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TOBACCO INDUSTRY TRIES, BUT FAILS, TO ARGUE FEDERAL PREEMPTION IN FIGHT TO BAN FLAVORED PRODUCTS

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DESPITE DECADES OF LOCAL, STATE, TRIBAL, AND FEDERAL EFFORTS to limit or discourage the sale of tobacco, it remains the leading cause of preventable death in the United States. Recognizing the significant role that flavored tobacco products play in luring impressionable young people into a lifetime of nicotine dependency,¹ policymakers have begun to limit or ban the sale of flavored tobacco. As of October 2022, at least 5 states, 360 localities, and 3 tribes restricted the sale of flavored tobacco products.² These policies contributed significantly to reduced tobacco use,³ denting tobacco industry profits.⁴

These efforts have not gone unnoticed by the tobacco industry, which has turned to the courts to argue that the federal Family Smoking Prevention and Tobacco Control Act (TCA)—landmark federal legislation adopted by Congress in 2009—preempts state and local restrictions on flavored tobacco products. To date, these efforts have been unsuccessful. Every court that has considered whether the TCA preempts state and local flavored tobacco restrictions has rejected the tobacco industry’s arguments.

Turning to the courts is not new for the tobacco industry, which has long used preemption arguments to thwart state and local efforts to reduce tobacco-related mortality and morbidity. But this trend is notable because recent court losses have not deterred the tobacco industry from challenging new restrictions. Even though the TCA is clear, continued legal challenges create uncertainty as to whether states and localities can restrict the sale of flavored tobacco products. This uncertainty may have a chilling effect on state and local control efforts, especially in litigation-averse jurisdictions.

This publication explains how the tobacco industry has invoked preemption under the TCA to challenge state and local limits on flavored tobacco—and why states and localities are on firm ground to regulate flavored tobacco products. The TCA is not a bar to jurisdictions that want to protect their communities from the scourge of flavored tobacco products.

Every court that has considered whether the Tobacco Control Act preempts state and local flavored tobacco restrictions has rejected the tobacco industry’s arguments.

A BRIEF HISTORY OF FEDERAL REGULATION OF TOBACCO

HISTORICALLY, STATES HAVE LED THE WAY IN REGULATING TOBACCO, with the federal government playing a limited role. Tobacco regulation falls within state traditional police powers to protect the welfare, health, and safety of the public.⁵ Successful state policies, in turn, informed federal legislative and regulatory action.⁶ Recognizing the role of state regulation in combating the tobacco epidemic, many tobacco laws enacted by Congress have explicitly addressed preemption.

The federal government's regulation of tobacco did not begin in earnest until the 1960s. Even then, these efforts focused on consumer education and warning labels. Following the 1964 Surgeon General's report finding that cigarette smoking caused various diseases such as lung cancer and heart disease,⁷ the federal government undertook modest measures to minimize the health harms of tobacco.⁸ In 1965, Congress enacted the Federal Cigarette Labeling and Advertising Act (FCLAA),⁹ which required cigarette packages to include health warnings.¹⁰ The FCLAA explicitly preempted state laws on tobacco labeling and advertising, invoking the need to ensure national uniformity in cigarette labeling and advertising.¹¹ Congress updated these cigarette warnings in subsequent legislation in 1970,¹² 1984,¹³ and 1986.¹⁴ The latter law, the Comprehensive Smokeless Tobacco Health Education Act, explicitly preempted state warnings on smokeless tobacco packaging and advertisements.¹⁵

More aggressive regulation followed a landmark Surgeon General report on nicotine addiction in 1988¹⁶ as well as studies showing that consumer education was inadequate because consumers—mostly children—became addicted to nicotine before they could fully appreciate the risks of tobacco use. The advancements in the scientific research of nicotine and its effect on developing brains prompted Congress's shift from a consumer-education-centered approach to prevention. In 1992, through the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act—known as the Synar Amendment—Congress conditioned states' eligibility for receiving certain federal funds on the states raising the minimum legal sales age of tobacco to at least 18 years.¹⁷

Then, in 1996, the FDA sought to regulate tobacco products after concluding that nicotine was a “drug” and cigarettes and smokeless tobacco were “devices” under the Food, Drug, and Cosmetic Act (FDCA).¹⁸ In *FDA v. Brown & Williamson Tobacco Corp.*, however, the Supreme Court struck down the FDA's regulations, holding, in 2000, that Congress had not given the FDA power to regulate tobacco products under FDCA.¹⁹

Nearly a decade later, Congress enacted the TCA to address the regulatory gap created by the *Brown & Williamson* decision and adopted various public health measures to mitigate tobacco health harms. Among its other provisions, the TCA prohibits flavors—except menthol—in cigarettes.²⁰ Congress, however, gave the FDA the authority to ban menthol in cigarettes through administrative rulemaking.²¹ For over a decade following the TCA's enactment, the FDA declined to do so. But in April 2021, following a suit against the FDA for its failure to prohibit menthol in cigarettes,²² the FDA issued a proposed rule to ban menthol in cigarettes in May 2022.

The TCA did not explicitly ban the use of flavors in types of tobacco products *other than* cigarettes (e.g., cigars, cigarillos, smokeless tobacco, etc.). Instead, the TCA empowered the FDA to adopt “tobacco product standards” to protect public health.²³ Congress did not define “tobacco

product standard,” the scope of which is being refined through the court decisions discussed below. Following the enactment of the TCA, the FDA considered addressing other flavored tobacco products, but it did not take any affirmative steps to remove them from the market.²⁴ In May 2022, the FDA issued a proposed rule to ban all flavors (including menthol) in cigars.²⁵

PREEMPTION AND THE TCA

UNDER THE SUPREMACY CLAUSE,²⁶ federal laws (including regulations) prevail over—and thus preempt—conflicting state laws.²⁷ Preemption can either be express or implied. The FCLAA, for instance, expressly preempts state laws that impose other health warnings on cigarette packages and advertising.²⁸ Even in cases when Congress has expressly preempted state law, courts may still determine the scope and effect of the express preemption.²⁹ State and local laws may be impliedly preempted if the structure and purpose of federal law implicitly precludes additional state regulation.³⁰

The TCA expressly preempts specified state tobacco regulations. Recognizing the pivotal role that states play in tobacco regulation, Congress balanced the need for streamlined national regulation while explicitly preserving state authority to adopt more stringent regulations on the sale of tobacco products.³¹

Narrow preemption of state and local laws. Congress recognized the FDA’s gatekeeping role in regulating tobacco products entering the stream of commerce. Thus, under the TCA, the FDA sets national standards for manufacturing tobacco products, labeling and warnings, and the ingredients used in such products.³² To maintain this role, the TCA bars state and local laws that implicate specified national interests. The TCA thus preempts state and local laws that differ from, or exceed, federal requirements for tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products. The scope of the TCA’s preemption clause is therefore narrow and bans only state or local limits that would set standards in eight limited categories that differ from those established at the federal level.³³

Explicit deference to state and local laws. The TCA’s narrow preemption is made even clearer by the TCA’s “preservation” and “savings” clauses where Congress explicitly preserved the role of states and localities in addressing tobacco’s health harms. Here, Congress made clear that the TCA does not displace state or local authority to adopt a wide range of tobacco regulations—including measures that are “in addition to, or more stringent than, requirements established” under the TCA. This allows the continuation of state or local measures to prohibit the “sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards.”³⁴ These types of state and local laws are not preempted by the TCA.

The TCA carefully balances national, state, and local regulatory interests. The FDA maintains its authority to regulate the national tobacco market, while states and localities may adopt more robust public health regulations.

EFFORTS BY THE TOBACCO INDUSTRY TO PREEMPT RESTRICTIONS ON FLAVORED TOBACCO

THAT THE TCA'S PREEMPTION SCOPE IS NARROW has not stopped the tobacco industry's relentless efforts to thwart state and local flavored tobacco regulation efforts. Preemption litigation has focused mainly on whether state and local flavored tobacco sales regulations are expressly or impliedly preempted by the TCA—or whether these limits are sales restrictions that are protected by the preservation and savings clauses.

In arguing express preemption, the tobacco industry has claimed that flavored tobacco sales restrictions are tobacco product standards because they require manufacturers to tailor their operations to meet local restrictions and reduce the overall production of flavored products. This effect on manufacturing, they argue, means the sales restrictions function as tobacco product standards or good manufacturing standards that are therefore preempted by the TCA.

To date, the First, Second, and Ninth Circuit Courts of Appeal—as well as a district court in Illinois—have rejected these arguments. These courts have uniformly concluded that the TCA's preemption standard is narrow and, as the Second Circuit put it in *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, the TCA should “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.”³⁵

The courts have concluded that state and local restrictions—including bans on all flavored tobacco products without exemptions—are not tobacco product standards under the TCA. These restrictions do not require tobacco manufacturers to change how they make their products.³⁶ And the fact that a restriction *affects* a manufacturer's production decision does not convert a sales restriction into a manufacturing standard.³⁷ Put simply, most courts have declined to interpret “product standard” so broadly as to include restrictions on retail sales.³⁸

That the Tobacco Control Act's preemption scope is narrow has not stopped the tobacco industry's relentless efforts to thwart state and local flavored tobacco regulation efforts

CASE	TYPE OF RESTRICTION*	YEAR OF ADOPTION	SUMMARY OF RESTRICTION	COURT DECISION
U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York	Partial Restriction	2009	New York City restricted the sale of flavored non-cigarette tobacco products, with exemptions for menthol tobacco products and sales within certain tobacco bars	New York City's restriction upheld by the Second Circuit (2013)
National Association of Tobacco Outlets, Inc. v. City of Providence	Partial Restriction	2012	Providence (Rhode Island) restricted the sale of non-cigarette tobacco products, with exemptions for certain smoking bars	Providence's restriction upheld by the First Circuit (2013)
Indeps. Gas & Serv. Stations Ass'n v. City of Chicago	Partial Restriction	2013	Chicago restricted the sale of flavored tobacco products (including menthol cigarettes) within 500 feet of a school, with exemptions for tobacco retail stores that derived at least 80% of gross revenue from tobacco products	Chicago's restriction upheld by a federal district court in Illinois (2015)
R.J. Reynolds v. Los Angeles County	Comprehensive Restriction	2019	Los Angeles County prohibited the sale of all flavored tobacco products (including menthol) within the unincorporated areas of the county	Los Angeles County's ban upheld by the Ninth Circuit (2022)
R.J. Reynolds Tobacco Co. v. City of Edina	Comprehensive Restriction	2020	Edina (Minnesota) prohibited the sale of all flavored tobacco products (including menthol)	Edina's ban upheld by a federal district court in Minnesota (2020)

* A "comprehensive restriction" restricts all flavors—including menthol—in all tobacco products. A "partial restriction" is short of comprehensive and exempts menthol or applies to only a limited class of tobacco products or in limited settings.

Even if restrictions on flavored tobacco sales could be considered a tobacco product standard—a conclusion reached by a district court in Minnesota—these laws would still be valid under the TCA's "savings" clause because they relate to the sale of a product. In *City of Edina*, the district court agreed with the tobacco industry that the city's sales restriction was a tobacco product standard—because it concerned flavors, a property of tobacco products—and was therefore preempted.³⁹ But the ordinance was still valid under the TCA's savings clause because it was a sales restriction. The court rejected the industry's argument that the TCA's savings clause must be limited to age-based or time, place, and manner sale restrictions. Rather, all sales restrictions—including a comprehensive ban of classes of tobacco products—are saved from preemption under the TCA.

The courts have concluded that state and local restrictions—including bans on all flavored tobacco products without exemptions—are not tobacco product standards under the Tobacco Control Act.

THE LATEST DECISION ON FLAVORS AND PREEMPTION: *R.J. REYNOLDS V. LOS ANGELES COUNTY*

Undeterred by earlier court decisions, the tobacco industry recently challenged a Los Angeles County ordinance prohibiting the sale of all flavored tobacco products. This ban, industry argued, was a “paradigmatic tobacco product standard” and therefore expressly preempted under the TCA.

In 2022, the Ninth Circuit—like all prior courts—rejected this argument. Under the TCA, a product standard refers only to “standards pertaining to the production and marketing stages up until the point of sale.” Interpreting “product standard” so broadly as to include restrictions that indirectly affect tobacco standards, as the industry argued it should, would gut the TCA’s preemption clause.

Even if the term “tobacco product standard” were to be read broadly, it would still be permissible because the TCA saves sales restrictions from preemption. Because the Los Angeles County ordinance prohibited the sale of flavored tobacco products throughout the county, it related to the sale of tobacco products and therefore fell squarely within the meaning of the “savings” clause. The Ninth Circuit therefore answered the question left open in earlier cases—by affirming that a total ban on a class of tobacco products was permissible under the TCA.

The Ninth Circuit also rejected the industry’s argument that the ordinance’s ban on the sale of menthol cigarettes was impliedly preempted. The industry argued that the TCA’s exemption of menthol required menthol cigarettes to remain on the market, which preempted Los Angeles County’s ban on the sale of menthol cigarettes. The court rejected this argument, finding that the TCA does not mandate that menthol cigarettes remain on the market and that the TCA explicitly allows states to adopt more stringent tobacco sales restrictions than those set by federal law.

On October 7, 2022, the tobacco industry asked the Supreme Court to overturn the Ninth Circuit’s decision, reiterating the same preemption arguments rejected by the lower courts. It remains to be seen whether the Supreme Court will agree to hear the case.

For implied preemption, the industry has focused on the regulation of menthol under the TCA. As noted above, Congress authorized the FDA to regulate menthol in cigarettes. Until recently, however, the FDA did not take any affirmative steps to remove menthol cigarettes from the market. The tobacco industry has thus argued that Congress intended for menthol-flavored products remain on the market. Thus, state and local bans on the sale of menthol products impede this federal objective and are impliedly preempted.

The two courts that addressed this issue have rejected these arguments, holding that the federal government's decision not to address menthol cigarettes and flavored e-cigarettes could not be construed as a decision that those products should remain on the market. And inaction by Congress and the FDA is not a federal mandate that products be available for purchase without any barriers. Without any such federal obligation, local bans on menthol are not impliedly preempted.

WHAT COULD THE FDA DO?

Although it has not yet done so, the FDA could issue guidance explicitly affirming state and local authority to regulate flavored tobacco products under the TCA. This type of guidance could help assure litigation-averse communities that restrictions on flavored tobacco sales—such as those adopted above—do not conflict with the FDA's regulatory role and are thus not preempted. Moreover, such an interpretation would align with all the courts that have addressed this issue.

CONCLUSION

For over a decade, the tobacco industry has deployed a preemption litigation strategy to thwart state and local efforts to minimize tobacco-related mortality and morbidity. The courts' rejection of the tobacco industry's preemption claims under the TCA has not deterred the tobacco industry from mounting litigation challenges. Even with more decisions on the horizon, these lawsuits lack merit. Every federal court that has considered whether the TCA preempts state or local flavored tobacco restrictions has rejected the tobacco industry's arguments. States and localities should continue to protect their communities and regulate or ban flavored tobacco products, and the FDA should explicitly affirm that states and localities retain this authority and will not be preempted by the TCA.

The FDA could issue guidance explicitly affirming state and local authority to regulate flavored tobacco products under the Tobacco Control Act.

ENDNOTES

- 1 Andrea C. Villanti et al., *Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014)*, 53 Am. J. Prev. Med. 139 (2017), doi:10.1016/j.amepre.2017.01.026.
- 2 Laura Bach, *Flavored Tobacco Sales Restrictions: Promising Evidence for Reducing Youth Access and Tobacco Use*, Campaign for Tobacco-Free Kids (Sept. 29, 2022), <https://tinyurl.com/2p83kkek>; Truth Initiative, *Flavored tobacco policy restrictions* (Mar. 31, 2022), https://truthinitiative.org/sites/default/files/media/files/2022/05/Q1_2022_FINAL.pdf.
- 3 Melody Kingsley et al., *Impact of flavoured tobacco restriction policies on flavoured product availability in Massachusetts*, 29 Tobacco Control 175 (2020), doi:10.1136/tobaccocontrol-2018-054703.
- 4 Doris G. Gammon et al., *Implementation of a comprehensive flavoured tobacco product sales restriction and retail tobacco sales*, Tobacco Control (June 4, 2021), doi:10.1136/tobaccocontrol-2021-056494.
- 5 *Austin v. Tennessee*, 179 U.S. 343 (1900).
- 6 Tobacco Control Legal Consortium, Pub. Health L. Ctr., *Untangling the Preemption Doctrine in Tobacco Control* (2018), <https://publichealthlawcenter.org/sites/default/files/resources/Untangling-the-Preemption-Doctrine-in-Tobacco-Control-2018.pdf>.
- 7 U.S. Surgeon Gen.'s Advisory Comm. on Smoking & Health, U.S. Dep't of Health, Educ., & Welfare, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* 30 (1964), <https://www.govinfo.gov/content/pkg/GPO-SMOKINGANDHEALTH/pdf/GPO-SMOKINGANDHEALTH.pdf>.
- 8 Although there were legislative efforts to grant the FDA the authority to regulate tobacco products following the Surgeon General's report, these legislative efforts failed. See H.R. 2248, 89th Cong., 1st Sess. (1965) ("a bill to amend the Federal Food, Drug, and Cosmetic Act so as to make that act applicable to smoking products.").
- 9 Pub. L. No. 89-92, 79 Stat. 282 (1965).
- 10 *Id.* at 283 ("Caution: Cigarette Smoking May Be Hazardous to Your Health.").
- 11 15 U.S.C. § 1331(2); *Cipollone v. Liggett Grp.*, 505 U.S. 504, 519 (1992) (noting that FCLAA's preemption of state labeling and advertising regulations "reflected Congress' efforts to prevent 'a multiplicity of State and local regulations pertaining to labeling of cigarette packages.'").
- 12 The Public Health Cigarette Smoking Act additionally prohibited the advertising of cigarettes on radio and television or any medium of communication under the jurisdiction of the Federal Communications Commission. Pub. L. No. 91-222, 84 Stat. 87 (1970).
- 13 The Comprehensive Smoking Education Act required a series of warning labels to appear on cigarette packages and advertisements rotationally. Pub. L. No. 98-474, 98 Stat. 2200 (1984).
- 14 The Comprehensive Smokeless Tobacco Health Education Act extended the packaging and advertising warning requirements and FCC restriction to smokeless tobacco. Pub. L. No. 99-252, 100 Stat. 30 (1986).
- 15 15 U.S.C. § 4406(b).
- 16 U.S. Surgeon Gen., U.S. Dep't of Health & Human Servs., *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General* (1988), <https://profiles.nlm.nih.gov/spotlight/nn/catalog/nlm:nlmuid-101584932X423-doc>.
- 17 Pub. L. No. 102-321, 106 Stat. 323 (1992). In 2019, Congress raised this age to 21 years.
- 18 *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, 61 Fed. Reg. 44396, 44396-618 (Aug. 28, 1996).
- 19 *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).
- 20 21 U.S.C. § 387g(a)(1)(A).
- 21 21 U.S.C. § 387g(a)(2).
- 22 *Afr. Am. Tobacco Control Leadership Council v. HHS*, 571 F. Supp. 3d 1144 (N.D. Cal. 2021).
- 23 21 U.S.C. § 387g(a)(3).
- 24 In 2020, the FDA took modest steps to regulate flavored e-cigarettes, but those products remain on the market. See FDA-2019-D-0661, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Apr. 2020), <https://bit.ly/3H2sZxs>.
- 25 Andrew Twinamatsiko, *FDA Proposes Action on Menthol Cigarettes and Flavored Cigars*, Health Affairs Forefront (May 13, 2022), <https://bit.ly/3MswpKL>.
- 26 U.S. CONST. art. VI, cl. 2. ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land.").
- 27 *Gibbons v. Ogden*, 22 U.S. 1 (1824).
- 28 15 U.S.C. § 1334(b); see *Cipollone v. Liggett Grp.*, 505 U.S. 504 (1992) (holding that FCLAA preempted state causes of action based on failure to warn because those claims relied on omissions or inclusions in federally mandated warnings in cigarette advertising).

- 29 Cipollone v. Liggett Grp., 505 U.S. 504 (1992) (addressing whether the FCLAA preempted tort claims against the tobacco industry for misrepresentation, intentional fraud, and breach of express warranty); see *also* Lorillard Tobacco Co. v. Riley, 533 US 525 (2001) (the Court had to determine whether FCLAA preempted states from adopting time, place, and manner cigarette advertising regulations).
- 30 Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). There are two categories of implied preemption: (i) field preemption—which occurs when federal law is so thorough and pervasive that it forecloses additional state regulation; and (ii) conflict preemption—which occurs when state law makes it impossible to comply with federal law or impedes the achievement of federal objectives. Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 363 (2000).
- 31 21 U.S.C. § 387p.
- 32 Pub. L. 111-31, Div. A, § 2, June 22, 2009, 123 Stat. 1776 (2009).
- 33 R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 553-54 (9th Cir. 2022).
- 34 21 U.S.C. § 387p(a)(1).
- 35 U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 434 (2d Cir. 2013).
- 36 *Id.*
- 37 *Id.*
- 38 R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th at 554.
- 39 R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 879 (D. Minn. 2020) (reasoning that tobacco product standards included “provisions respecting the properties of the tobacco product and restrictions on the sale and distribution of the tobacco product.”).