States Don't Need to Wait for FDA to Adopt Nicotine Reduction Endgame Strategies: Lessons from Flavored Tobacco Litigation

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ABSTRACT

Tobacco is the leading cause of preventable death, accounting for approximately 480,000 deaths per year in the United States. Nicotine—the identified drug in tobacco—is highly addictive, comparable to cocaine and heroin. Nicotine sustains tobacco use, causing repeated exposure to toxicants and carcinogens. The risk of nicotine addiction depends on the dose of nicotine delivered and how it is delivered.[1] Children and young adults are especially vulnerable to nicotine's addictiveness because their brains are still developing, and they may not fully appreciate the risks of tobacco use and addiction. For these reasons, policy makers have adopted several measures to prevent tobacco use initiation, such as raising the minimum legal sales age for tobacco products, restricting the sale of kid-friendly flavored tobacco products, and raising the prices of tobacco products. While these measures have helped achieve a great deal of success in the fight against the tobacco epidemic, there is more to be done. Because of nicotine's addictiveness, it becomes important to seek more robust measures to ensure that these highly addictive products are removed from the market. One such measure is prohibiting the sale of tobacco products whose nicotine levels exceed specified thresholds. In June 2022, the U.S. Food and Drug Administration (FDA) announced its plans to propose a product standard that would establish maximum nicotine levels in cigarettes and other finished tobacco products. It is uncertain when a concrete regulatory measure will materialize from this announcement. But states need not wait for FDA action—they can use their traditional police power to regulate nicotine levels in cigarettes. This will not only minimize death and disease from tobacco products, but it will also create an evidence base for federal action and political momentum for such regulation across the county. Although reducing the level of nicotine could be considered a tobacco product standard, whose regulation is preserved only for FDA, litigation related to federal

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[1] U.S. DEP'T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING—50 YEARS OF PROGRESS: A REPORT OF THE SURGEON GENERAL 109 (2014), https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf [hereinafter 2014 SURGEON GENERAL'S REPORT].

preemption of state flavored tobacco laws has shown that states can permissibly restrict the sales of categories of tobacco products, including banning categories of highly addictive tobacco products.

I. STATES AND TOBACCO POLICY EXPERIMENTATION

States have been described as "laboratories of democracy" in our federalist structure.[2] The history of public health policy experimentation at the state level in tobacco regulation exemplifies that description. Tobacco regulation falls within the states' inherent police power to protect the welfare, health, and safety of the people.[3] Throughout the years, states have adopted various innovative tobacco policies—such as smoke-free laws, minimum legal sales age restrictions, minimum price laws, and flavored tobacco sales restrictions—to minimize tobacco health harms. Successful policy experimentation in some states and localities has spurred other jurisdictions to enact similar or even more robust policies. Policy experimentation and replication at the state and local levels has also prompted the federal government to adopt similar policies.[4] Many of the federal tobacco point-of-sale policies restrictions, such as prohibiting tobacco sampling and use of tobacco vending machines, were first adopted at the state level and subsequently adopted by FDA. Indeed, when Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) in 2009, it drew upon the experience of state tobacco regulation.[5]

There has been a tremendous growth in the number of jurisdictions across the United States—mostly local governments—adopting flavored tobacco sales restrictions. Today, at least three Native American Tribes, five states, and over 375 localities have laws that restrict selling flavored tobacco products in some way.[6] In turn, these policies have significantly contributed to lowering tobacco use,[7] and

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[2] *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.").

[3] *See* Austin v. Tennessee, 179 U.S. 343 (1900) (holding that banning cigarettes was wholly within the state's power to preserve public health and safety); Packer Corp. v. Utah, 285 U.S. 105, 108 (1932) ("It is not denied that the state may, under the police power, regulate the business of selling tobacco products.").

[4] *Untangling the Preemption Doctrine in Tobacco Control*, PUB. HEALTH L. CTR. (Apr. 2018), https://publichealthlawcenter.org/sites/default/files/resources/Untangling-the-Preemption-Doctrine-in-Tobacco-Control-2018.pdf.

[5] *See* Paul A. Diller, *Why Do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 WASH. U. L. REV. 1219, 1231–36 (2014) (discussing various policies, including graphic warnings, flavored tobacco, use of tobacco vending machines, previously developed by political subdivisions of states that were eventually adopted at the federal level); 21 U.S.C. § 387g(a)(1)(A) (prohibiting flavors in cigarettes). *See also* 15 U.S.C. § 1333 note (directing the Secretary of the U.S. Department of Health and Human Services (HHS) to issue regulations identifying graphic warnings).

[6] *Fact Sheet: States and Localities that have Restricted the Sale of Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Apr. 19, 2022), https://tinyurl.com/2p83kkew [hereinafter CTFK, *Fact Sheet*]; *Flavored Tobacco Policy Restrictions*, TRUTH INITIATIVE (Sept. 26, 2023), https://truthinitiative.org/sites/default/files/media/ files/2022/05/Q1_2022_FINAL.pdf.

[7] *See generally* Melody Kingsley, Glory Song, Jennifer Robertson, Patricia Henley & W. W. Sanouri Ursprung, *Impact of Flavoured Tobacco Restriction Policies on Flavoured Product Availability in Massachusetts*, 2 TOBACCO CONTROL 175–82 (Mar. 29, 2020), https://tobaccocontrol.bmj.com/content/29/2/175.info.

consequently dented the tobacco industry's profits.[8] To stymie these public health efforts, the tobacco industry has turned to the courts.[9] The tobacco industry has unsuccessfully tried to use the courts to derail state and local policies that restrict the sale of flavored tobacco, mainly arguing that those restrictions conflict with the TCA and are therefore preempted.

Limiting state and local tobacco regulation through preemption has long been a tobacco industry goal.[10] And, to that end, the tobacco industry has consistently argued that the TCA preempts state and local flavored tobacco sales restrictions. But every court that has addressed this argument has ruled against the tobacco industry, finding that the TCA does not preempt states from restricting the sale of flavored tobacco.[11] This litigation—including the U.S. Supreme Court's recent denial of R.J. Reynolds' petition for certiorari in litigation involving a Los Angeles County flavored tobacco ordinance—has clarified the complementary roles of FDA and states in regulating flavored tobacco. What is more, these court decisions ultimately show how states can adopt even more robust endgame strategies—especially

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[8] Doris G. Gammon, Todd Rogers, Jennifer Gaber, James M. Nonnemaker, Ashley L. Feld, Lisa Henriksen, Trent O. Johnson, Terence Kelley & Elizabeth Andersen-Rodgers, *Implementation of a Comprehensive Flavoured Tobacco Product Sales Restriction and Retail Tobacco Sales*, 31 TOBACCO CONTROL 104–10 (June 4, 2021), https://tinyurl.com/2p8xsmvw.

[9] Additionally, the tobacco industry has sponsored referenda to reverse flavored tobacco legislation. *See* Patrick McGreevy, *California's Ban on Flavored Tobacco Sales Blocked as Referendum Qualifies for Ballot*, L.A. TIMES (Jan. 21, 2021), https://tinyurl.com/4brtasj6; Stanton A. Glantz, *RJ Reynolds Tobacco Continues to Be Sole Funder of Prop E, the Company's Effort to Repeal San Francisco's Prohibition on Selling Flavored Tobacco Products*, CTR. FOR TOBACCO CONTROL RSCH. & EDUC. (Apr. 28, 2018), https://tinyurl.com/yc4tdexw; Ryan J. Degan, *Livermore Voters to Decide Fate of City's Attempted Ban on Flavored Tobacco*, PLEASANTONWEEKLY.COM (Sept. 10, 2019), https://tinyurl.com/4u5tmwvj.

[10] Andrew A. Skolnick, *Cancer Converts Tobacco Lobbyist: Victor L. Crawford Goes on the Record*, 274 J. AM. MED. ASS'N 3. 199–202 (July 19, 1995), https://tinyurl.com/ynff6awy ("[T]he Tobacco Institute and tobacco companies' first priority has always been to preempt the field, preferably to put it all on the federal level, but if they can't do that, at least on the state level, because the health advocates can't compete with me on a state level."); *see, e.g.*, Cipollone v. Liggett Grp., Inc., 505 U.S. 504 (1992) (challenging state tort claims based on Federal Cigarette Labeling and Advertising Act (FCLAA) preemption); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (relying on FCLAA preemption to challenge outdoor advertising of tobacco); Graham v. R.J. Reynolds Tobacco Co., 857 F.3d 1169 (11th Cir. 2017) (arguing the federal laws regulating tobacco preempted state-law-based tort claims); Philip Morris Inc. v. Harshbarger, 122 F.3d 58 (1st Cir. 1997) (claiming that FCLAA and Comprehensive Smokeless Tobacco Health Education Act preempted Massachusetts' nicotine yield disclosure laws).

[11] *See* Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, 731 F.3d 71, 82 (1st Cir. 2013); U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 431 (2d Cir. 2013); Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 753 (N.D. Ill. 2015); GoodCat, LLC v. Cook, 202 F. Supp. 3d 896 (S.D. Ind. 2016); R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, No. CV 20-4880 DSF (KSX), 2020 WL 5405668 (C.D. Cal. Aug. 7, 2020), *aff'd*, 29 F.4th 542 (9th Cir. 2022); CA Smoke & Vape Ass'n, Inc. v. Cnty. of Los Angeles, No. CV 20-4065 DSF (KSX), 2020 WL 5440561 (C.D. Cal. Aug. 7, 2020); Neighborhood Mkt. Ass'n, Inc. v. Cnty. of San Diego, 529 F. Supp. 3d 1123 (S.D. Cal. 2021); R.J. Reynolds Tobacco Co. v. Cnty. of San Diego, 529 F. Supp. 3d 1147 (S.D. Cal. 2021); R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542 (9th Cir. 2022), *cert. denied*, 143 U.S. 979 (2023); R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875 (D. Minn. 2020), *aff'd*, 60 F.4th 1170 (8th Cir. 2023); R.J. Reynolds Tobacco Co. v. Bonta, No. 22-CV-01755-CAB-WVG, 2022 WL 16986580, (S.D. Cal. Nov. 15, 2022), *aff'd*, No. 22-56052, 2023 WL 2010990 (9th Cir. Jan. 27, 2023).

prohibiting the sale of tobacco products with high nicotine yields—without intruding on FDA's regulatory territory.[12]

This Article argues that states (and their political subdivisions) can permissibly adopt more robust endgame strategies—specifically restricting the sale of highly addictive tobacco products—within the confines of the TCA's preemption framework. First, the Article explores the history of federal tobacco regulation, while showing the important role the states have played in combating tobacco-related death and disease. Then it maps out specific provisions of the TCA, showing how Congress has given FDA authority to regulate tobacco products while ensuring states retain their traditional public health power over those products. It outlines the regulation of flavored tobacco on federal and state levels and then synthesizes the flavored tobacco cases that have been litigated over the last decade, parsing out how the courts have distinguished impermissible product standards from permissible sales restrictions. The Article then concludes by showing that based on the decisions in the flavored tobacco litigation, the TCA's text, and principles of federalism, states can permissibly adopt regulations on nicotine yields under the TCA without flouting the TCA's preemption provisions.

II. HISTORY OF FEDERAL REGULATION OF TOBACCO

Tobacco regulation in the United States has historically been at the state level, with the federal government playing a limited role. Tobacco regulation falls within the heartland of state traditional police powers, and the Supreme Court has long held that states have the authority to ban the sale of tobacco products.[13] The federal government's regulation of tobacco did not take off until the 1960s. Following the 1964 Surgeon General's report finding that cigarette smoking caused various diseases such as lung cancer and heart disease,[14] the federal government undertook modest measures to minimize the health harms of tobacco.[15] At the time, there was limited knowledge about nicotine's addictiveness, therefore most of the efforts went to educating consumers so that they made "informed" decisions.[16]

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[12] Endgame in this context refers to a combination of policy strategies that envision an end to the tobacco epidemic. *See* Ruth E. Malone, *Tobacco Endgames: What They Are and Are Not, Issues for Tobacco Control Strategic Planning and a Possible U.S. Scenario*, 22 TOBACCO CONTROL J. 1 (Apr. 15, 2013), https://tobaccocontrol.bmj.com/content/22/suppl_1/i42.

[13] Austin v. Tennessee, 179 U.S. 343 (1900).

[14] U.S. DEP'T OF HEALTH, EDUC. & WELFARE, PUB. HEALTH SERV., NO. 1103, 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.

[15] Although there were legislative efforts to grant 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").

[16] 2014 SURGEON GENERAL'S REPORT, *supra* note 1, at 23. The term "informed" here is used tongue-in-cheek because it implies deliberate, rational, autonomous choice. But due to tobacco's addictiveness, tobacco use is hardly a product of deliberate, rational, autonomous choice. *See* Joseph R. DiFranza, Judith A. Savageau, Kenneth Fletcher, Judith K. Ockene, Nancy A. Rigotti, Ann D. McNeill, Mardia Coleman & Constance Wood, *Measuring the Loss of Autonomy over Nicotine Use in Adolescents: The DANDY (Development and Assessment of Nicotine Dependence in Youths) Study*, 156 ARCHIVES OF PEDIATRIC & ADOLESCENT MED. 4, 397–403 (Apr. 2002), https://pubmed.ncbi.nlm.nih.gov/11929376/.

Embracing a consumer-education approach, Congress enacted the Federal Cigarette Labeling and Advertising Act (FCLAA) in 1965,[17] which required cigarette packages to bear health warnings.[18] At the same time, states were also adopting their own laws to address tobacco labeling and advertising. But Congress preempted these state laws to ensure national uniformity in cigarette labeling and advertising.[19] Congress updated the cigarette warning in 1969 when it enacted the Public Health Cigarette Smoking Act (PHCSA),[20] which also prohibited the advertising of cigarettes on radio and television or any medium of communication under the jurisdiction of the Federal Communications Commission (FCC). FCLAA was again amended in 1984 when Congress passed the Comprehensive Smoking Education Act (CSEA), which required a series of warning labels to appear on cigarette packages and advertisements rotationally.[21] In 1986, Congress enacted the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) and extended the packaging and advertising warning requirements and FCC restrictions to smokeless tobacco.[22] The CSTHEA also preempted state warnings on smokeless tobacco packaging and advertisements.[23]

Soon after, in 1988, the Surgeon General issued a report on nicotine addiction.[24] At the same time, studies continued to show that consumer education was inadequate to curb addiction because consumers—who were mostly children—became addicted to nicotine through experimentation before they could fully appreciate the risks of tobacco use. The advancements in the science of nicotine and its effect on developing brains prompted Congress' shift from a consumer education-centered approach to prevention. For that reason, to prevent youth access to tobacco products, Congress enacted the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act—known as the Synar Amendment—in 1992. Through the Synar Amendment, Congress conditioned state eligibility for certain grants on the states raising the minimum legal sales age of tobacco to at least eighteen years.[25]

Soon after that, in 1996, FDA—finding that nicotine was a "drug" and cigarettes and smokeless tobacco were "devices" under the Federal Food, Drug, and Cosmetic Act (FDCA)—sought to regulate tobacco products.[26] In *FDA v. Brown & Williamson Tobacco Corp.*, however, the Supreme Court struck down FDA's regulations,

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[17] Pub. L. No. 89-92, 79 Stat. 282 (1965).

[18] *Id.* § 4, 79 Stat. at 283 ("Caution: Cigarette Smoking May Be Hazardous to Your Health.").

[19] 15 U.S.C. § 1331(2); Cipollone v. Liggett Grp., Inc., 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'").

[20] Pub. L. No. 91-222, 84 Stat. 87 (1970). The updated warning stated: "Warning: The Surgeon General Has Determined That Smoking Is Dangerous to Your Health."

[21] Pub. L. No. 98-474, 98 Stat. 2200 (1984).

[22] *See* Pub. L. No. 99-252, 100 Stat. 30.

[23] 15 U.S.C. § 4406(b).

[24] *See generally* 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. The report concluded that nicotine was comparable to other addicting drugs such as heroin and cocaine.

[25] Pub. L. No. 102-321, 106 Stat. 323 (1992).

[26] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,615–18 (Aug. 28, 1996).

holding that Congress had not given FDA power to regulate tobacco products under FDCA.[27] Subsequently, in 2009, Congress enacted the TCA, adopting various public health measures to mitigate tobacco health and social harms and explicitly authorizing FDA to regulate tobacco products and "to set national standards controlling the manufacture of tobacco products."[28] Congress also directed FDA to re-issue the regulations that were invalidated in *Brown & Williamson*.[29] Using this authority, FDA has adopted various tobacco regulations, including deeming regulations for e-cigarettes, cigars, and other tobacco products[30] and issuing graphic warnings on cigarettes.[31]

III. FLAVORED TOBACCO REGULATION AND TCA PREEMPTION

A. Flavored Tobacco Under the TCA

When Congress enacted the TCA, it established a special rule for cigarettes. That rule prohibits flavors—except menthol—in cigarettes.[32] So while it is illegal to sell flavored cigarettes, it does not violate federal law to sell menthol cigarettes. But the TCA gives FDA the authority to revise this special rule and ban menthol in cigarettes to protect public health through administrative rulemaking.[33] Besides authorizing FDA to prohibit menthol in cigarettes, the TCA empowers FDA to adopt tobacco product standards if such standards are "appropriate for the protection of public health."[34] The TCA, however, does not precisely define "tobacco product standard." One court has said that phrase encompasses such matters as "nicotine yields; reduction or elimination of harmful components; product testing; sale and distribution restrictions; labeling; and construction, components, ingredients, additives, constituents, and properties of the tobacco product."[35] For over a decade following the TCA's enactment, FDA considered addressing flavored tobacco products, but it did not take any affirmative steps to remove them from the market.[36] On April 29, 2021, following a suit by public health groups against FDA for its

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[27] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

[28] Pub. L. No. 111-31, § 3(3), 123 Stat. 1778 (2009) (codified at 21 U.S.C. § 387).

[29] *Id.*

[30] *See* Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Final Rule, 81 Fed. Reg. 28,974 (May 10, 2016).

[31] *Cigarette Labeling and Health Warning Requirements*, U.S. FOOD & DRUG ADMIN. (Aug. 25, 2021), https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements.

[32] 21 U.S.C. § 387g(a)(1)(A).

[33] *Id.* § 387g(a)(2).

[34] *Id.* § 387g(a)(3).

[35] Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 753 (N.D. Ill. 2015).

[36] In 2020, FDA took modest steps to regulate flavored e-cigarettes, but those products remain on the market. *See* U.S. FOOD & DRUG ADMIN., ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEM (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION—GUIDANCE FOR INDUSTRY (Apr. 2020), https://bit.ly/3H2sZxs.

failure to prohibit menthol in cigarettes,[37] FDA announced that it would ban menthol in cigarettes. On May 4, 2022, FDA issued two proposed rules addressing flavored tobacco: one proposes to ban menthol in cigarettes while the other bans all flavors (including menthol) in cigars.[38]

B. TCA's Preservation and Preemption of State Tobacco Regulation

Recognizing the centrality of state regulation of tobacco, the TCA explicitly preserves the states' authority to regulate the sale of tobacco products, including banning them.[39] The TCA gives FDA the authority "to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products."[40] It gives FDA a gatekeeping role to regulate tobacco products entering the stream of commerce—product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products—but preserves the states' role in addressing tobacco's health harms.[41] Put differently, the TCA carefully balances the national and state regulatory interests by giving FDA the authority to regulate the national market, while permitting states to adopt more robust public health regulations, including opting out of the national tobacco market altogether.[42]

To balance the need for streamlined national regulation of tobacco products with continued state regulation, Congress crafted a three-part preemption framework that delineates the roles of the states and FDA.[43] Under that framework, the TCA preserves the states' police power to regulate tobacco while also reserving some regulatory power for FDA. The TCA's preemption framework has three essential clauses: the 1) preservation clause; 2) preemption clause; and 3) saving clause.

1. The Preservation Clause

The TCA sets the national regulatory floor but does not displace state regulation. The TCA's preservation clause declares that states retain their traditional regulatory authority and can therefore adopt more stringent regulations that go beyond the national regulatory floor.[44] The clause provides that the TCA does not displace the state's authority to adopt a wide range of tobacco regulations. The preservation clause states:

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[37] Afr. Am. Tobacco Control Leadership Council v. HHS, No. 20-CV-04012-KAW, 2021 WL 5480681 (N.D. Cal. Nov. 17, 2021).

[38] Andrew Twinamatsiko, *FDA Proposes Action on Menthol Cigarettes and Flavored Cigars*, HEALTH AFFS. (May 13, 2022), https://bit.ly/3MswpKL.

[39] 21 U.S.C. § 387p.

[40] Pub. L. No. 111-31, Div. A, § 2, 123 Stat. 1776 (2009).

[41] 21 U.S.C. § 387p(a)(2)(A); *see* U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 434 (2d Cir. 2013).

[42] R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 560 (9th Cir. 2022).

[43] *See* R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170, 1173 (8th Cir. 2023) ("To achieve national uniformity while still respecting States' police power, the Act has three sections relating to preemption: the Preservation Clause, the Preemption Clause, and the Savings Clause.").

[44] *See Cnty. of Los Angeles*, 29 F.4th at 553; Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 753 (N.D. Ill. 2015).

> Except as provided in [the preemption clause], nothing in [the TCA], shall be construed to limit the authority of . . . a State . . . to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.

Thus, under the preservation clause, apart from a narrow category of specified items, the TCA disclaims the intention to displace state regulation of tobacco products, including prohibiting their sale.

2. The Preemption Clause

The preemption clause is an exception to the preservation clause. It "carves out of the preservation clause—and thus preempts—certain requirements enacted by state and local governments."[45] The TCA delineates categories of tobacco regulation that implicate national interests and commits the regulation of those categories to FDA. The preemption clause outlines eight limited exceptions to the broad preservation of state authority.[46] The preempted categories address the production and marketing of tobacco products before they enter the stream of commerce.[47] In other words, the preemption clause makes it explicit that some forms of tobacco regulation implicate unique national interests and are therefore within FDA's exclusive purview. The preemption clause states:

> No State or subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to *tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products*. (emphasis added).

The reach of the preemption clause is therefore circumscribed. It limits state regulatory authority that would impose requirements that differ from those established at the federal level under the authority explicitly committed to FDA.

3. The Saving Clause

The saving clause operates as "an exception to an exception."[48] It states that the preemption clause—which is an exception to the preservation clause—does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products." So, under the saving clause, a state law implicating a product

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[45] R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 881 (D. Minn. 2020).

[46] *Cnty. of Los Angeles*, 29 F.4th at 553.

[47] *Id.* at 553–54.

[48] U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 431 (2d Cir. 2013).

standard, for example, would not be preempted if that law relates to the sale of tobacco products.[49]

4. Preservation of Product Liability Claims

The TCA also disclaims any congressional intention to displace tobacco-related product liability state law tort claims. Because the Supreme Court has noted that awarding damages in a tort action can functionally operate as legislation or regulation,[50] there is concern that tobacco-related tort actions could impermissibly conflict with federal tobacco regulation. Indeed, the tobacco industry has long claimed that by refusing to ban tobacco products—while comprehensively regulating them—Congress considers them to be lawful and intends that they remain on the market. Thus, because the threat of successful product liability tort claims would functionally ban tobacco products, such liability would conflict with the federal objective to permit the sale of tobacco products.[51] The TCA, however, puts that argument to rest and provides that it shall not be "construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."[52] That provision echoes the same preemption disclaimers of state tort actions relating to over-the-counter medications and cosmetics under the FDCA.[53]

The TCA's preemption scope is therefore narrow. But that has not prevented the tobacco industry from deploying the preemption doctrine to thwart state efforts to protect communities from the health harms of flavored tobacco. This preemption litigation has been mainly centered on whether state laws restricting the sale of flavored tobacco products are product standards that are preempted by the TCA, or whether they are sales restrictions that are protected by the preservation and saving clauses.

C. Federal Preemption Overview

The preemption doctrine stems from the Supremacy Clause, which gives federal law precedence over state law.[54] Thus, when federal and state laws conflict, federal law prevails, and state law is invalidated or preempted.[55] Preemption can either be

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[49] *Id.* at 435; *Indeps. Gas & Serv.*, 112 F. Supp. 3d at 753; *Cnty. of Los Angeles*, 29 F.4th at 553; *City of Edina*, 60 F.4th at 1175.

[50] Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992) ("State regulation can be as effectively exerted through an award of damages as through some form of preventive relief.").

[51] *See, e.g.*, Graham v. R.J. Reynolds Tobacco Co., 857 F.3d 1169 (11th Cir. 2017) (rejecting the argument that federal tobacco laws preempt state strict liability and negligence claims based on the inherent dangerousness of cigarettes).

[52] *See also* Berger v. Philip Morris USA, Inc., 185 F. Supp. 3d 1324, 1340 (M.D. Fla. 2016), *aff'd sub nom.*, Cote v. R.J. Reynolds Tobacco Co., 909 F.3d 1094 (11th Cir. 2018) ("Congress thus made plain what one would otherwise presume: that the states retained broad authority to regulate cigarettes, and specifically, to ban their sale, distribution, possession, or use outright. Moreover, Congress expressly stated that it did not intend to 'affect any action or the liability of any person under the product liability of any State.'").

[53] 21 U.S.C. § 379s(d) (exempting state tort liability from preemption based on labeling or packaging of cosmetics); *Id.* § 379r(e) (addressing the national uniformity of nonprescription drugs and exempting state product liability claims from preemption).

[54] 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.").

[55] Gibbons v. Ogden, 22 U.S. 1 (1824).

express or implied. Express preemption occurs when the text of federal law explicitly states its intention to displace state law. An example of express preemption in the tobacco regulation context is FCLAA, which expressly prohibits states from imposing more health warnings on cigarette packages and advertising.[56] Even when Congress has expressly preempted state law, courts still have to determine the scope and effect of the express preemption. In *Cipollone v. Liggett Grp. Inc.*, for example, although FCLAA expressly preempted state requirements of more warnings on cigarette packages and advertisements, the Supreme Court still had to decide whether FCLAA preempted tort claims against the tobacco industry for misrepresentation, intentional fraud, and breach of express warranty.[57]

Federal law can also impliedly preempt state law. Implied preemption is determined by looking at the structure and purpose of federal law to see if such federal law implicitly precludes additional state regulation.[58] Although it is hard to draw a neat taxonomy of implied preemption,[59] it is generally agreed that there are two categories of implied preemption: 1) field preemption and 2) conflict preemption.

Field preemption occurs when federal law is so thorough and pervasive that it forecloses additional state regulation.[60] Conflict preemption occurs when state law makes it impossible to comply with federal law or impedes the achievement of federal objectives.[61] *Arizona v. U.S.* is a relatively recent example of field preemption. That case involved a state law that required foreign nationals to carry documentation showing that they were lawfully present in the United States and made it a crime for undocumented aliens to work. The federal government challenged this law, arguing that it was preempted because it intruded "on a field in which Congress left no room for states to regulate."[62] The Court agreed, reasoning that congressionally enacted immigration framework "occupied the field of alien registration."[63] Because federal law established harmonious standards for alien registration, it foreclosed state complementary registration requirements. The Court noted that enforcing the state law would "diminish the federal government's control over enforcement and detract from the integrated scheme of regulation created by Congress."[64] The TCA's preservation clause disclaims field preemption because it

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[56] 15 U.S.C. § 1334 (b); *see* Cipollone v. Liggett Grp., Inc., 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).

[57] *Cipollone*, 505 U.S.; *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (requiring the Court to determine whether FCLAA preempted states from adopting time, place, and manner cigarette advertising regulations).

[58] Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) ("Pre-emption may be either expressed or implied, and 'is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose.'").

[59] *See* Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 n.6 (2000) ("We recognize, of course, that the categories of preemption are not 'rigidly distinct.' Because a variety of state laws and regulations may conflict with a federal statute, . . . ' field pre-emption may be understood as a species of conflict pre-emption[.]'" (internal citations omitted)).

[60] R.J. Reynolds Tobacco Co. v. Durham Cnty., 479 U.S. 130, 140 (1986).

[61] *Crosby*, 530 U.S. at 363.

[62] Arizona v. United States, 567 U.S. 387, 402 (2012).

[63] *Id.*

explicitly states that states, localities, Tribes, and other federal agencies can adopt additional or more stringent tobacco requirements.[65]

Conflict preemption—as the name suggests—occurs when state laws conflict with federal law, which generally occurs under two sets of circumstances: 1) when it is physically impossible to comply with both state and federal laws (aptly commonly called "impossibility preemption");[66] and 2) when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[67]

Both impossibility and obstacle preemption were at issue in *Wyeth v. Levine*,[68] a case involving a state failure-to-warn claim against a manufacturer of a drug that bore FDA-approved warnings. First, the manufacturer argued that because FDA had approved the warning labels and the manufacturer could not change the label without FDA's approval, it was "impossible for it to comply with state law duties underlying those claims and its federal labeling duties."[69] The Court, however, rejected this impossibility preemption argument, reasoning that federal law permitted the manufacturer to unilaterally change its warning label and that FDA's approval of the warning label did not per se prohibit the manufacturer's change of the label to meet state law tort requirements. The Court emphasized that the bar for establishing impossibility preemption is high.[70]

The manufacturer also argued that the failure-to-warn claim was preempted because additional warnings "would obstruct the purposes and objectives of the federal drug labeling regulation"[71] because Congress had entrusted only FDA with the role of making labeling decisions to balance competing objectives.[72] The Court rejected this argument as well, finding that Congress has designed the labeling process while recognizing that individuals could rely on state law remedies to vindicate harms from unsafe drugs. Thus, state failure-to-warn claims did not undermine any federal objectives.

In challenging state laws regulating the sale of flavored tobacco products, the tobacco industry has argued that the TCA both expressly and impliedly preempts these state laws. As for express preemption, the tobacco industry has argued that flavored tobacco sales restrictions are tobacco product standards and therefore fall within the scope of TCA's preemption clause. For implied preemption, the industry has argued state laws prohibiting the sale of flavored tobacco products that are not

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64 *Id.*

65 *See* R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170, 1174 (8th Cir. 2023).

66 *See* Wyeth v. Levine, 555 U.S. 555 (2009) (analyzing failure to warn claim under the impossibility preemption framework); PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011) (finding that a state law claim based on failure to warn was preempted because it was impossible to comply with both federal law and state law); Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013) (also finding state failure-to-warn tort claim was preempted because it was impossible to comply with federal law and state law).

67 *Arizona*, 567 U.S. at 399.

68 *Wyeth*, 555 U.S.

69 *Id.* at 568.

70 *Id.* at 573 ("Impossibility pre-emption is a demanding defense.").

71 *Id.*

72 *Id.*

prohibited by federal law (especially menthol) impermissibly hinder achieving a federal objective—that the federally unprohibited products remain on the market. A discussion on how these arguments have played out in the courts follows.

But first, a note on this Article's characterization of the varieties of flavored tobacco restrictions that have been challenged under the TCA's preemption framework. Policies restricting the sale of flavored tobacco products vary among states, localities, and Tribal governments. At one end of the spectrum, there are jurisdictions with partial flavored tobacco sales restrictions—for example, those that exempt menthol or apply to a limited class of tobacco products. On the other end of the spectrum, there are comprehensive flavored tobacco sales restrictions—for example, those restricting all flavors, including menthol, in all tobacco products. In this Article, the former will be called "partial flavored tobacco sales restrictions" and the latter "comprehensive flavored tobacco sales restrictions." For purposes of this discussion, lawsuits seeking to invalidate partial flavored tobacco sales restrictions—because of the timeline in which they were filed—are classified as "first wave litigation," while those challenging comprehensive flavored tobacco sales restrictions are classified as "second wave litigation."

IV. FLAVORED TOBACCO PREEMPTION LITIGATION UNDER THE TCA

A. First Wave Litigation

1. New York City, New York: U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York[73]

In 2009, New York City adopted an ordinance restricting selling flavored non-cigarette tobacco products within the city. The ordinance exempted menthol tobacco products and permitted flavored non-cigarette tobacco products to be sold in qualifying tobacco bars. At the time, there were only eight tobacco bars in the city, and none of them sold smokeless tobacco.[74] Thus, the ordinance effectively banned selling flavored smokeless tobacco in New York City.[75]

Smokeless tobacco manufacturers challenged the ordinance, arguing that it was preempted by the TCA. Although the ordinance restricted selling only flavored non-cigarette tobacco products, the challengers argued the restriction was functionally a tobacco product standard because it commanded tobacco manufacturers to meet the requirements of the sales restriction.[76] The industry essentially argued that by restricting the sale of a class of flavored tobacco products, the city had encroached on FDA's regulatory territory—to set tobacco product standards—and was therefore preempted.

But the Second Circuit rejected the industry's argument, finding that the ordinance was valid under TCA's preservation clause, which instructs that the TCA should "not be construed to limit the authority of a state or political subdivision of a state to enact

[73] 708 F.3d 428 (2d Cir. 2013).

[74] *Id.* at 432.

[75] *Id.*

[76] *Id.* at 434.

and enforce any measure prohibiting the sale of tobacco products."[77] The court ruled that the ordinance was not a tobacco product standard because it did not require tobacco manufacturers to change how they made their products. The ordinance would constitute a preempted product standard, the court reasoned, if it required "manufacturers to alter 'the construction, components, ingredients, additives, constituents and properties' of their products."[78] Because the ordinance did not "clearly infringe on FDA's authority to determine what chemicals and processes may be used in making tobacco products," it was not preempted.[79]

What is more, the court held that even if the city's flavored tobacco sales restriction were considered a tobacco product standard, it would still not be preempted because of the TCA's saving clause.[80] As previously noted, the saving clause exempts from preemption requirements relating to the sale of tobacco products, even if those requirements involve matters preserved for FDA, such as product standards. Because the New York City flavored tobacco restriction limited only the locations in the city at which flavored tobacco products could be sold, it was "a requirement relating to the sale of tobacco products within the meaning of the savings clause."[81] Put differently, even under the broadest interpretation of tobacco product standard, the TCA does not preempt tobacco sales restrictions because those sales restrictions are exempted from preemption by the saving clause.

Because the New York City ordinance exempted qualifying tobacco stores, however, the court did not address whether banning a whole class of tobacco products—or comprehensive restrictions of the second wave litigation—was permissible under the saving clause.[82] While the preservation clause states the TCA does not limit the states' authority to "*prohibit* the sale of tobacco products," the saving clause states the preemption clause "does not apply to *requirements* relating to the sale of tobacco products."[83] The tobacco industry has maintained that this prohibition/requirement distinction means that under the saving clause, states can impose only time, place, and manner sales restrictions, but states cannot ban categories of tobacco products.[84] In this case, the industry therefore argued that the

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[77] *Id.*

[78] *Id.*

[79] *Id.*

[80] *Id.* at 435.

[81] *Id.*

[82] *Id.*

[83] *Id.* (emphasis added).

[84] R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 881 (D. Minn. 2020) ("[P]laintiffs argue, state and local governments cannot prohibit sales of tobacco products; they may only regulate the time, place, and manner of sales and distribution."); *see also* Brief of Petitioner at 38–39, R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 2021 WL 917431 (C.A.9) ("[States] can, for example, raise the minimum age of purchase, adopt licensing regimes, impose restrictions on non-face-to-face sales, and restrict where products may be sold (e.g., not near schools). But one thing state and local governments cannot do is prohibit the sale of tobacco products because they disagree with federal tobacco product standards."). The tobacco industry, however, has struggled to define what time, place, and manner restrictions mean in this context. As the Ninth Circuit has noted, "place" in this context could mean the entire County of Los Angeles as Los Angeles in fact did. *See* R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 559 (9th Cir. 2022); *see also* Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 749 (N.D. Ill. 2015) (arguing that Chicago's prohibition of the sale of flavored tobacco products within 500 feet of a school was an impermissible tobacco product standard).

New York City ordinance did not fall under the saving clause because it was a total ban or *prohibition* of the sale of smokeless tobacco, not just a *requirement* relating to the sale of smokeless tobacco.[85] The court, however, did not decide this issue because flavored non-cigarette tobacco products could still be sold in qualifying tobacco bars within New York City, and therefore the ordinance was not a total ban/*prohibition*.[86] The tobacco industry argued that the ordinance was a functional prohibition because none of the existing tobacco bars sold the exempted products. But the court rejected this argument, finding that the tobacco bars did not sell those products due to the sellers' choice, not because of the ordinance.[87]

2. *Providence, Rhode Island:* Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence[88]

The First Circuit also addressed this preemption argument when the tobacco industry challenged Providence's flavored tobacco ordinance. In 2012, Providence, Rhode Island, adopted an ordinance prohibiting retailers from selling non-cigarette tobacco products. Just like the New York City ordinance at issue in *U.S. Smokeless Tobacco*, the Providence ordinance also prohibited the sale of flavored tobacco products, except in qualifying smoking bars.[89] Thus, the Providence ordinance did not totally ban flavored tobacco products. Again, the tobacco industry challenged this ordinance on preemption grounds, arguing that by effectively banning the sale of flavored smokeless tobacco, the ordinance regulated the operations of tobacco manufacturers, thus imposing another product standard or good manufacturing standard.[90] The First Circuit also rejected this argument, finding that the TCA's preemption of tobacco product standards and good manufacturing was narrow and did not apply to sales restrictions no matter the effect of such sales restrictions on manufacturing.[91] The court also rejected the argument that this ordinance fell outside the scope of the saving clause, because it was a *prohibition* and not a *requirement* relating to the sales of tobacco products.[92] The court ruled that the ordinance was not "a blanket prohibition" of flavored tobacco products because they could be sold in smoking bars.[93] Thus, the court concluded that the ordinance was a regulation relating to the sale of tobacco products, which fell within the saving clause.

3. *Chicago, Illinois:* Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago[94]

In 2013, Chicago adopted an ordinance restricting the sale of flavored tobacco products—including menthol cigarettes—within 500 feet of a school.[95] This

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85 *U.S. Smokeless Tobacco Mfg.*, 708 F.3d at 435 (emphasis added).

86 *Id.* at 435–36 (emphasis added).

87 *Id.* at 436 n.3.

88 731 F.3d 71 (1st Cir. 2013).

89 *Id.* at 82.

90 *Id.*

91 *Id.* at 83 n.11.

92 *Id.* at 82.

93 *Id.*

94 112 F. Supp. 3d 749 (N.D. Ill. 2015).

ordinance was the first law in the United States restricting the sale of menthol cigarettes following the TCA's enactment.[96] This restriction, however, exempted qualifying tobacco retail stores, just like the New York City and Providence ordinances. Under the Chicago ordinance, flavored tobacco products could still be sold in stores that derived more than 80% of their gross revenue from tobacco products.[97]

Reiterating the arguments in *U.S. Smokeless Tobacco* and *Nat'l Ass'n of Tobacco Outlets*, the tobacco industry argued that the ordinance was functionally a manufacturing standard because it would cause tobacco manufacturers to reduce the production of flavored products.[98] Relying on *U.S. Smokeless Tobacco*, the court rejected the industry's argument and found that the ordinance prohibited flavored tobacco products no matter how they were manufactured.[99] That the ordinance affected manufacturer's production decisions did not turn a sales restriction into a manufacturing standard because the restriction did not command manufacturers to implement particular manufacturing standards.[100] Rather, the restriction simply told retailers what they could and could not sell after the products had been produced.

Like the earlier decisions, the court in *Indeps. Gas & Serv. Stations Ass'ns* also held that the ordinance operated through a sales regulation and therefore fell within the TCA's saving clause. Citing *U.S. Smokeless Tobacco*, the court reasoned that the sales regulation did not ban flavored tobacco because those products could still be sold in qualifying tobacco retail stores and in stores located more than 500 feet from schools.[101]

This first wave of tobacco litigation mapped out some of the flavored tobacco regulatory contours, showing how states could permissibly restrict the sale of flavored tobacco products without offending the TCA's preemption clause. But this litigation left some questions unanswered. Because the New York City, Providence, and Chicago ordinances permitted flavored tobacco products to be sold in qualifying outlets, the litigation did not address whether it would be permissible to ban an entire category of flavored tobacco products—including menthol—without exceptions. This question was addressed in second wave litigation cases.

D. Second Wave Litigation: Comprehensive Flavored Tobacco Bans

The public health gains of flavored tobacco sales restrictions and their successful defense in litigation spurred other communities nationwide to adopt similar measures. Today, California is one of the leading jurisdictions in adopting laws restricting the sale of flavored tobacco products.[102] In 2017, San Francisco adopted

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[95] *Id.* at 751.

[96] *Chicago's Regulation of Menthol Flavored Tobacco Products—A Case Study*, 1, PUB. HEALTH L. CTR., https://tinyurl.com/2tzk4bdp.

[97] *Indeps. Gas & Serv.*, 112 F. Supp. 3d at 751.

[98] *Id.* at 754.

[99] *Id.*

[100] *Id.*

[101] *Id.* at 753.

[102] As of July 27, 2023, at least 139 California localities restricted the sale of flavored tobacco in some fashion. CTFK, *Fact Sheet*, *supra* note 6.

an ordinance banning the sale of all flavored tobacco products, including menthol.[103] To thwart this unprecedented public health achievement, the tobacco industry sponsored a referendum to overturn the ordinance. The tobacco industry giant R.J. Reynolds spent more than $11 million for this effort, but San Francisco voters overwhelmingly approved the ban.[104] Following San Francisco's lead, other jurisdictions in California have continued to adopt comprehensive laws prohibiting the sale of tobacco products. In 2020, the California legislature passed a law prohibiting the sale of flavored tobacco products, including menthol.[105] The tobacco industry again forced a referendum on this law, but California voters overwhelmingly approved the law in the November 2022 election.[106]

Unsurprisingly, the tobacco industry has mounted several legal challenges against California's flavored tobacco public health measures, mainly arguing that they are preempted by the TCA. As of today, the industry has filed at least seven suits in federal district courts in California challenging flavored tobacco laws.[107] This section addresses litigation challenging comprehensive flavored tobacco sales restrictions enacted in California and Minnesota.

1. Los Angeles, California: R.J. Reynolds v. Los Angeles Cnty.[108]

In 2019, Los Angeles County enacted an ordinance prohibiting the sale of all flavored tobacco products, including menthol, within the unincorporated areas of the county.[109] Undeterred by the decisions in the first wave litigation, the tobacco industry mounted another legal challenge in federal court, arguing that the TCA preempted the ordinance. Unlike the ordinances at issue in the first wave litigation, the Los Angeles County ordinance was more comprehensive—it prohibited all flavored tobacco products (including menthol)[110] and did not exempt any tobacco

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[103] Mark Matthews, *San Francisco Advances Ban on Flavored Tobacco Products*, NBC (June 20, 2017), https://tinyurl.com/599xjacr.

[104] Madison Park, *San Francisco Bans Sales of Flavored Tobacco Products*, CNN (June 6, 2018), https://tinyurl.com/3z49d8fd.

[105] S.B. 793, 2019–2020 Leg., Reg. Sess. (Cal. 2020), https://tinyurl.com/bdwk8p8h. The law, however, exempts hookah, premium cigars, and pipe tobacco.

[106] Hannah Wiley, *California Voters Approve Ban on Sale of Flavored Tobacco Products*, L.A. TIMES (Nov. 8, 2022), https://tinyurl.com/y2w3p7er.

[107] *See* CA Smoke & Vape Ass'n v. Cnty. of Los Angeles, No. CV 20-4065 DSF (KSx), 2020 WL 4390384 (C.D. Cal. June 9, 2020); CA Smoke & Vape Ass'n v. City of Palmdale, No. 2:20-cv-05039 (C.D. Cal. June 7, 2020); R.J. Reynolds Tobacco Co. v. Cnty. of San Diego, 529 F. Supp. 3d 1147 (S.D. Cal. 2021); Neighborhood Mkt. Ass'n v. Cnty. of San Diego, No. 3:20-cv-01124 (S.D. Cal. June 19, 2020); R.J. Reynolds Tobacco Co. v. Becerra, No. 3:20-cv-01990 (S.D. Cal. Oct. 9, 2020); R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542 (9th Cir. 2022); R.J. Reynolds Tobacco Co. v. Bonta, No. 22-CV-01755-CAB-WVG, 2022 WL 16986580 (S.D. Cal. Nov. 15, 2022).

[108] 29 F.4th 542 (9th Cir. 2022), *cert. denied*, 143 U.S. 979 (2023).

[109] *Cnty. of Los Angeles*, 29 F.4th at 551.

[110] LOS ANGELES COUNTY, CAL., HEALTH & SAFETY CODE § 11.35.020(C) ("'Characterizing flavor' means a taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product or any byproduct produced by the tobacco product, including, but not limited to, tastes or aromas relating to *menthol, mint, wintergreen*, fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb, or spice. Characterizing flavor includes flavor in any form, mixed with or otherwise added to any tobacco product or nicotine delivery device, including electronic smoking devices." (emphasis added)).

retailers (e.g., cigar bars).[111] Again, the industry argued that banning the sale of flavored tobacco products was a tobacco product standard and was therefore expressly preempted under the TCA.

But the Ninth Circuit declined to interpret "product standard" so broadly as to encompass retail sales restrictions. The court held that under the TCA's preemption framework, product standard refers only "to standards pertaining to the production and marketing stages up until the actual point of sale."[112] The court reasoned that interpreting "product standard" broadly to include state regulations that indirectly affect tobacco standards, as the industry argued, would effectively gut the preservation clause.[113] Under the industry's reading of the preservation clause, any prohibition of the sale of tobacco products (which is permissible under the preservation clause) would indirectly "relate" to a tobacco product standard.[114] Such a broad interpretation of product standard, the court said, would preempt every state sales regulation of tobacco because sales regulations indirectly affect product standards.[115] Thus, the court concluded that a state's total ban of the sale of tobacco products was not an impermissible product standard.

Further—and central to this Article's argument—the court held that the preservation of state regulation is so central to the TCA's framework that even if the term "tobacco product standard" were to be read broadly to include Los Angeles' flavored tobacco sales restriction, it would still be permissible because the TCA's saving clause exempts sales restrictions from preemption.[116] As earlier noted, the saving clause explicitly states that the TCA's prohibition of states from adopting tobacco product standards does not apply to requirements relating to the sale of tobacco products. Because the Los Angeles ordinance prohibited the sale of flavored tobacco products throughout the county, it was a requirement relating to the sale of tobacco products and therefore fell under the saving clause.[117]

The Ninth Circuit therefore answered the question that the first wave of tobacco litigation left open—whether a total ban or prohibition of a class of tobacco products was permissible under the TCA. The court ruled that prohibiting the sale of flavored tobacco products—a total ban on a class of tobacco products—was a permissible requirement relating to the sale of flavored tobacco products under the saving clause.[118]

The court also rejected the industry's argument that Los Angeles' prohibition of the sale of menthol cigarettes was impliedly preempted.[119] The industry argued that

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[111] LOS ANGELES COUNTY, CAL., HEALTH & SAFETY CODE § 11.35.070(E) ("[I]t shall be a violation of this Chapter for a tobacco retailer/licensee or its agent(s) or employee(s) to sell or offer for sale, or to possess with the intent to sell or offer for sale, any flavored tobacco product or any component, part, or accessory intended to impart, or imparting a characterizing flavor in any form, to any tobacco product or nicotine delivery device, including electronic smoking devices.").

[112] *Cnty. of Los Angeles*, 29 F.4th at 554.

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] *Id.* at 558.

[117] *Id.* ("A ban on the sale of flavored tobacco products is, simply put, a requirement that tobacco retailers or licensees throughout the County not sell flavored tobacco products.").

[118] *Id.* at 558–61.

[119] *Id.* at 561.

when Congress enacted the section of the TCA that exempts menthol from the prohibition of flavors in cigarettes, Congress essentially mandated that menthol cigarettes must remain on the market. By prohibiting the sale of menthol cigarettes, the industry argued, the flavored tobacco ordinance posed an obstacle to the federal objective that menthol cigarettes remain on the market.[120] The court tersely rejected this argument, finding that the TCA does not mandate that menthol cigarettes remain on the market and that the preservation clause explicitly allows states to adopt more stringent tobacco sales restrictions than those set by federal law.[121] The tobacco industry's efforts to appeal this decision to the Supreme Court were futile.[122]

2. *Edina, Minnesota:* R.J. Reynolds Tobacco Co. v. City of Edina[123]

In 2020, Edina, a city in Minnesota, enacted a comprehensive ordinance restricting selling flavored tobacco. The ordinance defined a flavored tobacco product as "any tobacco, tobacco-related product, or tobacco-related device that contains a taste or smell, other than the taste or smell of tobacco, that is distinguishable by an ordinary consumer either prior to or during consumption or use of the product or device[.]"[124] Simply put, the ordinance restricted selling flavored tobacco products, including menthol. Challenging this ordinance, industry again claimed that the TCA expressly and impliedly preempted the ordinance. The industry reiterated its argument that the flavored tobacco sales restriction was a tobacco product standard that impermissibly infringed on FDA's regulatory domain.

i. District Court Decision[125]

Departing from the other courts, the district court in *City of Edina* agreed with the industry that the flavored tobacco sales restriction was a tobacco product standard and therefore expressly preempted.[126] The court disagreed with all the other courts that tobacco product standards were limited to manufacturing processes, and reasoned that product standards also included "provisions respecting . . . the properties of the tobacco product and restrictions on the sale and distribution of the tobacco product."[127] The court thus concluded that the ordinance fell within this meaning because it concerned properties of tobacco products—i.e., flavors—and restricted the sale of tobacco products that contained those properties.[128]

Even so, the court found that the ordinance was still valid under the TCA's saving clause.[129] The saving clause exempts state laws implicating tobacco product

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[120] *Id.*

[121] *Id.*

[122] R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542 (9th Cir. 2022), *cert. denied*, 143 U.S. 979 (2023).

[123] R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170 (8th Cir. 2023).

[124] R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 877 (D. Minn. 2020).

[125] *See id.*

[126] *Id.* at 879–80.

[127] *Id.* at 879 (internal quotations and citation omitted).

[128] *Id.*

[129] *Id.* at 880 ("On its face, the Ordinance falls within the scope of the saving clause, as it is a requirement relating to the sale . . . of . . . tobacco products[.]") (internal quotations and citation omitted).

standards if those laws are requirements relating to the sale of tobacco products. Because the ordinance was a sales restriction, it was thus exempted from the TCA's preemption of tobacco product standards. The court rejected the industry's argument that the saving clause is limited to age-based or time, place, and manner sale restrictions. According to the industry, under the saving clause, the city could regulate only where and how tobacco products could be sold; it could not permissibly ban the sale of a class of tobacco products. The court held that the saving clause exempts from preemption all sales restrictions, including bans of classes of tobacco products.[130]

The court also disagreed with the industry that Edina's ordinance was impliedly preempted.[131] Again, as in the litigation in *R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, the industry argued that the ordinance was impliedly preempted because it stood as an obstacle to the achievement of federal objectives—uniform manufacturing standards for tobacco products and allowing certain flavored tobacco products to remain on the market.[132] According to the industry, the TCA authorizes only the FDA to establish manufacturing standards for tobacco products, "including standards governing the ingredients used in such products," and by banning tobacco products based on their ingredients (flavors, in this case), the ordinance undermined the established national standards for tobacco products.[133] The court rejected this argument, finding that the ordinance did not impose a manufacturing standard because it did not dictate how tobacco products had to be made.[134] Although prohibiting the sale of flavored tobacco products could reduce the manufacturers' sales volumes, the court reasoned, it would not cause tobacco manufacturers to change anything about how they made their products.[135]

As for menthol, the industry also argued that the ordinance interfered with the federal objective that flavored tobacco products, especially menthol cigarettes and flavored e-cigarettes, be marketed in the United States.[136] Specifically, the industry argued that Congress' exemption of menthol from the TCA's flavored cigarette ban, and FDA's failure to ban menthol cigarettes and certain flavored e-cigarettes, bore out a federal objective that those products remain on the market.[137] By restricting the sale of those products, the industry reasoned, the city sought to frustrate a clear federal objective, which was impermissible under the implied preemption doctrine.[138] But the court rejected this argument. The court ruled that the federal government's failure to act on those products could not be construed as an affirmative decision that they remain on the market.[139] Such inaction was not

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[130] *Id.* at 881–82.

[131] *Id.* at 882–86.

[132] *Id.* at 883.

[133] *See* Plaintiffs' Memorandum in Support of Motion for Preliminary Injunction, R.J. Reynolds Tobacco Co. v. City of Edina (D. Minn. 2020) (No. 20-cv-1402), 2020 WL 7407668.

[134] *City of Edina*, 482 F. Supp. 3d at 883.

[135] *Id.*

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.* at 884.

tantamount to a federal mandate that those products be available for purchase without hindrance.[140] Thus, because there was no such federal objective, the ordinance was not impliedly preempted.[141]

ii. Decision on Appeal to the Eighth Circuit

On appeal, the Eighth Circuit affirmed the district court decision but disagreed with the district court that the ordinance was a tobacco product standard. The court essentially adopted the reasoning of the First and Second Circuits in *U.S. Smokeless Tobacco* and *Nat'l Ass'n of Tobacco Outlets* and held that a flavored tobacco sales restriction was not a tobacco product standard because it did not dictate how manufacturers could make their products—it simply prohibited the sale of flavored tobacco products. Like the Ninth Circuit in *R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, the Eighth Circuit went further and held that even if the ordinance were a tobacco product standard, it would still be permissible under the saving clause.

Analyzing the role that the saving clause plays in TCA's preemption framework, the court set out to determine the meaning of the phrase "does not apply" in the saving clause. For this analysis' sake, the court assumed that Edina's flavor ordinance was a tobacco product standard. This phrase, the court said, could plausibly be read in two ways: as 1) a clarifying provision; or 2) an exception to the preemption clause.[142] Under the first reading, the phrase distinguishes between the set of state laws that are preempted and those that are not. Thus, if a state law is "more of a requirement 'relating to tobacco product standards,'" it would be preempted.[143] But if such law can be "better characterized as 'a requirement relating to the sale'" of tobacco, it would fall within the saving clause, and thus not preempted.[144] Under this reading, the saving clause serves as an interpretive provision, not "a freestanding shield to preemption."[145] This concededly narrows the scope of the saving clause and gives it no other effect than what is outlined in the preservation clause. As the court noted, this reading "risks rendering the Savings and Preservation Clauses synonymous and collapsing any distinction between them."[146] Consequently, this would limit the state's authority to regulate tobacco products. Under this reading, the Edina ordinance would be preempted.

Under the second reading, the phrase "does not apply" operates as an exception to the preemption clause.[147] Thus, an otherwise preempted tobacco statute would still be valid under the TCA if it regulated the sale of those products. In this context, an ordinance restricting the sale of flavored tobacco, though touching on a tobacco product standard (the presence of flavorings in tobacco products), would not be preempted because it regulates only how those products are sold. This reading, the court cautioned, "risks making the TCA's preemption of tobacco manufacturing standards meaningless, because States could effectively regulate manufacturing so

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[140] *Id.*

[141] *Id.*

[142] R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170, 1175 (8th Cir. 2023).

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] *Id.* at 1176.

[147] *Id.* at 1175.

long as they couch it in terms of sales."[148] Consequently, this reading would preserve states' traditional authority to regulate tobacco products and allow them to tailor policies to their communities' needs.[149] Under this reading, the Edina ordinance would not be preempted.

Presented with these two plausible interpretations of the saving clause, the court sought to ground its decision in principles of federalism.[150] Because the federal government is a government of limited, enumerated powers and states have unlimited police power, federal displacement of state power through preemption is disfavored. Preemption is permissible only when Congress has clearly expressed its intention to displace state power.[151] In *City of Edina*, because the Eighth Circuit found that the TCA's preemption was ambiguous, it adopted a reading that disfavors preemption and preserves traditional state police powers.[152] It thus adopted the second reading—the saving clause as an exception to preemption.[153] The court thus concluded that even if a tobacco product standard were read broadly to include an ordinance prohibiting the sale of flavored tobacco, that ordinance would still be permissible under the saving clause.[154]

V. TOBACCO PRODUCT STANDARDS AND THE SAVING CLAUSE

While the tobacco industry has engaged in a relentless campaign to derail public health efforts to minimize death and disease from its deadly products,[155] there is a silver lining in that litigation—clarification of the federal and state tobacco regulatory contours, especially those relating to product standards and the TCA's saving clause. Every federal appellate court that has addressed this issue has concluded that flavored tobacco sales restrictions are not product standards and therefore not preempted by the TCA.[156] The question about whether flavored tobacco sales restrictions that implicate tobacco product standards are permissible under the saving clause—a question left open by the first wave litigation—was recently finally addressed by both the Eighth and Ninth Circuits in *R.J. Reynolds Tobacco Co. v. City of Edina* and *R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles*, respectively.[157]

Although the *Cnty. of Los Angeles* and *City of Edina* courts rejected the industry's claim that the ordinance was a product standard, they ruled in the alternative that

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[148] *Id.* at 1176.

[149] *Id.* at 1177.

[150] *Id.* at 1176.

[151] *Id.* (quoting Altria Grp., Inc. v. Good, 555 U.S. 70, 77 (2008)).

[152] *Id.* at 1177.

[153] *Id.*

[154] *Id.*

[155] *See* Jeremy B. White, Lara Korte, Sakura Cannestra & Owen Tucker-Smith, *Tobacco's California Losing Streak Continues*, POLITICO (Dec. 12, 2022), https://tinyurl.com/3b43uv59; Meredith L. Nixon, Leila Mahmoud & Stanton A. Glantz, *Tobacco Industry Litigation to Deter Local Public Health Ordinances: The Industry Usually Loses in Court*, 13 TOBACCO CONTROL 65 (2004), https://tinyurl.com/3vzc9wuz; Park, *supra* note 104; Wiley, *supra* note 106.

[156] *See supra* Section IV.D.

[157] *See id.*

even if the term "tobacco product standard" were read broadly to encompass flavored tobacco sales restrictions, the ordinances at issue in those cases would still be permissible under the saving clause.[158] In arguing that the flavored tobacco sales restrictions fell outside the saving clause, the tobacco industry sought to differentiate the Los Angeles County and Edina ordinances from the Providence, New York City, and Chicago ordinances that were at issue in the first wave litigation. Unlike the first wave litigation ordinances that exempted certain tobacco products and certain tobacco outlets, the Los Angeles County and Edina ordinances were comprehensive and had no such exemptions. Thus, the tobacco industry argued that because these ordinances were comprehensive and totally banned the sale of classes of tobacco products, they were impermissible under the saving clause because the saving clause encompasses only "requirements relating to the sale" of tobacco products. A total ban, however, the industry argued, was a "prohibition," not a "requirement," and therefore outside the meaning of the saving clause. The industry's argument was based on the textual difference between the preservation clause and the saving clause. While the preservation clause's text says that states can "prohibit" the sale of tobacco products, the saving clause omits the "prohibition" language and says states can adopt "requirements relating to the sale of tobacco products." Thus, under the industry's reasoning, states can only adopt time, place, and manner restrictions because such restrictions fit within the meaning of "requirements," while a blanket prohibition does not.

The Ninth Circuit rejected this prohibition/requirement distinction and said that "[a] ban on the sale of flavored tobacco products is, simply put, a requirement that tobacco retailers or licensees throughout the County not sell flavored tobacco products."[159] The Eighth Circuit also tersely rejected this distinction, saying that it had no basis in the TCA. The Eighth Circuit reasoned that traditional state public health authority could not be displaced using such ambiguous statutory language. The upshot of the courts' reasoning about the scope of the saving clause is that tobacco sales prohibitions are permissible even if such prohibitions implicate otherwise preempted tobacco product standards. As the Ninth Circuit held, even if the "tobacco product standard" were read broadly as encompassing flavored tobacco sales restrictions, such restrictions would still be exempted from preemption under the saving clause.[160]

Challenging the *Cnty. of Los Angeles* decision before the Supreme Court, the industry claimed that under the lower court's reasoning, states could set their own tobacco product standards, provided those standards were framed as sales bans of products that did not meet those standards.[161] The industry drew a parade of tobacco product standards that would be permissible under the Ninth Circuit's interpretation of the saving clause, including localities establishing their own good manufacturing standards or their own labeling standards. Thus, the industry argued that, for example, a state could circumvent the TCA's preemption clause by banning the sale

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[158] *See* Section IV.D.

[159] R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 558 (9th Cir. 2022).

[160] *Id.*; *see also* R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170, 1175 (8th Cir. 2023) (upholding the Edina flavored tobacco ordinance after assuming that the ordinance constituted a tobacco product standard).

[161] *See* Petition for Writ of Certiorari at 20, R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 143 U.S. 979 (2023) (No. 22-338).

of tobacco products that did not bear the state's warning label.[162] The Court denied the industry's petition for certiorari, meaning that the industry did not raise a compelling reason for review.[163]

What is more, the Ninth Circuit's conclusion about the permissibility of tobacco sales restrictions that implicate tobacco product standards under the saving clause tracks the Second Circuit's reasoning that "pursuant to the saving clause, local laws that would otherwise fall within the preemption clause are exempted if they constitute 'requirements relating to the . . . sale . . . of tobacco products.'"[164] The same reasoning underscored the Eighth Circuit's decision in *City of Edina*. In fact, in *City of Edina*, the industry had specifically argued that reading the saving clause broadly to include blanket prohibitions could permit a state to set manufacturing standards, for example, "establish more *stringent nicotine requirements* by banning the sale of tobacco products that contain more nicotine than the local government would like."[165] Even so, the *City of Edina* court seemed to agree that such regulation would be permissible under the TCA's preemption framework. The court reasoned that the saving clause "can be plausibly interpreted as preserving state laws that relate to manufacturing, so long as they also relate to the sale of tobacco."[166]

VI. PERMISSIBILITY OF NICOTINE LEVEL LAWS UNDER THE SAVING CLAUSE

A. Prohibiting High Nicotine Tobacco Products Under the Saving Clause

The TCA both preserves broad traditional state authority to regulate tobacco products and disclaims any intention of preempting state and local tobacco sales restrictions, including those that implicate tobacco product standards. As three federal circuit courts have held, because the saving clause is an exception to the preemption clause, state laws that would otherwise be preempted—e.g., those relating to tobacco product standards—are permissible if they are sales restrictions. The tobacco industry's efforts to overturn the Ninth Circuit's decision on this issue have failed. It therefore stands to reason that under the saving clause, a jurisdiction may permissibly adopt a tobacco endgame policy prohibiting the sale of tobacco

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[162] This argument, however, is problematic because other federal law preempts labeling requirements of tobacco products, including e-cigarettes. *See* 21 U.S.C. § 387f(d)(2); 21 C.F.R. § 1143.3; *see also* Colgate v. JUUL Labs, Inc., 345 F. Supp. 3d 1178, 1188 (N.D. Cal. 2018) ("[U]nder the TCA's preemption provision, states and political subdivisions of states may not enact labeling requirements or warnings contrary or in addition to those prescribed under 21 C.F.R. §§ 1143.3(a)(1)(2).").

[163] *See* U.S. SUP. CT. R. 10.

[164] U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 433 (2d Cir. 2013).

[165] Brief of Appellants at 38–39, R.J. Reynolds Tobacco Co. v. City of v. Edina, 2020 WL 6553731 (C.A.8) (emphasis added); *see also* R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 882 (D. Minn. 2020) (arguing that under a broad reading of the saving clause, "a municipality could establish conflicting requirements concerning nicotine levels, premarket review processes, and other matters simply by banning the sale of products that do not meet these requirements").

[166] R.J. Reynolds Tobacco Co. v. City of Edina, 60 F.4th 1170, 1178 (8th Cir. 2023). Although the portion of the opinion on this issue is under the court's discussion of implied preemption, the court refers to its discussion of the preservation and saving clauses to emphasize the broad power states retain to regulate sales that implicate tobacco product standards.

products that exceed established nicotine thresholds.[167] This position is supported by the TCA's text and the courts' decisions that have interpreted that text. What is more, as the Eighth Circuit found in *City of Edina*, that position is grounded in federalism principles that have long preserved state traditional authority to protect public health.

The Surgeon General has identified reducing nicotine content to non-addicting levels as a tobacco endgame strategy.[168] Lowering nicotine content would substantially reduce tobacco-related morbidity and mortality.[169] Research has shown that nicotine reduction in tobacco products would prevent children and young adults experimenting with tobacco from becoming addicted. Low nicotine content in cigarettes also promotes cessation because those cigarettes are "less satisfying."[170] This finding is supported by studies on very low nicotine content (VLNC) cigarettes, which have shown that smoking VLNC cigarettes has not resulted in compensatory smoking—i.e., users smoking more cigarettes.[171] In fact, VLNC cigarette smokers have smoked fewer cigarettes. As noted in the 2020 Surgeon General's report on smoking cessation, most smokers (approximately 68%) want to quit, but only a few will often succeed in doing so because of nicotine's addictiveness. Nicotine reduction in tobacco products would therefore significantly enhance population-level cessation. It is estimated that reducing nicotine content to non-addicting levels would reduce the cigarette smoking rate in the United States to 1.4% by 2060.[172] Moreover, it would prevent 16 million people from starting to smoke and prevent 2.8 million tobacco-related deaths.[173]

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[167] It is also possible that such law would not be preempted under the TCA because nothing in the TCA prohibits a jurisdiction from banning a class of tobacco product. As the courts have noted, if the tobacco industry's requirement/prohibition dichotomy is to be taken to its logical conclusion, prohibiting the sale of a class of tobacco product would not be preempted because the preemption clause's text only mentions "requirements"—it does not address "prohibitions." *See* R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 559 (9th Cir. 2022) ("[I]f Appellants are correct that § 387p draws a sharp distinction between 'prohibitions' versus mere 'requirements relating to the sale . . . of[] tobacco products,' then the plain text of the preemption clause itself doesn't preempt any tobacco product 'prohibitions.'"); U.S. Smokeless Tobacco Mfg. Co. v. City of New York, No. 09-10511, 2011 WL 5569431, at *17 (S.D.N.Y. Nov. 15, 2011) ("Plaintiffs try to find meaning in the fact that the Preservation Clause purports to reach both sales restrictions 'and prohibitions,' while the Saving Clause reaches only sales restrictions . . . . But as the Preemption Clause is itself silent regarding sales prohibitions, it seems far more likely that prohibitions are preserved and never preempted, and therefore need never be saved."); *City of Edina*, 482 F. Supp. 3d at 881–82 ("[I]f the Ordinance is a prohibition—and a prohibition is not a 'requirement'—then the Ordinance is not preempted under the preemption clause, and it does not matter what the saving clause says.").

[168] 2014 SURGEON GENERAL'S REPORT, *supra* note 1, at 852–59.

[169] Benjamin J. Apelberg, Shari P. Feirman, Esther Salazar, Catherine G. Corey, Bridget K. Ambrose, Antonio Paredes, Elise Richman, Stephen J. Verzi, Eric D. Vugrin, Nancy S. Brodsky & Brian L. Rostron, *Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States*, 378 NEW ENG. J. MED. 1725 (2018).

[170] U.S. DEP'T OF HEALTH & HUMAN SERVS., SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL 653 (2020), https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf [hereinafter 2020 SURGEON GENERAL'S REPORT].

[171] Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818, 11,828 (proposed Mar. 16, 2018) (stating that VLNC cigarettes contain "as low as 0.4 mg nicotine/g of tobacco filler").

[172] Apelberg et al., *supra* note 169, at 1728.

[173] 2020 SURGEON GENERAL'S REPORT, *supra* note 170, at 654.

Because of the public health benefits of low nicotine in tobacco products, in 2022, FDA announced its plans to propose a product standard that would establish maximum nicotine levels in cigarettes and other finished tobacco products.[174] At this time, FDA has not issued a Notice of Proposed Rulemaking. It is uncertain when this rule will be proposed and finalized, the range of tobacco products it will encompass, the nicotine-yield thresholds that will be established, or how the rule would be effectively implemented and enforced. Even when FDA finalizes the rule, it is not guaranteed that all tobacco products will be covered. FDA may, for example, prioritize cigarettes, leaving other tobacco products—including little cigars, e-cigarettes, and smokeless tobacco—unaffected. Indeed, back in 2018 when FDA issued an Advance Notice of Proposed Rulemaking to address nicotine levels, it focused on cigarettes because of their addictiveness and prevalence.[175] This narrow approach, however, may undermine the health gains of reduced nicotine in cigarettes, as users are likely to migrate to other tobacco products to maintain their nicotine dose.[176]

It is also uncertain whether the maximum nicotine level set by FDA would be low enough to yield optimal health benefits of low nicotine tobacco products. A conventional cigarette, for example, yields about 1.1 to 1.7 milligrams of nicotine.[177] While FDA has previously noted that some VLNC cigarettes have a comparatively much lower yield (about 0.02–0.007 milligram of nicotine per VLNC), it is unclear on how to determine the appropriate maximum nicotine level to make cigarettes non-addictive. Moreover, even when FDA makes this determination, it may prefer taking "a stepped-down approach (where the nicotine is reduced gradually over time through a sequence of incremental levels and implementation dates) to reach the desired maximum nicotine level."[178]

These uncertainties are compounded by the likelihood of the tobacco industry seeking to derail this FDA measure through litigation or other strategies.[179] But states need not wait for FDA to protect their communities from tobacco-related morbidity and mortality. As the decisions in the flavored tobacco litigation have shown, under the TCA's saving clause, it is permissible for states to restrict the sale of categories of tobacco products—here, tobacco products with a high nicotine content—even when those restrictions implicate tobacco standards. To ensure optimal public health benefits, the sales restrictions will have to comprehensively address all tobacco products to guard against users switching to other tobacco products to maintain their nicotine dependence.

The FDA has characterized nicotine reduction in tobacco products as a tobacco product standard. Indeed, as one court has noted, "[t]he phrase 'tobacco product

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[174] Press Release, U.S. Food & Drug Admin., FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products (June 21, 2022), https://tinyurl.com/mr2hajyd.

[175] *See* Tobacco Product Standard for Nicotine Level of Combusted Cigarettes, 83 Fed. Reg. 11,818 (Mar. 16, 2018).

[176] *Id.* at 11,825.

[177] *Id.* at 11,826.

[178] *Id.* at 11,819.

[179] *See* Micah L. Berman, Patricia J. Zettler & David L. Ashley, *Anticipating Industry Arguments: The US Food and Drug Administration's Authority to Reduce Nicotine Levels in Cigarettes*, 133 PUB. HEALTH REPS. 502 (2018).

standards,' as used in the []TCA, encompasses a wide variety of issues, including: nicotine yields."[180] Regulating tobacco products based on their nicotine yield would be the kind of regulation that requires "manufacturers to alter the construction, components, ingredients, additives, constituents . . . and properties of their products."[181] For that reason, a state law regulating the amount of nicotine in tobacco products might be considered a tobacco product standard that falls within the TCA's preemption clause.[182]

That restricting the sale of tobacco products that exceed state law thresholds would constitute a product standard, however, does make such sales restriction impermissible under the TCA. As the decisions from second wave flavored tobacco litigation have shown, the TCA's preemption framework is designed to ensure that states retain their traditional power to address the health harms associated with tobacco products. The *Cnty. of Los Angeles* and *City of Edina* courts reasoned that the saving clause serves as an exemption to the preemption clause. The courts concluded that even if flavored tobacco sales restrictions were considered tobacco product standards, they would still be permissible because the saving clause exempts "requirements relating to the sale of tobacco products" from preemption. The same reasoning would equally apply to restricting the *sale* of high-nicotine-yield tobacco products. Such restriction, though implicating a product standard, would be "a requirement relating to the sale of tobacco products," thus falling within the TCA saving clause. This argument is further buttressed by federalism principles that guided the *City of Edina* court. Observing that tobacco regulation fell within the states' traditional police powers, the *City of Edina* court chose an interpretation that respected those powers and disfavored preemption. Here too, because the saving clause could be read as allowing sales restriction of tobacco products based on their nicotine yield, federalism principles would counsel against finding that the TCA preempts such sales restriction.

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[180] Indeps. Gas & Serv. Stations Ass'ns v. City of Chicago, 112 F. Supp. 3d 749, 752–53 (N.D. Ill. 2015).

[181] U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 434 (2d Cir. 2013) (internal quotations and citation omitted).

[182] Because this specific issue has not been litigated, it is impossible to say definitively whether such sales restriction would be an impermissible tobacco product standard under the TCA. The courts that have addressed tobacco product standards in the flavored tobacco context have avoided establishing bright line rules between preempted tobacco products and preserved tobacco sales prohibitions. *See id.* ("The line between regulating the sale of a finished product and establishing product standards will not always be easy to draw. Any finished product can be described in terms of its components or method of manufacture."); R.J. Reynolds Tobacco Co. v. City of Edina, 482 F. Supp. 3d 875, 878 (D. Minn. 2020) ("[T]he courts that have embraced this manufacturing/sales distinction have provided little in the way of justification—and, indeed, have sometimes provided little more than *ipse dixit*."); R.J. Reynolds Tobacco Co. v. Cnty. of Los Angeles, 29 F.4th 542, 564 (9th Cir. 2022) (Nelson, J., dissenting) ("[A] flavor ban remains a preempted tobacco product standard even if it operates at the point of sale."). This Article does not argue that a state law prohibiting the sale of high-nicotine-yield tobacco products are per se preempted; it simply concedes that position for the sake of arguing that such state law would be permissible under the saving clause. Moreover, as some courts have observed, it is plausible that the TCA does not preempt "prohibitions" of tobacco products because the preemption clause only mentions "requirements" relating to tobacco products. *See supra* note 167.

B. Implementation and Enforcement of Nicotine Yield Regulation

Even with the state regulation of nicotine yields being on solid legal ground from a preemption standpoint, questions remain about how states could implement these regulations without intruding on FDA's domain. The questions particularly concern how states would determine whether tobacco products exceed specified nicotine thresholds. Establishing testing methods to determine nicotine yields, for example, could be considered an intrusion on FDA's gatekeeping role.[183] But lessons from flavored tobacco regulation and litigation also help show how states could permissibly implement maximum nicotine thresholds in tobacco products without triggering preemption concerns.

The tobacco industry has tried to skirt flavored tobacco regulations by introducing concept flavors—tobacco products with ambiguous names, such as unicorn milk, jazz, arctic, and solar, "that imply flavor but do not explicitly indicate any particular flavor on the products labeling or packaging[.]"[184] To enforce flavored tobacco sales restrictions against concept flavors, regulators devised various mechanisms, such as developing a list of prohibited concept flavors, smelling the products to determine whether they were flavored, and considering how they were being advertised.[185]

Another proposed mechanism to implement flavored tobacco sales restrictions is for tobacco vendors to certify that their products are not flavored.[186] Under this approach, a state, for example, would require tobacco manufacturers and importers to submit to the state's attorney general's office a list of products that they manufacture or import certifying—under penalty of perjury—that the products are not flavored. This would put the burden on manufacturers to establish that their products can be permissibly marketed in the state. Consequently, the attorney general would develop a master list of products certified as not flavored.[187] This approach would not only avoid issues relating to the government's testing of products to ensure they are not flavored but also prompt retailers to sell only tobacco products on the master list of unflavored products.[188] This approach was previously proposed in California under Assembly Bill 1625, but the bill failed.

An approach that parallels the flavored tobacco self-certification and master list approach could be used in the nicotine content regulation regime. Like the unflavored tobacco list, a state restricting the sale of tobacco products that exceed a specified threshold could require tobacco manufacturers and importers to certify—under penalty of perjury—that their products' nicotine content does not exceed

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[183] *See Flavored Tobacco Sales Prohibitions: Enforcement Options*, MITCHEL HAMLINE SCH. OF LAW: PUB. HEALTH L. CTR. (Nov. 2022), https://tinyurl.com/4yx3aje9 (noting that chemical testing tobacco products to determine if they are flavored could be challenged as a tobacco product standard).

[184] Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396, 26,403 (May 4, 2022).

[185] *See generally* CAL. DEP'T OF PUB. HEALTH, CHALLENGES IN ENFORCING LOCAL FLAVORED TOBACCO RESTRICTIONS (Oct. 2019), https://tinyurl.com/44r4dvhr [hereinafter CDPH, CHALLENGES]; *see also* Cumberland Farms, Inc. v. Bd. of Health of Yarmouth, 144 N.E.3d 319 (Mass. App. Ct. 2020).

[186] CDPH, CHALLENGES, *supra* note 185.

[187] This approach was proposed in California in 2019. Assem. B. 1625, 2019–2020 Leg., Reg. Sess. (Cal. 2019), https://tinyurl.com/mujzxdjs.

[188] *Id.*

specified nicotine thresholds. The attorney general or other enforcement agency would then develop a master list of low nicotine products that could be legally sold within the state or jurisdiction. This would not only avoid the need to set up testing mechanisms that could raise more preemption issues but would also provide a cost-effective framework for ensuring that retailers are stocking only licit products.

VII. CONCLUSION

For over a decade now, 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 legal challenges. Every court that has addressed these preemption claims, however, has concluded that tobacco sales restrictions are not tobacco product standards and are therefore permissible under the TCA. The courts have also concluded that sales restrictions that implicate tobacco product standards are also permissible because they are requirements relating to the sale of tobacco products that fall within the saving clause. This litigation has helped demystify the overlapping roles that FDA and states play in combating the tobacco epidemic. Because the TCA's saving clause permits states to restrict the sale of categories of tobacco products, including sales restrictions that could be characterized as tobacco product standards, it is permissible for states to restrict retailers from selling tobacco products whose nicotine content exceeds specified thresholds. Such a policy would not only be supported by the TCA's text but also federalism principles—the history of federal regulation of tobacco that has long respected the important role that states play in protecting their communities from tobacco-related health harms. As laboratories of policy experimentation, states could leverage their police powers to create real-world evidence for nationwide action by FDA. Restricting the sale of highly addictive tobacco products would not only minimize tobacco-related health harms, which disproportionately affect racial and ethnic minorities, but also continue creating momentum for tobacco endgame policies that are already gaining traction in the United States.