Focus on Flavors

The authority of a state or local government to restrict or prohibit the sale or distribution of flavored tobacco products

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Focus on Flavors

May a state or local government restrict or prohibit the sale or distribution of flavored tobacco products?

A. Overview

A state or local government may restrict or prohibit the sale and or distribution of flavored tobacco products. State and local governments hold "police power" under the federal constitution, which means they have power to protect the health, safety and welfare of their citizens.[1] The Family Smoking Prevention and Tobacco Control Act (FSPTCA), a federal statute, expressly preserves state and local power to enact measures relating to the sale or distribution of tobacco products, even if those measures are more restrictive than federal law. Nationally, a number of local governments have enacted measures that restrict or prohibit the sale of flavored tobacco products. Three of those ordinances have, to date, been challenged in federal court, and all have been upheld.[2] However, courts have not ruled on all the possible variants of regulation of flavored tobacco products.

The regulatory power of a state or locality in this area is broad, but not unlimited: it must be based on police power, such as for the purpose of reducing youth smoking initiation,[3] it must be limited to a restriction of sales, distribution, or use of tobacco products within the jurisdiction; it may not regulate how products are manufactured or the ingredients they may contain; and it may not restrict the movement of products through the jurisdiction in commerce. Also, if the measure restricts speech, it may be vulnerable to challenge under the First Amendment.

Existing state and local measures that regulate flavored tobacco products define the regulated product by reference to its characterizing flavor.[4] This

"A state or locality may regulate the sale or distribution of tobacco products with any or all characterizing flavors"

[1] *See, e.g., Napier v. Atlantic Coast Line R.R. Co.*, 272 U.S. 605, 610 (1926).

[2] *U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York*, 708 F.3d 428 (2nd Cir. 2013); *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013); *Independents Gas & Serv. Stations Ass'ns, Inc. v. City of Chicago*, No. 14 C 7536, 2015 WL 4038743 (N.D. Ill., June 29, 2015). These decisions are not binding in California because they are in different states and circuits, but they are persuasive authority.

[3] California's interest in preventing the sale of tobacco products to minors dates back to at least 1891. See Cal. Penal § 308, Stats. 1891, c. 70, p. 64, § 1.

[4] The term "characterizing flavors" is not defined in the federal statute. It is used here to refer to products that have a taste or aroma that can be distinguished from the taste or aroma of tobacco during consumption of the product, or that are marketed as having such a characteristic.

is not a prescription for how a product must be made, but a description of the character of the product experienced by the consumer. This distinction is important because states and localities lack power to set manufacturing standards. A state or locality may regulate the sale or distribution of tobacco products with any or all characterizing flavors. Or a state or locality may except some flavors (such as menthol), as long as the inclusion or exception of the flavored product is based on police power (such as the protection of public health).

A state or locality may exercise this power over the full range of tobacco products, including cigarettes, cigarillos, and electronic cigarettes.[5] In 2009, in the FSPTCA, Congress gave the Food and Drug Administration (FDA) power to regulate only cigarettes, smokeless tobacco, and roll your-own (RYO) tobacco products. However, Congress also authorized the FDA to deem additional products to be within the FDA's regulatory power, and in 2014, the FDA issued a proposed rule to do just that. As of March 2016, those deeming regulations are not final. It is anticipated that the FDA will soon extend its regulatory authority over additional products, including electronic cigarettes, pipe tobacco, cigarillos, and cigars. Until that happens the FSPTCA presents no bar to state or local regulation of those products. Therefore, this paper proceeds on the assumption that a state or local government may regulate, for instance, cigarettes and electronic cigarettes, in exactly the same way.[6]

It is beyond the scope of this paper to consider the many policy and enforcement issues that might arise in the event a state or local government chooses to use its police power to regulate the sale or distribution of flavored tobacco products. Rather, this paper examines the legal authority for state or local action in this area. It first focuses on the ways in which states and localities may act, as distinct from areas in which only the federal government may act. This requires a discussion of the legal doctrine of federal preemption. This paper then examines the key provisions of the FSPTCA and returns to consider certain preemption issues in greater depth. Thereafter, it summarizes the three cases where courts have reviewed local ordinances regulating flavored tobacco products. The paper concludes with a discussion of other legal challenges that could be mounted against a state or local measure, as well as some miscellaneous issues arising from the definitions and scope of such measures.

[5] The term "electronic cigarettes" is used broadly to include all types of electronic devices and their components that deliver aerosolized or vaporized nicotine, tobacco or flavors.

[6] To be clear, in the event that the deeming regulations are not finalized, are invalidated by courts, or do not include all of the products identified above, the FSPTCA will not restrict the power of state or local governments to regulate the non-deemed products.

B. Federal preemption - briefly

Preemption refers to a legal doctrine that determines when a federal law displaces a state or local law (federal preemption) or when a state law displaces a local law (state preemption). For purposes of this paper, only federal preemption is likely to be relevant. Federal preemption is derived from the Supremacy Clause, which invalidates state or local measures that interfere with or are inconsistent with federal law. See *Hillsborough Cnty. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 712 (1985).

There are various types of federal preemption, of which two are likely to be raised in opposition to a state or local flavored product measure. One is express preemption, asking whether the preemption clause expressly states that the state or locality is prohibited from taking certain action. The other is conflict preemption, asking whether the state or local measure conflicts with federal law. See *Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt Dist.,* 498 F.3d 1031, 1039-40 (9th Cir. 2007). Thus, a court reviewing a state or local measure to regulate flavored tobacco products will both examine the FSPTCA's preemption scheme and consider whether the state or local measure is inconsistent with the FSPTCA or with FDA regulations. See *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008) ("Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose.")

At this point an analysis of preemption becomes less certain. Under the prevailing view, when a state or local measure is based on traditional police power, the reviewing court will start its analysis with a presumption against preemption. In other words, it will presume that the state or local government may properly enact measures that are stricter than federal law. This is in recognition that what is at issue is federal supremacy power versus state or local police power, both of which derive from the federal constitution. Thus, a state or local measure regulating sales or distribution of flavored tobacco products will not be displaced "unless that was the clear and manifest purpose of Congress." *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996). If "the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption." *Altria Group*, 555 U.S. at 77 (internal citation omitted). Similarly, if the federal statute contains a preemption clause and it does not specify that a certain area of regulation is preempted, that indicates a local or state measure regulating that area is not preempted. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.")

"Preemption refers to a legal doctrine that determines when a federal law displaces a state or local law (federal preemption) or when a state law displaces a local law (state preemption)"

However, not all current Supreme Court Justices agree with these principles. Some specifically reject the presumption against preemption when applied in express preemption cases, the use of legislative history to determine congressional intent regarding preemption, and the view that in express preemption cases there cannot also be preemption based on a conflict between federal and state law in an area not specifically referenced in the express preemption clause. See *Engine Mfrs. Ass'n v. South Coast Air Quality Mgmt Dist*., 541 U.S. 246, 256 (2004); *Altria Group*, 555 U.S. at 95, 99-102 (Thomas, J. dissenting); *Cipollone v. Liggett*, 505 U.S. at 548 (Scalia, J. dissenting). Therefore, in an abundance of caution, the analysis that follows relies neither on the presumption against preemption nor on the legislative history of the FSPTCA, and it applies the "ordinary principles of statutory construction." *Altria Group*, 555 U.S. at 101 (Thomas, J. dissenting).

With these principles in mind, this paper examines the FSPTCA's preemption scheme.

C. The operative federal statute: the Family Smoking Prevention and Tobacco Control Act (FSPTCA)

Congress gave the FDA authority to regulate "tobacco products" when it passed the FSPTCA in June 2009, and defined these products as cigarettes, cigarette tobacco, RYO tobacco, smokeless tobacco and any other tobacco products that the Secretary of Health and Human Services deems are subject to this authority by regulation.[7] *See* 21 U.S.C. § 387a(b). Under the FSPTCA, the FDA may establish tobacco product standards and regulate ingredients, additives, nicotine levels, testing, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, and modified risk tobacco products.[8] All of these can be categorized, broadly, as "product standards." "Product standards" are an area of exclusive FDA power.

[7] As discussed above, because Congress gave the FDA authority to deem other products to be tobacco products and the FDA's deeming rule appears to be close to final, this paper assumes that the FDA's authority extends to "new" products, including electronic cigarettes, cigars, cigarillos, and pipe tobacco.

[8] 21 U.S.C. § 387g gives the FDA power to regulate product standards; § 387h gives power to notice and recall defective products; § 387i requires manufacturers and importers to maintain and provide records to the FDA; § 387j sets forth requirements for new products and for pre-market review of products that are claimed to be substantially equivalent; § 387k sets forth requirements for products that claim to have a modified risk; § 387o requires the FDA to establish regulations regarding testing of ingredients and disclosure of such information; and § 387q concerns establishment of a scientific products advisory committee, which is required to have representatives of tobacco manufacturing and farming (but not retail or distribution).

C.1 The FSPTCA has a calibrated, hierarchical preemption structure

The FSPTCA's preemption scheme is hierarchical. The "preservation clause" comes first and is the broadest – it preserves the authority of federal agencies other than the FDA, the states, the political subdivisions of states (i.e., local governments created by the states), and the governments of Indian tribes. 21 U.S.C. § 387p(a)(1). Through the preservation clause Congress carved out an area for the FDA, but preserved all other powers for other entities – such as states, localities, tribes, and other federal agencies. Following the preservation clause is the "preemption clause" which describes the carve-out. *Id*. at § 387p(a)(2)(A). The preemption clause forbids only states and political subdivisions of states from acting in the preempted (or carved-out) areas, whereas actions by other federal agencies and tribes are not preempted. For the purposes of this paper, the most important preempted area is "product standards." The final part of the FSPTCA preemption scheme is the "savings clause." *Id*. at § 387p(a)(2)(B). Like the preemption clause it applies only to states and political subdivisions of states. The reason why the savings clause is relevant only to state and local governments is because by its own terms it references only the preemption clause – which concerns only state and local governments. It contains no provision to save the preserved powers of federal agencies other than the FDA or of tribes because none of their powers were preempted. Similarly, the savings clause saves only the state and local powers that could have been preempted. The savings clause ensures that the preserved powers of state and local governments are not preempted solely because they relate to a particular area, such as product standards, where direct state or local authority is prohibited.

"Through the preservation clause Congress carved out an area for the FDA, but preserved all other powers for other entities – such as states, localities, tribes, and other federal agencies"

C.2 The preemption clause

Congress placed the power to regulate "product standards" under FDA control using a preemption clause.[9] This clause limits the powers of states and localities. It provides that "[n]o State or political subdivision of a State may establish . . . with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the [FSPTCA] relating to tobacco product standards, premarket review, adulteration, misbranding,

[9] The full text of the preemption clause, 21 U.S.C. § 387p(a)(2)(A), is as follows:
(2) Preemption of certain State and local requirements
(A) In general
No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

labeling, registration, good manufacturing standards, or modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A). In other words, states and localities may not regulate product standards, even under their police powers, because any such regulation would likely be different from or in addition to federal law. This preemption clause underlies the argument presented to several courts, that local sales regulations are veiled, improper, product standards regulations.

C.3 The preservation clause

"Congress explicitly preserves the authority of a state or local government to regulate or prohibit the sale or distribution of tobacco products"

The argument that state or local sales and distribution regulations are impermissible product standards in disguise fails because Congress expressly preserved certain powers for state and local governments: Congress allowed state and local governments to adopt certain measures that are in addition to, or more stringent than, federal law. These powers are identified in the preservation clause.[10] This clause provides that, except for the areas identified as preempted in the preemption clause, "nothing" in the FSPTCA "shall be construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any law . . . or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under" the FSPTCA. 21 U.S.C. § 387p(a)(1). In other words, in those areas preserved for state or local regulation, the FSPTCA is a floor, not a ceiling, and "nothing" in the FSPTCA can take away from stricter state or local regulation.

The preservation clause continues, providing that this "includ[es] a law . . . 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." 21 U.S.C. § 387p(a)(1). Congress explicitly preserves the authority of a state or local government to regulate or prohibit the sale or distribution of tobacco products. This express recognition of state and local power is what makes permissible a state or local restriction or prohibition on the sale or distribution of flavored tobacco products.

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[10] The full text of the preservation clause, 21 U.S.C. § 387p(a)(1), is as follows:

(1) Preservation

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

The clause also preserves the power of a state or locality to regulate or prohibit the possession or use of tobacco products. *See* 21 U.S.C. § 387p(a)(1). A state or locality may do this for individuals of any age – this is not merely a grant of authority to set a higher minimum purchase age or to ban possession of tobacco products by minors. *Id*. A state or locality may also regulate advertising and promotions.[11] *Id*. Finally, the preservation clause states that no provision of the FSPTCA "shall limit or otherwise affect any State, tribal, or local taxation of tobacco products." *Id*. In short, states and localities have power to regulate or prohibit the sale or distribution of tobacco products.

C.4 The savings clause

State and local power is not only set forth in the preservation clause, but also in the savings clause.[12] The savings clause reiterates that, notwithstanding the preemption clause, the powers of states and localities are preserved. It states that, regardless of the preemption clause, states may impose "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." 21 U.S.C. § 387p(a)(2)(B). Thus, the bar on state and local regulation of product standards under the preemption clause does not impair a state or local sales or distribution measure even if that measure relates in some way to a product standard. Put another way, a state or locality may adopt a measure that relates to a product standard as long as the measure is only a regulation of the sale or distribution of products – such as a restriction on the sale of flavored tobacco products within the jurisdiction.

C.5.a The power of state and local governments to prohibit survives the preemption clause even though it is not expressly included in the savings clause

Challengers to local flavored product restrictions have argued that, in the savings clause, Congress saved the power of local and state governments only to "restrict," but not to "prohibit," sales of tobacco products. *See U.S. Smokeless Tobacco v. New York*, 708 F.3d at 435; *Nat'l Ass'n of Tobacco Outlets*

"A state or locality may adopt a measure that relates to a product standard as long as the measure is only a regulation of the sale or distribution of products – such as a restriction on the sale of flavored tobacco products within the jurisdiction"

[11] *See, e.g.*, the City of Providence, RI, ordinance prohibiting retailers from redeeming coupons, approved in *Nat'l Ass'n of Tobacco Outlets v. Providence*, 731 F.3d at 74, 76-81.

[12] The full text of the savings clause, 21 U.S.C. § 387p(a)(2)(B), is as follows:

(B) Exception

Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of Title 5 shall be treated as a trade secret and confidential information by the State.

v. Providence, 731 F.3d at 82; *Independents Gas & Serv. Stations v. Chicago*, 2015 WL 4038743 at *3. The argument is as follows: in the preservation clause Congress explicitly preserved power to "prohibit" when it gave a state or locality power to pass measures both "relating to" or "prohibiting" sales. However, Congress narrowed that power in the preemption clause and in the savings clause when it clarified which powers survived preemption, it did not include the word "prohibit." Thus, goes the argument, the power to "prohibit" was not "saved" for state or local governments. The three courts that considered this argument appear not to have been persuaded by it, but did not squarely resolve the issue because none of the operative ordinances were complete prohibitions and each court relied on that fact to pass on the issue. (*Id.*) It is therefore useful to consider at greater length whether the power to prohibit survives preemption.

"Because the preemption clause does not use the word 'prohibiting,' the power to prohibit was not preempted and thus need not be saved"

The simplest counter to such an argument is that "relating to" is broader than, and encompasses, prohibition. Therefore, because the power to "prohibit" was originally granted, and the power to regulate in ways that "relate" was saved, then the power to "prohibit" was also saved. More conclusively, the presence of the words "relating to" and the absence of the word "prohibiting" in the savings clause are explained by the fact that the savings clause simply mirrors the language in the preceding preemption clause: the savings clause merely states what is saved from preemption. Because the preemption clause does not use the word "prohibiting," the power to prohibit was not preempted and thus need not be saved.[13]

C.5.b The Fire Safety Act is an example that the power to prohibit in areas that relate to product standards survives the preemption clause

The interplay of the preservation, preemption and savings clauses is also illustrated by the assignment of power to regulate cigarette fire safety standards. This example is illuminating because, like characterizing flavors, fire safety standards implicate both the state's police power and the FDA's power to set product standards. The FSPTCA assigns this fire safety power as follows: The preservation clause explicitly preserves state authority to enact "measures relating to fire safety standards for tobacco products." 21 U.S.C. § 387p(a)(1)(A). The preemption clause then prohibits state or local governments from enacting differing or additional measures relating to product standards. *Id.* at § 387p(a)(2). However, California's Cigarette Fire

[13] The hierarchy of the preemption scheme is also illustrated by the fact that the preservation clause preserves the authority of federal agencies other than the FDA, the states, political subdivisions of states, and governments of Indian tribes; whereas the preemption clause prohibits only states and political subdivisions of states from acting in the preempted areas, leaving other federal agencies and tribal governments unaffected; thus the savings clause contains no provision for saving the powers of other federal agencies or tribes because none of their powers were preempted. Similarly, because the power to prohibit was never preempted, it need not be saved.

Safety and Firefighter Protection Act (Fire Safety Act) requires cigarette manufacturers to submit laboratory test results regarding ignition propensity to the State Fire Marshal. *See* Cal. Health & Safety §§ 14950-60. California's statute sets forth detailed product standards. *Id*. at § 14952. The statute therefore appears to be preempted: it imposes different and additional requirements "relating to" product standards. 21 U.S.C. § 387p(a)(2)(A). However, the savings clause states that the preemption clause does not apply to requirements "relating to fire safety standards for tobacco products." *Id*. at § 387p(a)(2)(B). Thus it saves this power for states even though the state measure is "relating to" a product standard. *Id*. The Fire Safety Act therefore exemplifies how state and local power to regulate sales or distribution of flavored tobacco products is saved, even if that measure relates in some way to product standards.

Moreover, the Fire Safety Act is a sales and distribution *prohibition*, not merely a restriction. Cal. Health & Safety § 14951(a) ("A person shall not sell, offer, or possess for sale in this state cigarettes not in compliance . . ."). This demonstrates that the power to prohibit is retained despite arguments (above) to the contrary.

No court has been asked to address the issue of whether California's Fire Safety Act is preempted by the FSPTCA, either as an impermissible prohibition under the savings clause or as an impermissible product standard under the preemption clause of the FSPTCA. However, the fact that all states have enacted fire safety laws very similar to California's illustrates that states have broad authority, using police power, to restrict or prohibit sales and distribution of tobacco products even when the regulation relates to product standards. This power is guaranteed under the preservation clause and, even though the restriction or prohibition relates in some way to product standards, because of the savings clause it is not preempted.[14]

"The Fire Safety Act therefore exemplifies how state and local power to regulate sales or distribution of flavored tobacco products is saved, even if that measure relates in some way to product standards"

[14] Several other provisions in the FSPTCA provide additional examples that Congress intended states and localities to possess certain regulatory powers even if exercising those powers related to product standards. For instance, the Fire Safety Act requires that an approved mark be placed on the pack. See Cal. Health & Safety § 14954. This implicates the labeling power that is reserved for the FDA under the preemption clause and which is not explicitly saved for the state in the savings clause. This shows the limits of federal preemption in an area where the state exercises its power to regulate sales or distribution. Similarly, regarding the federal Freedom of Information Act, the savings clause instructs that "[i]nformation disclosed to a State [regarding product standards] that is exempt from disclosure under [the Freedom of Information Act] shall be treated as a trade secret and confidential information by the State." 21 U.S.C. § 387p(a)(2)(B). This indicates that Congress contemplated that states might require reporting of information that relates to product standards – otherwise it would have been unnecessary to require that states treat such information as confidential. Also, the FSPTCA includes a provision stating that nothing in the FSPTCA shall be construed to modify or affect state product liability law. 21 U.S.C. § 387p(b). Even though product liability litigation may have a powerful impact on product standards, Congress made it clear that state product liability law is preserved. All of these examples show that the thrust of the savings clause was not to expand federal power beyond the parameters of the preemption clause, but the opposite – to clarify that state and local power to regulate sales and distribution is not preempted even when such measures implicate product standards.

C.6 Tobacco product characterizing flavor restrictions in the FSPTCA

The FSPTCA contains two provisions regarding flavors. One is a ban on cigarettes with characterizing flavors other than menthol or tobacco. 21 U.S.C. § 387g(a)(1)(A). This is not a ban on sales or distribution, but a complete prohibition: "a cigarette . . . shall not contain . . . [a] flavor . . . [other than tobacco or menthol]." *Id*. The second is a grant of authority to the FDA to regulate or prohibit menthol cigarettes in the future, but to do so only after conducting research into the impact of menthol-flavored cigarettes on public health.[15] *Id*. at § 387g(e). Congress did not prohibit flavored smokeless or RYO tobacco products, but it gave the FDA authority to prohibit such products, and, through the deeming process, to prohibit other flavored tobacco products as well. *Id*. at § 387g(a)(3) & (4). Altogether, these provisions show that Congress banned certain flavored products and gave the FDA authority to regulate or ban other flavored products through its power to set product standards. This is distinct from the power preserved for states and localities, which is the power to regulate sales and distribution (and expressly excludes the power to regulate product standards.) *Id*. at § 387p(a)(2)(A). Thus, there is no inconsistency between the FSPTCA and the power of states or localities to enact measures regarding sales or distribution of flavored tobacco products.

"The FSPTCA does not limit the power of a state or locality to ban or restrict the sale or distribution of particular products, such as flavored products"

C.7 Tobacco product category restrictions in the FSPTCA

The FDA's powers in the area of product regulation are not unlimited. "Because of the importance of a decision" the FDA is prohibited from "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll your-own tobacco products" or "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. § 387g(d)(3). The FSPTCA does not, however, limit the power of a state or locality to ban or restrict the sale or distribution of particular products, such as flavored products. In fact, while early versions of the bill reserved the power to ban or restrict the sale or distribution of products to the FDA, the enacted statute denied this exclusive power to the FDA and gave it to states, localities, other federal agencies, and tribes. *See U.S. Smokeless Tobacco v. New York*, 708 F.3d at 433, n.1. This reversal during the legislative process indicates congressional intent that states and localities hold power to regulate the sale or distribution of entire categories of products.

[15] The California Attorney General and 26 other state and territorial Attorneys General are on record as supporting a prohibition on menthol flavored cigarettes. *See* Comment from State Attorneys General to FDA re: Menthol in Cigarettes, FDA-2013-N-0521, Nov. 8, 2013.

C.8 The FDA's power to regulate sales and distribution of tobacco products

Finally, it is instructive to consider that the FSPTCA gives authority not only to states and localities, but also to the FDA, to regulate sales and distribution of tobacco products. See 21 U.S.C. § 387f(d)(1) (authorizing FDA to restrict sale and distribution of a tobacco product, including restrictions on advertising and promotion, to protect public health). However, unlike the regulation of product standards that Congress assigned exclusively to the FDA in the preemption clause and in detail in other provisions of the FSPTCA, there is nothing in section 387f or in the preemption clause that limits the power to regulate sales and distribution to the FDA. Rather, the preservation and savings clauses assign such power to states and localities.[16] In other words, the fact that the FSPTCA gives the FDA power to regulate sales and distribution does not imply that that power is not also possessed by state and local governments.

C.9 Authority of tribal governments to restrict or prohibit sale or distribution of flavored tobacco products

The power of tribal governments (and of federal agencies other than the FDA) to enact measures that are stricter than federal law, specifically including sales or distribution measures, is set forth in the preservation clause just as it is for state and local governments.[17] However, unlike state and local governments, the preemption clause in no way limits those powers of tribal governments. *See* 21 U.S.C. § 387p(a)(1) (containing no reference to tribal governments or other federal agencies). In other words, a tribe's power to enact a measure restricting or prohibiting the sale or distribution of flavored tobacco products on its reservation is not expressly preempted. However, if a tribe enacted a product standard that was inconsistent with a product standard set by the

"The power of tribal governments (and of federal agencies other than the FDA) to enact measures that are stricter than federal law, specifically including sales or distribution measures, is set forth in the preservation clause just as it is for state and local governments"

[16] Similarly, the FSPTCA forbids the FDA from prohibiting the sale of tobacco products in a specific category of retail outlets or from raising the minimum purchase age above 18 years. 21 U.S.C. § 387f(d)(3)(A). But the Act neither bars state or local governments from doing so nor expressly assigns those powers to state or local governments. Illustrating the fact that these powers are not preempted, despite not being expressly assigned to state or local governments, many localities and states have successfully raised the minimum age above 18 years and/or prohibited sale of tobacco products in certain retail outlets such as pharmacies. *See, e.g.*, TOBACCO EIGHTEEN TWENTY-ONE http://tobacco21.org/ (last visited Jan. 27, 2016).

[17] The relevant portions of this clause, 21 U.S.C. § 387p(a)(1), are as follows:

> . . . nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of . . . the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, . . . or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any . . . tribal . . . taxation of tobacco products.

FDA, the tribal measure could be challenged as inconsistent with federal law (i.e., conflict preemption.) This suggests that a tribe would be better advised to regulate sales or distribution rather than enact product manufacturing standards.

D. Preemption – in greater detail

Challengers to the New York City, Providence, and Chicago flavored tobacco product ordinances based their preemption arguments on two recent U.S. Supreme Court cases. In both cases the Supreme Court held that the state or local measure was preempted and also did not apply the traditional presumption against preemption even though the state or local measure was based on the exercise of police power. However, review of these two cases reveals that they do not support preemption of state or local flavored product measures under the FSPTCA.

D.1 *National Meat Association v. Harris*, - U.S. -, 132 S.Ct. 965, 181 L.Ed.2d 950 (2012)

The first case that may be cited as authority for preemption of a state or local measure restricting sale or distribution of flavored tobacco products is *National Meat Association v. Harris,* - U.S. -, 132 S.Ct. 965 (2012). The Federal Meat Inspection Act (FMIA) regulates operations at slaughterhouses. A preemption clause prohibits states from imposing additional or different requirements regarding those operations or facilities. 21 U.S.C. § 678. The federal statute and regulations specify how nonambulatory animals are to be processed. 9 C.F.R. § 309. A California statute prohibited slaughterhouses from purchasing, selling, or processing nonambulatory animals. Cal. Penal § 599f(a) & (b). A trade association challenged the state statute. California and others argued that the state statute was not preempted because it did not regulate the slaughtering process, only the kinds of animals that may be slaughtered and the sale of such meat. The Supreme Court disagreed, stating that California had imposed different operational requirements: "Where under federal law a slaughterhouse may take one course of action in handling a nonambulatory pig, under state law the slaughterhouse must take another." *Nat'l Meat Ass'n*, 132 S.Ct. at 970. The state statute was therefore preempted.

The reasoning, preemption scheme, and facts in *National Meat Association*, however, are quite different from those pertaining to a flavored tobacco product sales restriction under the FSPTCA. The preempted state statute regarding nonambulatory animals regulated facilities (slaughterhouses) and operations (how non-ambulatory animals were to be processed at those

facilities). Cal. Penal § 599f(c) ("No slaughterhouse shall hold a nonambulatory animal without taking immediate action to humanely euthanize the animal.") It did so even though the FMIA specifically stated that non-federal regulation of facilities and operations was preempted. 21 U.S.C. § 678. Unlike the FSPTCA, the FMIA contains no savings clause that permits limited non-federal regulation of facilities or operations. *See id*. Rather, the FMIA savings clause provides for non-federal regulation only over matters "other" than the facilities and operations regulated by the FMIA. *Id*. In other words, the FMIA savings clause is markedly different from the FSPTCA savings clause (that expressly permits non-federal regulation of sales and distribution even if it relates to the preempted area of product standards). *See Nat'l Ass'n of Tobacco Outlets v. Providence*, 731 F.3d at 82.

California contended that its sales ban operated only as an "incentive" for slaughterhouses to make certain operational choices. *Nat'l Meat Ass'n*, 132 S.Ct. at 972. The Supreme Court disagreed, stating that "the sales ban instead functions as a command to slaughterhouses to structure their operations in the exact way the [state statute] mandates." *Id*. at 972-73. However, for the reasons explained above, a state or local restriction on the sale of flavored tobacco products would be at most an incentive to manufacturers to produce non-flavored products. It would not contain an operational command similar to the instruction as to how nonambulatory animals must be handled in a production facility so as to avoid a criminal sanction.

California also argued that there was no conflict between state and federal law because its statute only designated which animals were to be removed from the slaughtering process altogether, whereas the federal law only regulated the animals that were going to be turned into meat. *Nat'l Meat Ass'n*, 132 S.Ct. at 973. "We think not," concluded the Supreme Court. *Id*. The Court pointed out that federal regulations regulated not only which animals may be turned into meat, but also which ones may not be. *Id.* The requirements of the state statute, therefore, did not fall outside the scope of the federal act but overlapped, and, being different, were preempted. *Id*. at 974. In contrast, a non-federal measure restricting sale of flavored tobacco products would regulate in an area that the FSPTCA expressly preserved and saved for state or local government action.[18]

"In contrast, a non-federal measure restricting sale of flavored tobacco products would regulate in an area that the FSPTCA expressly preserved and saved for state or local government action"

[18] Interestingly, in dicta the *National Meat Association* Court distinguished cases that upheld the power of a state to ban slaughtering horses for human consumption: "A ban on butchering horses for human consumption works at a remove from the sites and activities that the FMIA most directly governs. When such a ban is in effect, no horses will be delivered to, inspected at, or handled by a slaughterhouse, because no horses will be ordered for purchase in the first instance." 132 S.Ct. at 974. This illustrates that a prohibition of a category of product does not amount to operational interference. Thus, a state or local measure that specifies an upper threshold of intensity of rum-flavored cigarillos to avoid a sales prohibition might be open to challenge (as similar to a restriction on processing of nonambulatory pigs), whereas a measure banning the sale of all flavored cigarillos is a prohibition of a category and not an operational command (similar to a prohibition on slaughter of any horse for human consumption.) This suggests that *National Meat Association* stands for the proposition that a state or local government would be on stronger ground when it regulates without exception, than when it permits an exception that is based on a product standard.

In sum, not only are the preemption schemes of the FSPTCA and FMIA distinct, but so is a state or local restriction on the sale of flavored tobacco products likely to be very different from the state statute held to be preempted by *National Meat Association*. The reasoning and outcome of *National Meat Association* is therefore not a guide for how a court might review a state or local measure restricting the sale of flavored tobacco products.

D.2 *Engine Manufacturers Association v. South Coast Air Quality Management District*, 541 U.S. 246 (2004)

The other case that may be cited as authority for preemption of a state or local measure restricting sale or distribution of flavored tobacco products is *Engine Manufacturers Association v. South Coast Air Quality Management District* 541 U.S. 246 (2004). However, like *National Meat Association*, it can readily be distinguished because the preemption scheme is so different from that under the FSPTCA.

The Clean Air Act contains an express preemption clause that prohibits the enactment of state or local standards relating to vehicle emissions controls. 42 U.S.C. § 7543(a). An Air Quality Management District adopted Fleet Rules that applied to many types of vehicles in the greater Los Angeles basin. The Fleet Rules limited the types of vehicles that fleet operators could purchase or lease. *Engine Mfrs. Ass'n*, 541 U.S. at 249. The district court and 9th Circuit concluded that the Fleet Rules were not preempted because they only regulated the purchase of vehicles and did not compel manufacturers to meet an emissions "standard." *Id*. at 250. The Supreme Court disagreed, explaining that a local regulation of vehicle purchases was in effect a regulation of the underlying federal manufacturing standards. *Id*.

On its face, this decision appears to doom a local or state measure restricting the sale or distribution of flavored tobacco products. However, unlike the FSPTCA which in both the preservation and savings clauses carved out sales and distribution restrictions as proper areas for state or local regulation, the Clean Air Act did not carve out purchase regulations for state or local action. Rather, it did the opposite: the Clean Air Act included vehicle purchase provisions within the area of federally-approved action, as a way to meet federal clean air standards. 42 U.S.C. §§ 7581–7590; see also *Engine Mfrs. Ass'n*, 541 U.S. at 254-55. The status of non federal regulation of product purchases under the Clean Air Act and of non-federal regulation of product sales under the FSPTCA is therefore dissimilar. *Engine Manufacturers Association* does not support the view that state or local measures regulating the sale or distribution of flavored tobacco products are preempted under the FSPTCA.

E. Litigation arising from local measures regulating sale of flavored tobacco products

An increasing number of local governments,[19] and one state,[20] have passed measures that, in one way or another, restrict sales of flavored tobacco products. Three of these measures have been challenged and all were upheld. Although none of these legal decisions bind a court evaluating a measure in California, they provide a clear guide for how a court might review a state or local measure enacted in California. A discussion of these three decisions follows:

E.1 The New York City ordinance and litigation

In October 2009, soon after passage of the FSPTCA, New York City adopted an ordinance that prohibited the sale of all flavored tobacco products, except in tobacco bars,[21] and it did not prohibit the sale of products with menthol, mint, wintergreen or tobacco flavors. N.Y. City Admin. Code § 17-715.

U.S. Smokeless Tobacco Company ("USST") immediately sought an injunction against enforcement of the ordinance, arguing it was preempted by the FSPTCA. USST makes and distributes flavored smokeless tobacco products like chew, dip and snuff, so it was impacted by the ordinance. The U.S. District Court for the Southern District of New York denied USST's preliminary injunction motion. *U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York*, No. 09 CIV. 10511 CM, 2011 WL 5569431 (S.D.N.Y., Nov. 15, 2011). In 2011, it granted summary judgment in favor of the City. *U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York*, 703 F.Supp.2d 329 (S.D.N.Y. 2010). In 2013, the Second Circuit affirmed, agreeing that the ordinance was not preempted. *U.S. Smokeless Tobacco v. New York*, 708 F.3d 428.

USST argued that Congress, when it passed the FSPTCA, recognized the paradox between the harm caused by tobacco and the fact that many citizens smoke, and also that there is no national consensus to ban tobacco products altogether. *U.S. Smokeless Tobacco v. New York*, 708 F.3d at 433. Therefore, USST argued, Congress banned flavored cigarettes (other than tobacco and

[19] Including, in California, Santa Clara County, and the Cities of Berkeley, El Cerrito, Hayward, and Sonoma. Sonoma's ordinance excepts menthol but the other ordinances prohibit all flavors.

[20] Maine, which has since 2009 prohibited cigars with flavors other than tobacco. 22 Me. Rev. Stat. Health & Welfare § 1650-D.

[21] The ordinance defined a tobacco bar as a bar that, in 2001, generated 10% or more of its annual gross income from the on-site sale of tobacco products and rental of humidors. N.Y. City Admin. Code § 17-502(jj).

menthol flavors), yet forbade the FDA from banning cigarettes altogether. *Id*., citing 21 U.S.C. § 387g(a) and (d)(3). USST argued that Congress did not intend for localities to upset that balance by prohibiting a flavored tobacco product altogether. *Id*. The court, however, disagreed, concluding that even though the FSPTCA denies that power to the FDA, it "nowhere extends that prohibition to state and local governments." *Id*. Further, the court observed that while earlier versions of the legislation did reserve the power to prohibit exclusively to the federal government, the version that was actually enacted "does not forbid such bans by state and local governments." *Id*. at 433, n.1.

The court also addressed USST's express preemption argument, concluding that the preservation clause,

> expressly *preserves* localities' traditional power to adopt any 'measure relating to or prohibiting the sale' of tobacco products. § 387p(a)(2)(B). That authority is limited only to the extent that a state or local regulation contravenes one of the specific prohibitions of the preemption clause. *Id*. The only prohibition relevant here forbids local governments to impose 'any requirement . . . relating to tobacco product standards.'
>
> 708 F.3d at 433 (emphasis in original).

Turning to those product standards, the court held that the statute "reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects . . ." 708 F.3d at 434. USST contended that the ordinance was artfully crafted to evade preemption by appearing to be a sales regulation, but was in effect a product standard. *Id*. The court was not persuaded because to accept USST's contention would make the preservation clause superfluous: why would Congress give localities power to prohibit the sale of a product in one clause only to take it away in the next? The court therefore adopted "a narrower reading of the preemption clause that also gives effect to the preservation clause." *Id*. Because the ordinance does "not clearly infringe" on the FDA's authority to regulate the manufacturing of the products, it is not preempted. *Id*.

The court drew a distinction between the manufacturing process and the characteristics of a finished consumer product, observing that the local ordinance permissibly regulated the sale of a finished product that had certain characteristics, whereas the FDA's exclusive authority applied to regulating the manufacturing process of that product. 708 F.3d at 434-35. "[T]he City does not care what goes into the tobacco or how the flavor is produced, but only whether final tobacco products are ultimately characterized by – or marketed as having – a flavor." *Id*.

The court also reasoned that even if the ordinance did indirectly set a product standard within the terms of the preemption clause, it would still not be preempted because it fell within the savings clause. The savings clause allows state and local governments to set "requirements relating to the sale" of tobacco products. 708 F.3d at 435. USST argued that although the savings clause allows for "requirements," it does not mention and therefore does not permit a complete "prohibition." *Id*. The court decided it did not need to resolve that issue because the New York ordinance was not actually a prohibition: sales were permitted in tobacco bars. *Id*. at 435-36. It was uncontested that USST products were not actually sold in any of the eight tobacco bars in the City, but that was a result of a commercial choice rather than the statute on review, and there was also no evidence as to whether flavored products, other than smokeless tobacco, were sold at tobacco bars. *Id*. at 432, 436 n.3. Thus, the court did not resolve whether the savings clause encompassed an ordinance that was a complete prohibition.[22]

Finally, the court assessed the overall purposes of the FSPTCA, to consider whether its interpretation of the ordinance and its conclusion that the ordinance was not preempted, comported with the overall objectives of Congress. Noting the shared goals of the FSPTCA and the ordinance – reducing tobacco use especially by young people – it concluded that the ordinance was not preempted. 708 F.3d at 436.

The *City of New York* case stands for the capacity of a local government to restrict the sale of tobacco products (other than cigarettes) that have flavors (other than menthol), and to do so even if the practical effect of the measure is to make the products commercially unavailable in the jurisdiction.

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E.2 The City of Providence ordinance and litigation

In 2012 Providence, Rhode Island, adopted two ordinances regulating the sale of tobacco products. A price ordinance prohibited retailers from redeeming coupons that discounted tobacco products; the price ordinance is not relevant to this paper. A flavor ordinance prohibited all retailers, other than tobacco bars, from selling flavored tobacco products, but it exempted cigarettes and exempted the flavors of menthol, mint, wintergreen and tobacco. Providence, R.I., Code of Ordinances § 14-309. In other words, the flavor ordinance was very similar to the New York City ordinance discussed above. The legislative purpose was to reduce use of tobacco by youth. *Nat'l Ass'n of Tobacco Outlets v. Providence*, 731 F.3d at 75. In February 2012, the National Association of Tobacco Outlets, Inc. (NATO) and various manufacturers filed suit. The parties moved for summary judgment. The district court denied

[22] The court also described the ordinance as regulating a "niche product, not a broad category of products such as cigarettes." *Id*. at 436. This suggests that the court might have looked less favorably on a broader regulation that, for instance, prohibited sale of all cigarettes.

NATO's motion and granted the City's motion, and in 2013 the First Circuit affirmed. *Id*. at 74.

Plaintiffs argued that the ordinance was a product standard in disguise, and thus preempted. 731 F.3d at 82. Plaintiffs also argued that the ordinance was not encompassed within the savings clause because it was effectively a prohibition and the savings clause did not save local regulations that prohibited sales. *Id*. The court disagreed, noting that the ordinance "is not a blanket prohibition because it allows the sale of flavored tobacco products in smoking bars." *Id*. Thus, like the Second Circuit in the *City of New York* case, the First Circuit did not resolve the issue of whether a regulation prohibiting sales was within the scope of the savings clause.

"The *City of Providence* case stands for the proposition that a local government may restrict the sale of tobacco products other than cigarettes that have flavors other than menthol, even if by doing so it has an operational effect on product standards"

The First Circuit disagreed with the Second Circuit only on the issue of whether a sales restriction that functions as a command to manufacturers to operate in accord with a local standard is necessarily preempted. *Id*. at 83, n.11. The First Circuit concluded that "[g]iven Congress' decision to exempt sales regulations from preemption, whether those regulations have an impact on manufacturing is irrelevant." *Id*. Thus, in the view of the First Circuit, the nature or scale of the impact of a state or local measure on product standards – whether it is an incentive, motive or command – has no bearing on its validity, as long as it is a regulation only of sales or distribution.[23]

The *City of Providence* case stands for the proposition that a local government may restrict the sale of tobacco products other than cigarettes that have flavors other than menthol, even if by doing so it has an operational effect on product standards.

E.3 The City of Chicago ordinance and litigation

In 2013 Chicago adopted an ordinance that went significantly further than the New York and Providence ordinances. It regulated selling or dealing in any tobacco products, including cigarettes, with a characterizing flavor, including menthol. Chicago, Ill. Code § 4-64-098. Such sales and dealing were prohibited at retail locations within 500 feet of a school, but permitted elsewhere and also permitted regardless of location at tobacconists that derived over 80% of gross revenue from sale of tobacco products. *Id*. The purpose of the restriction was to reduce smoking by adults and youth. Chicago, Ill. Ordinance 02013-9185 (Dec. 11, 2013). In 2014, an association of gas stations and small businesses in Chicago, and a convenience store that sold flavored tobacco products, filed suit in federal court. In 2015, the court granted the City's motion to dismiss the suit. Independents *Gas & Serv. Stations v. Chicago*, 2015 WL 4038743. The parties did not appeal.

[23] Plaintiffs raised other challenges to the flavored products ordinance based on the state constitution, but those contentions also failed. *Id*. at 83-85.

The district court accepted the reasoning and conclusions, without exception, of the Second Circuit in the *City of New York* case. *See Independents Gas & Serv. Stations v. Chicago*, 2015 WL 4038743 at *3-4. The court reasoned that by its plain terms the ordinance operated as a sales regulation and therefore fell squarely within the savings clause. *Id*. at *3. The Plaintiffs argued, as did the Plaintiffs in the First and Second Circuit cases, that while the preservation clause applied to measures that either related to or prohibited the sale of tobacco products, the savings clause only applied to measures that related to the sale of tobacco products. *Id*. at *3. Thus, they concluded, because the ordinance prohibited sales in certain areas and the power to prohibit was not saved, the ordinance was preempted. *Id*. The court found this argument "unpersuasive," pointing out that the ordinance was not actually a prohibition because it allowed the sale of flavored products both beyond the 500 foot zone and in tobacconists. *Id*.

The Plaintiffs also argued that the ordinance was "a manufacturing regulation disguised as a sales regulation because it will cause manufacturers to reduce production of flavored tobacco product." *Id*. at *3. The court held that "to run afoul of the preemption clause, the ordinance must function as a command to tobacco manufacturers" rather than only an "incentive or motivator." Id. (internal quotations omitted). Concluding that the "ordinance regulates flavored tobacco products without regard for how they are manufactured . . . it is not a command to implement particular manufacturing standards and . . . is exempt from the FSPTCA's preemption clause." *Id*. at *4.[24]

The *City of Chicago* case stands for the proposition that a local government may restrict the sale of all tobacco products, including cigarettes, that have any characterizing flavor other than tobacco, and may severely restrict sales within certain areas.

"The *City of Chicago* case stands for the proposition that a local government may restrict the sale of all tobacco products, including cigarettes, that have any characterizing flavor other than tobacco, and may severely restrict sales within certain areas"

F. Other issues arising from regulation of flavored tobacco products

Federal preemption is the most likely, but not the only, legal argument that could be mounted against state or local measures regulating sales of flavored tobacco products.

F.1 Equal protection challenges

Legislation that contains an exemption for a particular type of retailer could be challenged by other similarly-situated retailers as arbitrary and

[24] The court also rejected arguments based on vagueness, retroactivity, and vested rights. (*Id*. at *4-6.)

[25] Note that the exemption for tobacco bars in New York City was not challenged because the lawsuit was filed by a manufacturer and not by a tobacconist.

capricious, in violation of the constitutional guarantee of equal protection. For instance, in 2008, the City of San Francisco banned tobacco product sales in pharmacies, but exempted supermarkets and 'big box' stores that had pharmacies. Walgreen successfully challenged the ordinance on the ground that the City violated equal protection by not exempting Walgreen stores that, like supermarkets, also sold general merchandise. *See Walgreen Co. v. City and Cnty of San Francisco*, 185 Cal. App. 4th 424, 443–44 (2010). However, if the exception is based on protection of public health or there is no exception at all, the measure is more likely to satisfy rational basis review and be upheld. *See Safeway Inc. v. City and Cnty of San Francisco*, 797 F. Supp. 2d 964, 973 (N.D. Cal. 2011) (upholding San Francisco's amended pharmacy ordinance that contained no exception). It is important to be clear that an equal protection challenge does not go to the power of a state or local government to act, but only whether it may except certain businesses from its action. Thus, a tobacco bar might raise an equal protection challenge against a flavored product sales ordinance that excepts hookah bars but not tobacco bars.[25]

F.2 Vested interest and retroactivity challenges

A retailer or manufacturer could argue that it has a constitutionally protected right to sell flavored tobacco products. The fact, however, that current law or a license may permit an entity to sell a product does not mean that the right has vested and cannot be removed. Courts have not recognized a constitutional right to sell specific tobacco products. Further, California law recognizes that even if a right has vested it must yield to the state's police power, unless a specific business is arbitrarily singled out. See O'Hagen v. Bd. of Zoning Adjustment, 19 Cal. App. 3d 151, 159; see also Safeway v. San Francisco, 797 F. Supp. 2d at 970-71. Again, this is not a challenge to the state or local government's power to act in general, but its power to regulate a specific entity. This points to the importance of basing any exemptions on well supported grounds.

Related to this argument, a retailer or manufacturer could argue that a law violates due process because it applies retroactively. The standard for impermissible retroactivity, however, is whether the new law "attaches new legal consequences to events completed before its enactment," not just that it unsettles existing expectations. *Landgraf v. USI Film Products*, 511 U.S. 244, 270 (1994); *see also Independents Gas & Serv. Stations v. Chicago*, 2015 WL 4038743 at *4-6. In other words, a law that takes away the retail tobacco license from a store that sells flavored tobacco products might be vulnerable

[25] Note that the exemption for tobacco bars in New York City was not challenged because the lawsuit was filed by a manufacturer and not by a tobacconist.

to challenge, but one that permits the store to continue to do business and to renew its license while prohibiting only its sale of flavored products, attaches no new legal consequence other than the limited one supported by police power.[26]

F.3 First Amendment challenges

It could be argued that a regulation of flavored tobacco products implicates the speech rights of a retailer or manufacturer if the measure provides that a claim that a product has a certain flavor constitutes presumptive evidence that the product is in fact a flavored product.[27] However, if a measure regulates only sales of a product, not speech, then the First Amendment is not implicated: as long as only sale is prohibited, the retailer and manufacturer are free to say whatever they want about the product. Because First Amendment rights are not implicated, the state or locality need show only that the law has a rational basis, and the protection of public health satisfies this test. Indeed, even if speech rights were implicated, a state or locality could argue that the protection of public health was a compelling interest.[28]

"If a measure regulates only sales of a product, not speech, then the First Amendment is not implicated: as long as only sale is prohibited, the retailer and manufacturer are free to say whatever they want about the product"

It could also be argued that a prohibition on the "offer" for sale of flavored tobacco products implicates the First Amendment because an "offer" is a form of commercial speech. However, if the law prohibits the sale of the products, then an offer to sell them would be an offer to engage in unlawful conduct. Such an offer does not receive First Amendment protection. *United States v. Williams*, 553 U.S. 285, 297 (2008).

F.4 Vagueness

Legislation is often challenged on grounds of vagueness.[29] Prevention is the best cure, i.e., a well-drafted law. For instance, if an ordinance prohibits sales from stores located within 1,000 feet of a school, it might be prudent to

[26] A retroactivity argument based on the Ex Post Facto Clause would likely fail unless the ordinance includes criminal penalties.

[27] For instance, a measure providing that: "A public statement, claim or indicia made or disseminated by the manufacturer of a tobacco product, or by any person authorized or permitted by the manufacturer to make or disseminate public statements concerning such product, that such product has or produces a characterizing flavor shall constitute presumptive evidence that the product is a flavored tobacco product."

[28] Such arguments were raised, analyzed at length, and rejected in *National Association of Tobacco Outlets v. Providence*, 2012 WL 6128707 at *4-9. However, because of the possibility that the inclusion of this evidentiary presumption could lead to litigation and delay in enforcement, state or local governments may choose to avoid including such a presumption. In that case, a state or local government could introduce evidence of, for instance, a pack of cigarettes with the word "menthol" printed on it in green letters, and then argue that this labeling tended to show that the cigarettes had a characterizing flavor of menthol and/or was offered for sale and purchased with that expectation. But there would be no legal presumption favoring that argument.

[29] An ordinance is unconstitutionally vague "if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits," or "if it authorizes or even encourages arbitrary and discriminatory enforcement." *Hill v. Colorado*, 530 U.S. 703, 732 (2000).

specify whether this distance is measured from the exterior boundary of the school or from a central point, whether it includes charter and/or private schools, and that enforcement of the ordinance will begin only after all retailers have received notice. Similarly, prudence counsels that a law specify whether it prohibits only the sale of a product, or also distribution, offer for sale and/or possession for sale.

"It is unlikely that a state preemption challenge could be brought against a local ordinance restricting sale of flavored tobacco products because no state law limits the authority of local governments to regulate the distribution or sale of flavored tobacco products within their boundaries"

F.5 State preemption

It is unlikely that a state preemption challenge could be brought against a local ordinance restricting sale of flavored tobacco products because no state law limits the authority of local governments to regulate the distribution or sale of flavored tobacco products within their boundaries. See Cal. Health & Safety § 118950(e); Cal. Bus. & Prof. §§ 22960(c), 22961(b), 22962(e), and § 22971.3.

G. Definitions and scope of state or local measures

It is beyond the scope of this paper to consider the pros and cons of regulating the sale of flavored tobacco products, or what the proper scope of a state or local measure should be. However, the following general points are offered.

The measure should define what constitutes a "flavored tobacco product." This is typically done by reference to a "characterizing flavor."[30] The term "characterizing flavor" also needs definition, in particular as to whether or not it includes menthol flavor.[31] The first local restrictions on flavored products excluded menthol, but it appears that this was a result of policy rather than legal considerations. As explained earlier, although the FSPTCA imposes limits on the FDA's power to regulate products with menthol flavor, it does not place those limits on the powers of state or local governments to enact sales or distribution restrictions.

Some of the existing ordinances give examples of prohibited flavors, such as candy or alcohol flavors. This is not necessary, but may serve to emphasize that the government is specifically seeking to reduce youth smoking and initiation by restricting sale of products with flavors with youth appeal. The greater the extent to which the restriction is defined by the characteristics of the consumer product, the more impervious it will be against a challenge that it is a disguised product standard. Thus, some existing ordinances include a

[30] For instance, a "flavored tobacco product" means any tobacco product or component thereof that imparts a characterizing flavor.

[31] For instance, the term "characterizing flavor" means a distinguishable taste or aroma, other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product. This type of definition, which is based on the character of the product as experienced by a consumer, sets the regulation apart from one based on a product standard.

clause that "no tobacco product shall be determined to have a characterizing flavor solely because of the use of additives or flavorings or the provision of ingredient information." Such language may tend to demonstrate that the sales regulation is entirely distinct from a product standard.[32] Some measures also include an evidentiary rule that any statement characterizing the flavor of the product, made by the manufacturer or its agent, amounts to a presumption that it is a flavored tobacco product.

It is also advisable to identify clearly what constitutes a regulated product. For instance, does it include electronic nicotine delivery devices and/or components, such as flavored e-liquids? Does it include electronic aerosol or vapor delivery devices that do not contain nicotine or tobacco and are not marketed as tobacco products or nicotine delivery devices?[33]

"It is also advisable to identify clearly what constitutes a regulated product. For instance, does it include electronic nicotine delivery devices and/ or components, such as flavored e-liquids? Does it include electronic aerosol or vapor delivery devices that do not contain nicotine or tobacco and are not marketed as tobacco products or nicotine delivery devices?"

Finally, the legislative body should make findings, state the purpose of the measure, and explain how the measure is intended to achieve that purpose.[34] This purpose, presumably, will be within the entity's police power to safeguard public health, welfare, and safety. It would therefore be consistent with the statutory directive from Congress to the FDA to act so as to protect the public health. See, e.g., 21 U.S.C. § 387g(a). Consistency between the purposes of federal, state, and local statutory measures will tend to protect state and local measures from federal preemption.

H. Other areas of state and local authority

This paper focuses on the power preserved under the FSPTCA for state and local governments to regulate sales and distribution of tobacco products. However, the FSPTCA also preserves state and local power to enact other measures. For instance, local restrictions and prohibitions on the use and possession of flavored tobacco products are not preempted, but they might be difficult to enforce. For instance, if a citizen returns from another state with a prohibited product in his or her possession, what effective enforcement mechanism would a city or state possess? If enforcement was attempted, would it be an efficient means to achieve the purpose of the

[32] Legislators should also be aware that the characterizing flavor of "tobacco" is itself an elaborate construct. *See* Robert N. Proctor, *Golden Holocaust: Origins of the Cigarette Catastrophe and the Case for Abolition* 31-45, 494-505, 2011. The leaves of a tobacco plant are a far cry from the product found rolled within a tobacco-flavored cigarette tube. Tobacco is cured in ways that change its pH to make it inhalable and sweeter, and sugars and flavoring agents are added to create what is then characterized as "tobacco" flavor. *Id*.

[33] This would regulate electronic devices that impart only a flavor, or that provide flavor to marijuana or other substances.

[34] Legislators should make these findings and state these purposes in an explicit fashion, rather than rely on them being inferred from legislative history or testimony. As discussed above, some judges are skeptical about the value of legislative history in statutory analysis.

measure, which might be to reduce youth access to flavored products? A ban on possession might also prompt challenges under the Commerce Clause. How would a truck transporting prohibited products through the jurisdiction be distinguished from one delivering products for sale within the jurisdiction? The FSPTCA also gives states and localities power to restrict advertising. Such regulations would be likely to raise expensive and time-consuming First Amendment challenges. A pragmatic view might be that if a retailer cannot sell an item within the jurisdiction then the retailer is unlikely to devote resources to advertising it or offering coupons, thus making unnecessary a restriction on marketing or promotion. It is beyond the scope of this paper to consider the many policy and enforcement issues that might be implicated by state or local measures that go beyond limiting the sale and/or distribution of menthol cigarettes, flavored tobacco products, and flavored electronic smoking devices or the cartridges and liquids sold separately for these devices.

"There does not, appear to be a legal barrier to a state or local government enacting a complete sales prohibition on the sale of menthol cigarettes, flavored tobacco products, and/or flavored electronic cigarettes"

I. Conclusions

State and local governments have police power to act to protect public health. This includes enacting measures to regulate tobacco products. Under the FSPTCA, state and local power to enact sales and/or distribution measures is expressly preserved and saved from preemption. This is the case even if the measures are more stringent than under federal law and even if the measures relate to a product standard. (State and local governments have no power to regulate product standards themselves.) The power includes the power to regulate all types of tobacco products, including cigarettes, and all characterizing flavors, including menthol. A state or local measure may contain exceptions. Several existing measures contain exceptions for certain products (e.g., menthol cigarettes), for certain retailers (e.g., tobacco bars), or for certain areas (e.g., zones around schools). Three such ordinances have, to date, been challenged in courts, and all have been upheld by federal courts in New York, Rhode Island, and Illinois. All of these ordinances contain limited exceptions of various kinds. Thus, no court, to date, has been required to consider the validity of a complete prohibition of sales and distribution of all types of tobacco products that have any characterizing flavor other than tobacco. There does not, however, appear to be a legal barrier to a state or local government enacting a complete sales prohibition on the sale of menthol cigarettes, flavored tobacco products, and/or flavored electronic cigarettes.