# APPENDIX

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# APPENDIX A

**FOR PUBLICATION**

**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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| R.J. REYNOLDS TOBACCO COMPANY; AMERICAN SNUFF COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.,<br>*Plaintiffs-Appellants*,<br>v.<br>COUNTY OF LOS ANGELES; COUNTY OF LOS ANGELES BOARD OF SUPERVISORS; HILDA L. SOLIS; MARK RIDLEY-THOMAS; SHEILA KUEHL; JANICE HAHN; KATHRYN BARGER, each in his or her official capacity as a member of the Board of Supervisors,<br>*Defendants-Appellees*. | No. 20-55930<br><br>D.C. No. 2:20-cv-04880-DSF-KS<br><br>OPINION |

Appeal from the United States District Court
for the Central District of California
Dale S. Fischer, District Judge, Presiding

Argued and Submitted October 19, 2021
Pasadena, California

Filed March 18, 2022

Before: Ryan D. Nelson and Lawrence VanDyke, Circuit Judges, and Karen E. Schreier,[*] District Judge.

Opinion by Judge VanDyke;
Dissent by Judge Nelson

## SUMMARY[**]

### Preemption / Tobacco Control Act

The panel affirmed the district court's dismissal of an action brought by tobacco companies, alleging that the Family Smoking Prevention and Tobacco Control Act ("TCA") preempts the County of Los Angeles's ban on the sale of all flavored tobacco products.

The panel held that the TCA authorizes the Food and Drug Administration to regulate tobacco products and expressly preempts some contrary state or local regulations, while also expressly preserving and saving from preemption other state and local regulatory authority over tobacco. The panel held that the TCA's text, framework, and historical context reveal that it carefully balances federal and local power by carving out the federal government's sole authority to establish the standards for tobacco products, while preserving state, local, and tribal

[*] The Honorable Karen E. Schreier, United States District Judge for the District of South Dakota, sitting by designation.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

authority to regulate or ban altogether sales of some or all tobacco products.

The panel wrote that the TCA's "unique tripartite preemption structure" governed its analysis. The TCA includes a "preservation clause," which preserves state, local, and tribal power to enact any regulation concerning tobacco products that is "in addition to or more stringent" than those promulgated by the TCA. The TCA's preemption clause reads as follows: "No . . . 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 [the TCA] relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." An immediately following savings clause instructs that the preemption 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."

The panel held that, properly understood, the TCA's preemption clause does not preclude non-federal sales regulations such as the County's sales ban. But even if it did, the County's sales ban would nonetheless be exempted from preemption because it falls within that clause's text as an allowed local requirement relating to the sale of tobacco products. Either way, the TCA does not expressly preempt the County's sales ban. The panel also held that, because the TCA explicitly preserves local authority to enact more stringent

regulations than the TCA, the County's sales ban does not pose an impermissible obstacle to the TCA's purposes or objectives regarding flavored tobacco. Accordingly, the County's sales ban is neither expressly nor impliedly preempted.

Dissenting, Judge R. Nelson wrote that because Los Angeles's ban falls within the TCA's preemption clause and is neither preserved nor saved, he would hold that it is expressly preempted. Judge R. Nelson wrote that the ban fell within the preemption clause because it was a requirement different from or in addition to any TCA requirement relating to tobacco product standards, which can relate both to manufacturing and to sales. Judge R. Nelson wrote that, by its terms, the preservation clause does not apply to the preemption clause, but rather clarifies that no other provision of the statute has any preemptive effect and that the authorities of federal agencies and Indian tribes are not preempted by the TCA. Finally, Judge R. Nelson would hold that the savings clause only saves for states the authority to enact age requirements.

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## OPINION

VANDYKE, Circuit Judge:

## I. INTRODUCTION

Until just over a decade ago, tobacco products were regulated almost exclusively by the states and local governments, with little federal involvement. Then beginning in the late 1990's, the U.S. Food and Drug Administration first sought to exert federal regulatory authority over such products. This initial attempt was swiftly rebuffed by the Supreme Court, which concluded the FDA lacked that authority under then-existing statutes. *See FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000). In response, Congress passed the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), *codified at* 21 U.S.C. § 387 *et seq.*, which authorized the FDA to regulate tobacco products and expressly preempted some contrary state or local regulations, while also expressly preserving and saving from preemption other state and local regulatory authority over tobacco.

The boundary between the TCA's preemption clause and its preservation and savings clauses is the subject of the dispute in this case. The County of Los Angeles claims that the TCA's preservation and savings clauses permit its decision to ban the sale of all flavored tobacco products. Predictably, multiple tobacco companies have challenged the County's ban, arguing that the TCA's preemption clause both expressly and impliedly preempts the ban.

The TCA's unique tripartite preemption structure governs our analysis of these issues. Its text, framework, and historical context reveal that it

carefully balances federal and local power by carving out the federal government's sole authority to *establish* the standards for tobacco products, while preserving state, local, and tribal authority to regulate or ban altogether sales of some or all tobacco products. Properly understood, the TCA's preemption clause does not preclude non-federal sales regulations such as the County's sales ban challenged in this case. But even if it did, the County's sales ban would nonetheless be exempted from preemption by the TCA's savings clause because it easily falls within that clause's text as an allowed local "requirement[] relating to the sale . . . of[] tobacco products." 21 U.S.C. § 387p(a)(2)(B). Either way, the TCA does not expressly preempt the County's sales ban. And given that the TCA explicitly preserves local authority to enact "more stringent" regulations than the TCA, the County's sales ban does not pose an impermissible obstacle to the TCA's purposes or objectives regarding flavored tobacco. It is therefore neither expressly nor impliedly preempted, and we affirm the district court.

## II. BACKGROUND

### 1. States and Localities Historically Possessed Broad Power to Regulate and Ban Tobacco Products.

The TCA's tripartite preemption provision can be properly understood only against the historical backdrop of states and localities' longstanding role as the primary regulators of tobacco products. *See Stewart v. Dutra Const. Co.*, 543 U.S. 481, 487 (2005) (interpreting a federal statute by looking to the "backdrop against which Congress" acted). Over a century ago, the Supreme Court first recognized that

states, because of public health concerns, could prohibit the sale of cigarettes. *See Austin v. State of Tennessee*, 179 U.S. 343, 348–49 (1900) ("[W]e think it within the province of the legislature to say how far [cigarettes] may be sold, or to prohibit their sale entirely . . . provided no discrimination be used . . . and there be no reason to doubt that the act in question is designed for the protection of the public health."). In the intervening century, and in response to growing awareness of the harmful effects of cigarettes, Congress enacted various statutory provisions focusing on consumer education through advertising and labeling requirements. *See, e.g.*, Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331–1341), *see also Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1186–87 (11th Cir. 2017) (en banc) (surveying the development of federal tobacco laws).[1] But these federal statutes

[1] *See also* Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. No. 99-252, 100 Stat. 30. While "the ADAMHA Reorganization Act, Pub. L. No. 102-321, 106 Stat. 323 (1992), condition[ed] certain block grants on states making it unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18," *Graham*, 857 F.3d at 1187 (citation and internal quotation marks omitted), the strings attached to federal grants did not preempt state or local authority from regulating the sale or ban of these products; quite the opposite, they strongly incentivized states to exercise their traditional authority over tobacco-related sales. *See* 42 U.S.C. § 300x-26.

never preempted state and localities' traditional power to restrict or ban sales of tobacco products. *See id.*

During this period, states also played key roles in indirectly regulating tobacco products through litigation. In the 1990s, after numerous heads of major tobacco companies denied under oath the addictiveness of nicotine, several states sued their companies. *See Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health & the Env't*, 103d Cong. 628 (1994); Barry Meier, *Remaining States Approve the Pact on Tobacco Suits*, N.Y. TIMES, Nov. 21, 1998, at A1. The lawsuits resulted in a "landmark agreement" between the tobacco companies and the states, where the companies agreed to monetary payments and permanent injunctive relief. *See Lorillard Tobacco v. Reilly*, 533 U.S. 525, 533 (2001).

Meanwhile, states continued to enact laws regulating the sale and use of cigarettes and tobacco products, including imposing numerous restrictions on tobacco sales.[2] These restrictions included, for

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[2] *See, e.g.*, Stop Tobacco Access to Kids Enforcement ("STAKE") Act, 1994 Cal. Stat. 1009 (codified at Cal. Bus. & Prof. Code §§ 22950–64) (including mandates such as "no cigarette or tobacco product shall be sold, offered for sale, or distributed from a vending machine or appliance, or any other coin or token operated mechanical device designed or used for vending purposes, *id.* § 22960(a)); *see also* Cigarette and Tobacco Products Licensing Act of 2003 (codified at Cal. Bus. & Prof. Code §§ 22970–22995) (requiring licensing throughout the distribution chain from manufacturer to retailer); Cal. Rev. & Tax. Code §§ 30131–30131.6 (significantly increasing the state's cigarette and tobacco taxes to fund, in part, anti-smoking efforts).

example, prohibitions on sales of tobacco products in vending machines and near schools. *See* Paul A. Diller, *Why Do Cities Innovate in Public Health? Implications of Scale and Structure*, 91 Wash. U. L. Rev 1219, 1231–35 (2014) (discussing state and local bans of flavored cigarettes passed before the TCA). Some localities even banned sales of cigarettes and vape products entirely from retail stores. *See, e.g.*, Manhattan Beach, Cal., Ordinance 20-0007. Because the FDA lacked authority to regulate tobacco products until Congress enacted the TCA in 2009,[3] the history of tobacco regulation is, until recently, one of state and local action.

**2. The TCA Continued to Preserve State and Local Power Over Tobacco Sales.**

Given this extensive background of state and local tobacco regulation, it would have been surprising if Congress had broadly jettisoned the longstanding tradition of states and localities' role in the regulation of sales of tobacco products when it enacted the TCA in 2009. The text of the TCA itself demonstrates that it did not. Instead, Congress made an "explicit decision to preserve for the states a robust role in regulating, and even banning, sales of tobacco

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[3] *See R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 880–81 (D. Minn. 2020) (observing that the TCA "was partly a response to the FDA's earlier unsuccessful attempt to assert jurisdiction over tobacco products in order to enact age-specific tobacco regulations" (citing *Brown & Williamson Tobacco Corp.*, 529 U.S. at 125–26)); *see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 703 F. Supp. 2d 329, 336 (S.D.N.Y. 2010) (same).

products." *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013).

Specifically, the TCA sought to "authorize the [FDA] to set national standards controlling the *manufacture* of tobacco products and the identity, public disclosure, and amount of *ingredients used* in such products." Pub. L. No. 111-31, 123 Stat. 1778 (2009) (emphasis added). In doing so, the TCA balances state and federal power over tobacco regulation by way of a unique three-layered preservation provision.[4] The first clause of the provision, labeled the preservation clause, broadly preserves state, local, and tribal power to enact *any* regulation concerning tobacco products that is "in addition to or more stringent" than those promulgated by the TCA:

> Except as provided in [the preemption clause], nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit

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[4] Because this is a case about preemption, it is easy to refer to 21 U.S.C. § 387p of the TCA as a "preemption provision." But it is more properly characterized as a "*preservation* provision." While § 387p does contain the preemption clause that forms the basis of Appellants' challenge to the County's ban (*see id.* § 387p(a)(2)(A)), that preemption clause is sandwiched between two clauses that expressly preserve and exempt from preemption broad non-federal regulatory authority over tobacco products (*see id.* §§ 387p(a)(1), (a)(2)(B)). Indeed, even the title of § 387p ("Preservation of State and Local Authority") evinces its predominant purpose to *preserve* rather than *preempt* non-federal regulatory authority. This overall structure of the TCA's "preservation provision" cannot be overemphasized, and as discussed further below, distinguishes the TCA's preemption clause from dissimilar provisions in other federal statutes considered by the Supreme Court.

> the authority of a . . . political subdivision 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. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

21 U.S.C. § 387p(a)(1) (emphasis added). Of particular relevance here, the TCA expressly reserves localities' ability to enact any regulations "relating to or prohibiting the sale . . . or use of tobacco products by individuals of any age." *Id.*[5]

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[5] There is a scrivener's error in both the TCA's preservation and savings clauses. Both clauses contain similar statements allowing nonfederal laws "relating to or prohibiting the sale . . . or use of tobacco products *by* individuals of any age." *Id.* § 387p(a)(1) (emphasis added); *see also id.* § 387p(a)(2)(B) (similar). The drafters of these clauses used the preposition "by" in the last prepositional phrase "by individuals of any age," presumably because the preposition "by" matches the closest object ("use") in the preceding series of objects (thus, "use . . . by individuals of any age"). But while the preposition "by" makes sense for some of the other objects in the series (e.g., "possession . . . by individuals of any age"), it doesn't make sense for others, such as "sale" (it should be "sale . . . [*to*] individuals of any age") or "advertising and promotion" ("advertising and

The TCA then immediately follows its broad preservation clause with a preemption clause that expressly overrides the preservation clause in the case of any conflict between the two provision's terms. The preemption clause reads:

> No . . . 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.

*Id.* § 387p(a)(2)(A) (emphasis added). While the TCA does not explicitly define "tobacco product standards," it uses that phrase elsewhere in the TCA when referring to various characteristics of tobacco products, such as "the construction, components, ingredients, additives, constituents . . . and properties of the tobacco products" (among other references). *See id.* § 387g(a)(4)(B)(i). It also uses the phrase broadly as encompassing some federal "sale and distribution . . . restrict[ions]," *id.* § 387g(a)(4)(B)(v)—including the federal ban on most flavored cigarettes, *id.* § 387g(a)(1)(A)—as well as tobacco labeling requirements. *Id.* § 387g(a)(4)(C).

Immediately following the TCA's preemption clause, a savings clause then excepts various broadly defined categories from preemption. *See id.*

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promotion . . . [*to*] individuals of any age"). Correcting for this drafting error, we replace the word "by" with a bracketed "[to]" in subsequent quotations in this opinion where appropriate.

§ 387p(a)(2)(B). Specifically, the savings clause instructs that the preemption 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.

*Id.* § 387p(a)(2)(B).

**3. Los Angeles County Banned the Sale of Flavored Tobacco Products.**

In September 2019, as part of amendments to its business licenses and health and safety code, Los Angeles County joined at least three states and over 300 local jurisdictions across the country by enacting a prohibition on the sale of flavored tobacco products. The County's ordinance reads:

> [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.

LOS ANGELES COUNTY, CAL., CODE § 11.35.070(E) (2019); see also CTFK, Fact Sheet (Oct. 23, 2020), https://perma.cc/JGX3-3VZP. The ordinance defines "flavored tobacco product" as "any tobacco product, as defined in this Chapter, which imparts a characterizing flavor." Id. § 11.35.020(J). It further defines "characterizing flavor" as "a taste or aroma,

other than the taste or aroma of tobacco, imparted either prior to or during consumption of a tobacco product." Id. § 11.35.020(C). The ordinance therefore only permits the sale of tobacco products with either the taste or aroma of tobacco, or no taste or aroma at all. See id.

**4. The District Court Dismissed Appellants' Case.**

Appellants R.J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc. (Appellants) sued the County of Los Angeles and various County officials (Appellees), alleging that the TCA expressly and impliedly preempts the County's ordinance. The district court first denied Appellants' motion for a preliminary injunction, finding that they were not likely to succeed on the merits of their claims. It then subsequently granted Appellees' Rule 12(b)(6) motion, incorporating the reasoning from its denial of the preliminary injunction. It also denied Appellants' motion for summary judgment as moot. Judgment was later entered, and Appellants appeal that judgment.

## III. JURISDICTION AND STANDARD OF REVIEW

"We have appellate jurisdiction under 28 U.S.C. § 1291." *Kashem v. Barr*, 941 F.3d 358, 369 (9th Cir. 2019). "A dismissal for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6) is reviewed *de novo*." *Marder v. Lopez*, 450 F.3d 445, 448 (9th Cir. 2006). "We [also] review *de novo* a district court's application of preemption principles."

*U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 432 (citation omitted).

## IV. DISCUSSION

"The Supremacy Clause provides that the laws of the United States 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Gonzalez v. Arizona*, 677 F.3d 383, 391–92 (9th Cir. 2012) (en banc) (quoting U.S. Const. art. VI, cl. 2). "Under our system of dual sovereignty, courts deciding whether a particular state law is preempted under the Supremacy Clause must strive to maintain the delicate balance between the States and the Federal Government, especially when Congress is regulating in an area traditionally occupied by the States." *Id.* (citations and internal quotation marks omitted).

The TCA's text, framework, and historical context reflect its attempt to strike such a balance. Its unique preemption structure gives the federal government exclusive power to set "tobacco product standards," while preserving state, local, and tribal authority to regulate or ban sales of those products altogether. Consistent with this structure, it would be a mistake to read "tobacco product standards" in the TCA's preemption clause so broadly as to encompass the type of sales ban challenged in this case—particularly since the TCA both expressly preserves and exempts from preemption local authority over that exact type of regulation. The preemption clause therefore does not cover the County's sales ban. But even if it did, the savings clause "saves" it from preemption because a sales ban qualifies as a "requirement[] relating to the sale" of tobacco products.

We therefore hold that TCA does not expressly preempt the County's sales ban. And given that Congress explicitly preserved local authority to enact the very type of sales ban at issue here, we also reject Appellants' claim of implied preemption.

**1. The TCA Does Not Expressly Preempt the County's Sales Ban.**

The TCA's text, structure, and historical context precludes express preemption in this case. "Where, as here, Congress has specifically addressed the preemption issue, our task is primarily one of interpreting what Congress has said on the subject." *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 432.[6]

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[6] The parties dispute whether a presumption against preemption applies, but the Supreme Court has already determined that if a "statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Puerto Rico v. Franklin California Tax-Free Tr. (Franklin)*, 579 U.S. 115, 125 (2016) (citation and internal quotation marks omitted); *see also Int'l Bhd. of Teamsters, Loc. 2785 v. Fed. Motor Carrier Safety Admin.*, 986 F.3d 841, 853 (9th Cir. 2021) (relying on Franklin in determining that the existence of an express presumption clause negated any presumption against preemption); *Atay v. Cty. of Maui*, 842 F.3d 688, 699 (9th Cir. 2016) (same). Appellees argue that these cases suggest that only *unambiguous* express preemption clauses override the presumption. But this runs counter to *Franklin*, where the majority and dissent's debate over the scope of the preemption clause at issue in that case demonstrates that it was not, in fact, unambiguous. *See* 579 U.S. at 135–37 (Sotomayor, J., dissenting). Appellees also rely on two post-Franklin cases from our court that rely on the presumption of preemption when evaluating an express preemption clause. *See Miller v. C.H.*

We "begin with the wording of [the TCA's preemption provision], but we must also consider the statute as a whole to determine whether the local ordinance actually conflicts with the overall federal regulatory scheme." *Id.* (citation omitted); *see also Brown & Williamson Tobacco Corp.*, 529 U.S. at 133 ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (citation and internal quotation marks omitted)). In interpreting statutes wholistically, we must strive to "giv[e] effect to each word and mak[e] every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous." *Shelby v. Bartlett*, 391 F.3d 1061, 1064 (9th Cir. 2004) (citation omitted). We also "assum[e] that the ordinary meaning of that language accurately expresses the legislative purpose." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (citation omitted).

**a. *The Preemption Clause Doesn't Cover the County's Sales Ban.***

Applying these well-established principles, we first conclude that the phrase "tobacco product standards" in the TCA's preemption clause does not encompass the County's sales ban.

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*Robinson Worldwide, Inc.*, 976 F.3d 1016, 1021 (9th Cir. 2020); *California Ins. Guarantee Ass'n v. Azar*, 940 F.3d 1061, 1067 (9th Cir. 2019). But the parties in both of those cases failed to address *Franklin*. Pursuant to *Franklin* and our court's application of *Franklin*, therefore, our focus is on the meaning of the TCA's text without any presumptive thumb on the scale.

We begin with the text of all three adjacent clauses—preservation, preemption, and savings—considered together. In § 387p of the TCA, the initial preservation clause broadly preserves state, local, and tribal authority to enact a variety of regulations that are "in addition to, or more stringent than" the TCA's requirements. *See* 21 U.S.C. § 387p(a)(1). While under the TCA the federal government sets the regulatory floor, the plain text of the preservation clause allows state, local, and tribal governments to go beyond that, including even "*prohibiting the sale* . . . of tobacco products [to] individuals of any age." *Id.* (emphasis added).

The subsequent preemption clause then carves out eight limited exceptions to the preservation clause, each of which relates most obviously to the production or marketing stages—and not the retail sale—of tobacco products: "tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." *Id.* § 387p(a)(2)(A). For example, the TCA describes "adulteration" in terms of various issues that could arise during the manufacturing or marketing stages. *See id.* § 387b. Similarly, "registration" requires that "every person who owns or operates any establishment in any State engaged in the *manufacture, preparation, compounding, or processing* of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person." *Id.* § 387e(b) (emphasis added). And to qualify as a "modified risk tobacco product," details about the manufacturing and marketing processes must be provided. *See id.* § 387k(d).

While the TCA does not explicitly define "tobacco product standards," it describes that phrase in terms of the manufacturing and marketing stages. *See e.g.*, § 387g(a)(4)(B)(i) (requiring tobacco product standards to include, where appropriate, "provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product"). Consistent with its surrounding categories, it makes sense to view "tobacco product standards" in the TCA's preemption clause as most naturally referring to standards pertaining to the production or marketing stages up until the actual point of sale. *See Rizo v. Yovino*, 950 F.3d 1217, 1224 (9th Cir. 2020) (en banc) (noting the "well-settled rule[] of statutory construction" that "words grouped together should be given similar or related meaning to avoid giving unintended breadth to the Acts of Congress" (citation and internal quotation marks omitted)).

This is not to say that the phrase "tobacco product standards" is incapable of being read more broadly. Since the phrase is not defined by the TCA, it could in theory conceivably encompass essentially anything and everything related to tobacco products that might influence how they are produced. For example, "tobacco product standards" could encompass "labeling," since how tobacco products must be labeled will, no doubt, affect how they are produced. Indeed, as noted above, the TCA itself "include[s]" labeling under the "tobacco product standards" that the FDA is elsewhere empowered to regulate. *See id.* § 387g(a)(4)(C).

But reading "tobacco product standards" in the preemption clause so capaciously runs immediately

into several textual problems. First, the preemption clause itself lists "labeling" as a separate preempted category, which would be redundant if "tobacco product standards" in that same clause was meant to have its broadest possible interpretation.

Second, reading "tobacco product standards" as covering any non-federal regulations that even *indirectly* affect such standards would render much of the preceding preservation clause a nullity. Every state or local regulation "relating to or prohibiting the sale . . . of tobacco products" (preservation clause) can be said to "relate to tobacco product standards" (preemption clause) in *some* indirect way. If Congress had meant to broadly preempt all such state and local sales regulations or bans via the ambiguous "tobacco product standards" language in the preemption clause, why would it have "preserved" to states and localities that authority in the very proceeding provision? In short, reading "tobacco product standards" in the TCA's preemption clause broadly creates superfluity problems in *both* the TCA's preemption clause and its preservation clause, whereas reading "tobacco product standards" in the preemption clause more narrowly avoids these interpretive problems.

The savings clause immediately follows the preemption clause and "except[s]" broad categories from preemption, including "requirements relating to the sale . . . of[] tobacco products [to] individuals of any age." *Id.* § 387p(a)(2)(B). In doing so, the TCA reinforces what it first established in the preservation clause: that the regulation and prohibition of tobacco product sales falls squarely within the purview of states, localities, and tribal entities. The savings

clause also solidifies the narrower interpretation of "tobacco product standards" discussed above. If "tobacco product standards" was to be interpreted as broadly encompassing (and therefore preempting) states and localities' laws "relating to or prohibiting the sale" of tobacco products, then one must assume that Congress (1) included a superfluous "preservation" of states and localities' ability to regulate sales, while simultaneously (2) taking away their ability to do just that in the preemption clause, while also simultaneously (3) giving back their ability to do just that in the savings clause when it broadly "except[ed]" from the preemption clause any state or local "requirements relating to the sale" of tobacco products. That tortured path is avoided only by reading the preemption clause's "tobacco product standards" as not reaching state and local sales bans.

In short, the TCA's text sandwiches limited production and marketing categories of preemption between clauses broadly preserving and saving local authority, including any "requirements relating to the sale" of tobacco products. This unique "preservation sandwich" enveloping the TCA's preemption clause reveals a careful balance of power between federal authority and state, local, and tribal authority, whereby Congress has allowed the federal government to set the standards regarding how a product would be manufactured and marketed, but has left states, localities, and tribal entities the ability to restrict or opt out of that market altogether. We are not alone in reaching this interpretation of the TCA's unique preemption structure: when evaluating whether the TCA preempted a local ordinance prohibiting the sale of flavored tobacco products

except in tobacco bars, the Second Circuit similarly determined that the TCA's preemption provision "distinguishes between manufacturing and the retail sale of finished products; it reserves regulation at the manufacturing stage exclusively to the federal government, but allows states and localities to continue to regulate sales and other consumer-related aspects of the industry in the absence of conflicting federal regulation." *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434.

This interpretation is consistent with the historical "backdrop against which Congress" acted in enacting the TCA. *See Stewart*, 543 U.S. at 487. As previously noted, the states and localities have historically played a primary role in regulating the sale of tobacco products. And after the Supreme Court over a century ago explicitly ruled that states have the power to opt out of the tobacco product market, none of the subsequent federal enactments have stripped localities of this power. The TCA effectively *carves out* federal power from a historical body of state and local authority by setting the floor for production and marketing standards, while still preserving states and localities' broad power over regulation of the sales of those products. The County's sales ban fits comfortably within the historical authority of states, localities, and tribal entities that Congress clearly preserved in the TCA's preservation sandwich.

Appellants' arguments to the contrary are unpersuasive. The crux of Appellants' argument is that the County's sales ban qualifies as the "paradigmatic tobacco product standard" and therefore falls under the preemption clause. But not only does this interpretation contravene the TCA's

text, framework, and historical context for the reasons just articulated, it also nullifies key aspects of the preservation clause and undermines the commonly understood meaning of the phrase "product standard."

First, as already discussed, interpreting "tobacco product standards" to encompass the County's sales ban at issue here renders meaningless the preservation clause's "preservation" of localities' authority to "prohibit sales." Under Appellants' broad interpretation of "tobacco product standards," it is hard to imagine any sales prohibition—which the preservation clause expressly preserves—that would *not* be preempted under the preemption clause. It is unlikely that Congress would purport to preserve something for state and local authority, only to preempt it in the very next provision. "Such a broad reading of the preemption clause, which collapses the distinction between sales and product regulations, would render superfluous [the preservation statute]'s three-part structure, and in particular would vitiate the preservation clause's instruction that the [TCA] not be 'construed to limit the authority of a State or political subdivision of a State to enact and enforce any measure prohibiting the sale of tobacco products.'" *U.S. Smokeless Tobacco Mfg. Co.*, 708 F.3d at 434 (quoting 21 U.S.C. § 387p(a)(1)) (alteration marks omitted). "Because statutes should be construed, if possible, to give effect to every clause and word," we agree with our sister circuit and "adopt a narrower reading of the preemption clause that also gives effect to the preservation clause." *Id.* (internal citations and alterations omitted).

Second, Appellants' interpretation unnecessarily trades the most common and natural understanding

of "product standards" for the broadest interpretation possible. While there can be a relationship between product standards and sales bans, we must not lose sight that they are, in fact, different things. A total ban on all tobacco products would not naturally be characterized as merely a "tobacco product standard." *Compare Ban*, Merriam-Webster's Dictionary Online, https://www.merriam-webster.com/dictionary/ban (last visited Dec. 26, 2021) ("to prohibit especially by legal means"), *with Standard*, Merriam-Webster's Dictionary Online, https://www.merriam-webster.com/dictionary/standard (last visited Dec. 26, 2021) ("a level of quality, achievement, etc. that is considered acceptable or desirable"); *see also United States v. Carter*, 421 F.3d 909, 911 (9th Cir. 2005) ("[A] fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning." (citation and internal quotation marks omitted)); *United States v. TRW Rifle 7.62X51mm Caliber, One Model 14 Serial 593006*, 447 F.3d 686, 689 (9th Cir. 2006) (recognizing "the common practice of consulting dictionary definitions to clarify [statutory terms'] ordinary meaning" (citation omitted)). While regulations regarding the length or diameter of a cigarette are easily considered a "product standard," for example, *banning* the sale of cigarettes over a certain length or diameter is just as obviously not *directly* a regulation of a tobacco product standard. It is merely banning the sale of a certain type of tobacco product, not dictating how that product must be produced.

It is true that the Supreme Court has repeatedly found that a state or local sales ban *can* run afoul of

the preemptive force of a federal product standard, because in some cases the sales ban undermined the federal standards protected by broad federal preemption clauses. *See Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 455 (2012); *Engine Mfrs. Ass'n*, 541 U.S. 246, 252 (2004). Appellants lean heavily on these two cases, arguing that the County's sales ban is similarly doomed by the TCA's preemption of state or local tobacco product standards. But neither *National Meat* nor *Engine Manufacturers* considered anything like the preservation sandwich included in the TCA.

In *National Meat*, the Supreme Court held that the Federal Meat Inspection Act (FMIA), which "regulates the inspection, handling, and slaughter of livestock for human consumption," expressly preempted a California law that prohibited the buying or selling of nonambulatory animals (i.e., animals that cannot walk). 565 U.S. at 455, 458–59.[7] In doing so, the Court emphasized that "[t]he FMIA's preemption clause sweeps widely." *Id.* at 459. It therefore rejected the respondent's attempted distinction between sales bans and the meat production process. Instead, the Court reasoned that "the sales ban . . . functions as a command to slaughterhouses to structure their operations in the exact way the remainder of [the California law] mandates." *Id.* at 464. "[I]f the sales ban were to avoid the FMIA's

[7] While the FMIA's preemption provision included a savings clause, this clause did not save states' ability to regulate sales. *See id.* at 458 n.3 ("The preemption provision also includes a saving clause, which states that the Act 'shall not preclude any State . . . from making requirement[s] or taking other action, consistent with this [Act], with respect to any other matters regulated under this [Act]." (quoting 21 U.S.C. § 678)).

preemption clause," it explained, "then any State could impose any regulation on slaughterhouses just by framing it as a ban on the sale of meat produced in whatever way the State disapproved. That would make a mockery of the FMIA's preemption provision." *Id.* Notably, nothing in the FMIA's preemption provision expressly preserved or saved states or localities' authority to regulate sales. *See* 21 U.S.C. § 678. And whereas the Supreme Court in *National Meat* saw no distinction between a sales ban and the production process in *that* case, in this case Congress has statutorily recognized precisely that distinction when it expressly preempted non-federal "tobacco product standards," while in the same statutory section expressly preserved and exempted from preemption state and local "requirements relating to . . . sale[s]."

Like it did in *National Meat*, the Supreme Court also rejected an attempted distinction between general production processes and sales bans when interpreting the Clean Air Act (CAA)'s preemption provision in *Engine Manufacturers*. 541 U.S. at 253–55. The CAA's preemption provision provided that "[n]o State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part." 541 U.S. at 252 (quoting 42 U.S.C. § 7543(a)). The local regulation challenged in *Engine Manufacturers* "prohibit[ed] the purchase or lease by various public and private fleet operators of vehicles that do not comply with stringent emission requirements." *Id.* at 248. The respondents argued that the CAA's preemption provision's reference to "standards" only

referred to "a *production* mandate that requires *manufacturers* to ensure that the vehicles they produce have particular emissions characteristics, whether individually or in the aggregate." *Id.* at 253 (citation and internal alteration omitted). But the Court rejected this argument, reasoning in part that "[t]he language of [the CAA's preemption provision] is categorical. It is . . . impossible to find in it an exception for standards imposed through purchase restrictions rather than directly upon manufacturers." *Id.* at 256; *see also id.* at 255 (concluding that "treating sales restrictions and purchase restrictions differently for pre-emption purposes" had "no basis in the text of the statute"). The Court ultimately "decline[d] to read into [the preemption provision] a purchase/sale distinction that is not to be found in the text of [the preemption provision] or the structure of the CAA." *Id.* at 255.

The TCA includes a fundamentally different preemption provision than either of the provisions considered by the *Supreme Court in National Meat and Engine Manufacturers*. Neither of the federal statutes in those cases sandwiched their preemption clause between preservation and savings clauses that explicitly and repeatedly reiterated local authority over product sales. Unlike the preemption provisions considered in those cases—which the Supreme Court characterized as "sweep[ing] widely" and "categorical"—the TCA's plain text distinguishes between tobacco product standards and state or local regulation of the final sale of tobacco products, preempting the former while allowing the latter. *National Meat* and *Engine Manufacturers* are inapposite and don't control this case. Rather than

following precedent interpreting very different federal statutory language, we must instead be guided by the TCA's unique text, framework, and history.

**b. *Alternatively, the Savings Clause Saves the County's Sales Ban from Preemption.***

Even if we read "tobacco product standards" as broadly as Appellants urge and therefore concluded that the County's sales ban fell within the text of the TCA's preemption clause, the ban would still be "except[ed]" from preemption by the TCA's savings clause. 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. It therefore fits within the savings clause as a "requirement[] relating to the sale . . . of[] tobacco products [to] individuals of any age." 21 U.S.C.A. § 387p(a)(2)(B).

Appellants nevertheless contend that the savings clause doesn't apply. They first argue that the savings clause only saves sales *requirements*, not sales *prohibitions*, from preemption. In support, they contrast the saving clause's omission of the phrase "or prohibiting" with the preservation clause's inclusion of that phrase. *Compare id.* § 387p(a)(2)(B) ("requirements *relating to the sale* . . . of[] tobacco products"), *with id.* § 387p(a)(1) ("requirements . . . relating to *or prohibiting* the sale . . . of tobacco products") (emphasis added). To give meaning to both phases, Appellants argue, the saving clause's omission of the word "prohibiting" must mean that state and local governments can broadly impose sales "requirements," but must stop short of "prohibiting" the sale of any tobacco products. Appellants conclude

by claiming that a holding otherwise would render the preemption clause a "dead letter," by allowing states and localities the ability to indirectly regulate tobacco product standards by simply banning any disapproved products.

The problem with Appellants' argument is that the preemption clause also omits the word "prohibiting." Like the savings clause, the preemption clause simply references "any requirement . . . relating to tobacco products standards." *Id.* § 387p(a)(2)(A). So if 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." *See R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 881–82 (D. Minn. 2020) (rejecting the same argument on similar rationale); *see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, No. 09-10511, 2011 WL 5569431, at *7 (S.D.N.Y. Nov. 15, 2011) (rejecting a similar argument and concluding that "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"), *aff'd*, 708 F.3d 428 (2d Cir. 2013).

Appellants attempt to avoid the textual import of their argument by parsing out the preemption clause's use of the word "any," such that the preemption clause's reference to "*any* requirement . . . relating to tobacco products standards" means that it also includes prohibition-type requirements. But aside from injecting an enormous amount of hidden meaning into the word "any," this argument runs into

the same problem as Appellants' "tobacco products standards" argument: if the preemption clause preempts all state and local regulations prohibiting the sale of tobacco products, then the preservation clause's preservation of those exact prohibitions is rendered entirely superfluous. Because "[w]e avoid statutory interpretations that render entire sections of the statute superfluous," *United States v. Leon H.*, 365 F.3d 750, 753 (9th Cir. 2004), we decline to assign different meanings to the preemption and saving's clause use of word "requirement."

Appellants' the-County-may-regulate-but-not-prohibit-sales argument would also create a hopelessly inadministrable standard. Appellants concede that "state and local governments retain their broad, traditional power to *regulate* the sale of tobacco products"—which would include "restrictions on where products may be sold (e.g., not near schools)"—but argue that the "one thing they cannot do is *prohibit* the sale of those products." But as other courts have observed, "it would be nearly impossible to distinguish a permissible 'restriction' from an impermissible 'prohibition'" because "[n]early any regulation can be characterized as a 'prohibition,' including the . . . restrictions that [Appellants] contend are within the meaning of the word 'requirement.'" *City of Edina*, 482 F. Supp. 3d at 881 n.4. For example, a restriction on sales of tobacco products near schools, which Appellants concede is permissible, can easily be characterized as a prohibition of tobacco sales in a specified area (which, by way of banning such sales only throughout the County, is exactly what the County's sales ban does here). Or by way of another example, under

Appellants' interpretation of the savings clause, a city could impose a 105-year-old minimum age "requirement" for purchases of flavored tobacco products, which would lead to effectively the same result as the County's sales ban. Because "prohibitions" can almost always be practically achieved by mere well-crafted partial "regulations," it makes little sense to interpret the savings clause as drawing the amorphous line that Appellants urge. "We must avoid an interpretation that would produce absurd results," *United States v. LKAV*, 712 F.3d 436, 444 (9th Cir. 2013) (citation and internal quotation marks omitted), and the better understanding is that Congress intended to allow the federal government the sole authority to set tobacco product standards, while retaining for states and localities their longstanding authority to say: "not here."

Nor is Appellants' "dead letter" argument persuasive. Even though the preemption clause does not preempt sales bans, it's hardly useless. It still preempts states from setting actual product standards. A state cannot *require* tobacco companies to make their products according to any particular standard—only the federal government can do that. But a state can place restrictions on the retail sale of a tobacco product, including banning its sale altogether. In other words, as noted above, the balance of power struck by the TCA allows state and local governments to opt out of the market, but it doesn't allow them to otherwise set parameters for that market that conflict with the federal government's tobacco product standards. That is the "delicate balance" established by Congress in § 387p's unique preservation sandwich.

Appellants finally argue that the savings clause's reference to "individuals of any age" limits the scope of the clause to age-based requirements. But "[a]s other courts have noted, [Appellants]' interpretation turns the plain meaning of this phrase on its head." *City of Edina*, 482 F. Supp. 3d at 880. The actual text of the phrase reveals the opposite of Appellants' interpretation. "Of any age" suggests that state and local governments are not limited to enacting only age-based rules, but rather can enact regulations for people "of any age"—in other words, for everyone. *See U.S. Smokeless Tobacco Mfg. Co.*, 703 F. Supp. 2d at 345 ("Indeed, read literally, the saving clause does not relate to the sale or distribution of tobacco products to anyone at all—only *by* anyone—and that 'anyone' can be a person of any age.").

Appellants argue that this interpretation renders the phrase superfluous, but it actually clarifies that states and local governments are *not* limited to enacting regulations tied to certain age ranges. This makes sense given the TCA's framework and historical context, where the TCA preserved state, local, and tribal authority to enact regulations "in addition to, or more stringent than, requirements . . . relating to or prohibiting the sale . . . of tobacco products," 21 U.S.C. § 387p(a)(1), and where the federal government had previously attempted to assert jurisdiction over tobacco products to enact age-specific tobacco regulations. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 125–26 (holding that FDA, which had promulgated regulations to reduce tobacco use among children and adolescents, lacked jurisdiction to regulate tobacco products). In other words, the TCA expressly preserves local authority to

enact *more* stringent requirements than the federal government, which had a history of attempting to target specific ages when enacting tobacco regulations. Because the County banned the sale of flavored tobacco products to all individuals "of any age," the savings clause squarely applies.

Appellants' superfluity argument suffers from another flaw, which is that adding "individuals of any age" to pretty much any statutory text will in some respects always be superfluous. For example, if a statute prohibits "driving cars without a license," adding "by individuals of any age" to the prohibition technically does nothing because nothing in the basic prohibition itself indicates it is age-limited. But a legislature might add such "superfluous" language to the prohibition if it is concerned that something about the history of such prohibitions could tempt courts to read into the prohibition an *implicit* age restriction. That best explains why § 387p repeatedly clarifies that the powers preserved to non-federal governments are *not* age-restricted, particularly since so much historic tobacco product regulation has involved age restrictions.

**2. The TCA Does Not Impliedly Preempt the Sales Ban.**

Finally, the TCA also does not impliedly preempt the County's sales ban. Appellants argue that the County's sales ban poses an obstacle to the FDA's current judgment that menthol cigarettes should remain on the market. "[O]bstacle preemption occurs when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Chamber of Com. of*

*United States v. Bonta*, 13 F.4th 766, 774 (9th Cir. 2021) (citation and internal quotation marks omitted). With implied preemption, "we start with the assumption that the historic police powers of the States are not preempted unless that was the clear and manifest purpose of Congress." *In re Volkswagen "Clean Diesel" Mktg., Sales Pracs., & Prod. Liab. Litig.*, 959 F.3d 1201, 1212 (9th Cir. 2020) (citation and internal quotation marks omitted). Courts also "give[] great weight to Congress' inclusion of a provision preserving states' enforcement authority." *Id.* at 1213.

Here, while the TCA permitted the FDA to enact future regulations upon making certain findings, *see* 21 U.S.C. § 387g(a)(3)(A)–(B), it did not mandate that certain tobacco flavors *must* remain available for sale. And while the TCA bans all cigarette flavors *except* menthol and tobacco, *id.* § 387g(a)(1)(A), it nowhere prohibits states from going further. To the contrary, as discussed above, the preservation clause explicitly allows states, localities, and tribal entities to enact regulations "more stringent than" the TCA's requirements—including regulations "relating to or prohibiting the sale . . . of tobacco products." *Id.* § 387p(a)(1). Given that the TCA does not mandate that certain flavors must remain available for sale, and expressly preserves local authority to enact sales regulations more stringent than the TCA, the County's sales ban does not "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" expressed in the TCA. *Chamber of Com. of United States*, 13 F.4th at 774 (citation omitted). It is therefore not impliedly preempted.

## V. CONCLUSION

For the reasons stated herein, the County of Los Angeles's ban on the sale of flavored tobacco products is neither expressly nor impliedly preempted by the Tobacco Control Act. The district court is **AFFIRMED**.[8]

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R. NELSON, Circuit Judge, dissenting:

Twice we have been reversed for interpreting an express preemption clause to allow states and municipalities to defeat its entire purpose with a sales ban. Still, the majority thinks that this time is different, in particular because this statute has a preservation clause and a savings clause. But those clauses can't get the majority where it needs to go. The Tobacco Control Act's (TCA's) preservation clause does not limit the preemption clause at all. Instead, it clarifies that no other section of the statute (or regulation promulgated under it) has a preemptive effect and that federal agencies (including the armed forces) and Indian tribes are unaffected by the preemption clause. And the savings clause only allows states to enact age bans. Because Los Angeles's ban falls within the preemption clause and is neither preserved nor saved, I would hold that it is expressly preempted.[1]

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[8] We **GRANT** Appellees' unopposed request for judicial notice.

[1] I agree with the majority that there is no presumption against express preemption, and that the ban is not impliedly preempted.

I

In the last two decades, the Supreme Court has twice reversed us for failing to find California regulations expressly preempted. *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246 (2004); *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012). In *Engine Manufacturers*, Los Angeles's Air Quality Management District required public and private fleet operators to purchase cars which met certain emission specifications. *See* 541 U.S. at 248–49. The manufacturers sued and argued that the rule was preempted by the Clean Air Act, *see id.*, which says that states cannot adopt "standard[s] relating to the control of emissions from new motor vehicles," 42 U.S.C. § 7543(a).

Los Angeles argued that a "standard" was only "a production mandate" that required manufacturers to do certain things, and thus that its purchase requirement was not preempted because it was not a standard but a sales regulation. 541 U.S. at 254–55. The Supreme Court soundly rejected the argument, reasoning that "a standard is a standard even when not enforced through manufacturer-directed regulation." *Id.* at 254. Los Angeles's rule didn't regulate car manufacturers directly, but by banning the sale of cars made in some ways, it effectively forced manufacturers to make cars in certain other, state-approved ways. *Id.* Even though it did not regulate manufacturers directly, the Supreme Court held that it was a standard all the same. *Id.*

The Supreme Court built on this reasoning in *National Meat*, 565 U.S. at 452–68. In that case, California banned slaughterhouses from selling meat

from animals that could no longer walk. *Id.* at 455. Meat manufacturers argued that the law was preempted by the Federal Meat Inspection Act (FMIA), which prohibits states from adopting "requirements within the scope of [the FMIA] with respect to premises, facilities and operations of any establishment at which inspection is provided under . . . [the FMIA] which are in addition to, or different than those made under [the FMIA]." Id. at 458; 21 U.S.C. § 678. California argued much Los Angeles had in *Engine Manufacturers*—that its rule only regulated sales, not manufacturing, and thus was not preempted. *Nat'l Meat*, 565 U.S. at 463. The Supreme Court again soundly rejected the argument.

Rather than read it as just an "incentive" or "motivator," as California had asked it to, the Court held that the sales ban "instead functions as a command to slaughterhouses to structure their operations in the exact way" provided for by the law. *Id.* at 463–64. The Court further reasoned that if a ban like this were not preempted, then "any State could impose any regulation on slaughterhouses just by framing it as a ban on the sale of meat produced in whatever way the State disapproved," which "would make a mockery of the FMIA's preemption provision." *Id.* at 464.

Of course, these cases and this case each deal with a different express preemption provision. But the import of *Engine Manufacturers* and *National Meat* is clear. When Congress expressly preempts state regulation, states can't get around Congress's prohibition by disguising that type of regulation as a sales ban.

II

*Engine Manufacturers* and *National Meat* require us to hold that Los Angeles's ban is covered by the preemption clause. Still, the majority, relying on the TCA's preservation clause and savings clause, holds that this case is different. It is not. I first explain why the ban is covered by the preemption clause, and then explain why the ban is neither preserved nor saved.

A

The TCA's preemption clause provides that "[n]o 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 [the TCA] relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A). Whether Los Angeles's ban is preempted thus depends on whether it is a requirement different from or in addition to any TCA requirement relating to tobacco product standards. It is, and the statute itself shows why.

The TCA provides that no cigarette shall have any "artificial or natural flavor (other than tobacco or menthol)." *Id.* § 387g(a)(1). In the same section, the statute then calls this requirement a "tobacco product standard." *Id.* § 387g(a)(2). Congress has spoken: Cigarettes cannot have any flavors except tobacco and menthol, and that requirement is a tobacco product standard. In other words, a flavor ban is a tobacco product standard.

Los Angeles's sales ban is also a ban aimed at flavors, but it operates at the point of sale, rather than at the manufacturing stage. So, if Los Angeles's ban is not a tobacco product standard, it must be because

tobacco product standards can relate only to manufacturing, and not to sales.

The problem for Los Angeles is that the Supreme Court has already rejected that argument. *See Engine Mfrs.*, 541 U.S at 254. The majority holds that tobacco product standards are only about what can happen at the manufacturing process, not afterwards. But that's exactly the argument that the Supreme Court has twice rejected. Of course, the statute in *Engine Manufacturers* was not the TCA. But it used the same term—"standard"—and just like the statute at issue there, nothing in the TCA expressly limits tobacco product standards to manufacturing.

So tobacco product standards can be aimed at the manufacturing stage or the sales stage. The TCA itself contains a flavor ban aimed at the manufacturing stage and calls it a tobacco product standard. That flavor ban is a tobacco product standard, so Los Angeles's ban of sales of certain flavors must be a tobacco product standard, too.

Since Los Angeles's ban is itself a tobacco product standard, the only remaining question is whether Los Angeles's ban is a requirement with respect to a tobacco product "which is different from, or in addition to, any requirement under the provisions of [the TCA] relating to tobacco product standards." 21 U.S.C. § 387p(a)(2)(A). It is.

There's no dispute that Los Angeles's ban is different from or in addition to the TCA's flavor ban. And the TCA's flavor ban is related to tobacco product standards, because it is one. So our inquiry is limited to whether Los Angeles's ban and the TCA's tobacco product standard are "requirements." I would hold

that they are, for three reasons. First, the majority and Los Angeles both concede that the sales ban is a requirement, for the purpose of the savings clause, and I agree with the majority that the word should keep the same meaning across different subsections. Second, it would be incongruous to read the preemption clause to cover all requirements relating in any way to tobacco product standards, but then not to cover tobacco product standards themselves. And third, *National Meat* itself held that a sales ban can be a preempted requirement. 565 U.S. at 459–64.

Several other courts have interpreted these provisions of the TCA. None of them have adopted the majority's reading. The majority reasons that it is "not alone" because the Second Circuit adopted a similar analysis. Majority at 21–22; *see U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428, 434 (2d Cir. 2013). But the Second Circuit upheld a more limited regulation that still allowed sales of flavored tobacco, and just required that they take place in tobacco bars. *Id.* at 431. That court did adopt a version of the majority's sales vs. manufacturing distinction, but in doing so, it was careful to avoid implying that a complete sales ban would be permissible. *Id.* at 436. I agree with the *Smokeless Tobacco* court that a regulation of how sales may take place is not a tobacco product standard. But a flavor ban remains a preempted tobacco product standard even if it operates at the point of sale. And the *Edina* court forcefully rejected the majority's analysis, reasoning that courts adopting the manufacturing vs. sales distinction had "provided little in the way of justification" and even sometimes "little more than ipse dixit." *R.J. Reynolds*

*Tobacco Co. v. City of Edina*, 482 F. Supp. 3d 875, 878 (D. Minn. 2020). I agree.

B

In reaching the opposite conclusion, distinguishing *Engine Manufacturers and National Meat*, and holding that Los Angeles's ban is not covered by the preemption clause, the majority first relies heavily on the preservation clause. But the majority ignores the plain language of that clause. By its terms, the preservation clause does not apply to the preemption clause at all. Instead, it has three separate functions, none of which affect the preemption clause.

First, the preservation clause begins with the words "[e]xcept as provided in paragraph (2)(A)," which is the preemption clause. The preservation clause then preserves state authority from all sections elsewhere in the TCA. The preemption clause has no qualifier. Because it is qualified by the preemption clause, the preservation clause preserves nothing that falls within the preemption clause; it is a command that other sections of the TCA do not have any preemptive effect.

Second, unlike the other two clauses, the preservation clause also refers to "rules promulgated under the [TCA]." 21 U.S.C. § 387p(a)(1). The second function of the preservation clause is to prohibit regulations from having any preemptive effect.

Third, unlike the preemption and savings clauses, the preservation clause applies not just to states and political subdivisions of states, but also to federal agencies (including the armed forces) and the governments of Indian tribes. Because the preemption and savings clauses apply only to states

and political subdivisions, the preservation clause thus clarifies that federal agencies and Indian tribes are not preempted from doing anything at all.

The majority declines to adopt my reading of the preemption clause, arguing that it would make the preservation clause "a nullity." Majority at 20. But my interpretation does no such thing. The preservation clause has three important functions: It "clears the field" for the preemption clause by clarifying that neither other sections of the TCA nor regulations pursuant to the TCA can have a preemptive effect, and it applies to federal agencies and the governments of Indian tribes. My reading of the preemption clause does not disturb these functions.

C

Having dealt with the preservation clause, the majority's argument now hangs just on the savings clause. While a closer call than the preservation clause, the savings clause can't bear the majority's argument either.

The savings clause saves from preemption "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." 21 U.S.C. § 387p(a)(2)(B). The question is thus whether Los Angeles's ban is a "requirement[] relating to the sale . . . of tobacco products [to]

individuals of any age." *Id.*[2] I would hold that it is not. The savings clause only saves for states the authority to enact age requirements. Any other reading makes the clause "[to] individuals of any age" superfluous.

First, "a statute should not be construed so as to render any of its provisions mere surplusage." *United States v. Wenner*, 351 F.3d 969, 975 (9th Cir. 2003). But that's exactly how the majority construes the TCA here. If "[to] individuals of any age" allows any kind of ban, then Congress should have just left the entire phrase out, because it adds nothing. The savings clause would read just as well without the phrase: it would cover, in relevant part, "requirements relating to the sale of[] tobacco products." 21 U.S.C. § 387p(a)(2)(B) (altered to omit "by individuals of any age"). Plus, if Congress intended to allow any kind of ban, and if Los Angeles's reading is right, then Congress also might as well have said, "by individuals of any hair color" or "by individuals of any religious persuasion." Los Angeles's reading is thus not permitted.

Second, that "of any age" refers to age bans is supported by the statutory context. One of Congress's main priorities in passing the TCA was addressing underage smoking. *See* Tobacco Control Act, Pub. L. No. 111-31, Div. A, § 2, 123 Stat. 1,781 (2009) (codified at 21 U.S.C. § 387). But in 2009, many states already had laws restricting tobacco sales to young adults, not just minors. *See, e.g.*, S.B. 300, 1997 Sen., Reg. Sess.

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[2] I agree with the majority that the clause covers requirements relating to the sale of tobacco products "to" people of any age, and not "by" people of any age. Majority at 12 n.5.

(Ala. 1997) (nineteen years old). Congress was concerned about underage smoking and did not want to block the states' efforts to address smoking by young adults. So when Congress preempted some tobacco regulation, it made sure to continue to allow states to set any age restrictions, to avoid interfering with states' efforts to combat smoking among young people generally.

On "of any age," the Second and First Circuits adopted the majority's reading, but their reasoning was not convincing. In *Smokeless Tobacco*, when quoting the TCA's savings clause, the Second Circuit just left off the "by individuals of any age" language entirely. *See* 708 F.3d at 435. The First Circuit did the same in *National Association of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 82 (1st Cir. 2013).

The district court in *Edina*, on the other hand, addressed the argument in depth. *See* 482 F. Supp. 3d at 880–81. But contrary to its holding ("of any age" allows any ban), its reasoning supports the opposite outcome. The *Edina* court pointed first to the "broader context of the Act," reflecting that the FDA had tried before to enact age restrictions, and second to the "congressional findings memorialized in the Act, which highlight the problem of tobacco use by children and adolescents." *Id.* The court reasoned that "[a]gainst this backdrop, Congress would have reason to emphasize that, although the Act grew out of concerns over tobacco use by minors, state and local governments are not limited to enacting age-related restrictions." *Id.* at 881. In support of this point, the court cited the district court's opinion in *Smokeless Tobacco*, which held that the TCA's "reference to

'individuals of any age' was Congress'[] way of saying that the carve-outs for state prerogative would not be limited to enacting laws aimed only at minors." 482 F. Supp. 3d at 881 (citing 703 F. Supp. 2d 329, 348 (S.D.N.Y. 2010)).

I agree with this reasoning, but it supports the opposite conclusion. The S.D.N.Y. had it exactly right: Congress wasn't limited to saving laws aimed just at minors. Rather, it saved age bans aimed at individuals of *any age*—minors or adults. That's why Congress included the phrase "individuals of any age." Congress was focused on smoking by young people and some states already banned cigarette sales to young adults. These are reasons to think that Congress was trying to save only age bans, not other bans.

The majority avoids my interpretation by arguing that it leads to an absurd result—that states cannot ban flavored tobacco products but can simply set a minimum age of 105. But an age ban with a minimum age of 105 is not really an age ban; it is, in effect, a blanket ban. Courts are well-equipped to tell the difference between a real age ban and a purported age ban that is really a de facto ban. That the line might be hard to draw in some hypothetical future case is no reason to throw the baby out with the bathwater. We must avoid reading statutes in absurd ways, *United States v. LKAV*, 712 F.3d 436, 444 (9th Cir. 2013) (citation and internal quotation marks omitted), but no canon of statutory interpretation requires us to avoid any reading of a statute under which one can craft an absurd argument.

## III

To sum up, first, the preservation clause does not affect the preemption clause. Instead, it clarifies that no other provision of the statute (or regulation made under it) has any preemptive effect. It also clarifies that the authorities of federal agencies and Indian tribes are not preempted by the TCA. Second, the preemption clause preempts all requirements different from or in addition to the TCA's requirements relating to tobacco product standards. That includes Los Angeles's ban, which is itself a tobacco product standard enforced at the point of sale. And third, the savings clause only permits states and municipalities to enact age bans. Los Angeles's ban is thus preempted.

The majority reads these three clauses as a "preservation sandwich served up by the TCA." Majority at 25. But in holding that Los Angeles's ban is not preempted, the majority has actually folded itself into a pretzel. The majority argues that the preemption clause is "hardly useless," because the federal government is still the only one that can technically set standards. Majority at 30–31. But under the majority's reading, states and municipalities can ban anything made with standards that they don't like, and thus can "opt out of [the federal standards]" entirely. *Id.* This is the very reasoning that the Supreme Court says "make[s] a mockery" of a preemption clause. *Nat'l Meat*, 565 U.S. at 464. By construing the TCA's preemption clause to allow sales bans that defeat its entire purpose, the majority does just that.

I would hold that Los Angeles's ban is preempted by the TCA. I thus respectfully dissent.

## APPENDIX B

**UNITED STATES DISTRICT COURT**
**CENTRAL DISTRICT OF CALIFORNIA**

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| R.J. REYNOLDS TOBACCO COMPANY, et al.,<br>Plaintiffs,<br>v.<br>COUNTY OF LOS ANGELES, et al.,<br>Defendants. | CV 20-4880 DSF (KSx)<br>Order GRANTING Defendants' Motion to Dismiss (Dkt. 33) and DENYING Plaintiffs' Motion for Summary Judgment as Moot (Dkt. 32) |

Defendants move to dismiss the complaint in its entirety. Dkt. 33 (Mot.). Plaintiffs oppose, Dkt. 37 (Opp'n), and move for summary judgment, Dkt. 32-1 (MSJ). The Court deems this matter appropriate for decision without oral argument. *See* Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, Defendants' motion to dismiss is GRANTED and Plaintiffs' motion for summary judgment is DENIED as moot.

### I. BACKGROUND

Los Angeles County Code Section 11.35 (the Ordinance) regulates the sale of tobacco. Amendments to the Ordinance were passed at the September 24, 2019 County Board of Supervisors meeting and became effective on May 1, 2020. *See* Dkt. 1 (Compl.) ¶¶ 22, 28. The Ordinance prohibits tobacco retailers from "sell[ing] or offer[ing] for sale, or . . . possess[ing] 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." *Id.* § 11.35.070(E). A "Flavored Tobacco Product" is defined as "any tobacco product . . . which imparts a characterizing flavor." *Id.* § 11.35.020(J). A "tobacco product" is "[a]ny product containing, made, or derived from tobacco or nicotine," including cigarettes, and "[a]ny electronic smoking device that delivers nicotine or other substances," including e-cigarettes and vaping devices. *Id.* § 11.35.020(U)(1)–(2). A "characterizing flavor" is defined as:

> 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.

*Id.* § 11.35.020(C).

## II. LEGAL STANDARD

"Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. "[W]hen ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551

U.S. 89, 94 (2007) (per curiam). However, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (alteration in original) (quoting *Twombly*, 550 U.S. at 557). A complaint must "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. This means that the complaint must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. There must be "sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

Ruling on a motion to dismiss will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged — but it has not 'show[n]' — 'that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied

when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber Distrib. Co. v. Serv-Well Furniture Co.*, 806 F.2d 1393, 1401 (9th Cir. 1986).

## III. DISCUSSION

### A. Express Preemption (Count I)

Plaintiffs allege that the Family Smoking Prevention and Tobacco Control Act (the FSPTCA), 21 U.S.C. §§ 387–387u, expressly preempts the Ordinance because it "is 'different from, or in addition to,' the requirements of federal law" "relating to federal 'tobacco product standards.'" Compl. ¶ 38. As set forth in the Court's Order denying Plaintiffs' motion for a preliminary injunction, Dkt. 35 (PI Order), preemption under the FSPTCA is governed by a Preemption Clause, a Preservation Clause, and a Savings Clause:

- Preemption Clause. "[W]ith respect to a tobacco product," the FSPTCA preempts, "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." 21 U.S.C. § 387p(a)(2)(A).
- Preservation Clause. "Except as provided in [the Preemption Clause]," the FSPTCA does not limit the County's authority to enact requirements "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).

- Savings Clause. The Preemption 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." 21 U.S.C. § 387p(a)(2)(B).

For the reasons stated in the PI Order, *id.* at 3–12, the Court concludes that the Ordinance is not expressly preempted by the FSPTCA because it does not regulate tobacco product standards and therefore is protected by the Preservation Clause, which permits states and localities to prohibit the sale of tobacco products even if those sales bans are stricter than federal law. Because this is a question of statutory interpretation only, the Court concludes that "the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber*, 806 F.2d at 1401. Therefore, Count I is DISMISSED with prejudice.

**B. Implied Preemption (Count II)**

Plaintiffs allege that the Ordinance is also impliedly preempted because it "undermines the [FSPTCA's] ability to set . . . national standards" for "controlling the manufacture of tobacco products and the . . . amount of ingredients used in such products," Compl. ¶¶ 42–43 (third alteration in original), and because it "directly conflicts with the federal

government's ongoing and active efforts to address flavors in tobacco products," *id.* ¶ 46. For the reasons stated in the PI Order, *id.* at 12–14, the Court concludes the Ordinance is not impliedly preempted by the FSPTCA because the FSPTCA expressly gives state and local governments the power to prohibit the sale of tobacco products. That is so even if those sales bans are stricter than the federal ban, so long as the regulation does not set a tobacco product standard. The Court concludes the Ordinance does not. Because this is a question of statutory interpretation only, the Court concludes that "the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency." *Schreiber*, 806 F.2d at 1401. Therefore, Count II is DISMISSED with prejudice.

## IV. CONCLUSION

Defendants' motion to dismiss is GRANTED. The Complaint is DISMISSED with prejudice. Plaintiffs' motion for summary judgment is DENIED as moot.

IT IS SO ORDERED.

Date: August 7, 2020

Dale S. Fischer
United States District Judge

## APPENDIX C

**UNITED STATES DISTRICT COURT**
**CENTRAL DISTRICT OF CALIFORNIA**

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| R.J. REYNOLDS TOBACCO COMPANY, et al.,<br>Plaintiffs,<br>v.<br>COUNTY OF LOS ANGELES, et al.,<br>Defendants. | CV 20-4880 DSF (KSx)<br>Order DENYING Plaintiffs' Motion for Preliminary Injunction (Dkt. 17) |

Plaintiffs R.J. Reynolds Tobacco Company, American Snuff Company, LLC, and Santa Fe Natural Tobacco Company, Inc. move for an order enjoining Defendant County of Los Angeles from enforcing a County ordinance that prohibits the sale of flavored tobacco products. Dkt. 17-1 (Mot.). The County opposes. Dkt. 28 (Opp'n). The Court deems this matter appropriate for decision without oral argument. *See* Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, the motion is DENIED.

### I. BACKGROUND

Los Angeles County Code Section 11.35 (the Ordinance) regulates the sale of tobacco. Amendments to the Ordinance were passed at the September 24, 2019 County Board of Supervisors meeting, enacted on November 1, 2019, and became effective on May 1, 2020. Relevant here, the Ordinance prohibits tobacco retailers from "sell[ing]

or offer[ing] for sale, or . . . possess[ing] 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." *Id.* § 11.35.070(E). A "Flavored Tobacco Product" is defined as "any tobacco product . . . which imparts a characterizing flavor." *Id.* § 11.35.020(J). A "tobacco product" is "[a]ny product containing, made, or derived from tobacco or nicotine," including cigarettes, and "[a]ny electronic smoking device that delivers nicotine or other substances," including e-cigarettes and vaping devices. *Id.* § 11.35.020(U)(1)–(2). A "characterizing flavor" is defined as:

> 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.

*Id.* § 11.35.020(C).

## II. LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as a matter of right." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 24 (2008). "A plaintiff seeking a preliminary injunction must

establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 20. Although a plaintiff seeking a preliminary injunction must make a showing on each factor, the Ninth Circuit employs a "version of the sliding scale" approach where "a stronger showing of one element may offset a weaker showing of another." *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131–35 (9th Cir. 2011). Under this approach, a court may issue a preliminary injunction where there are "serious questions going to the merits and a balance of hardships that tips sharply towards the plaintiff . . . , so long as the plaintiff also shows that there is a likelihood of irreparable injury and that the injunction is in the public interest." *Id.* at 1135 (internal quotation marks omitted). "When the government is a party, the last two factors (equities and public interest) merge." *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1271 (9th Cir. 2020).

## III. DISCUSSION

Plaintiffs contend that they are likely to succeed on the merits of their claims that the Ordinance is unconstitutional under the Supremacy Clause. The Court disagrees. Because Plaintiffs have not established that they are likely to succeed on the merits or even that there are serious questions going to the merits, the Court need not consider the other *Winter* factors. *See Garcia v. Google, Inc.*, 786 F.3d 733, 740 (9th Cir. 2015) (en banc) ("[W]hen a plaintiff has failed to show the likelihood of success on the merits, we need not consider the remaining three

[*Winter* elements]" (alteration in original) (internal quotation marks omitted) (quoting *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 944 (9th Cir. 2013))).

**A. Express Preemption**

Plaintiffs contend that the Family Smoking Prevention and Tobacco Control Act (the FSPTCA), 21 U.S.C. §§ 387–387u, expressly preempts the Ordinance because the Ordinance impermissibly "establishes a state requirement that is 'different from' and 'in addition to' federal requirements related to tobacco product standards." Mot. at 11. Preemption under the FSPTCA is governed by a Preemption Clause, a Preservation Clause, and a Savings Clause:

- Preemption Clause. "[W]ith respect to a tobacco product," the FSPTCA preempts, "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." 21 U.S.C. § 387p(a)(2)(A).
- Preservation Clause. "Except as provided in [the Preemption Clause]," the FSPTCA does not limit the County's authority to enact requirements "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).

- Savings Clause. The Preemption 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." 21 U.S.C. § 387p(a)(2)(B).

Under the Preemption Clause, the first question the Court must answer is whether the Ordinance relates to "tobacco product standards." The FSPTCA has a section on "Tobacco Product Standards." 21 U.S.C. § 387g. That section sets out two "[s]pecial rules," *id.* § 387g(a)(1), and then gives the FDA authority to revise those rules, *id.* § 387g(a)(2), and adopt additional tobacco standards, *id.* § 387g(a)(3). The first of those special rules is the "Special rule for cigarettes" which prohibits cigarettes from "contain[ing], as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) . . . ." 21 U.S.C. § 387g(a)(1)(A) (the Special Rule). Plaintiffs contend that "[i]f a ban on all flavored cigarettes except menthol is a tobacco product standard — indeed, the paradigmatic example of a tobacco product standard — then a state law or local ordinance that bans all flavored tobacco products *including* menthol is a tobacco product standard as well." Mot. at 12; *see also id.* at 13 ("at a bare minimum, the County's ban on 'menthol cigarettes' is 'different from' and 'in addition to' the Tobacco Control Act's express allowance (subject to FDA's authority) of menthol cigarettes"). Additionally, future tobacco product standards "shall, where appropriate for the protection of the public

health, include . . . provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product." 21 U.S.C. § 387g(a)(4)(B)(i). Plaintiffs note that both "additives" and "properties" of tobacco products include flavoring. Mot. at 11 ("'additives' include 'substances intended for use as a flavoring.'" (quoting 21 U.S.C. § 387(1)); Dkt. 31 (Reply) at 8–9 ("A 'property' of a product is an 'attribute, characteristic, or quality' of the product" and "the 'taste or aroma' of a product is an 'attribute, characteristic, or quality' of the product." (first quoting *Oxford English Dictionary*, "Property" (2020), available at https://www.oed.com; then quoting *Webster's Third New International Dictionary* 1818 (1981)).[1] Plaintiffs contend that putting all of these provisions together, "a 'tobacco product standard' includes any provision respecting the substances intended for use as a tobacco-product flavoring." Mot.

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[1] Plaintiffs also point to various advance notices of proposed rulemaking, and other FDA documents, purportedly "contemplating the adoption of 'tobacco product standard[s]' banning various flavored tobacco products, including menthol cigarettes and flavored vapor products." Mot. at 12–13; *see also* Reply at 9. For example, in a recently released FDA Guidance document, the FDA explains that the final guidance "is not setting tobacco product standards, such as a tobacco product standard restricting or eliminating the use of flavors in ENDS." Mot. at 12–13 (citing FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and other Deemed Products on the Market Without Premarket Authorization* 34 (Apr. 2020)). However, the various FDA documents are not controlling and the Court concludes that these documents do not require the Ordinance to be considered a tobacco product standard.

at 11–12. The Court disagrees with Plaintiffs' analysis.

The courts to have addressed the preemption of local flavored tobacco bans have held that the local ordinances were not preempted. *See Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 85 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 436 (2d Cir. 2013); *Indeps. Gas & Serv. Stations Associations, Inc. v. City of Chicago*, 112 F. Supp. 3d 749, 754 (N.D. Ill. 2015). The Ordinance at issue here is more restrictive than the ordinances previously held not to be preempted. Nevertheless, the Court finds those cases to be instructive.

In *U.S. Smokeless Tobacco*, the Second Circuit concluded that a ban on flavored tobacco products was not a tobacco product standard because the ordinance addressed only "whether final tobacco products are ultimately characterized by — or marketed as having — a flavor" and "is not easily read to direct manufacturers as to which ingredients they may or may not include in their products." 708 F.3d at 435. The Second Circuit concluded that so long as a sales regulation does not "clearly infringe on the FDA's authority to determine what chemicals and processes may be used in making tobacco products," it is not a tobacco product standard and is not preempted. *Id.* at 434. The court of appeals contrasted the Special Rule that "prohibits manufacturers from producing cigarettes that contain 'an artificial or natural flavor' as a constituent or additive" with the New York ordinance, which "explicitly does not turn on 'the use of additives or flavorings,' but rather on whether the product itself imparts 'a distinguishable taste or

aroma.'" *Id.* The Ordinance here also defines "characterizing flavor" based on "a taste or aroma" — not constituents or additives. *See* L.A. Cty. Code § 11.35.020(C). The County contends, therefore, that like the New York ordinance, the Ordinance here "is not attempting to tell manufacture[r]s how to *make* their products. Rather, the Ordinance bans the *sale* of a final product, *i.e.*, tobacco products with 'a taste or aroma, other than the taste or aroma of tobacco' *regardless* of how that taste or aroma comes to be, which sales regulation the FSPTCA expressly preserves for state and local governments." Opp'n at 17–18 (emphases in original). Plaintiffs point out that "there is only one way a taste or aroma other than the taste or aroma of tobacco can come to be in a tobacco product — through an additive." Reply at 8. Assuming, without concluding, that this is true, this fact does not change the analysis of the Second Circuit, which the Court finds to be persuasive.

Plaintiffs also contend that *U.S. Smokeless Tobacco* is distinguishable because the Second Circuit noted (in dicta) that the ordinance in that case "regulates a niche product, not a broad category of products such as cigarettes or smokeless tobacco." Mot. at 13 (quoting *U.S. Smokeless Tobacco*, 708 F.3d at 436). However, this comment did not control the court's analysis of whether the ordinance at issue was a tobacco product standard. Regardless of which tobacco products are included and which flavors are prohibited, the reasoning underlying the Second Circuit's opinion remains the same — a sales ordinance that does not direct manufacturers as to which ingredients they may or may not include is not a preempted tobacco product standard. And if an

ordinance is not a product standard, it does not matter if it is "different from, or in addition to" a federal product standard.[2]

Plaintiffs further contend that the Ordinance here, unlike the ordinance in *U.S. Smokeless Tobacco*, is "directed at the manufacturing process" because the Ordinance "regulates what can be 'mixed with or otherwise added to any tobacco product.'" Mot. at 14 (quoting L.A. Cty. Code § 11.35.020(C)). Plaintiffs' selective quotation is misleading. The entire sentence says that a "characterizing flavor" can be a "flavor in any form, mixed with or otherwise added to any tobacco product or nicotine delivery device, including electronic smoking devices." L.A. Cty. Code

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[2] Plaintiffs relatedly contend that *U.S. Smokeless Tobacco* and *National Ass'n* are distinguishable because they were not complete prohibitions on flavored tobacco products, and therefore appropriately fell into the Savings Clause. Mot. at 18–19. The New York City ordinance prohibited the sale, "except in a tobacco bar," of "any flavored tobacco product," which was defined as "any item, not including cigarettes, that contains both tobacco and 'a constituent that imparts a characterizing flavor' . . . 'other than the taste or aroma of tobacco, menthol, mint or wintergreen.'" *U.S. Smokeless Tobacco*, 708 F.3d at 431. The similar Providence ordinance prohibited the sale, "except in a smoking bar," of any "flavored tobacco product," which "expressly excludes cigarettes" and includes other tobacco products that "contain[] a constituent that imparts a characterizing flavor," *National Ass'n*, 731 F.3d at 74 & n.2, except for the "taste or aroma of tobacco, menthol, mint or wintergreen," *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, No. CA 12-96-ML, 2012 WL 6128707, at *8 (D.R.I. Dec. 10, 2012). The County contends that because the Ordinance does not prohibit tobacco-flavored products, it is not a complete ban either. Opp'n at 20–21. Because the issue of whether an ordinance is a regulation or a ban is only potentially relevant to application of the Savings Clause, the Court does not wade into this dispute.

§ 11.35.020(C). The County notes that "[t]he point of this clarifying language is . . . to state that the sale of tobacco products with flavors other than tobacco, ***no matter how they are created***, and whether non-tobacco flavor is added during manufacture or imparted during consumption, is banned. The Ordinance does not make any distinction between tobacco products with flavors other than tobacco based on ***how*** flavor is added, but rather bans the sale of them wholesale based on their sensory impact on the consumer." Opp'n at 18 (emphasis in original). The Court agrees and interprets this part of the definition of "characterizing flavor" only to ensure that devices that impart flavor "in any form" during consumption are included in the ban. It does not address "mixing or adding" constituents or additives during the manufacturing stage.

Next, Plaintiffs contend that because the FSPTCA enforces its tobacco product standards "through a ban on the sale of offending products," it is no answer to say that because the Ordinance prohibits sales, it is not a tobacco product standard. *See* Mot. at 14. The Second Circuit persuasively rejected a similar argument. In *U.S. Smokeless Tobacco*, the Second Circuit contrasted the ordinance at issue with the challenged state law in *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452 (2012), which "expressly prohibited the sale of meat that was not produced in accordance with specific rules to be applied at the slaughterhouse,"[3]

[3] The Federal Meat Inspection Act preempts any requirements "with respect to premises, facilities and operations of any establishment at which inspection is provided under" the act, such as slaughterhouses. *Nat'l Meat*, 565 U.S. at 458. The challenged state law in *National Meat* prohibited the processing

noting that the flavored tobacco ban "does not concern itself with the mode of manufacturing, or with the ingredients that may be included in tobacco products." *U.S. Smokeless Tobacco*, 708 F.3d at 435 n.2. Instead, because the FSPTCA expressly incorporates a distinction between sales regulations and "regulation at the manufacturing stage," a different result is warranted. *Id.* at 434.[4] Holding otherwise would "render superfluous § 916's three-part structure, and in particular would vitiate the preservation clause's instruction that the Act not be 'construed to limit the authority of . . . a State or political subdivision of a State . . . to enact . . . and enforce any . . . measure . . . prohibiting the sale . . . of tobacco products.'" *Id.* (alterations in original) (quoting 21 U.S.C.A. § 387p(a)(1)); *see also Nat'l Ass'n*, 731 F.3d at 82, 83 n.10 (holding that a flavored tobacco ban was not a

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or selling of meat from nonambulatory animals for human consumption. *Id.* at 458–59. The Supreme Court held that because the sales ban aided other sections of the law that more directly regulated slaughterhouse operations, and because the "idea — and the inevitable effect — of the provision is to make sure that slaughterhouses remove nonambulatory pigs from the production process," the sales ban was a preempted regulation of "how slaughterhouses must deal with non-ambulatory pigs on their premises." *Id.* at 463–64.

[4] The First Circuit also emphasized that the preemption clause in *National Meat* "did not contain a savings clause expressly exempting regulations 'relating to the sale' of the product from preemption," *Nat'l Ass'n*, 731 F.3d at 82, and that the same is true regarding the preemption provision at issue in *Engine Manufacturers Ass'n v. South Coast Air Quality Management District*, 541 U.S. 246 (2004), *id.* at 83 n.10 ("[T]he statutory scheme at issue there, like that in *National Meat*, did not contain a preservation clause that directly exempted sales regulations from preemption.").

"sales restriction[] effectively and impermissibly impos[ing] a new product or manufacturing standard in violation of the preemption provision," noting that "the distinction between sales and manufacturing regulations is clearly supported by 21 U.S.C. § 387p(a)(1)"); *Indeps Gas*, 112 F. Supp. 3d at 754 ("an ordinance that banned tobacco products flavored using a particular manufacturing process might be preempted by the FSPTCA," but the ordinance at issue "regulates flavored tobacco products without regard for how they are manufactured . . . and, accordingly, is exempt from the FSPTCA's preemption clause").

Additionally, as the Second Circuit aptly explained, the flavored tobacco ban at issue "prohibits the sale of a recognized category of tobacco products, characterized by their flavor and marketed as a distinct product. Plaintiffs' effort to characterize the ordinance as a manufacturing standard is tantamount to describing a ban on cigarettes as a manufacturing standard mandating that cigars be manufactured in minimum sizes and with tobacco-leaf rather than paper wrappings." *U.S. Smokeless Tobacco*, 708 F.3d at 435 n.2. A prohibition on the sale of a distinct product is simply not a product standard.[5] As the County points out, this conclusion further distinguishes *National Meat* because "in that case the end product — meat — was the same regardless of whether processed from an ambulatory or nonambulatory animal. Thus, the *only* way to determine whether a product was banned was to

[5] For this reason, the Court finds Plaintiffs' parade of horribles, Mot. at 17, unpersuasive.

consider how it was manufactured." Opp'n at 19 (emphasis in original). Here, banned products can be identified based on how they are marketed and sold.

Finally, the Court acknowledges the general presumption that "when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption.'" *CTS Corp. v. Waldburger*, 573 U.S. 1, 19 (2014) (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). "The effect of that presumption is to support, where plausible, 'a narrow interpretation' of an express pre-emption provision, . . . especially 'when Congress has legislated in a field traditionally occupied by the States[.]'" *Id.* (first quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); then quoting *Altria*, 555 U.S. at 77).[6] The

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[6] Plaintiffs contend that any presumption against preemption "has no place" where there is an express preemption clause. Reply at 7 (quoting *Puerto Rico v. Franklin California Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016)). However, the Supreme Court in *Franklin* did not so hold. Rather, it held that it would not invoke the presumption against preemption where the statute's language was plain. *Franklin*, 136 S. Ct. at 1946. The presumption addressed above applies where there is ambiguity. Plaintiffs' argument assumes the primary disputed issue in this case — that the Ordinance qualifies as a tobacco product standard. *See* Reply at 8. Plaintiffs also note that "[t]he Supreme Court has 'repeatedly declined to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.'" Mot. at 16 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 870 (2000)). This applies only to the scope of savings clauses, not to the scope of preemption clauses. And even if it somehow applied here, the regulatory scheme is not intended to prevent states and localities from prohibiting the sale of tobacco products, as stated explicitly by the Preservation Clause.

Supreme Court recognized no later than 1900 that a "cigarette ban [i]s the type of legislation that states may enact 'for the preservation of the public health or safety' under their police powers." *Graham v. R.J. Reynolds Tobacco Co.*, 857 F.3d 1169, 1190–91 (11th Cir. 2017) (quoting *Austin v. State of Tennessee*, 179 U.S. 343, 349 (1900)). Here, to the extent the Preemption Clause is "susceptible of more than one plausible reading," the Court accepts the narrower plausible interpretation — that the flavored tobacco ban is not a tobacco product standard. *See U.S. Smokeless Tobacco*, 708 F.3d at 433 (2d Cir. 2013) ("if there is any ambiguity as to whether the local and federal laws can coexist, we must uphold the ordinance"); *see also U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, No. 09 CIV. 10511 CM, 2011 WL 5569431, at *7 (S.D.N.Y. Nov. 15, 2011) ("[A]s 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. Insofar as the latter inference is more consistent with the statute's language, structure, and purpose, I opt for it.").[7]

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[7] Although raised primarily in the context of the Savings Clause, the Court addresses two additional arguments that could equally apply to the Preservation Clause. First, Plaintiffs contend that "the phrase 'by individuals of any age' limits the scope of the saving clause to age-based requirements." Mot. at 15; *see also* Reply at 13 ("The preservation clause is also limited to age-based prohibitions in any event"). The plain meaning of that phrase is the opposite of what Plaintiffs suggest — states and localities are free to enact requirements regardless of age. Rather than being "superfluous," Reply at 12, the language emphasizes that regulations are permissible beyond age-based restrictions. Second, Plaintiffs contend that the Savings Clause

For these reasons, the Court agrees with the First and Second Circuits that a flavored tobacco ban is not a regulation of tobacco product standards and therefore is not preempted. The Court need not decide whether the Savings Clause would save the Ordinance if it did regulate tobacco product standards. The Ordinance may very well have negative foreseen or unforeseen consequences, not just on the people who sell flavored tobacco products, but also on the people who use them. Such concerns should be directed to the appropriate legislative bodies. Plaintiffs have not demonstrated serious questions going to, or a likelihood of success on, the merits of their express preemption claim.

**B. Implied Preemption**

Plaintiffs contend that even if the Ordinance is not expressly preempted, it is "impliedly preempted because it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Mot. at 22 (citing *Crosby*

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permits only regulations of "the time, place, and manner of the product's sale and distribution." Mot. at 15. Plaintiffs provide no support for such a claim. Plaintiffs may be importing to the Savings Clause limitations found in another statute regulating advertising and labeling: "a State or locality may enact statutes and promulgate regulations, based on smoking and health, . . . imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes." 15 U.S.C. § 1334(c). Plaintiffs have provided no explanation as to why this requirement would apply to sales regulations under the Savings (or Preservation) Clauses. The district court in *U.S. Smokeless Tobacco* convincingly rejected the argument that there is any "time, place, and manner" limitation on tobacco product sales regulations. 2011 WL 5569431, at *5.

*v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)). "As with express preemption, courts assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." *Ass'n des Éleveurs de Canards et d'Oies du Québec v. Becerra*, 870 F.3d 1140, 1153 (9th Cir. 2017) (internal quotation marks omitted) (quoting *Arizona v. United States*, 567 U.S. 387, 400 (2012)).

First, Plaintiffs contend that the FSPTCA was adopted to set national standards for the manufacturing of, and the ingredients in, tobacco products. *Id.* Because the Court has concluded that the Ordinance is neither a manufacturing standard nor does it regulate the ingredients of tobacco products, the Ordinance is not an obstacle to this purpose.

Second, Plaintiffs contend that the Ordinance "would undermine Congress's and the FDA's judgment that certain flavored tobacco products — including menthol cigarettes — should remain on the market." *Id.* at 23. However, the FSPTCA expressly gives state and local governments the power to prohibit the sale of tobacco products, even if those sales bans are stricter than the federal ban, so long as the regulation is not covered by the Preemption Clause. *See U.S. Smokeless Tobacco*, 708 F.3d at 433 ("While § 907(d)(3) prohibits the FDA from banning entire categories of tobacco products throughout the country, 21 U.S.C. § 387g(d)(3), the FSPTCA nowhere extends that prohibition to state and local governments. To the contrary, the preservation clause of § 916 expressly *preserves* localities' traditional power to adopt any 'measure relating to or

prohibiting the sale' of tobacco products" (footnote omitted)); *see also Berger v. Philip Morris USA, Inc.*, 185 F. Supp. 3d 1324, 1340–41 (M.D. Fla. 2016), *aff'd sub nom. Cote v. R.J. Reynolds Tobacco Co.*, 909 F.3d 1094 (11th Cir. 2018) ("state-law prohibitions on cigarette sales can stand side-by-side with the fact that Congress has tolerated cigarettes and purposefully refrained from banning them").[8] In fact, local regulations covered by the Preservation Clause, like the Ordinance, can promote the purposes and objectives of the FSPTCA by acting as testing grounds for new and innovative policies aiming to protect public health, and particularly the health of underage purchasers. Therefore, the Ordinance does not stand as an obstacle to the FSPTCA.

Plaintiffs have not demonstrated serious questions going to, or a likelihood of success on, the merits of their implied preemption claim.

## IV. CONCLUSION

Plaintiffs' motion for a preliminary injunction is DENIED.

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[8] The cases cited by Plaintiffs, Reply at 16, largely pre-date the FSPTCA (and the Preservation Clause) and address only claims that cigarettes are defectively designed, not state or local power to enact tobacco product bans. *See, e.g.*, *Pooshs v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009, 1025–26 (N.D. Cal. 2012) (rejecting contention that cigarettes are defectively designed, relying in part on *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) which held that "[a] ban of tobacco products ***by the FDA*** would therefore plainly contradict congressional policy." *Id.* at 139 (emphasis added)); *see also Graham*, 857 F.3d at 1190 ("Although federal agencies have only the authority granted to them by Congress, states are sovereign").

IT IS SO ORDERED.

Date: July 13, 2020

Dale S. Fischer
United States District Judge

## APPENDIX D

**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

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| R.J. REYNOLDS TOBACCO COMPANY; AMERICAN SNUFF COMPANY; SANTA FE NATURAL TOBACCO COMPANY, INC.,<br>Plaintiffs-Appellants,<br>v.<br>COUNTY OF LOS ANGELES; COUNTY OF LOS ANGELES BOARD OF SUPERVISORS; HILDA L. SOLIS; MARK RIDLEY-THOMAS; SHEILA KUEHL; JANICE HAHN; KATHRYN BARGER, each in his or her official capacity as a member of the Board of Supervisors,<br>Defendants-Appellees. | No. 20-55930<br>D.C. No. 2:20-cv-04880-DSF-KS<br>Central District of California, Los Angeles<br>ORDER<br>FILED<br>MAY 11 2022<br>MOLLY C. DWYER, CLERK<br>U.S. COURT OF APPEALS |

Before: R. NELSON and VANDYKE, Circuit Judges, and SCHREIER,* District Judge.

Judge Nelson has voted to grant rehearing en banc. Judge VanDyke has voted to deny rehearing en banc, and Judge Schreier has recommended to deny the

* The Honorable Karen E. Schreier, United States District Judge for the District of South Dakota, sitting by designation.

same. The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35. Petitioner's petition for rehearing en banc, ECF No. 52, is DENIED.

## APPENDIX E

### Federal Food, Drug, and Cosmetic Act § 301
### 21 U.S.C. § 331
### Prohibited acts

The following acts and the causing thereof are prohibited:

**(a)** The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

**(b)** The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

**(c)** The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

**(d)** The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

**(e)** The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 379aa, 379aa-1, 387i, or 387t of this title or the refusal to permit access to or verification

or copying of any such required record; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm).

**(f)** The refusal to permit entry or inspection as authorized by section 374 of this title.

**(g)** The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

**(h)** The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

**(i)(1)** Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

**(2)** Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing

upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

**(3)** The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

**(j)** The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..[1] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

**(k)** The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

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[1] So in original.

**(l)** Repealed. Pub.L. 105-115, Title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

**(m)** The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

**(n)** The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

**(o)** In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

**(p)** The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

**(q)(1)** The failure or refusal—

**(A)** to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387*o* of this title;

**(B)** to furnish any notification or other material or information required by or under section 360i, 360j(g), 387d, 387i, or 387t of this title; or

**(C)** to comply with a requirement under section 360*l* or 387m of this title.

**(2)** With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

**(r)** The movement of a device, drug, or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

**(s)** The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

**(t)** The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a

coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, the distribution of drugs in violation of section 353(e) of this title, failure to comply with the requirements under section 360eee-1 of this title, the failure to comply with the requirements under section 360eee-3 of this title, as applicable, or the failure to otherwise comply with the requirements of section 353(e) of this title.

**(u)** The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

**(v)** The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

**(w)** The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of Title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

**(x)** The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

**(y)** In the case of a drug, device, or food—

**(1)** the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

**(2)** the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

**(3)** the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

**(z)** Omitted

**(aa)** The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

**(bb)** The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

**(cc)** The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 335a(b)(3) of this title.

**(dd)** The failure to register in accordance with section 350d of this title.

**(ee)** The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

**(ff)** The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

**(gg)** The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

**(hh)** The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

**(ii)** The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa-1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa-1 of this title) submitted to the Secretary.

**(jj)(1)** The failure to submit the certification required by section 282(j)(5)(B) of Title 42, or knowingly submitting a false certification under such section.

**(2)** The failure to submit clinical trial information required under subsection (j) of section 282 of Title 42.

**(3)** The submission of clinical trial information under subsection (j) of section 282 of Title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

**(kk)** The dissemination of a television advertisement without complying with section 353c of this title.

**(*ll*)** The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of Title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

**(1)** such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of Title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

**(2)** the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

**(3)** the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

**(A)** a regulation issued under section 348 of this title prescribing conditions of safe use in food;

**(B)** a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

**(C)** the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

**(D)** a food contact substance notification that is effective under section 348(h) of this title; or

**(E)** such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

**(4)** the drug is a new animal drug whose use is not unsafe under section 360b of this title.

**(mm)** The failure to submit a report or provide a notification required under section 350f(d) of this title.

**(nn)** The falsification of a report or notification required under section 350f(d) of this title.

**(oo)** The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

**(pp)** The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

**(qq)(1)** Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

**(2)** Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

**(3)** The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

**(rr)** The charitable distribution of tobacco products.

**(ss)** The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

**(tt)** Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

**(1)** the product is approved by the Food and Drug Administration;

**(2)** the Food and Drug Administration deems the product to be safe for use by consumers;

**(3)** the product is endorsed by the Food and Drug Administration for use by consumers; or

**(4)** the product is safe or less harmful by virtue of—

**(A)** its regulation or inspection by the Food and Drug Administration; or

**(B)** its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

**(uu)** The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

**(vv)** The failure to comply with the requirements under section 350h of this title.

**(ww)** The failure to comply with section 350i of this title.

**(xx)** The refusal or failure to follow an order under section 350*l* of this title.

**(yy)** The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

**(zz)** The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

**(aaa)** The failure to register in accordance with section 381(s) of this title.

**(bbb)** The failure to notify the Secretary in violation of section 360bbb-7 of this title.

**(ccc)(1)** The resale of a compounded drug that is labeled "not for resale" in accordance with section 353b of this title.

**(2)** With respect to a drug to be compounded pursuant to section 353a or 353b of this title, the intentional falsification of a prescription, as applicable.

**(3)** The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title.

**(ddd)(1)** The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

**(2)** In this paragraph—

**(A)** the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

**(B)** the term "rinse-off cosmetic" includes toothpaste.

**(eee)** The failure to comply with any order issued under section 360bbb-8d of this title.

**Federal Food, Drug, and Cosmetic Act § 900**
**21 U.S.C. § 387**
**Definitions**

In this subchapter:

**(1) Additive**

The term "additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

**(2) Brand**

The term "brand" means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

**(3) Cigarette**

The term "cigarette"—

**(A)** means a product that—

**(i)** is a tobacco product; and

**(ii)** meets the definition of the term "cigarette" in section 1332(1) of Title 15; and

**(B)** includes tobacco, in any form, that is functional in the product, which, because of its

appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

**(4) Cigarette tobacco**

The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this subchapter shall also apply to cigarette tobacco.

**(5) Commerce**

The term "commerce" has the meaning given that term by section 1332(2) of Title 15.

**(6) Counterfeit tobacco product**

The term "counterfeit tobacco product" means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 387e(i)(1) of this title.

**(7) Distributor**

The term "distributor" as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this subchapter.

**(8) Illicit trade**

The term "illicit trade" means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

**(9) Indian country**

The term "Indian country" has the meaning given such term in section 1151 of Title 18.

**(10) Indian tribe**

The term "Indian tribe" has the meaning given such term in section 5304(e) of Title 25.

**(11) Little cigar**

The term "little cigar" means a product that—

**(A)** is a tobacco product; and

**(B)** meets the definition of the term "little cigar" in section 1332(7) of Title 15.

**(12) Nicotine**

The term "nicotine" means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

**(13) Package**

The term "package" means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

**(14) Retailer**

The term "retailer" means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

**(15) Roll-your-own tobacco**

The term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

**(16) Small tobacco product manufacturer**

The term "small tobacco product manufacturer" means a tobacco product manufacturer that employs fewer than 350 employees. For purposes of determining the number of employees of a manufacturer under the preceding sentence, the employees of a manufacturer are deemed to include the employees of each entity that controls, is controlled by, or is under common control with such manufacturer.

**(17) Smoke constituent**

The term "smoke constituent" means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

**(18) Smokeless tobacco**

The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

**(19) State; Territory**

The terms "State" and "Territory" shall have the meanings given to such terms in section 321 of this title.

**(20) Tobacco product manufacturer**

The term "tobacco product manufacturer" means any person, including any repacker or relabeler, who—

**(A)** manufactures, fabricates, assembles, processes, or labels a tobacco product; or

**(B)** imports a finished tobacco product for sale or distribution in the United States.

**(21) Tobacco warehouse**

**(A)** Subject to subparagraphs (B) and (C), the term "tobacco warehouse" includes any person—

**(i)** who—

**(I)** removes foreign material from tobacco leaf through nothing other than a mechanical process;

**(II)** humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

**(III)** de-stems, dries, and packs tobacco leaf for storage and shipment;

**(ii)** who performs no other actions with respect to tobacco leaf; and

**(iii)** who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this chapter.

**(B)** The term "tobacco warehouse" excludes any person who—

**(i)** reconstitutes tobacco leaf;

**(ii)** is a manufacturer, distributor, or retailer of a tobacco product; or

**(iii)** applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

**(C)** The definition of the term "tobacco warehouse" in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this subchapter of the actions described in such subparagraph is appropriate for the protection of the public health.

**(22) United States**

The term "United States" means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

**Federal Food, Drug, and Cosmetic Act § 901**
**21 U.S.C. § 387a**
**FDA authority over tobacco products**

**(a) In general**

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 387k of this title, shall be regulated by the Secretary under this subchapter and shall not be subject to the provisions of subchapter V.

**(b) Applicability**

This subchapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter.

**(c) Scope**

**(1) In general**

Nothing in this subchapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of Title I, Title II, or Title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under subchapter V or any other subchapter.

**(2) Limitation of authority**

**(A) In general**

The provisions of this subchapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the

producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

**(B) Exception**

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this subchapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

**(C) Rule of construction**

Nothing in this subchapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

**(d) Rulemaking procedures**

Each rulemaking under this subchapter shall be in accordance with chapter 5 of Title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

**(e) Center for Tobacco Products**

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and related matters assigned by the Commissioner.

**(f) Office to assist small tobacco product manufacturers**

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

**(g) Consultation prior to rulemaking**

Prior to promulgating rules under this subchapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

**Federal Food, Drug, and Cosmetic Act § 902**
**21 U.S.C. § 387b**
**Adulterated tobacco products**

A tobacco product shall be deemed to be adulterated if—

**(1)** it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

**(2)** it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

**(3)** its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

**(4)** the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 387s of this title by the date specified in section 387s of this title or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

**(5)** it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 387g of this title unless such tobacco product is in all respects in conformity with such standard;

**(6)(A)** it is required by section 387j(a) of this title to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i) of this title; or

**(B)** it is in violation of an order under section 387j(c)(1)(A) of this title;

**(7)** the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 387f(e)(1) of this title or an applicable condition prescribed by an order under section 387f(e)(2) of this title; or

**(8)** it is in violation of section 387k of this title.

**Federal Food, Drug, and Cosmetic Act § 907**
**21 U.S.C. § 387g**
**Tobacco product standards**

**(a) In general**

**(1) Special rules**

**(A) Special rule for cigarettes**

Beginning 3 months after June 22, 2009, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

**(B) Additional special rule**

Beginning 2 years after June 22, 2009, a tobacco product manufacturer shall not use tobacco, including foreign grown tobacco, that contains a pesticide chemical residue that is at a level greater than is specified by any tolerance applicable under Federal law to domestically grown tobacco.

**(2) Revision of tobacco product standards**

The Secretary may revise the tobacco product standards in paragraph (1) in accordance with subsection (c).

**(3) Tobacco product standards**

**(A) In general**

The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

**(B) Determinations**

**(i) Considerations**

In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

**(I)** the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

**(II)** the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

**(III)** the increased or decreased likelihood that those who do not use tobacco products will start using such products.

**(ii) Additional considerations**

In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an

additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

**(4) Content of tobacco product standards**

A tobacco product standard established under this section for a tobacco product—

**(A)** shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

**(i)** for nicotine yields of the product;

**(ii)** for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

**(iii)** relating to any other requirement under subparagraph (B);

**(B)** shall, where appropriate for the protection of the public health, include—

**(i)** provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

**(ii)** provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

**(iii)** provisions for the measurement of the tobacco product characteristics of the tobacco product;

**(iv)** provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

**(v)** a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title;

**(C)** shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

**(D)** shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

**(5) Periodic reevaluation of tobacco product standards**

The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may

provide for testing under paragraph (4)(B) by any person.

**(6) Involvement of other agencies; informed persons**

In carrying out duties under this section, the Secretary shall endeavor to—

**(A)** use personnel, facilities, and other technical support available in other Federal agencies;

**(B)** consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

**(C)** invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, agricultural, or consumer organizations who in the Secretary's judgment can make a significant contribution.

**(b) Considerations by Secretary**

**(1) Technical achievability**

The Secretary shall consider information submitted in connection with a proposed standard regarding the technical achievability of compliance with such standard.

**(2) Other considerations**

The Secretary shall consider all other information submitted in connection with a proposed standard, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband

or other tobacco products that do not meet the requirements of this subchapter and the significance of such demand.

**(c) Proposed standards**

**(1) In general**

The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

**(2) Requirements of notice**

A notice of proposed rulemaking for the establishment or amendment of a tobacco product standard for a tobacco product shall—

**(A)** set forth a finding with supporting justification that the tobacco product standard is appropriate for the protection of the public health;

**(B)** invite interested persons to submit a draft or proposed tobacco product standard for consideration by the Secretary;

**(C)** invite interested persons to submit comments on structuring the standard so that it does not advantage foreign-grown tobacco over domestically grown tobacco; and

**(D)** invite the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard.

**(3) Finding**

A notice of proposed rulemaking for the revocation of a tobacco product standard shall set forth a

finding with supporting justification that the tobacco product standard is no longer appropriate for the protection of the public health.

**(4) Comment**

The Secretary shall provide for a comment period of not less than 60 days.

**(d) Promulgation**

**(1) In general**

After the expiration of the period for comment on a notice of proposed rulemaking published under subsection (c) respecting a tobacco product standard and after consideration of comments submitted under subsections (b) and (c) and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

**(A)** if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard and publish in the Federal Register findings on the matters referred to in subsection (c); or

**(B)** publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

**(2) Effective date**

A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

Such date or dates shall be established so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade. In establishing such effective date or dates, the Secretary shall consider information submitted in connection with a proposed product standard by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the timeframe envisioned in the proposed standard. If the Secretary determines, based on the Secretary's evaluation of submitted comments, that a product standard can be met only by manufacturers requiring substantial changes to the methods of farming the domestically grown tobacco used by the manufacturer, the effective date of that product standard shall be not less than 2 years after the date of publication of the final regulation establishing the standard.

**(3) Limitation on power granted to the Food and Drug Administration**

Because of the importance of a decision of the Secretary to issue a regulation—

**(A)** 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

**(B)** requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this chapter.

**(4) Amendment; revocation**

**(A) Authority**

The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

**(B) Effective date**

The Secretary may declare a proposed amendment of a tobacco product standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if the Secretary determines that making it so effective is in the public interest.

**(5) Referral to Advisory Committee**

**(A) In general**

The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

**(B) Initiation of referral**

The Secretary may make a referral under this paragraph—

**(i)** on the Secretary's own initiative; or

**(ii)** upon the request of an interested person that—

**(I)** demonstrates good cause for the referral; and

**(II)** is made before the expiration of the period for submission of comments on the proposed regulation.

**(C) Provision of data**

If a proposed regulation is referred under this paragraph to the Tobacco Products Scientific Advisory Committee, the Secretary shall provide the Advisory Committee with the data and information on which such proposed regulation is based.

**(D) Report and recommendation**

The Tobacco Products Scientific Advisory Committee shall, within 60 days after the referral of a proposed regulation under this paragraph and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation.

**(E) Public availability**

The Secretary shall make a copy of each report and recommendation under subparagraph (D) publicly available.

**(e) Menthol cigarettes**

**(1) Referral; considerations**

Immediately upon the establishment of the Tobacco Products Scientific Advisory Committee under

section 387q(a) of this title, the Secretary shall refer to the Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsections (a)(3)(B)(i) and (b).

**(2) Report and recommendation**

Not later than 1 year after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

**(3) Rule of construction**

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol.

**(f) Dissolvable tobacco products**

**(1) Referral; considerations**

The Secretary shall refer to the Tobacco Products Scientific Advisory Committee for report and recommendation, under section 387q(c)(4) of this title, the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. In its review, the Tobacco Products Scientific Advisory Committee shall address the considerations listed in subsection (a)(3)(B)(i).

**(2) Report and recommendation**

Not later than 2 years after its establishment, the Tobacco Product Scientific Advisory Committee shall submit to the Secretary the report and recommendations required pursuant to paragraph (1).

**(3) Rule of construction**

Nothing in this subsection shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter at any time applicable to any dissolvable tobacco product.

## Federal Food, Drug, and Cosmetic Act § 910
## 21 U.S.C. § 387j
## Application for review of certain tobacco products

### (a) In general

#### (1) New tobacco product defined

For purposes of this section the term "new tobacco product" means—

**(A)** any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

**(B)** any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

#### (2) Premarket review required

##### (A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

**(i)** the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product—

**(I)** is substantially equivalent to a tobacco product commercially marketed (other than

for test marketing) in the United States as of February 15, 2007; and

**(II)** is in compliance with the requirements of this chapter; or

**(ii)** the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

**(B) Application to certain post-February 15, 2007, products**

Subparagraph (A) shall not apply to a tobacco product—

**(i)** that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

**(ii)** for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

**(3) Substantially equivalent defined**

**(A) In general**

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

**(i)** has the same characteristics as the predicate tobacco product; or

**(ii)** has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

**(B) Characteristics**

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

**(C) Limitation**

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

**(4) Health information**

**(A) Summary**

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

**(B) Required information**

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

**(b) Application**

**(1) Contents**

An application under this section shall contain—

**(A)** full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

**(B)** a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

**(C)** a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

**(D)** an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product

fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

**(E)** such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

**(F)** specimens of the labeling proposed to be used for such tobacco product; and

**(G)** such other information relevant to the subject matter of the application as the Secretary may require.

**(2) Referral to Tobacco Products Scientific Advisory Committee**

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

**(A)** may, on the Secretary's own initiative; or

**(B)** may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

**(c) Action on application**

**(1) Deadline**

**(A) In general**

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after

considering the report and recommendation submitted under subsection (b)(2), shall—

**(i)** issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

**(ii)** issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

**(B) Restrictions on sale and distribution**

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

**(2) Denial of application**

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

**(A)** there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

**(B)** the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

**(C)** based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

**(D)** such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

**(3) Denial information**

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

**(4) Basis for finding**

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

**(A)** the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

**(B)** the increased or decreased likelihood that those who do not use tobacco products will start using such products.

**(5) Basis for action**

**(A) Investigations**

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

**(B) Other evidence**

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

**(d) Withdrawal and temporary suspension**

**(1) In general**

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order

was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

**(A)** that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

**(B)** that the application contained or was accompanied by an untrue statement of a material fact;

**(C)** that the applicant—

**(i)** has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

**(ii)** has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

**(iii)** has not complied with the requirements of section 387e of this title;

**(D)** on the basis of new information before the Secretary with respect to such tobacco product, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

**(E)** on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

**(F)** on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

**(2) Appeal**

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387*l* of this title.

**(3) Temporary suspension**

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences

or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

**(e) Service of order**

An order issued by the Secretary under this section shall be served—

**(1)** in person by any officer or employee of the department designated by the Secretary; or

**(2)** by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

**(f) Records**

**(1) Additional information**

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

**(2) Access to records**

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

**(g) Investigational tobacco product exemption for investigational use**

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

## Federal Food, Drug, and Cosmetic Act § 916
## 21 U.S.C. § 387p
## Preservation of State and local authority

### (a) In general

#### (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.

#### (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.

**(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.

**(b) Rule of construction regarding product liability**

No provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

**L.A. Cnty. Code § 7.83.020**
**Definitions**

For the purpose of this Chapter, the words and terms listed below shall have the following meanings:

A. "Cigarette" is any roll of tobacco wrapped in paper or in any substance not containing tobacco, or any roll of tobacco wrapped in any substance containing tobacco, which is likely to be offered, or purchased as a cigarette, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling.

B. "Electronic smoking device" is an electronic device which can be used to deliver an inhaled dose of nicotine or other substances, including any component, part, or accessory of such a device, whether manufactured, distributed, marketed, or sold as an electronic cigarette, electronic cigar or cigarillo, electronic pipe, electronic hookah, vaping device, or any other product name or descriptor.

C. "Little cigar" is any roll of tobacco other than a cigarette wrapped entirely or in part in tobacco or any substance containing tobacco and weighing no more than three pounds per thousand units. "Little cigar" includes, but is not limited to, tobacco products known or labeled as small cigar, little cigar or cigarillo.

D. "Loitering" means delaying or lingering without an apparently proper purpose for being on the property.

E. "Smokers' lounge" has the same meaning as defined by the California Labor Code Section 6404.5(e)(2)(A) and (B).

F. "Tobacco paraphernalia" is any cigarette papers or wrappers, pipes, holders of smoking materials of all types, cigarette rolling machines, characterizing flavors in any form, mixed with or otherwise added to any tobacco product or nicotine delivery device, including electronic smoking devices, and any other item designed or used for the smoking or ingestion of tobacco products.

G. "Tobacco product" means the following:

1. Any product containing, made, or derived from tobacco or nicotine, whether natural or synthetic, that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including, but not limited to cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, and snuff; or

2. Any electronic smoking device that delivers nicotine or other substances, whether natural or synthetic, to the person inhaling from the device, including, but not limited to, an electronic cigarette, electronic cigar, electronic pipe, electronic hookah, or vaping device.

3. Notwithstanding any provision of subsections (1) and (2) to the contrary, "tobacco product" includes any component, part, or accessory intended or reasonably expected to be used with a tobacco product, whether or not sold separately.

4. "Tobacco product" does not include drugs, devices or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Drug and Cosmetic Act.

H. "Tobacco Shop" is any retail business devoted exclusively or predominantly to the sale of tobacco, tobacco products, and tobacco paraphernalia, including but not limited to cigarettes, cigars, pipe tobacco, electronic cigarettes, vaping devices, and any components, parts, or accessories.

**L.A. Cnty. Code § 11.35.020**
**Definitions**

For the purpose of this Chapter, the words and terms listed below shall have the following meanings:

A. "Accessory" means equipment, products, or materials that are used, intended for use, or designed for use in smoking, vaping, ingesting, inhaling, or otherwise introducing tobacco or tobacco products into the human body and can be an object or device that is not essential in itself but adds to the beauty, convenience, or effectiveness of something else.

B. "Arm's length transaction" means a sale in good faith and for valuable consideration that reflects the fair market value in the open market between two informed and willing parties, when neither is under any compulsion to participate in the transaction. A sale between relatives, related companies or partners, or a sale for the primary purpose of avoiding the effect of the violations of this Chapter that occurred at the location, is presumed not to be an arm's length transaction.

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.

D. "Cigarette" is any roll of tobacco wrapped in paper or in any substance not containing tobacco, or any roll of tobacco wrapped in any substance containing tobacco which is likely to be offered to, or purchased as a cigarette, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling.

E. "Cigarillo" means any roll of tobacco other than a cigarette wrapped entirely or in part in tobacco or any substance containing tobacco and weighing no more than three pounds per thousand units. "Cigarillo" includes, but is not limited to, tobacco products known or labeled as small cigar or little cigar.

F. "Component" means any item intended or reasonably expected to be used with or for the human consumption of a tobacco product.

G. "Department" means the Los Angeles County Department of Public Health.

H. "Director" means the Director of the Los Angeles County Department of Public Health or designee.

I. "Electronic Smoking Device" means an electronic device, including but not limited to an electronic cigarette, electronic cigar or cigarillo, electronic pipe, electronic hookah, vaping device, or any other product name or descriptor, which can be used to deliver an inhaled dose of nicotine or other substances, including any component, part, or accessory of such a device, whether

manufactured, distributed, marketed, or sold as such.

J. "Flavored Tobacco Product" means any tobacco product, as defined in this Chapter, which imparts a characterizing flavor.

K. "License" means a Tobacco Retail License issued by the County pursuant to this Section.

L. "Licensee" means any proprietor holding a license issued by the County pursuant to this Chapter.

M. "Little Cigar" means any roll of tobacco other than a cigarette wrapped entirely or in part in tobacco or any substance containing tobacco and weighing no more than three pounds per thousand units. "Little Cigar" includes, but is not limited to, tobacco products known or labeled as small cigar or cigarillo.

N. "Package" or "Packaging" means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane) in which a tobacco product is sold or offered for sale.

O. "Part" means a piece or segment of something, which combined with other pieces makes up the whole.

P. "Person" means any individual, entity, firm, partnership, joint venture, limited liability company, association, social or professional club, fraternal organization, corporation, estate, trust, business trust, receiver, trustee, syndicate, or other group or combination of the above acting as a single unit.

Q. "Pharmacy" means any retail establishment, including any location with an on-site pharmacy, in which the profession of pharmacy is practiced by a pharmacist licensed by the State of California in accordance with the Business and Professions Code and where prescription pharmaceuticals are offered for sale, regardless of whether the retail establishment sells other retail goods in addition to prescription pharmaceuticals.

R. "Proprietor" means a person with an ownership interest in a business. An ownership interest shall be deemed to exist when a person has a ten percent or greater interest in the stock, assets, or income of a business other than the sole interest of security for debt.

S. "Self-service Display" means the open display or storage of tobacco products or tobacco paraphernalia in a manner that is physically accessible in any way to the general public without the assistance of the retailer or employee of the retailer and a direct person-to-person transfer between the purchaser and the retailer or employee of the retailer. A vending machine is a form of self-service display.

T. "Tobacco Paraphernalia" means cigarette papers or wrappers, pipes, holders of smoking materials of all types, cigarette rolling machines, characterizing flavors in any form, mixed with or otherwise added to any tobacco product or nicotine delivery device, including electronic smoking devices, and any other item

designed or used for the smoking or ingestion of tobacco products.

U. "Tobacco Product" means the following:

1. Any product containing, made, or derived from tobacco or nicotine whether natural or synthetic, that is intended for human consumption, whether smoked, heated, chewed, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, including, but not limited to cigarettes, cigars, little cigars, chewing tobacco, pipe tobacco, and snuff; or
2. Any electronic smoking device that delivers nicotine or other substances, whether natural or synthetic, to the person inhaling from the device, including, but not limited to, an electronic cigarette, electronic cigar, electronic pipe, electronic hookah, or vaping device.
3. Notwithstanding any provision of subsections (1) and (2) to the contrary, "tobacco product" includes any component, part, or accessory intended or reasonably expected to be used with a tobacco product, whether or not sold separately.
4. "Tobacco Product" does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug and Cosmetic Act.

V. "Tobacco Retailer" means any person who sells, offers for sale or distribution, exchanges, or offers to exchange for any form of consideration,

tobacco, tobacco products, or tobacco paraphernalia without regard to the quantity sold, distributed, exchanged, or offered for exchange.

W. "Tobacco Retailing" means selling, offering for sale, exchanging, or offering to exchange for any form of consideration, tobacco, tobacco products, or tobacco paraphernalia without regard to the quantity sold, offered for sale, exchanged, or offered for exchange.

**L.A. Cnty. Code § 11.35.070**
**Violations**

A. It shall be a violation of this Chapter for a tobacco retailer/licensee, or its agent(s) or employee(s), to violate any federal, State, or local tobacco law or regulation, including any provision of this Chapter.

B. Causing, permitting, aiding, abetting, or concealing a violation of any provision of this Chapter shall constitute a violation.

C. Failure to prominently display the Tobacco Retail License in a publicly visible location at the licensed premises shall constitute a violation.

D. The failure of the tobacco retailer/licensee, or the applicant's agent(s) or employee(s) to allow any peace officer, the Director, or any authorized County official to conduct unscheduled inspections of the premises of the business for the purpose of ensuring compliance with any federal, State, or local tobacco law or regulation, including any provision of this Chapter, at any time the business is open for business shall constitute a violation.

E. After 180 days of the effective date of the Ordinance codified in this Chapter, it 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.

F. No tobacco retailer/licensee or its agent(s) or employee(s) may sell or offer for sale any little cigar or cigarillo unless it is sold in a package of at least 20 little cigars or cigarillos. Little cigars or cigarillos may not be sold individually or in packages of less than 20 units.

G. Tobacco retailing by means of a self-service display is prohibited, pursuant to State law.

H. A Tobacco Retail License may be issued to authorize tobacco retailing at a fixed location only. Tobacco retailing on foot or from vehicles, carts, or any other non-fixed location, is prohibited and shall be considered a violation of this Chapter.

I. No Tobacco Retail License may issue and no existing Tobacco Retail License may be renewed, to authorize tobacco retailing in a pharmacy, including any location with an on-site pharmacy.

J. Each tobacco retailer/licensee and its agent(s) or employee(s) must be over the age of 21 in order to sell tobacco and/or tobacco products.