No. 20-55930

In the
United States Court of Appeals for the Ninth Circuit

R.J. REYNOLDS TOBACCO COMPANY, ET AL.
Plaintiffs-Appellants,
v.

COUNTY OF LOS ANGELES, ET AL.,
Defendants-Appellees.

On Appeal from the United States District Court
for the Central District of California, No. 2:20-cv-4880 (Hon. Dale S. Fischer)

BRIEF OF AMICI CURIAE PUBLIC HEALTH LAW CENTER, ACTION ON SMOKING AND HEALTH, CALIFORNIA STATE ASSOCIATION OF COUNTIES, CHANGELAB SOLUTIONS, INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION, INTERNATIONAL MUNICIPAL LAWYERS ASSOCIATION, LEGAL RESOURCE CENTER FOR PUBLIC HEALTH POLICY, NATIONAL ASSOCIATION OF COUNTIES, NATIONAL LEAGUE OF CITIES, PUBLIC HEALTH ADVOCACY INSTITUTE, AND U.S. CONFERENCE OF MAYORS IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

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

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INTRODUCTION[1]

Los Angeles County's Ordinance does one thing—it prohibits tobacco *retailers* from selling certain flavored tobacco products within the County's borders. Tobacco *manufacturers* can still make their products with whatever processes, ingredients, components, filters, and other properties they choose, so long as they are complying with federal regulations. The Ordinance does not require the manufacture of any special cigarette, cigar, vape product, or chew tobacco. And the County does not even prohibit the possession or use of flavored tobacco products within its borders. Nor does it prohibit the manufacture of any flavored tobacco products in its jurisdiction. Instead, what the Ordinance mandates is that of all tobacco products that manufacturers place in the stream of commerce, some—those imparting a distinct non-tobacco taste or aroma—cannot be sold within its borders. That's it.

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 reserved to the Food and Drug Administration (FDA). *See* 21 U.S.C. § 387g, p. Thus, as the district court held, the Ordinance is not preempted.

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[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.

Los Angeles County, following the Surgeon General's reporting, determined that this Ordinance was necessary to reduce youth access to flavored tobacco. *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"). Flavors hook youth on nicotine, leading to deleterious and fatal health consequences. The tobacco companies want this Court to believe that, given what they characterize as their "longstanding efforts to keep tobacco products away from youth," such measures are unnecessary. RJR Br. at 13. 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 County 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).

Los Angeles County joined 300 local jurisdictions across the country and two states that have banned or restricted the sale of flavored tobacco products to curb youth use and protect the health and safety of their residents. CTFK, Fact Sheet (Oct. 23, 2020), https://perma.cc/JGX3-3VZP. And the tobacco companies have sued many of them—states, municipalities, counties, and townships, large and small. No court in the country has held that any of these regulations is preempted by the TCA. Unsurprisingly the lower court here agreed. Undeterred, the tobacco companies continue to argue that these hundreds of local laws—including 101 laws

within the Ninth Circuit's jurisdiction—should be invalidated. *Id.* This Court too should reject the industry's plea. Reversing the lower court would not only part ways with every other sister circuit and court to reach the issue, but it would endanger hundreds of democratically enacted state and local public health laws targeted at protecting vulnerable groups.

Given the threat to local public health regulation, amici submit this brief first to explain why Los Angeles County's regulation is not a "product standard" and, hence, why it is not expressly preempted by the TCA. Under the TCA, a "product standard" is a restriction on the manufacturer; for example, specifying the ingredients the manufacturer may use. Like every other category mentioned in the TCA's preemption clause, a product standard is directed to manufacturers and to pre-market activities—not to retail sales bans, which are explicitly preserved for local governments. Adopting the tobacco industry's interpretation 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.

Furthermore, this Court should reject the plaintiffs' argument that the Ordinance is impliedly preempted because it poses an "obstacle" to the FDA's decision to allow flavored tobacco products on the market. That argument was wrong when made, and is now upended by the FDA's announcement that it will propose a rule banning the manufacture of menthol cigarettes and cigars. Press

Release (April 29, 2021), https://perma.cc/QDA4-KYRW. Forced to backtrack, the industry will no doubt attempt to reframe its argument. But however it attempts to do so should be rejected. Regardless of the FDA's decisions, the TCA provides a framework for shared and often overlapping federal and local regulation of tobacco products that allows local governments to be more protective than the FDA. Adopting the plaintiffs' argument would expand obstacle preemption beyond its narrow moorings, threatening local authority not only as to tobacco restrictions, but also in other areas of public health.

INTEREST OF AMICI CURIAE

Amici curiae are 11 of the nation's leading nonprofit organizations supporting state and local government authority to protect public health. They are committed to supporting democratically enacted policies by state and local governments that educate the public about, and protect the public from, the devastating health consequences of tobacco.[2] 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

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

products provide a gateway for youth to initiate tobacco use, getting each new generation addicted. SG Rep't (2012) at 537–539.

Amici submit this brief to protect the authority of state and local governments to enact public health measures regarding tobacco products that will protect their communities. Amici recognize that local governments play a historic and critical role in protecting the health of their communities. Each community has a different experience with health concerns, even with respect to tobacco control. Various social groups—based on age, race, sexual orientation, income, history of tobacco-industry targeting, and intersections of these and other factors—may be more or less likely to use tobacco products and may use different products. Because of these variations, state and local governments may determine that different approaches are necessary to address the health needs and advance health equity in their communities. And the TCA empowers them to do so. The tobacco industry's efforts to expand the scope of the TCA's preemption would hamper local democratic efforts to address public health and health equity—the opposite of the power Congress explicitly "preserved" and "saved" for state and local governments in the TCA.

To forward local democracy and public health, amici have worked with governments at every level—Tribal, federal, state, and local—to implement policies to protect health. 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, even after the TCA in 2009. 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 Los Angeles County 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). Some localities have banned sales of cigarettes and vape products entirely from retail stores. *See, e.g.*, Beverly Hills, Cal., Mun. Code 4-2-2101 *et seq.*; Manhattan Beach, Cal., Ordinance 20-0007. 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, 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 "primary" authority (as plaintiffs assert at 2, 9) 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 manufacturing stage before a product hits the market: "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. *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, contrary to the industry's argument, 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. Nothing in the TCA says localities cannot "absolutely prohibit such sales." RJR Br. at 5. Quite the opposite: the TCA expressly preserved that power, courts have upheld it, and hundreds have localities have duly enacted ordinances doing just that.

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 or premarket stage 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 . . . ." 21 U.S.C

§ 387b(2). The preemption of "good manufacturing standards" speaks for itself—it also targets the manufacturers of tobacco products, not retail sellers. The same is true of "modified risk tobacco products"—*manufacturers* submit information to the FDA to prove a product has reduced risk to consumers and only then can it go to market as a modified risk product. *See* 21 U.S.C. § 387k.

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. Here too manufacturers are not forced to make new products for each jurisdiction. While the TCA gave the FDA exclusive authority to standardize manufacturing regulations nationwide and the regulatory process to bring a product to market, consumer-retail sales provisions are still within state and local power. *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 434.

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

Following the unique structure of the TCA, the district court rejected the industry's argument that the Ordinance should be considered a preempted "product standard." This Court should affirm.

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 define a "product standard" 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 the County's 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 that "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 the protection of 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.

B. The industry's contrary arguments are wrong.

The industry makes three primary arguments to demonstrate that the Ordinance is a "product standard"—all are wrong.

First, the industry relies 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." RJR Br. at 26 (quoting 21 U.S.C. § 387g(a)(4)(B)(i)). The word "properties," it contends, means an "attribute" like a flavor, and hence, it concludes, any regulation about a flavor must be a product standard. But, because a word is known by the company it keeps (noscitur a sociis), the reference to "properties" in section 387g(a)(4)(B)(i) is best understood as referring to manufacturing standards akin to all the preceding categories listed in the provision.

More critically, while a product standard may "include[] provisions respecting . . . properties" of a tobacco product, that doesn't mean that all regulations relating to "properties" of cigars, cigarettes, or vape products are deemed preempted "product standards." The TCA also says that future product standards may "include . . . a provision regarding sale," but not even the tobacco industry can contend that all sales restrictions (i.e., a law raising the cigarette sales age) amount to "product standards." Nor does a "product standard" encompass any local measure "respecting the . . . properties of the tobacco product," as plaintiffs argue. If so, localities' decisions to

tax cigars differently than cigarettes would be a "product standard" (i.e., excise taxes depend on the item's weight and whether it is wrapped in paper or tobacco, an "attribute" of the product). *See, e.g.*, Cal. Revenue and Taxation Code § 30003. So too localities' decisions to prohibit e-cigarette sales would be a "product standard" (i.e., sales depends on the type of nicotine delivery system a product utilizes—an "attribute"—including whether the product produces smoke or whether nicotine is aerosolized or vaporized). *See, e.g.*, San Francisco Health Code § 19S.2. There would be no room for local authority if "product standard" were defined so expansively; the preemption provision would swallow the preservation clause and over one hundred years of history.

Second, the tobacco industry argues that allowing sales restrictions like the County's enables 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 32–36. 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). The industry claims that there is "no practical difference between telling a manufacturer that it may not

add an ingredient that imparts a flavor to a product and telling a manufacturer that it may not sell [that product]," RJR Br. at 21—but that is wrong. The County has not told the tobacco industry it cannot make products imparting non-tobacco flavor. It can do so, even in factories in Los Angeles County. And it can sell them to any locality where it is legal.

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." *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 435. That is because 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.'" *Indep. 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).

This is not a situation, as in *National Meat Association v. Harris*, where the sales restriction on non-conforming meat was meant to "help implement and enforce" the law's *separate* manufacturing standards which prohibited processing

meat in a particular way. The law there was a "command [to companies] to structure their operations in the exact way" the law mandated. 565 U.S. 452, 463–64 (2012).

The industry's argument also ignores that, unlike in *National Meat*, 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 2, 22. 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 for sales. Its decision to explicitly preserve sales bans and restrictions must be honored.

Third, the tobacco industry argues that the TCA preempts the Ordinance because otherwise there would be a "hodgepodge" of local regulations regarding tobacco products. RJR Br. at 6, 57. But the TCA explicitly allows—and expects—a

"hodgepodge" of sales restrictions and prohibitions; amici don't call it a "hodgepodge," they call it federalism and local democracy. And while the TCA may have ensured that tobacco manufactures got a "single set" of manufacturing standards, *id.* at 10, that does not insulate the industry from varying *retail* restrictions in differing jurisdictions. Indeed, the industry's repeated concession that localities can maintain different time, place, and manner restrictions on all or some tobacco product sales undercuts its argument that the TCA must be read to avoid a so-called "hodgepodge." Just as localities can choose to prohibit certain flavored tobacco sales near a school (as the plaintiffs admit they can at 2), they can also choose to prohibit such sales entirely (as the Ordinance does). Neither is a product standard because neither forces manufacturers to follow a different standard. The inconsistency in the industry's argument reveals its folly.

The TCA's scheme is like a menu. The FDA regulates manufacturers, establishing the menu of products allowed 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, localities get to choose which of those products go on the shelves of their stores to be sold to their citizenry.

C. No circuit court has ever concluded that a ban on the sale of flavored tobacco products is a "product standard."

No circuit court 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 County'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 these circuits have reached the same conclusion, including the lower court here. *See, e.g.*, *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"). *But see RJR v. City of Edina*, 482 F. Supp. 3d 875 (D. Minn. 2020) (appeal pending).[3]

The tobacco industry wants to paint this case as different. It isn't. The distinctions between Los Angeles County'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 semantic game: it characterizes the County's

[3] The district court in *City of Edina* held that the city's flavor ordinance was not preempted because of the TCA's savings clause. Though the district court stated that it thought the ordinance constituted a "product standard,"—the only court in the entire country to do so—that discussion was dicta, as it was not necessary for the court's decision given that it upheld the ordinance under the savings clause.

ordinance as a "prohibition" and the other ordinances as "restrictions." RJR Br. at 30. 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 the County'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.[4] Regardless, this false distinction cannot stand given 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 because the flavor ordinances did not direct which ingredients manufacturers may use. The industry in each of these cases made the same arguments as here, and those courts rejected them based on the text and structure of the TCA. This Court should do the same.

III. Los Angeles County'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.

Moving from the statute's text, the plaintiffs make a last-ditch implied preemption argument resting on the fact that the FDA had not banned menthol

[4] For this same reason, the Ordinance is a "requirement relating to the sale" of tobacco products and falls within the TCA's savings clause. Amici adopt the County's argument as to the savings clause. *See* Cty Br. at 45.

cigarettes, while the Ordinance prohibits all menthol-flavored tobacco product sales. RJR Br. at 50 ("local governments . . . do not have such power with regard to menthol tobacco products"). But—whether looking at the question from the time the plaintiffs briefed the issue, or now, after the FDA announced its intention to ban menthol in combustible tobacco products—the industry cannot satisfy the "high threshold" needed for obstacle preemption. *Chamber of Comm. 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. Courts, then, do not have to discern whether

local regulation may be antithetical to the statutory scheme; Congress already said—except in expressly preempted areas—it is not.

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. *Whiting* at 604. There is no such direct interference here.

B. The 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 50. The FDA's decision, it turns out, is the exact opposite.

Even when the tobacco industry filed its brief, it was disingenuous to represent that the FDA had decided not to ban menthol. The FDA was in the process of contemplating a menthol ban, had made no decision, and expressly "disclaimed any decision not to ban menthol" in a recent lawsuit. Order, Dkt. 34, *AATCLC v. FDA*, No. 4:20-cv-04012-KAW, at 9 (N.D. Cal. Nov. 12, 2020). The credibility of the industry's argument is further undermined because the FDA has since announced its intention to promulgate a rule banning the sale of menthol cigarettes and cigars. Press Release (April 29, 2021), https://perma.cc/QDA4-KYRW. This announcement only underscores what Los Angeles County knows: menthol tobacco

products are harmful to public health, particularly for youth and minority groups. Far from being an obstacle, the Ordinance is consistent with the FDA's indication that it will move forward with promulgating a rule to prohibit menthol cigarettes and cigars. And, to the extent a locality decides to be stricter than a national standard, it does not pose an "obstacle" to the scheme, especially here, where the TCA expressly sanctions local restrictions that are "different from, or in addition to" FDA regulations. 21 U.S.C. § 387p(a)(2)(A).

Moreover, even if after the rulemaking process the FDA decides not to take action on menthol, that inaction could not support 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)). "[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). Quite simply, the decision of a federal agency not to issue a *nationwide* regulation is not the same thing as a decision that *state and local governments* should not be allowed to regulate. And the TCA was clear that local governments have that power. In short, regardless of the FDA's action as to menthol, the Ordinance stands.

C. The industry's implied preemption argument would have grave consequences for local public health laws that often serve as policy laboratories.

The industry's implied preemption argument, if adopted, would have grave consequences for public health law because it would invalidate all local laws that are more protective than federal regulations. "[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 and other key public health measures may not have survived.

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 Los Angeles County's Ordinance is not impliedly preempted.

CONCLUSION

Amici respectfully request that this Court affirm.

Respectfully submitted,

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FOR THE NINTH CIRCUIT

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I hereby certify that on May 14, 2021, 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.

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ADDENDUM: IDENTITY OF AMICI CURIAE

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 (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.

The **California State Association of Counties** (CSAC) is a non-profit corporation. The membership consists of the 58 California counties. CSAC sponsors a Litigation Coordination Program, which is administered by the County Counsels' Association of California and is overseen by the Association's Litigation Overview Committee, comprised of county counsels throughout the state. The Litigation Overview Committee monitors litigation of concern to counties statewide and has determined that this case is a matter affecting all counties.

ChangeLab Solutions works across the nation to advance equitable laws and policies that ensure healthy lives for all. With more than two decades of experience in enacting policy, systems, and environmental changes at local and state levels, ChangeLab Solutions focuses on eliminating health disparities by addressing the social determinants of health. ChangeLab Solutions is an interdisciplinary team of lawyers, planners, policy analysts, public health practitioners, and other professionals who collaborate with community-based organizations, local and state governments, and anchor institutions to create thriving, just communities. ChangeLab Solutions supports communities across the country in the development, adoption,

implementation, and enforcement of laws and policies that advance tobacco-related health equity, including laws prohibiting the sale of menthol cigarettes and other flavored tobacco products.

The **International City/County Management Association** (ICMA) is a nonprofit professional and educational organization of more than 9,000 appointed chief executives and assistants serving cities, counties, towns, and regional entities. ICMA's mission is to create excellence in local governance by advocating and developing the professional management of local governments throughout the world.

International Municipal Lawyers Association (IMLA) has been an advocate and resource for local government attorneys since 1935. Owned solely by its more than 2,500 members, IMLA serves as an international clearinghouse for legal information and cooperation on municipal legal matters.

The **Legal Resource Center for Public Health Policy** (LRC) at the University of Maryland Francis King Carey School of Law provides technical legal assistance on a wide-range of public health issues, including tobacco regulation. In addition, the LRC works closely with state agencies such as the Office of the Comptroller and the Office of the Attorney General. Established in 2001, the LRC offers legal guidance to state and local governments, legislators, non-governmental organizations, health advocacy groups, and Maryland residents.

The **National Association of Counties** (NACo) is the only national organization that represents county governments in the United States. Founded in 1935, NACo provides essential services to the nation's 3,069 counties through advocacy, education, and research.

The **National League of Cities** (NLC) is dedicated to helping city leaders build better communities. NLC is a resource and advocate for 19,000 cities, towns, and villages, representing more than 218 million Americans.

The interest of the **Public Health Advocacy Institute** (PHAI) in this case arises from its mission to improve public health by reducing the use of and exposure to tobacco products in the United States. A 501(c)(3) since 1979, PHAI has experience in tobacco control issues generally, as well as longstanding and specific expertise in tobacco litigation and public health.

The **U.S. Conference of Mayors** (USCM), founded in 1932, is the official nonpartisan organization of all United States cities with a population of more than 30,000 people, which includes more than 1,200 cities at present. Each city is represented in USCM by its chief elected official, the mayor.