirements" and "will not cause any manufacturer to change anything about the ingredients that it uses or anything else about the way it manufacturers its products." Add. 16. Based on this conclusion, the district court held that the Ordinance was a sales restriction, saved by the savings clause of § 916. It should have also recognized that Edina's Ordinance is not a "product standard," was never preempted in the first place, and was expressly preserved by the TCA.

B. No court in the nation, until the lower court here, has ever concluded that a ban on the sale of flavored tobacco products is a "product standard."

No court (except the district court below) has ever concluded that a restriction on the sale of flavored tobacco products constitutes a "product standard." To the contrary, both the First and Second Circuits have concluded that prohibitions on sales of flavored products are not "product standard[s]." *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82 (concluding that the city's flavor sales restrictions did not impose a new product standard); *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 434–35 (same). District courts outside of these circuits have reached the same conclusion. *See CA Smoke & Vape Ass'n, Inc. v. Cty. of Los Angeles*, No. CV-20-

4065, 2020 WL 4390384, at *6 (S.D. Cal. June 9, 2020) (agreeing with circuits "that a flavored tobacco ban is not a regulation of tobacco product standards"); *R.J. Reynolds Tobacco Co. v. Cty. of Los Angeles*, No. 20-4880, 2020 WL 4390375, at *6 (C.D. Cal. July 13, 2020) (same). *See also Indeps. Gas*, 112 F. Supp. 3d at 754 (Chicago's ordinance not preempted because it "regulates flavored tobacco products without regard for how they are manufactured").

The tobacco industry wants to paint this case as different. It isn't. The distinctions between Edina's Ordinance and any of the myriad flavor ordinances analyzed in these other cases are not materially different with respect to preemption. The industry is playing a semantics game: it characterizes Edina's ordinance as a "prohibition" and the other ordinances as "restrictions." RJR Br. at 41–42. But restrictions on sale "will always prohibit sale under certain circumstances, namely when the requirements . . . are not met." *Indeps. Gas*, 112 F. Supp. at 753. And Edina's Ordinance could likewise be characterized as a "restriction" on the sale of tobacco products; stores can sell tobacco products and are just restricted from selling those that have a non-tobacco taste or aroma. Regardless, this false distinction cannot stand in light of the TCA's express preservation of states' power to enact laws "relating to or prohibiting the sale . . . of tobacco products." 21 U.S.C. § 387p(a)(1). Accordingly, every one of these precedents has rejected the industry's preemption claims not based on whether the

ordinance was a prohibition or restriction, but instead based on the fact that the ordinances target retail sales, rather than mandate manufacturing standards. The critical factor in *all* these precedents is that the flavor ordinances did not direct which ingredients manufacturers may use, but instead restricted or prohibited the sale of a final product. Notably, the industry in each one of these cases made the exact same arguments as here, and those courts rejected them based on the text and structure of the TCA. This Court should do the same.

C. The district court's view that Edina's Ordinance is a product standard is based on flawed reasoning.

The lower court dismissed this unbroken line of precedents as "ipse dixit." Add. 7. These circuits and district courts analyzed the text, statutory structure, and purpose of the TCA. It is the district court's analysis that is flawed.

The district court misread the statutory language and pulled it out of context. In holding that Edina's sale's restriction was a "product standard," it relied first on the fact that the TCA says future product standards may include "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product." *Id.* (quoting 21 U.S.C. § 387g(a)(4)(B)(i)). Based on this text it reasoned that "[c]learly" product standards "are not limited to provisions that relate to manufacturing processes and components; they also include 'provisions respecting the . . . properties' of the tobacco product.'" *Id.* at 8. But the reference to

"properties" in § 387g(a)(4)(B)(i) is best understood as referring to like manufacturing standards, as with all the preceding categories listed in the provision. *In re Eilbert*, 162 F.3d 523, 527 (8th Cir. 1998) (when a word in a statute "is broad and generic, we apply the interpretive canons *noscitur a sociis* (a term is known from its associates) and *ejusdem generis* (general words in an enumeration are construed as similar to more specific words in the enumeration)"). If a "product standard" encompassed any local measure "respecting the . . . properties of the tobacco product" then there would be no room for local authority; the preemption provision would swallow the preservation clause and over 100-years of history whole. It would preempt even local indoor air ordinances (those "respect" a property of tobacco products—smoke).

The district court further erred in relying on the fact that the TCA states that product standards may "where appropriate" include provisions restricting the "sale and distribution" of a product. Add. 7 (citing 21 U.S.C. § 387g(a)(4)(B)(v)). The TCA sets forth many types of provisions that tobacco standards may include—those relating to "construction," "testing," "measurement," "labeling," and "sale and distribution." 21 U.S.C. § 387g(a)(4)(B)–(C). But that just means that tobacco product standards may *also* include "a provision related to the sale and distribution of the tobacco product to be restricted," just like they may also include a provision about testing or measurement. *Id.* § 387g(a)(4)(B)(v). But that does not

render every sales restriction a tobacco product standard, especially in light of the text in § 916 distinguishing sales and manufacturing requirements.

The district court also improperly relied on *National Meat Association v. Harris*, 565 U.S. 452 (2012), and *Engine Manufacturers Association v. South Coast Quality Management District*, 541 U.S. 246 (2004), to support its conclusion. Add. 9. Neither of the statutes in those cases had an express "preservation clause that directly exempted sales regulations from preemption," or otherwise had a textual basis for "the distinction between sales and manufacturing regulations [that] is clearly supported by [§ 916]." *Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82 n.10 And unlike the local law in *National Meat*, which "reache[d] into the slaughterhouse's facilities and affect[ed] its daily activities," even the district court here recognized that Edina's Ordinance did no such thing. *See U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 434. The sales restriction on non-conforming meat was meant to "help implement and enforce" separate manufacturing standards established by the local law. *Nat'l Meat*, 565 U.S. at 463–64. By contrast, there are no manufacturing standards in the Edina Ordinance. Unsurprisingly then, every other court analyzing flavor restrictions has rejected the tobacco industry's reliance on these precedents. *See also CA Smoke & Vape Ass'n*, 2020 WL 4390384, at *4; *Indeps. Gas*, 112 F. Supp. at 754.

III. Edina's Ordinance is not impliedly preempted because local sales bans on flavored tobacco products do not pose an obstacle to the FDA's regulatory authority.

Edina's Ordinance is also not impliedly preempted by the TCA. The tobacco industry argues that local restrictions on the sale of flavored tobacco products pose an "obstacle" to the federal scheme and particularly to the FDA's (unexercised) authority to restrict menthol-flavored products. But a locality's decision to be stricter than a national standard does not pose an "obstacle" to the scheme. As explained above, it is expressly allowed. The industry's argument rests on "broad atextual notions of congressional purpose, and even congressional inaction in order to pre-empt state law." *Wyeth*, 555 U.S. at 594 (Thomas, J., concurring). That fails the "high threshold" needed for obstacle preemption. *Chamber of Commerce v. Whiting*, 563 U.S. 582, 607 (2011).

A. There is a "high threshold" for obstacle preemption especially where Congress has explicitly preserved state authority.

The tobacco industry faces a high burden to prove implied obstacle preemption, especially where, as here, Congress expressly stated the scope of preemption it intended *and included a preservation clause*. Following an expressio unius logic, the Supreme Court has often found it "powerful evidence" that Congress decided to expressly preempt some state laws, but not the challenged law. *Wyeth*, 555 U.S. at 574-75 ("despite its 1976 enactment of an express pre-emption

provision . . . Congress has not enacted such a provision for [the challenged state law]"); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008) ("Congress could have applied the pre-emption clause [more broadly]. It did not do so."). There is even more powerful evidence here that Congress expected states to regulate tobacco sales alongside the federal government because it included a preservation and savings clause in the TCA. 21 U.S.C. § 387p.

Rather than look to what Congress has said, the tobacco industry invites this court to engage in "a freewheeling judicial inquiry" into whether it is good policy to prohibit menthol, but that "undercut[s] the principle that it is Congress rather than the courts that pre-empts state law." *Whiting*, 563 U.S. at 607. Given that obstacle preemption quashes duly-enacted state laws even where Congress has not textually expressed its intent to do so, courts strictly limit obstacle preemption to areas where state laws "directly interfere[] with the operation" of a federal program. *Id.* at 604. There is no such direct interference here.

B. Edina's Ordinance is not impliedly preempted by the FDA's inaction on menthol.

The industry's main implied preemption argument—which was properly rejected by the district court—is that "FDA to date has repeatedly decided *not* to prohibit menthol in cigarettes" and that the Ordinance "stands as an obstacle" to that decision. RJR Br. at 46. That is wrong on multiple counts.

First, the FDA has *not* made any decision with respect to whether to prohibit the sale of menthol cigarettes—and even represented as much in court earlier this month in a lawsuit seeking to force the FDA to make a decision whether to prohibit menthol cigarettes. Order, Dkt. 34, *AATCLC v. FDA*, No. 4:20-cv-04012-KAW, at 9 (N.D. Cal. Nov. 12, 2020) (the FDA "disclaimed any decision not to ban menthol"). Two years ago, in announcing an Advance Notice of Proposed Rulemaking to gather more data on the issue, the FDA expressed its intention "to ban menthol in combustible tobacco products, including cigarettes and cigars[.]" Statement from FDA Comm'r Scott Gottlieb (Nov. 15, 2018), https://perma.cc/L2R8-FHBT. At this point, then, the FDA has not yet formally issued any rule or determination as to menthol.[4] Because there is no FDA decision, the Ordinance could not possibly be an obstacle to it.

Second, even assuming that the FDA decided not to take action on menthol, such inaction could not form the basis for obstacle preemption. The industry's argument runs "contrary to settled law that inaction by [the federal government] cannot serve as justification for finding federal preemption of state law." *Graham*, 857 F.3d at 1190 (citing *Wyeth*, 555 U.S. at 602–03 (Thomas, J. concurring)). *See also Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) ("[A] Coast Guard decision

[4] Contrary to plaintiffs' argument, the fact that *the industry submitted comments* asserting *its own, self-interested and unfounded view* that a menthol ban would create an illicit market does not dictate what the *FDA* has decided. RJR Br. at 9 n.2, 48.

not to regulate a particular aspect of boating safety is fully consistent with an intent to preserve state regulatory authority . . . ."). "[O]therwise, deliberate federal inaction could always imply pre-emption, which cannot be. There is no federal pre-emption *in vacuo*, without a constitutional text or a federal statute to assert it." *P.R. Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1998). *See also Berger*, 185 F. Supp. 3d at 1337 (except for areas where Congress has occupied the field, "inaction alone cannot support an inference of preemption").

As the district court recognized, "the decision of a federal agency not to issue a *nationwide* regulation is not the same thing as a decision by Congress (or even that agency) that *state and local governments* should not be allowed to regulate." Add. 18. So even assuming arguendo that the FDA decides not to prohibit menthol nationally, that does not equate with Congress desiring state and local governments to be deprived their century-old power to prohibit tobacco product sales.

Lastly, were the Court to adopt the industry's implied preemption argument, it would have grave consequences for public health. "[I]nferring that a state-law prohibition frustrates the objectives of Congress whenever Congress chooses to regulate a product or activity, but stops itself short of enacting a complete ban, would represent a breathtaking expansion of obstacle preemption that would threaten to contract greatly the states' police powers." *Berger*, 185 F. Supp. 3d at 1337 (citing Micah Berman, *Eleventh Circuit Finds Tobacco Suits Preempted: Trouble for*

Future Public Health Regulations? YALE J. ON REG. (Apr. 19, 2015). All sorts of local regulations would be preempted just because Congress or an agency decided not to take such action at that time or decided to adopt more modest measures.

Autonomy for state and local governments to develop public health laws serves a valuable role "as laboratories for experimentation to devise various solutions where the best solution is far from clear." *United States v. Lopez*, 514 U.S. 549, 581 (1995) (Kennedy, J., concurring). Public health scholars recognize that "[s]tates serve a vital function as laboratories of legislative ingenuity in meeting the disparate public health needs across the nation." James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 356 (1998). "[R]esults from actual field implementations of laws . . . facilitat[e] diffusion of successful approaches to other jurisdictions, resulting in major improvements in population health." Alexander C. Wagenaar & Kelli A. Komro, NATURAL EXPERIMENTS: DESIGN ELEMENTS FOR OPTIMAL CAUSAL INFERENCE 24 (2011).

This iterative dynamic between the states and federal government is responsible for key nationwide public health measures. For example, lead paint is now a well-known toxin, but at the outset the federal government only banned lead paint in public housing. Baltimore, New York and other major cities took the first steps in enacting more complete bans on the use of lead paint, recognizing the huge dangers that lead poisoning presents to children. The federal government

followed the lead of states, and later banned lead paint use more generally in 1978. *See* 16 C.F.R. § 1303 (1977); Gerald Markowitz & David Rosner, LEAD WARS 29, 57 (2013). The same iterative process is true of trans fats, where the FDA first decided only to require nutrition labels to list trans fats, but then followed the lead of states that fully banned them. *See* 80 Fed. Reg. 34650 (June 17, 2015). These are just two examples.

Under the rule the industry proposes, these key public health measures may not have survived. These cities would have been preempted from enacting broader regulations because Congress chose not to and, in plaintiffs' view, it would pose an "obstacle" to the purported balance Congress sought. As these examples demonstrate, however, when Congress regulates in an area, or decides not to ban a product, state and local laws are not preempted unless Congress specifically intends to cut off state autonomy and experimentation. Courts presume that Congress does not want to disrupt state autonomy and dynamic federalism. *Wyeth*, 555 U.S. at 565. Particularly here, where Congress made plain in the preservation clause that state and local governments retain their historic power to regulate and prohibit tobacco sales, the district court correctly concluded that Edina's Ordinance is not impliedly preempted.

CONCLUSION

Amici respectfully request that this Court affirm.

Respectfully submitted,

/s/ Rachel Bloomekatz

Rachel Bloomekatz
1148 Neil Avenue
Columbus, OH 43201
(614) 259-7611
rachel@bloomekatzlaw.com
Counsel for Amici Curiae

December 2, 2020

CERTIFICATE OF COMPLIANCE

I hereby certify that my word processing program, Microsoft Word, counted 6492 words in the foregoing brief, exclusive of the portions excluded by Rule 32(f). This brief also complies with the typeface and type style requirements of Rules 32(a)(5) and 32(a)(6) because it appears in 14-point roman Baskerville, a proportionally spaced typeface.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

December 2, 2020

CERTIFICATE OF ELECTRONIC SUBMISSION

I hereby certify that any required privacy redactions have been made, the electronic submission of this document is an exact copy of any corresponding paper document, and the document has been scanned for viruses and is free from viruses.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

December 2, 2020

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2020, I electronically filed the foregoing brief by using the Appellate CM/ECF system. All participants are registered CM/ECF users and will be served by the Appellate CM/ECF system.

/s/ Rachel Bloomekatz
Rachel Bloomekatz

ADDENDUM: IDENTITY OF AMICI CURIAE

Public Health Law Center

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. The Center is particularly well-suited to address the scope of preemption under the TCA and the historic role local governments have played and continue to play in tobacco regulation. The Center has been involved with more than sixty briefs as amicus curiae filed in the highest courts in the United States and before international bodies.

Action on Smoking and Health

Action on Smoking and Health (ASH) is the nation's oldest anti-tobacco organization. ASH is dedicated to ending the global death, disease, and damage caused by tobacco consumption and nicotine addiction through public policy, litigation, and public education. The marketing and sale of tobacco products is a violation of basic human rights, and ASH works to end the tobacco epidemic by attacking its root—the tobacco industry.

African American Tobacco Control Leadership Council

The African American Tobacco Control Leadership Council (AATCLC) was formed in California in 2008. It educates the public about the effects of tobacco on Black American and African Immigrant populations, the tobacco industry's predatory marketing tactics, and need to regulate menthol cigarettes and all flavored tobacco products. To more effectively reach and save Black lives, AATCLC also partners with community stakeholders and public serving agencies to inform and direct tobacco control policies, practices, and priorities.

American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nonpartisan advocacy affiliate of the American Cancer Society. According to a recent study by American Cancer Society researchers, 19% of all cancers are

caused by smoking. Thus, ACS CAN advocates for comprehensive tobacco control by federal, state and local governments nationwide.

American Heart Association
The American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Its mission is to be relentless force for a world of longer, healthier lives.

American Lung Association
The American Lung Association is the nation's oldest voluntary health organization. It has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, including supporting eliminating the sale of all flavored tobacco products.

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. AMA members practice in every medical specialty and in every state, including Minnesota. The AMA and MMA join this brief on their own behalves and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

American Public Health Association
The American Public Health Association (APHA) champions the health of all people and all communities, strengthens the profession of public health, shares the latest research and information, promotes best practices, and advocates for public health policies grounded in research. APHA represents over 23,000 individual members and is the only organization that combines a nearly 150-year perspective and a broad-based member community with an interest in improving the public's health. APHA advocates for tobacco control measures to protect the public's health from the adverse effects of tobacco products.

American Thoracic Society
Founded in the 1905, the American Thoracic Society is a medical professional society comprised of over 16,000 physicians, scientists, nurses, respiratory therapists and allied health professionals dedicated to the prevention, detection, treatment, cure and research of pulmonary disease, critical care illness and sleep disordered breathing. The American Thoracic Society's members seek to improve health through research, education, clinical care and advocacy. As respiratory experts, its members are all too familiar with disease, death, and emotional destruction caused by tobacco products.

Americans for Nonsmokers' Rights
Americans for Nonsmokers' Rights (ANR) is a national non-profit tobacco control advocacy organization based in Berkeley, California. Since its formation in 1976, ANR has been dedicated to protecting nonsmokers' rights to breathe smokefree air in enclosed public places and workplaces and to preventing youth addiction to nicotine, including use of e-cigarettes and other flavored tobacco products. ANR represents a national constituency of over 12,000 individuals and organizations concerned about the health risks that tobacco and other nicotine products pose to the health and safety of smokers and nonsmokers alike and committed to reducing and preventing tobacco and e-cigarette use.

Asian Pacific Partners for Empowerment, Advocacy and Leadership
Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL) is a national organization working towards health and social justice for Asian American and Native Hawaiian and Pacific Islander (AA and NHPI) communities. Founded in 1994, APPEAL is dedicated to achieving racial and health equity for AAs and NHPIs and other marginalized communities. It has established itself as an important national network providing key advocacy, community building, leadership and resource development on commercial tobacco control, cancer prevention and healthy eating and active living issues.

Association for Nonsmokers—Minnesota
The Association for Nonsmokers—Minnesota (ANSR) is a statewide organization founded in 1973. It has led or participated in every statewide and most city/county tobacco use prevention initiatives since that time. ANSR supported the adoption of the Edina tobacco flavor restriction by providing research and educational materials to city staff and elected officials, educated community members on the issues and provided testimony to the council. ANSR led similar initiatives in Saint Paul, Minneapolis, Lauderdale, Bloomington, Hennepin County, Golden Valley, Fridley, Saint Louis Park, New Hope, and Arden Hills.

Blue Cross Blue Shield of Minnesota
Blue Cross and Blue Shield of Minnesota was chartered in 1933 as Minnesota's first health plan and continues to carry out its charter mission today as a health company: to promote a wider, more economical and timely availability of health services for the people of Minnesota. Blue Cross is a not-for-profit, taxable organization. Blue Cross and Blue Shield of Minnesota is an independent licensee of the Blue Cross and Blue Shield Association, headquartered in Chicago.

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 smoking, help smokers quit and protect everyone from secondhand smoke.

Center for Black Health and Equity
The Center for Black Health & Equity (formerly NAATPN, Inc.) is a national nonprofit organization that facilitates public health programs and services to benefit communities and people of African descent. It is committed to addressing social, political and economic injustices that have marginalized African American voices and led to deep health disparities in African American communities. For over a decade, the Center has operated as one of eight designated national networks under the CDC's Office on Smoking and Health. In this capacity, the Center provides tobacco control leadership in the African American community. Its expert comment, research, and education have resulted in cities and institutions adopting smoke-free policies and flavor restrictions.

ChangeLab Solutions
ChangeLab Solutions is a national organization that advances equitable laws and policies to ensure healthy lives for all. ChangeLab Solutions prioritizes communities whose residents are at highest risk for poor health. Its multidisciplinary team of lawyers, planners, policy analysts, and other professionals works with state and local governments, advocacy organizations, and anchor institutions to create thriving communities.

ClearWay[SM]
ClearWay Minnesota[SM] is a private, independent nonprofit corporation created in 1998 with a limited lifetime, ending in 2021 (subject to court approval). The mission of ClearWay Minnesota is to enhance life in Minnesota by reducing tobacco use and exposure to secondhand smoke through research, action and

collaboration. ClearWay Minnesota's work has encompassed public policy, research, cessation, community development, and marketing and communications activities, and over the past two decades has helped bring about outcomes including adult and youth smoking declines, billions of dollars in medical costs and worker productivity saved, and thousands of deaths, cancers and hospitalizations prevented.

Massachusetts Association of Health Boards

The mission of the Massachusetts Association of Health Boards (MAHB) is to assist and support boards of health in meeting their statutory and service responsibilities, through programs of education, technical assistance, representation, and resource development. Massachusetts Boards of Health are responsible under general laws, state, and local regulations for disease prevention and control, health and environmental protection, and promoting a healthy community.

Minnesota Medical Association

The Minnesota Medical Association (MMA) is a non-profit professional association representing more than 10,000 physicians, residents, and medical students in Minnesota. The MMA seeks to be the leading voice of medicine to make Minnesota the healthiest state and the best place to practice. The MMA advances health and health system change; fosters physician resilience, trust, and community; improves physician efficacy; and convenes physicians and partners to address emerging critical issues. For more than 165 years, the MMA and its members have worked together to safeguard the quality of medical care in Minnesota and to improve the health of all Minnesotans. The MMA has long worked to reduce the harmful effects of tobacco and to limit minors' access to tobacco products.

National LGBT Cancer Network

The National LGBT Cancer Network is home to the CDC-funded Tobacco Related Cancer Project. This national network aims to reduce tobacco and cancer-related disparities in LGBTQ+ populations. It accomplishes this by:

- administering a national network of partners, including CDC-funded tobacco and cancer programs, national organizations, and state and local departments of health;
- providing training and technical assistance to network members & CDC grantees;
- increasing the reach of national, state, tribal, territorial, and local interventions; and

- increasing the reach of mass health communications through tailored messaging.

Additionally, it leverages its network of LGBTQ+ partner organizations, coalitions, and grassroots movements to actively participate in their local jurisdictions. Through the provision of educational resources and tailored materials, LGBTQ+ individuals are engaged as key stakeholders in developing tobacco policies that enhance the health of their communities.

National Native Network

The National Native Network is a network of Tribes, tribal organizations, and tribal-serving programs across the U.S. working to decrease the burden of cancer and commercial tobacco health disparities in American Indian and Alaska Native (AI/AN) communities.

Parents Against Vaping e-cigarettes

Founded in 2018 by three moms as a grassroots response to the youth vaping epidemic, Parents Against Vaping e-cigarettes (PAVe) is a national advocacy and education organization powered by parent volunteers fighting to protect our kids from the dangers of flavored e-cigarettes and the predatory practices of Big Tobacco.

Public Health Advocacy Institute

The Public Health Advocacy Institute (PHAI) is a legal research center focused on public health law at Northeastern University School of Law. PHAI's goal is to support and enhance a commitment to public health in individuals and institutes who shape public policy through law. It is committed to research in public health law, public health policy development; to legal technical assistance; and to collaborative work at the intersection of law and public health. PHAI's current areas of work include tobacco control and childhood obesity.

Public Health and Tobacco Policy Center

The Public Health and Tobacco Policy Center is a resource for communities striving to improve public health through implementing evidence-based policies. The Center provides legal and technical support for policies that reduce the availability of and market for tobacco products; reduce unwanted exposure to secondhand smoke; minimize exposure to tobacco advertising and promotion; increase cancer screening rates; and promote healthy behaviors. The Center is housed in the Public Health Advocacy Institute at the Northeastern University School of Law. The Center dedicates its legal and advocacy expertise to improve

the understanding, commitment, and effectiveness of policymakers and lawyers to protect public health.

Truth Initiative

Truth Initiative is a national public health organization that is inspiring tobacco-free lives and building a culture where all youth and young adults reject smoking, vaping and nicotine. The truth about tobacco and the tobacco industry are at the heart of its proven-effective and nationally recognized truth® public education campaign, its rigorous and scientific research and policy studies, and its innovative community and youth engagement programs supporting populations at high risk of using tobacco. The Washington D.C.-based organization, formerly known as the American Legacy Foundation, was established and funded through the 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories and the tobacco industry.