Challenges in Enforcing Local Flavored Tobacco Restrictions
Abstract
This white paper addresses the challenges facing the enforcement of local restrictions on flavored tobacco products, with a view towards assessing the utility of existing and potential lists that itemize either flavored or unflavored tobacco products.

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Preface

This white paper sets out the perspective of state and local public health officials, as well as national tobacco control experts, in their attempts to confront growth in the usage of flavored tobacco products, particularly among youth and other communities frequently targeted by the tobacco industry.

Background

Tobacco use is the leading preventable cause of over 480,000 deaths annually in the United States (U.S.) and is a major cause of chronic smoking-related illness.\(^1\) Given the spate of illness and deaths due to vaping in the recent past,\(^2\) of further and topical concern is the rapid increase in the use of e-cigarettes by youth; more than 5 million youth used e-cigarettes in 2019, up from 3.6 million in 2018 and 1.5 million in 2017.\(^3\) E-cigarette usage increased 135 percent in high schools and 218 percent in middle schools from 2017-2019.\(^4\)

Overwhelmingly, flavored tobacco is the point of entry for youth tobacco use. In the U.S., 80.8 percent of youth (12-17 years old) who had ever used a tobacco product began with a flavored tobacco product, with 79.8 percent of current youth tobacco users using a flavored tobacco product in the past month.\(^5\) The susceptibility of


\(^2\) The Centers for Disease Control and Prevention report that as of October 15, 2019, 1,479 lung injury cases associated with the use of e-cigarette, or vaping, products have been reported from 49 states, the District of Columbia, and 1 U.S. territory. Thirty-three deaths have been confirmed in 24 states.


\(^4\) FDA, supra note 3.

youth to flavored tobacco is underscored by studies showing that individuals 18 to 24 years old had an 89 percent increased odds of using a flavored tobacco product compared to those aged 25-34 years old.6 In California, 86.4 percent of youth tobacco users reported using flavored tobacco products.7 Moreover, 63.6 percent of current and former California smokers start smoking by the age of 18, and 96.3 percent start by the age of 26.8 The importance of flavored tobacco as an influencer for youth usage is evidenced by this data point: 45 percent of surveyed California high school students believed people their age would not use a tobacco product if it only came in tobacco flavor.9

These data firmly suggest that the attractiveness of flavor additives in tobacco products is leading to the creation of a new customer base for the tobacco industry. Moreover, the tobacco industry’s predatory marketing tactics targeted at marginalized populations continue to cause disproportionately adverse health outcomes due to higher rates of tobacco use and inadequate access to healthcare in those communities.10

Federal Law on Flavored Tobacco

Through the 2009 Family Smoking Prevention and Tobacco Control Act (TCA), the federal government prohibited the manufacture of cigarettes containing any “characterizing flavor” other than menthol and tobacco flavor itself.11 Federal law does not restrict the sale of menthol cigarettes or other flavored tobacco products (cigars, little cigars, cigarillos, smokeless tobacco, hookah tobacco, electronic smoking devices and their solutions). The TCA prohibition led to significant declines in youth cigarette use, but may have contributed to significant increases in use of menthol cigarettes, as well as cigars and other tobacco products, which often contain flavors.12 These flavored tobacco products contain candy and fruit flavors.

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9 CRITC, supra note 8.
such as bubblegum, cotton candy, grape, and chocolate, with some flavored tobacco products sharing the names, packaging, and flavor chemicals as popular candy brands like Jolly Rancher and Life Savers.\textsuperscript{13}

### Numerous California and United States Jurisdictions Have Enacted Flavored Tobacco Bans

States and local jurisdictions have the authority to regulate the sale of flavored tobacco and menthol products.\textsuperscript{14} In addition to numerous U.S. cities, as of this writing, 49 jurisdictions in California have taken aim at the influence of flavored tobacco by restricting\textsuperscript{15} the sale of flavored tobacco products.\textsuperscript{16} The Los Angeles County Board of Supervisors voted unanimously to ban the sale of flavored tobacco products on October 1, 2019.

### The Benefits of Banning Flavors: Research Shows Flavored Tobacco Bans Have Resulted in a Decline in Tobacco Use Among Youth

Local laws restricting flavored tobacco sales to adult-only stores resulted in reductions in sales of flavored tobacco products in the cities of New York,\textsuperscript{17} St. Paul,\textsuperscript{18} Minneapolis,\textsuperscript{19} Providence, and the state of Massachusetts.\textsuperscript{20} Although, as will be discussed below, evidence suggests that the rise of concept flavors


\textsuperscript{14} Wellington, Office of the Attorney General of California, Focus on Flavors: The authority of a state or local government to restrict or prohibit the sale or distribution of flavored tobacco products (2016), available at: \url{https://archive.cdph.ca.gov/programs/tobacco/Documents/CDPH%20CTCP%20Refresh/Policy/Flavored-Menthol/Final-Wellington_Focus_on_Flavors.pdf}; although it should be noted local authority to regulate flavored tobacco products may be preempted by state authority in some states (not California, however).

\textsuperscript{15} This paper will use the term “restricted” to signify some form of flavored tobacco regulation, including a full ban on sales in the jurisdiction, as well as bans with exemptions for adult-only stores.

\textsuperscript{16} Cities restricting flavored tobacco products include Chicago, Providence, R.I. and New York City; California jurisdictions with flavor restrictions now number 49. Campaign for Tobacco-Free Kids, “States & Localities that Have Restricted the Sale of Flavored Tobacco Products,” available at: \url{https://www.tobaccofreekids.org/assets/factsheets/0398.pdf}.


\textsuperscript{18} Telephone interview with Jeanne Weigum, President, Association for Nonsmokers – MN (June 12, 2019).


\textsuperscript{20} Kingsley et al., “Impact of flavoured tobacco restriction policies on flavoured product availability in Massachusetts,” Tob Control, dx.doi.org/10.1136/tobaccocontrol-2018-054703 (2019).
Local laws restricting flavored tobacco sales to adult-only stores resulted in reductions in sales of flavored tobacco products in the cities of New York, St. Paul, Minneapolis, Providence, and the state of Massachusetts. (tobacco products with packaging that does not expressly refer to the flavors therein) and definitional issues around enforcement may complicate the clear story of success. Specifically, a New York study found a 37 percent reduction in teens having tried flavored tobacco and a 28 percent lower chance of teens using any type of tobacco product after enforcement of a tobacco product sales ban began, even when surrounding jurisdictions fail to ban flavored tobacco.21

Providence’s policy had similar success. According to one study, average weekly sales of flavored cigars in Providence decreased by 51 percent after the policy went into effect, while sales increased by 10 percent in the rest of the state without a flavor restriction.22 A 2019 study finds that current use of any tobacco product declining in the Providence high school population to 12.1 percent in 2018 from 22.2 percent in 2016, although it should be noted that the flavor restrictions were already in place before the interval of the dataset.23

Surveys were conducted in Massachusetts high schools in two communities, one with a flavor restriction, one without.24 Over a period of six months, Massachusetts Department of Public Health officials found that the flavored tobacco product restrictions were associated with greater reductions in use of both flavored and non-flavored tobacco, compared to communities without restrictions.25 Additionally, in the community with the flavored tobacco restriction, use of tobacco among the students decreased while in the other it increased.26

21 Farley (2017), supra note 18.
22 Rogers et al., “Changes in cigar sales following implementation of a local policy restricting sales of flavoured non-cigarette tobacco products,” Tob Control, doi:10.1136/tobaccocontrol-2019-055004. The authors note that “[t]he Providence results are due to a 93% reduction in sales of cigars labelled with explicit-flavour names, which did not change significantly in ROS [the rest of state]. Sales of cigars labelled with concept-flavour names increased by 74% in Providence and 119% in ROS (both p<0.01). Sales of all cigars—flavoured and otherwise—decreased by 31% in Providence (p<0.01).”
24 Email interview with Lindsay Kephart, Epidemiologist, Tobacco Cessation and Prevention Program, Massachusetts Department of Public Health (June 25, 2019).
25 Email interview with Lindsay Kephart (June 25, 2019).
26 Kingsley et al., “Short-Term Impact of a Flavored Tobacco Restriction: Changes in Youth Tobacco Use in a Massachusetts Community,” American Journal of Preventive Medicine (2019), available at: https://www.ajpmonline.org/article/S0749-3797(19)30348-4/fulltext (finding that in the community with the flavor restriction, flavored tobacco availability decreased by 70 percentage points from baseline in comparison to the community without the flavor restriction, where there was no significant change in flavored tobacco availability).
I. Enforcement Challenges

While flavored tobacco restrictions have proven to be beneficial, California and national experts point to numerous challenges in enforcing flavored tobacco bans that prevent the restrictions from fully preventing the use of flavored tobacco in youth and other vulnerable populations.

A. The Failure to Detect Flavored Tobacco Products on Shelves

The main enforcement problem cited by health and tobacco control experts and enforcement personnel is determining which products are in fact flavored. Many jurisdictions with flavored tobacco restrictions rely on explicit product descriptions and packaging to determine whether a product is flavored. For example, New York City prioritized enforcement efforts on flavored tobacco products that are clearly labeled as flavored, even though the flavored tobacco ordinance captures a broader set of flavored tobacco products: a “public statement or claim made or disseminated by the manufacturer of a tobacco product...that such tobacco product has or produces a characterizing flavor shall constitute presumptive evidence that the tobacco product is a flavored tobacco product.”

Other jurisdictions with flavored tobacco restrictions also rely on product names as the (sole) mechanism to identify flavored products. In response to flavored tobacco sales restrictions, many tobacco manufacturers changed the way they describe, package and market flavored tobacco products to avoid using explicit descriptors; these so-called “concept” flavors are defined as tobacco products with packaging that does not expressly refer to the flavors therein.

27 Telephone interview with Janine Young, Senior Health Inspector, San Francisco Department of Public Health (June 5, 2019).
29 Farley (2018), supra note 29.
30 Telephone interview with Janine Young, Senior Health Inspector, San Francisco Department of Public Health (June 5, 2019); Farley (2018), supra note 29.
Concept Flavors

Some tobacco companies sell so-called “concept” flavors, which describe or label a product as “Blue” or “Jazz” to signal that the product is flavored without explicitly labeling it as such. "Jazz," has been used to indicate that the tobacco product contains a minty flavor, while "Blue" may indicate the product contains a blueberry flavor.31 Concept flavors pose significant challenges for enforcement officers, complicating their determination whether a tobacco product fits the definition of a flavored tobacco product.32 Moreover, the tobacco industry has alleged that a jurisdiction must be able to name/classify a product flavor in order to enforce a flavor sales restriction, arguing that a finding that it is “not tobacco flavor” is insufficient.33 Enforcement officers have the difficult decision to make as to whether to ticket the retailer for a violation, which may later prove out not to be a violation at all.

Consequently, an abundance of caution may result in enforcement officers to err on the side of not citing concept flavors, due to the concern of punishing an innocent retailer. An example of this ambi

Note: for purposes of this paper, “tobacco manufacturer” will follow the definition of “tobacco product manufacturer” in the TCA, section 900: “The term ‘tobacco product manufacturer’ means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product; or imports a finished tobacco product for sale or distribution in the United States.” Also, given the change in California law wrought by Senate Bill 5 (Leno, 2015-16 Second Extraordinary Session), “tobacco product” will include “an electronic device that delivers nicotine or other vaporized liquids.” Calif. Bus. & Prof. Code 22950.5.

31 Telephone interview with Michael Tynan, Public Health Analyst, Centers for Disease Control and Prevention (June 5, 2019).
An example of the difficulties in describing concept flavors is Black & Mild “Jazz” cigarillos. On YouTube, these cigarillos as described as “fruity” and “berry” flavored (https://www.youtube.com/watch?v=-OtvYWZmik), while Black & Mild’s marketing information mentions “taste” three times: "Jazz Cigarillo delivers an unmatched taste from a brand that has one of the most loyal following in the industry. Black & Mild delivers yet another tasty addition to add to their repertoire of pipe tobacco filled cigarillos. You have to taste it to believe it!” Available at https://www.thompsoncigar.com/p/black-mild-jazz-cigarillo-natural-25-pack/95343/.

32 Email interview with Lindsay Kephart (June 25, 2019).
33 Email from Ilana Knopf, Director, Public Health and Tobacco Policy Center (Oct. 26, 2019).

California Tobacco Control Program
guity comes from the federal ban on flavored cigarettes: the use of colors as brand identifiers has con-

New York City chooses not to direct its enforcement efforts towards concept flavors, even in cases where
there might be extrinsic evidence as to the presence of a flavor.35 As a result, concept flavors may stealthily
continue to be sold in many jurisdictions, even if they indeed contain characterizing flavors.36 One national
tobacco control expert has pointed to the possibility of an even stealthier manner of marketing flavored
tobacco products under the radar of enforcement: the use of paid (or unpaid) YouTube influencers to
steer tobacco users to flavored tobacco products without explicit or implicit packaging cues.37

Perhaps the strongest evidence of the phenomenon of stealth flavors is a New York City study that sam-
pelled 16 tobacco products without explicit flavor names.38 Fourteen out of the sixteen tested tobacco
products that did not contain explicit flavor names (labeled with descriptors such as “blue” or “Royale”) but
were found to contain flavor chemicals at levels higher than explicitly labeled flavored tobacco
products, likely in violation of the ordinance.39 Furthermore, the study found that New York City tobacco
retailers are selling an increasing number of tobacco products with colorful packaging, or descriptors
such as “blue” or “pink” instead of blueberry or strawberry.40 These findings may indicate that tobacco
manufacturers either anticipated or reacted to flavor restrictions by changing their packaging to remove
explicit flavor names.41 Similarly in a study of Boston retailers, the remaining flavored products post im-
plementation of flavor restrictions were often concept flavors such as “Jazz” and “blue.”42

Other studies have shown a marked increase in concept flavors, as well: from 2008 to 2014, the percent-
age of cigars with fruit-flavored names declined from 28.7 percent to 20.9 percent, while the “other”
category (including concept labels such as “Jazz,” “Golden,” and “Royale”) rose from 0.8 percent to 6.9
percent of flavored cigar sales.43 Another study demonstrated that the proportion of concept-flavored
cigar sales increased from 9 percent to 15 percent from 2012 to 2016.44

35 Telephone interview with Kevin Schroth, Associate Professor, Department of Health Behavior, Society and Policy, Rutgers University (June 10, 2019).
36 Email interview with Lindsay Kephart (June 25, 2019).
37 Telephone interview with Ilana Knopf, Director, Public Health and Tobacco Policy Center (June 29, 2019).
38 Farley (2018), supra note 29.
39 Id.
40 Id.
41 Id.
43 Viola, et al., “A Cigar by any other name would taste as sweet,” Tob Control 25(5): 605-606 (2018). The authors also theorize that the move away from overt flavor descriptors is an anticipatory move by the tobacco industry to avoid broader flavored tobacco restrictions.
Experts agree that bypassing enforcement on concept flavors creates an opportunity for the tobacco industry to continue rebranding its products to keep selling flavored products in jurisdictions restricting their sale; however, enforcing against concept flavors creates potential litigation risk.47

Expanding the definition of flavor to include “sweet” or “sweet aromatic” and concept flavors could be overly broad in terms of enforceability, creating vagueness considerations.

B. Litigation Risk45

The decision by some jurisdictions not to enforce against concept flavors stems, in part, from a concern about litigation risk.46 Experts agree that bypassing enforcement on concept flavors creates an opportunity for the tobacco industry to continue rebranding its products to keep selling flavored products in jurisdictions restricting their sale; however, enforcing against concept flavors creates potential litigation risk.47

A special example of this is the problem of “sweet” as a descriptor. While tobacco control experts agree sweet descriptors usually indicate that a tobacco product has been modified and artificially enhanced to bring out flavor, City of Oakland enforcement authorities have decided not to prohibit the sale of tobacco products that have “sweet aromatic” on the label under the Oakland flavored tobacco sales restrictions.48 Additionally, the Public Health Law Center removed the word “sweetness” from the definition of “flavored tobacco” in its model flavored tobacco ordinance in order to avoid potential litigation.49 Expanding the definition of flavor to include “sweet” or “sweet aromatic” and concept flavors could be overly broad in terms of enforceability, creating vagueness considerations.

45 Concerns about litigation risk animate a great deal of tobacco control policy, for instance, the successful defense of the New York City and Providence flavor restrictions led to a number of jurisdictions modeling their own efforts similarly, particularly around providing exemptions for adult-only establishments. Kingsley, supra note 21.

One advantage of a statewide unflavored tobacco directory would be its capacity to minimize the amount of litigation at the local level, as definitional questions and the scope of the list itself would be centralized and litigated efficiently at the state level, provided that local jurisdictions would have to adopt parallel definitions of flavored tobacco products.

46 Local jurisdictions have patterned flavor restrictions after the litigation-tested definitions used in Providence. Kingsley, supra note 21.

47 Telephone interview with Mark Meaney, Lead Senior Staff Attorney, Public Health Law Center (June 26, 2019) (if an ambiguously labeled product is cited as being flavored, the reviewing judge may disagree or refuse to admit into evidence the statements of third parties corroborating the flavored nature of the product).

48 Telephone interview with Rachel Gratz-Lazarus, Senior Program Specialist, Tobacco Control Program, Alameda County Public Health Department (June 6, 2019).

broad in terms of enforceability, creating vagueness considerations. For example, it is possible that “sweet aromatic” refers to how the tobacco is grown or cured, hence enforcing against “sweetness” on the label would amount to a First Amendment violation. The tobacco industry argues that it can produce sweeter tobacco in the way it is grown or flue cured, as opposed to adding a characterizing flavor.

Unilaterally imputing flavor to a product based on a label’s concept language in conjunction with third party statements by those not in a business relationship with the manufacturer may raise a First Amendment concern, although this risk is mitigated by the fact that regulators can independently confirm the presence of characterizing flavors. In addition, the Public Health and Tobacco Policy Center performed research on value chain statements in order to determine whether they could impute flavors to packages without overt indicia of flavor. In doing so, the Center came upon YouTubers making claims about flavors. However, it was unclear whether the individuals were paid influencers, which would enable them to attribute the statements to a retailer and hold them liable, or whether the individuals were unaffiliated with the tobacco industry and retailers and instead were making statements based on their own opinions.

C. Evaluation of Retailer Compliance

The data from public health departments as well as independent researchers indicate that retailers attempt to comply, if imperfectly, with flavored tobacco restrictions. The Massachusetts Department of Public Health observed high retailer compliance and a significant reduction in flavored tobacco products on retail shelves as a result of the policies in cities that adopted them. In a study of 461 stores, the

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50 Telephone interview with Mark Meaney (June 4, 2019) (Yarmouth litigation around concept flavors; vagueness challenge upheld).
51 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
52 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
53 Telephone interview with Derek Carr, Senior Attorney, ChangeLab Solutions (June 12, 2019).
54 Telephone interview with Ilana Knopf (June 29, 2019) (this effort built on the work of the Massachusetts Dept. of Public Health, which first utilized social media comments in building a flavored tobacco list).
55 Telephone interview with Ilana Knopf (June 29, 2019).
56 Id.
57 Telephone interview with Lindsay Kephart (June 25, 2019).
Some tobacco distributors continue to push flavored products on unwitting retailers.

The inability of both retailers and enforcement officers to accurately identify flavored products could create a false sense of compliance. However, it is likely that flavored tobacco continues to be sold in many jurisdictions with flavor bans. Some tobacco distributors continue to push flavored products on unwitting retailers. The inability of both retailers and enforcement officers to accurately identify flavored products could create a false sense of compliance. The presence of flavors could be underreported because flavored tobacco products elude enforcement officers, thereby inflating compliance percentages.

As noted above, the rise in concept flavors may mean that inspectors simply fail to cite flavored tobacco products illicitly on shelves. After Oakland’s flavored tobacco law went into effect, due to the adult-only tobacco store exemption flavored tobacco is now disproportionately being sold in low-income areas of Oakland.

While national experts also believe that retailers attempt to comply with tobacco control policies such as minimum sales age for tobacco

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58 Massachusetts’s Retailer Flavor Product Survey results, reported by Massachusetts Dept. of Pub. Health, Flavored Enforcement Tobacco Product Guide Restriction, available at http://files.hria.org/files/TC3476.rtf (last visited June 20, 2019)(among those retailers in violation, the average number of flavored products sold dropped from 19 to 3 in Boston, and 24 to 2 in Attleboro; these data do not reveal how much sales volume persisted in the banned category, however, partly explaining the discrepancies in the percentage given above).

59 Kephart, supra note 43.

60 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019) (indicating that “retailers want to be in compliance.”).

61 Telephone interview with Michael Tynan (June 5, 2019).

62 Telephone interview with Kevin Schroth (June 10, 2019).

63 Email from Rachel Gratz-Lazarus (Oct. 29, 2019) (noting that Alameda County Tobacco Control Coalition is trying to tighten the ordinance by removing the exemption which allows adult-only tobacco retailers to sell flavored tobacco despite the restrictions).

“The marketing of tobacco products is not uniform; it is clear from industry documents that the tobacco industry has calibrated its marketing to target specific demographic groups defined by race” among other demographic attributes. Lee, et al., “A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing,” Am J Public Health 105(9): e8–e18 (Sept. 2015), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4529779/.
products of 21 years of age (T21), in California, 34.9 percent of tobacco and vape shops and 25.3 percent of convenience stores sell tobacco products to underage customers.\textsuperscript{64} This apparent noncompliance with the T21 laws suggests that retailers could also be under-complying with flavored tobacco restrictions.

The most troubling evidence of retailer non-compliance comes from Chicago: the city reported only 57 percent retailer compliance with the ban on menthol cigarette sales within 500 feet of schools.\textsuperscript{65} Another potential problem with retailer compliance (or leakage from surrounding jurisdictions) comes from New York City, where researchers collected discarded cigar packaging from the streets.\textsuperscript{66} Of the 886 harvested wrappers, some 19.2 percent were explicitly flavored, with another 9.4 percent “implicitly” flavored. Researchers did note that the retailers might have themselves been unaware of the concept flavors.\textsuperscript{67} These findings build upon the earlier cited work that sampled 16 tobacco products sold in New York City without explicit flavor names, 14 of which contained flavor levels higher than the control set of flavored products.\textsuperscript{68} But at the same time, a recent study suggests that compliance with New York City’s restrictions is actually very robust: from the November 2010 start of enforcement through February 2015, the Department of Consumer Affairs (DCA) conducted 78,670 tobacco retailer inspections, with only 3,222 flavor violations during this period for a violation rate of 4.1 percent.\textsuperscript{69}

Apart from witting (or unwitting) retailer sales of flavored tobacco products, the phenomenon of cross-border sales (from a jurisdiction not restricting flavored tobacco sales into a jurisdiction with restrictions) could also help explain the enforcement gap.\textsuperscript{70} A similar cross-border sales phenomenon might be evidenced in Rhode Island: as sales of flavored cigars dropped by 51 percent in Providence after the flavor restrictions took effect, while there was a 10 percent increase in the same set of products in the rest of the state.\textsuperscript{71} Some of the growth in the rest of the state could have been from Providence residents sourcing flavored product outside the city limits.

\begin{footnotes}
\textsuperscript{64} California Department of Public Health (CDPH), California Tobacco Control Program, CALIFORNIA TOBACCO FACTS AND FIGURES 2019, available at: https://www.cdph.ca.gov/Programs/CCDPHP/DCDIC/CTCB/CDPH\%20Document\%20Library/ResearchandEvaluation/FactsandFigures/CA%5B1\%5D/\%20Tobacco\%20FactsandFigures2019.pdf
\textsuperscript{66} Brown et al., “Implementation of the New York City Policy Restricting Sales of Flavored Non-Cigarette Tobacco Products,” \textit{Health Education and Behavior} 46(5) 782–789, doi: 10.1177/1090198119853608 (2019). It should be noted again, however, that New York City has made the decision not to enforce against concept flavors, which might lead to the underreporting and persistence of flavored tobacco products on retail shelves.
\textsuperscript{67} Brown (2019), supra note 68.
\textsuperscript{68} Farley (2018), supra note 29.
\textsuperscript{69} Brown (2019), supra note 68.
\textsuperscript{70} Czaplicki et al., “Compliance with the City of Chicago’s partial ban on menthol cigarette sales,” \textit{Tob Control} 28:161–167 (2019).
\textsuperscript{71} Rogers, supra note 23 (the authors flagging cross-border sales possibility as a topic for future inquiry).
\end{footnotes}
The FDA and the flavored cigarette ban

The FDA conducts inspections of tobacco product retailers to determine a retailer’s compliance with federal laws and regulations, including The Federal Food, Drug, and Cosmetic Act, TCA, and FDA rules and regulations. For present purposes, the FDA’s implementation of the flavored cigarette ban in the TCA represents one of the deepest sets of compliance data. Unfortunately, our researchers were not able to schedule an interview with the FDA regarding enforcement, and whether the concept flavor issue arose in this enforcement context.\(^\text{72}\) Still, the relative paucity of FDA enforcement actions against flavored cigarettes is perhaps illustrative of overestimating compliance with a flavor ban.

By practice, the FDA issues a warning letter to a retailer for the first violation. After FDA has issued a warning letter, it conducts a follow-up compliance check of that outlet without further notice to the retailer. If the FDA identifies a violation during a follow-up compliance check or at a subsequent inspection at that retail establishment, it generally seeks Civil Money Penalties (CMPs) to the extent they are appropriate.\(^\text{73}\) From 2009-2013, of the 18,960 warning letters the FDA issued, only 37 were for the sale of flavored cigarettes.\(^\text{74}\) Similarly, from January 14, 2014 to October 2019, the FDA issued 3,225 warning letters, of which only five were issued for flavored cigarettes.\(^\text{75}\) Of the five warning letters issued for flavored cigarette violations, all of the violations were self-evident from each of the manufacturers’ claims, marketing, and labeling of their products. The following is an exhaustive list of all the cigarette products that the FDA has issued a warning letter from since 2009: “Prime Time Strawberry,” “Cheyenne 100’s Wild Cherry,” “Aroma Rich Apple,” “Aroma Rich Rum & Cherry,” “Kiss Mohito,” “Kiss Super Slims Clubnichka 100’s” (strawberry), “Kiss Super Slims Fresh Apple 100’s,” “Richmond Cherry,” “Richmond Cherry 4,” “Richmond Cherry Gold Super Slims 100s,” “Richmond Cherry Super Slims 100s,” “Sobranie Slims Mints 100’s” and “Swisher Sweets Grape.” Of note is the fact that none of the cited cigarettes carries concept flavor names.

From 2009 to 2019, the FDA conducted 1,136,080 retail inspections, and issued 23,519 CMPs. While enforcement data for observed violations is not kept in a searchable format, review of a representative sample of 150 of these CMPs yielded no violations for the sale of flavored cigarettes, in line with the FDA’s reported rate of less than 0.2 percent flavored cigarette violations for the years between 2009 and 2013.

\(^\text{72}\) Although this is of minimal precedential import, in an email, an FDA staffer noted that “FDA does not maintain a whitelist of products. We are not aware of anything in the TCA that would prohibit a state from creating their own list.”

\(^\text{73}\) U.S. Food & Drug Admin. (FDA), Center for Tobacco Products, 2009-2013 Compliance and Enforcement Report, available at https://www.fda.gov/tobacco-products/compliance-enforcement-training/compliance-and-enforcement-report. It should be noted that the enforcement landscapes are distinct in the flavored cigarette and flavored non-cigarette realms: since the federal flavored cigarette ban (binding on manufacturers), retailers that would flout the rule would be hard-pressed to locate flavored cigarette inventory. Since restrictions on other flavored tobacco products are not national, manufacturers are free to produce and market those products, with the resulting restrictions at the point-of-sale in some jurisdictions.

\(^\text{74}\) Id.

Perhaps this is not wholly surprising, as before the flavored cigarette ban took effect, only 1 percent of cigarettes sales were for flavored cigarettes. Sokol, supra note 53.

D. General Enforcement Challenges: Training and Resources

Lack of Training

Tobacco enforcement officers may lack adequate training to effectively and comprehensively enforce a flavor ban. First, there is a general confusion around which products contain flavors, especially given the growing prevalence of concept flavors. For example, Alameda County Tobacco Control Program has provided technical support to enforcement officers in Oakland to help clarify whether “tropical fusion” is a flavored tobacco product, and shared online descriptions that support the conclusion that the product is in fact flavored.76 Second, enforcement officers may be confused about the nuances of the local ordinance. Enforcement officers may be confused as to whether the flavor ban applies to sweet aromatics, which some jurisdictions allow while others do not.77 Third, certain jurisdictions’ flavored tobacco sales ordinances contain exemptions, which create additional challenges for enforcers. As discussed in further detail below, Oakland’s flavored tobacco sales ban includes an exemption that applies to tobacco stores which generate over 60 percent of their gross revenue annually from the sale of tobacco and tobacco paraphernalia.78 This exemption puts the enforcement officers in the uncomfortable position of being accountants in order to determine whether a retailer is exempt or subject to the flavor ban.79

Special issue: police departments as enforcement officers

Several California jurisdictions tasked their police department with enforcing flavored tobacco sales restrictions; however, relying on the

76 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019); Swisher Sweets, “Swisher Sweets Tropical Fusion Cigarillo 60-Count,” https://www.thompsoncigar.com/p/swisher-sweets-tropical-fusion-cigarillo-60-count/89553/ (“Swisher Sweets Tropical Fusion Cigarillo (4 7/8” x 28) are mouth-watering little cigars produced with a quality of blend of tobaccos enhanced with delicious Tropical flavors and a sweetened cap. It puts the “sweet” in Swisher Sweet, plus some extra flavoring for your enjoyment.”)
77 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019); also note that the tobacco industry has used sweeteners as an additive to make tobacco use more attractive. Miao, et al, “High-Intensity Sweeteners in Alternative Tobacco Products,” Nicotine & Tobacco Research 18(11): 2169-2173 (Nov. 2016).
78 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
79 Id.
police is suboptimal, as police officers do not have the expertise or time to comb through shelves of tobacco products to identify those that are flavored. In addition, protecting the public and investigating crimes remain the priority for law enforcement; moreover, the tragic death of Eric Garner in New York City for allegedly selling loose cigarettes underscores the concern that many communities have about involving police departments in tobacco enforcement.

The Oakland Police Department enforces Oakland’s flavored tobacco sales restriction. The police issue and renew tobacco retail licenses annually, and monitor merchants’ compliance with flavored tobacco sales requirements, along with all other tobacco retail license requirements. The Alameda Public Health Department collaborates with the Oakland Police Department and provides support around identifying flavored tobacco products. This collaboration has been beneficial; however, the police are not tobacco control experts and, like other enforcement agencies tasked with the charge, have difficulties in determining which tobacco products contain flavors, as product packaging is not clearly marked, and new tobacco products are constantly being introduced to the market.

Similarly, Manhattan Beach’s police department enforces tobacco restrictions. However, they rely on merchants to comply with the tobacco ordinances and enforce the flavor bans on a complaint basis only. Additionally, the department does not proactively enforce any flavored tobacco prohibitions.

Interagency Jurisdictional Challenges and Limited Resources

New York City has similar challenges in enforcing their flavor ordinance. The Department of Health conducts inspections of food service establishments, including hookah bars, while the Department of Consumer Affairs (DCA) has jurisdiction over tobacco retailers. Budget strains also impact enforcement. At times, the DCA resisted unfunded enforcement responsibilities, arguing that it required supplemental appropriations. A similar issue arose in Chicago, as demonstrated by the struggle between the Health Department (which created the banned products list) and the Bureau of Alcohol and Consumer Protection (charged with enforcing the flavor restrictions in Chicago, as the cost of list maintenance was daunting). This also highlights the extraordinary costs of compiling and maintaining a banned products list of flavored tobacco products. Although Chicago based its initial flavored tobacco list on Universal Product Code (UPC) information at a time when the tobacco industry still provided information on flavors to the data aggregators, the building of the list took many weeks of research, and it was out of date upon completion.

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80 Interview with Rachel Gratz-Lazarus (June 6, 2019).
81 Id.
82 Telephone interview with Jackie Harris, Code Enforcement Officer, Manhattan Beach (May 28, 2019).
83 Id.
84 Id.
85 Telephone interview with Kevin Schroth (June 10, 2019).
86 Id.
87 Telephone interview with Kendall Stagg, Director, Community Health, Kaiser Permanente (July 26, 2019).
88 Id.
Honest Retailer Confusion about Flavors

Similarly to enforcement officers, retailers can be confused about which tobacco products contain flavors and what the law prohibits.\(^9\) Rachel Gratz-Lazarus, Senior Program Specialist at Alameda County’s Tobacco Control Program, has spent significant time educating tobacco retailers on the details of Oakland and Alameda flavored tobacco ordinance regulations.\(^9\) She and her team have conducted in-person retailer education focused on compliance in 455 stores (55 in City of Alameda and 400 in City of Oakland) and found that many retailers can be confused about what the laws require.\(^9\)

A recent study also notes the amount of efforts and resources it takes to educate retailers about shifts in tobacco control policy. In New York City, regulators “educated retailers and wholesalers through letters, online materials, and informational sessions,” and in addition, inspectors went to each of the city’s retailers, providing further on the ground feedback about the flavor restrictions.\(^9\) Both of these examples underscore the extraordinary resource demands upon regulators to ensure retailer compliance with flavor restrictions, in due part to the profusion of flavored tobacco products. As noted later, the idea of a shorter of unflavored tobacco products would be far easier for both retailers and regulators to rely upon.

By way of contrast, the city and county of San Francisco places the initial responsibility for determining whether tobacco products are compliant on the retailers themselves, although SFDPH provides formal review for ambiguously labeled products.\(^9\)

“The City recommends the following to determine whether a tobacco product may be sold in San Francisco:

a. Work with your vendor or supplier.
b. Read the label. Does it state “unflavored”, “no flavors”, “unsweetened”, or “not sweet”?
c. Read websites, advertisements, and customer comments about the tobacco product.
d. Smell the product.
e. When in doubt, refuse to sell the product.”\(^9\)

Leakage from Adjoining Jurisdictions and Online Sales

Internet and cross border sales undermine the efficacy of local flavor bans, although the growing number of jurisdictions with flavor bans in California may render this issue less problematic over time. Several

\(^{89}\) Telephone interview with Lindsey Freitas, Senior Director, Advocacy, American Lung Association (June 7, 2019); telephone interview with Rachel Gratz-Lazarus (June 6, 2019).

\(^{90}\) Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).

\(^{91}\) Id.

\(^{92}\) Brown (2019), supra note 68.

\(^{93}\) Email from Janine Young, SF Dept. of Public Health (Oct. 29, 2019).

Many jurisdictions’ flavor ban ordinances contain exemptions allowing a retailer to sell flavored tobacco under certain circumstances, creating significant enforcement challenges and unintended outcomes.

California tobacco control experts cited cross border and internet sales as challenges. In California, a county may adopt a restriction on the sale of flavored tobacco that is effective only within the unincorporated areas of the county. Thus, each city within the county must adopt its own restriction. Santa Clara County’s ordinance applies only to unincorporated areas, so leakage is difficult to determine because many merchants are not subject to the ordinance.95 Cross border sales pose a similar challenge for the City of Oakland, as some nearby cities do not prohibit flavored tobacco sales and there is relative ease of getting to those jurisdictions.96 Additionally, in San Francisco, there are rumors of an underground market and sales out of homes.97 Perhaps most significantly, sources estimate that about 30–50 percent of total e-cigarette sales are transacted on the internet.98 What is more disturbing is that teenagers have been successful in obtaining e-cigarette solutions over the internet: one small study showed an overall success rate for youth purchases of e-cigarettes of 93.7 percent.99

Preventing cross border leakage and internet sales is difficult, raising enforcement and legal issues of their own. While banning online sales would be useful in helping to prevent flavored tobacco sales in jurisdictions with flavored tobacco product restrictions, and while retailers may support a ban on internet sales, a ban could raise dormant commerce clause and preemption concerns.100 Additionally,

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95 Telephone interview with Joyce Villalobos, Health Program Specialist, Public Health Department, Santa Clara County (June 5, 2019).
96 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019) (her research shows 6% of flavored sales are internet, generally e-cigarettes; also, youth tend to be geographically limited, and hence not as likely to get to adjoining jurisdictions to purchase flavored tobacco products); also see email interview with DJ Wilson, Tobacco Control Director and Public Health Liaison, Massachusetts Municipal Association (June 4, 2019) (leakage from adjoining jurisdictions has not been an issue; the spike in e-cigarettes usage among youth is likely due to marketing efforts targeting marginal communities).
97 Telephone interview with Janine Young (June 5, 2019).
100 Email from Derek Carr (Oct. 22, 2019).
while well-resourced cities and counties may be able to enforce such a ban, less well-resourced local governments would need state or federal support.\textsuperscript{101}

To combat unlawful internet sales, the Los Angeles City Attorney filed a complaint in the Superior Court of the State of California for the County of Los Angeles against certain websites for violating the Stop Tobacco Access to Kids Enforcement Act (STAKE Act) by failing to follow age verification protocols (Case No. 18STCV03046).\textsuperscript{102} On October 3, 2019, the Court entered the Stipulated Final Judgment in this action. The defendants agreed to comply with the STAKE Act for all their California internet sales of tobacco products by verifying customer’s name, date of birth, and address against a database of public records of persons verified to be 21 years of age or older and requiring the customer to upload a government issued identification demonstrating that the purchaser is at least 21 years old.

Sidebar: The problem of exemptions to flavor bans

Although this report focuses on the enforcement challenges stemming from the often difficult to detect distinction between flavored and unflavored tobacco products, our interviews with tobacco control experts often morphed into a discussion of the ways in which exemptions to complete flavored tobacco bans complicate enforcement efforts. These exemptions stem in part from the dicta in early cases upholding flavor bans, where the courts pointed to the fact that the bans were not complete, and hence didn’t run afoul of the TCA’s preemption language.

To wit, many jurisdictions’ flavor ban ordinances contain exemptions allowing a retailer to sell flavored tobacco under certain circumstances, creating significant enforcement challenges and unintended outcomes. While these enforcement challenges will not be solved by a non-flavored tobacco list as discussed below, they do indicate a clear need for better legislative drafting, which should be considered by local, state, and national governments in any future flavored tobacco restrictions or requirements.

Oakland’s primary enforcement challenge is the regulation’s exemption which allows adult-only tobacco stores which meet eligibility requirements to continue selling flavored tobacco products in the City.\textsuperscript{103} In Oakland, flavored tobacco merchants are required to file an affidavit attesting to their compliance with the conditions set forth in the exemption.\textsuperscript{104} When the ordinance was enacted, there were 400 tobacco retail licenses and no more than five stores in the city that qualified under the exemption.\textsuperscript{105} Howev

\footnotesize{Note: the City and County of San Francisco recently passed Article 19R and 19S, banning all internet sales shipped into San Francisco. This ordinance has been stayed to permit the electorate to consider a referendum on the November 5, 2019 ballot. If the referendum does not garner a majority vote, the law will become effective on January 28, 2019. The ordinance would be enforced by the San Francisco City Attorney’s Office with assistance from the SFDPH.}

\textsuperscript{101} Email from Derek Carr (Oct. 22, 2019).
\textsuperscript{102} Stipulated order on file with the authors.
\textsuperscript{103} Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
\textsuperscript{104} Id.
\textsuperscript{105} Id.
When the ordinance was enacted, there were 400 tobacco retail licenses and no more than five stores in the city that qualified under the exemption. However, after the ordinance became effective, the number of qualified stores grew to 52. In order to meet these requirements, some merchants created a separate area for sales of tobacco products. For example, one store created a “hut” within the store for tobacco sales; similarly and some gas stations identified separate areas for tobacco sales. These establishments keep separate accounting of tobacco sales from other sales to achieve the revenue percentage required to qualify for the exemption. As a result, the exemption in the ordinance merely increased the number of adult-only tobacco retailers in the jurisdiction, ultimately making it easier to obtain flavored tobacco by keeping it widely available in certain low-income areas of the city where these stores are located. It is important to note, however, that there is still an unintended benefit from these isolated tobacco sales in that they may help limit the exposure of youth to flavored tobacco products, although without an ID card requirement the adult-only requirement is difficult to enforce.

Such rapid growth in exempted tobacco retailers indicates a need for more care in exempting adult only retailers: some jurisdictions are using Oakland’s exemption as an example of the dangers of a loosely defined exemption. A national tobacco control expert commented off the record that one solution to Oakland’s exemption is to require one license per business. A licensee would not be eligible to sell flavored tobacco products unless the entire property is off limits for individuals under 21 years old.

Santa Clara County also has difficulty in determining when their flavored tobacco ban exemption applies, making enforcement challenging. Specifically, the exemption applies if the merchant generates more than 60 percent of its gross revenue annually from the sale of tobacco products. Ascertaining whether the requisite percentage was achieved presents a challenge to enforcement officers.

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106 Id.; email from Rachel Gratz-Lazarus (Oct. 29, 2019).
107 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
108 Id.
109 Telephone interview with Doug Kress, Director of Health and Human Services, Somerville Board of Health (May 31, 2019).
110 Telephone interview with Jim Knox, Vice President, Legislative Advocacy, American Cancer Society (May 31, 2019).
111 Telephone interview with Joyce Villalobos (June 5, 2019); telephone interview with Jeanne Weigum (June 12, 2019).
The paradox of the adult-only store exemption is that those stores often have poorer compliance with underage tobacco sales restrictions than other retailers. In Massachusetts, adult only stores have poorer compliance with underage sales, and in California, adult-only tobacco stores and vape shops have higher rates of illegal sales to underage young adults than any other store type. In 2018, more than one-third of tobacco-only stores and vape shops in California sold tobacco products to underage customers. Still, given the relatively small numbers of adult-only stores, flavor restrictions still carry significant impact.

Flavor exemptions for adult only stores have also led to litigation. Cumberland Farms filed a lawsuit against the state of Massachusetts on June 24, 2019, alleging that the Board of Health’s decision to limit flavored sales to adult only shops is discriminatory based on the notion that there is no public health justification for sequestering flavored tobacco sales, especially given that vape shops have proven to be less compliant about checking age.

Despite these problems afflicting the adult-only store exemption, there remain net public health benefits to having fewer retailers, such as reducing access, changing norms, and deterring underage sales.

Oakland enforcers are similarly vexed by this as they are “not accountants” and have to engage in independent financial analysis as to whether a store meets the exemption qualifications of generating over 60 percent of its gross revenues annually from the sale of tobacco products and tobacco paraphernalia, or not. Interview with Rachel Gratz-Lazarus (June 6, 2019).

Roeseler et al., “Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops,” JAMA Pediatrics 173(8):795-797 (June 2019) (almost half of tobacco and vape shops illegally sold nicotine-containing products to teens; liquor stores, supermarkets and pharmacies were significantly less likely to do so).

CDPH, supra note 65.

Telephone interview with Ilana Knopf (June 29, 2019).


Telephone interview with Ilana Knopf (June 29, 2019).
II. Solutions

Any tobacco product not set out in the non-flavored list may be presumed to be flavored, and hence, illegal to be sold.

One solution to these enforcement challenges is to develop a list for enforcement officers and retailers to use to help determine whether a tobacco product contains characterizing flavors. There are two main types of lists: a banned products list, which sets out all tobacco products that meet the jurisdiction’s definition of flavored tobacco; or, a non-flavored list, which lists all tobacco products that do NOT have added flavors and are not restricted by a flavor ban. A comprehensive statewide “non-flavored list” could be used by local jurisdictions in writing their own flavor restrictions and incorporated by reference in local flavor bans. Hence, any tobacco product not set out in the non-flavored list may be presumed to be flavored, and hence, illegal to be sold. Another solution is a “sniff” test, and our proposal for a tax on flavored tobacco products in California.

A. Banned Products List

While several jurisdictions have used a banned products lists setting out flavored tobacco products that may not be sold, it has proven to be an ineffective enforcement tool: these lists are bulky, costly to build, nearly impossible to maintain, and difficult to use. According to a University of California, San Diego study of e-cigarette companies and flavored e-cigarettes, as of January 2014 there were 466 brands (each with its own website) and 7,764 unique flavors.116 During the 17-month study, there was a net increase of 10.5 brands and 242 new flavors per month.117 As of 2017, there were more than 15,500 unique e-cigarette flavors available online.118

National tobacco experts agree that creating, maintaining and using a banned products list is onerous and counterproductive.119 The

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116 Zhu, supra note 99.
117 Id.
119 Interview with Derek Carr (June 12, 2019); interview with Mark Meaney (June 26, 2019); interview with Lindsey Freitas (June 7, 2019); interview with Ilana Knopf (June 29, 2019); email from Kevin Schroth, Associate Professor, Department of Health Behavior, Society and Policy, Rutgers University (Oct. 24, 2019).
banned products list model originated in Chicago and was based on a purchased scanner data. However, the list was out of date almost immediately, and Chicago has since ceased actively maintaining it. Given the incomplete and out-of-date nature of existing banned product lists, enforcement officers rely on them at the peril of missing new and stealthy concept flavors. Researchers found that the rise in those concept flavors coincided with the enactment of restrictions on flavored tobacco, with the greatest increases in sales of concept tobacco products in the Northeast.

In California, Alameda County Tobacco Control Program researched a small subset of all tobacco products -- 96 ambiguously labeled tobacco products -- to help enforcement agents identify whether the products contained characterizing flavors, and thereby should be regulated under flavored tobacco sales ordinances. Staffers took computer screen shots of tobacco marketing pages evidencing the presence of flavors, as tobacco webpages are changed and cleansed to avoid enforcement actions. The research on those 96 products alone took 50-80 hours. Consider, also, the seminal study of the 16 tobacco products from New York City, 14 of which were determined to be flavored after chemical analysis of a sort that is not available to local regulators. Perhaps the best anecdotal evidence for the difficulty in amassing a comprehensive banned list is seen in San Francisco’s terse answer of “no” to the question of “Will the City develop a list of flavored tobacco products that may not be sold in San Francisco?” in its online Flavored Tobacco Ban Frequently Asked Questions, although San Francisco is planning on publishing a short list of 29 ambiguously labelled tobacco products that the Department of Public Health has determined to be flavored.

If all jurisdictions with flavor restrictions were required to research and/or test those ambiguous tobacco products sold regionally, it would be enormously labor intensive, costly, and duplicative, particularly in view of the recent explosion in the numbers of concept flavors. Even if this effort were consolidated at the state level, a statewide list may actually miss the regional variations in products and names, as well

120 We were not able to confirm this with the City of Chicago, but the restricted tobacco list available on the Internet was last updated on December 18, 2015. City of Chicago, Health and Human Services, Restricted Flavored Tobacco Products, available at: https://data.cityofchicago.org/Health-Human-Services/Restricted-Flavored-Tobacco-Products/5wce-bks2; interview with Derek Carr (June 12, 2019).
121 Gammon, supra note 45 (“Sales restriction policies may be weakened by inclusive lists of flavoured products that become outdated, exclude certain flavours or contain other language that reduces the comprehensiveness of the regulation”); interview with Lindsey Freitas (June 7, 2019).
122 Gammon, supra note 45.
123 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
124 Id.
125 Farley (2018), supra note 29.
126 SFDPH, supra note 95.
127 Telephone interview with Rachel Gratz-Lazarus (June 6, 2019).
Even if the banned product list were comprehensive, a list with thousands of products is unwieldy and time consuming to use, as enforcement officers are required to cross match thousands of banned products with the hundreds of products in a retail store. At the same time, some interview subjects suggested that a pared down list of the most common “concept” flavors would suffice to catch the bulk of flavors on shelves, and be useful to jurisdictions in their early days of enforcing a new flavor restriction. An example of this is a short list of 58 products with pictures created by the San Francisco Department of Public Health (SFDPH), although as of this writing the list is not available on the Internet; SFDPH is planning to upload a shorter list of 29 products that research confirmed to be flavored.

128 Telephone interview with Derek Carr (June 12, 2019).
129 Id.
130 Telephone interview with Jeanne Weigum (June 12, 2019).
131 The San Francisco Public Health Department isolate 58 questionable tobacco products; of those 58, 29 products were clearly identified as flavors through its research. For the remaining products, the research was inconclusive. SFDPH is planning to publish these 29 flavored products to its website soon at https://www.sfdph.org/dph/files/EHSdocs/Tobacco/SFDPH_Flavored_Tobacco_Products_List.pdf; email from Janine Young, SFDPH (Oct. 29, 2019)(the published list will not contain a photograph of the flavored tobacco product, although SFDPH maintains an internal file of product photos as screenshots of manufacturers’ websites).
A final downside to a banned product list is the potential for litigation. Concept flavors are difficult to capture in a list that requires constant updating and may create litigation risk based on vagueness challenges. Massachusetts witnessed a litigation issue based on the unique aspects of local health boards not exercising independent judgement about whether tobacco products are flavored (this risk is not at issue in California).

Banned Product Lists in Massachusetts and Minnesota

Field staff in Massachusetts, who perform data collection and inspections in retail stores, created an inventory of flavored tobacco products. The list was initially based on an online restricted tobacco products list that Chicago published, which included mint flavored products. The Massachusetts Department of Public Health Tobacco Control Program removed the mint products, added new flavors, and attempted to include concept flavors. To do so, they would find online evidence showing that products were flavored, including manufacturer claims, distributor claims, and reviews of the product, including reviews on YouTube and other social media platforms. While the list provided assistance for retailers and field staff to identify which tobacco products could no longer be sold, it was over-relied on despite the fact that it was meant for guidance only and required independent verification. If a new concept flavor product came on the market that was not on the list yet, retailers and enforcement officers were stumped. Additionally, some tobacco distributors continued to provide products on the list, in direct violation of flavored product restrictions. The list has not been updated and Massachusetts is currently seeking a new enforcement model focused on a sniff test, discussed in more detail below.

Minnesota’s banned products list contains several hundred flavored tobacco products, despite the fact that there are thousands of flavored tobacco products on the market. However, Minnesota jurisdictions do not rely on the list as much as other jurisdictions, mainly using it as a guide for enforcement personnel in jurisdictions with newly enacted flavor restrictions. St. Paul, in particular, does not require a comprehensive list because their enforcement officers are believed to be well-trained and effective.

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133 Telephone interview with Mark Meaney (June 26, 2019).
134 Cumberland Farms has attacked the banned products list as an illicit reliance on a private party’s resource, arguing that it abdicated police power to private parties. The Massachusetts Association of Health Boards developed a list that was meant to be a guide and was not meant to be controlling or comprehensive; however, many jurisdictions simply adopted the list. Yarmouth did conduct independent analysis as to whether “jazz” was in fact a flavor, which led to a finding that the banned products list’s adoption was an abdication of discretion. The Health Board should have been instructed to use the banned products list as a guideline for products that they wanted to review and then made an independent determination as to whether the product could be sold.
135 Email interview with Lindsay Kephart (June 25, 2019).
136 Email interview with DJ Wilson (June 4, 2019).
137 Id.
138 Id.
139 Email interview with Lindsay Kephart (June 25, 2019).
140 Email Interview with DJ Wilson (June 4, 2019).
141 Email interview with Lindsay Kephart (June 25, 2019).
142 Id.
143 “Minnesota flavored tobacco list” produced by the Association for Nonsmokers – MN, on file with authors.
144 Telephone interview with Jeanne Weigum (June 12, 2019).
145 Id.; Brock (2019), supra note 20.
B. Non-Flavored list for Unflavored Tobacco Products

A California non-flavored list, comprised of unflavored tobacco products that could be legitimately sold in all parts of the state, could be created by requiring tobacco manufacturers to report all unflavored tobacco products sold in the California market to the Attorney General (AG).

Benefits

A non-flavored list, which includes all tobacco products that may be sold in a particular jurisdiction, has several substantial benefits. First, developing, maintaining and using a non-flavored list is significantly easier than a banned product list. Whereas a banned products list may contain thousands of products, a non-flavored list might only contain several hundred unflavored products.146 As a result, a non-flavored list will be easier to maintain and use for both enforcement officers and retailers looking to comply with flavored tobacco restrictions.147

Additionally, a non-flavored list will make enforcement easier; unflavored tobacco products are less likely to be regional in nature, as regional variations are found in flavors.148 Further, California’s non-flavored list could be incorporated by reference in other states reducing the duplicative work required in building regional lists. Given the relatively static roster of unflavored tobacco products, a non-flavored list will require less training for enforcement personnel and be less vulnerable to enforcement difficulties at the retail level.

Experts also agree that developing a non-flavored list will be easier than developing a banned products list. Assembly Bill 1625 (AB 1625), which was introduced by Assembly Member Robert Rivas

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146 Email interview with DJ Wilson (June 4, 2019).
147 Telephone interview with Mark Meaney (June 26, 2019) (noting that a non-flavored list will be easier to maintain over time); telephone interview with Lindsey Freitas (June 7, 2019) (noting that a non-flavored list will be most useful for retailers).
148 Telephone interview with Derek Carr (June 12, 2019).
Challenges in Enforcing Local Flavored Tobacco Restrictions (2019-20 Regular Legislative Session), discussed in detail below, would have the further benefit of encouraging tobacco manufacturers and distributors to report to the state tobacco products with no characterizing flavor other than tobacco being marketed in California, as opposed to putting the entire burden on regulators to create a list.149

A non-flavored list would be significantly easier to create and maintain even if regulators were to take the lead in creating it. Experts in Massachusetts noted that to create a non-flavored list, they would start with the state’s cigarette list using their minimum price law that requires a listing of all brands allowed to be sold.150 They would remove any flavored products and highlight mint, menthol or wintergreen, as several municipalities (but not all) are now incorporating them in flavor bans.151 The state does not maintain a similar list for smokeless tobacco, cigars, or e-cigarettes, so they would have to research and add those products to the list.152 Regardless, developing a comprehensive non-flavored list would be easier than listing every candy and fruit-flavored product available, particularly in light of the growing prevalence of concept flavors.153

Ultimately, national experts agree that a non-flavored list would be helpful and prefer that an unflavored tobacco non-flavor list be a statutory requirement.154 In the absence of a statutory requirement, experts still agree that a non-flavored list would be helpful and the benefits of having a list would outweigh any negatives.155

149 It would remain for local jurisdictions to define “characterizing flavor” in parallel with the state’s definition, to facilitate enforcement efforts; in addition, the ultimate discretion to enforce against a particular tobacco product remains with the local authorities.
150 Email interview with DJ Wilson (June 4, 2019).
151 Id.
152 Id.
153 Id.; email from Ilana Knopf (Oct. 25, 2019) (a smaller list is more amenable to being tested chemical, to verify manufacturers’ certifications).
154 Telephone interview with Joyce Villalobos (June 5, 2019); telephone interview with Derek Carr (June 12, 2019); interview with Lindsey Freitas (June 7, 2019); telephone interview with Karri Halcomb, Outreach Specialist, Tobacco Intervention Program (Aug. 14, 2019); telephone interview with Rachel Gratz-Lazarus (June 6, 2019); telephone interview with Jackie Harris (May 28, 2019); email from Kevin Schroth (Oct. 24, 2019).
155 Telephone interview with Karri Halcomb (Aug. 14, 2019); telephone interview with Rachel Gratz-Lazarus (June 6, 2019)
It is important to stress that a statewide non-flavored list cannot completely end the independent efforts of local enforcement, particularly where the definition of “characterizing flavor” (or indeed, the products covered) differ between the state and the locality.

**Downsides**

A comprehensive non-flavored list should have several hundred unflavored tobacco products listed. While significantly shorter than a banned products list, it is still challenging for enforcement officers to quickly compare all products to those included on the non-flavored list. Additionally, similarly to a banned products list, enforcement officers may rely too heavily on a non-flavored list, a particular problem if the non-flavored list is not comprehensive, or up-to-date. In that case, a mechanically applied algorithm of “if the product is not on the list, then a citation is issued,” would sweep up patently unflavored tobacco products, undermining the relationship of enforcer and retailer, and lessening confidence in the integrity of the enforcement system. However, so long as the non-flavored list certification process is clear and well-defined, non-flavored list overreliance should not be an issue. In addition, if manufacturers and distributors do not certify their unflavored tobacco products at the state level, they risk undermining local retailers.

Further, as was the case in Massachusetts with the banned products list, if a retailer challenges a citation over the sale of a product not on the non-flavored list, the challenge would turn into an examination of the validity of the non-flavored list, how it was put together, who put it together, how often it was updated, and why certain products were included or excluded. Courts might be disinclined to hold local retailers liable for the errors or omissions committed by national manufacturers and distributors, or regulators who have erred in creating a comprehensive non-flavored list. Of course, this situation is no different from the current scenarios unfolding with errors in locally maintained banned lists, with the collateral benefit of holding manufacturers and distributors liable at the state level for erroneous submissions to the non-flavored list.

It is important to stress that a statewide non-flavored list cannot completely end the independent efforts of local enforcement, particularly where the definition of “characterizing flavor” (or indeed, the products covered) differ between the state and the locality. For instance, in jurisdictions with flavor restrictions that exempt mint

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156 Telephone interview with Mark Meaney (June 26, 2019).
157 Email interview with DJ Wilson (June 4, 2019).
158 Telephone Interview with Michael Tynan (June 5, 2019).
flavored products (or otherwise deviate from the statewide definition of flavored tobacco), the unflavored tobacco non-flavored list would be suboptimal.\footnote{On the other hand, this issue may incentivize jurisdictions with partial flavor bans to take the next step and restrict mint-flavored tobacco products, as well.} Potentially, enforcement officers working off the non-flavored list could mechanically cite retailers for menthol and mint flavored tobacco products, particularly mint flavored products with concept names. Those jurisdictions could adjust the non-flavored list by adding in permissible mint flavored products, although this would swell the list considerably and make it less workable for enforcement officers.

A related problem ensues for jurisdictions, such as San Francisco, with flavor bans that do not restrict flavored juices without nicotine. These juices are sold next to unflavored tobacco products and mixed together after sale by the consumer.\footnote{This DIY process carries public health implications in the selling of highly concentrated nicotine to consumers who will then mix it with flavorings. Email from Mark Meaney, Deputy Director of Commercial Tobacco Control Programs, Public Health Law Center (Oct. 29, 2019).} The flavored juices would not be on the non-flavored tobacco list; hence enforcement officers would need additional training to avoid citing retailers selling these permissible products. A similar issue arises with respect to flavored component parts designed to be used with e-cigarettes or other tobacco products: these items would not appear on a California non-flavored list, but may or may not be restricted in a particular jurisdiction, depending on how the local restriction is drafted.\footnote{It should be noted that the California non-flavored list is simply a tool to expedite local flavored tobacco enforcement; local jurisdictions are free to restrict a more comprehensive set of tobacco products, but would be on their own regarding enforcement decisions. If local jurisdictions wish to use the California non-flavored list to help guide the enforcement process, they may also choose to make the absence of a product on the non-flavored list a rebuttable presumption that a tobacco product is flavored. That way, local jurisdictions retain independent judgement.}

## C. The Sniff Test

Another option for determining whether a tobacco product contains flavors is a sniff test. By some reports, Massachusetts is no longer updating their banned products list and are abandoning it for a sniff test.\footnote{Email interview with DJ Wilson (June 4, 2019).} If an enforcing agent thinks a product is flavored, she will buy two – one to open onsite and if the tobacco smells flavored, she will take the second one back to the Board of Health for them to open and do the same.\footnote{Id.} The average Board of Health member, with an average sense of smell, is sufficient for this – perfumists are not required.\footnote{Id.} However, a sniff test raises an enforcement issue regarding what flavors smell like.\footnote{Telephone interview with Lindsey Freitas (June 7, 2019).} In a similar vein, Maine’s flavored cigar sniff test seems ineffective, although this may result from insufficient enforcement.\footnote{Telephone interview with Mark Meaney (June 26, 2019).} Jurisdictions may also wish to avoid having their enforcement officers sniff tobacco products continually.\footnote{Telephone interview with Lindsey Freitas (June 7, 2019).}
The Tobacco Tax Act of 2016 could be amended to impose an additional (even if nominal) tax on flavored tobacco products requiring a special tax stamp, making the product clearly identified as flavored.

Downsides to the sniff test include the inherently subjective nature of smelling non-combusted tobacco products: in one enforcement action, lawyers for the tobacco industry and retailer claimed that the tobacco did not smell flavored, while the enforcement staff claimed it did. In addition, jurisdictions may be disinclined to (or be barred from) spend public funds on purchasing ambiguously labeled tobacco products.\(^{168}\) Moreover, the sniff test might miss instances where the flavors become evident upon combustion or other use; many definitions of “flavored tobacco products” capture flavorants that become evident only upon use.\(^{169}\)

D. A Statewide Tax on Flavored Tobacco Products

An alternative (or supplementary measure) to a California non-flavored list would be amending the California Healthcare, Research and Prevention Tobacco Tax Act of 2016. This act was an initiative measure (Proposition 56) adopted by the voters at the 2016 General Election. While Proposition 56 opponents outraised supporters two-to-one raising $70.98 million (two of the largest cigarette manufacturers in the U.S., Philip Morris USA, R.J. Reynolds Tobacco Company, and their affiliates, together contributed over $69 million to “No on 56” and proponents raised $35.53 million), Proposition 56 was approved by 64.43 percent of the voters.\(^{170}\)

This measure could be amended to impose an additional (even if nominal) tax on flavored tobacco products requiring a special tax stamp, making the product clearly identified as flavored.\(^{171}\) Thus, a distributor would be required to identify a flavored product and failure to do so would be a violation of tax law. The threat of a tax violation (with associated penalties) may greatly increase the quality of self-reporting on the part of tobacco distributors.

\(^{168}\) Email from Derek Carr (Oct. 22, 2019).

\(^{169}\) For instance, the TCA states that, “a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, 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.” (emphasis added) 21 U.S.C. §387g.


\(^{171}\) A nominal tax might not change the tobacco product user’s incentives, but would effectively serve as a flag to local enforcement officials that a particular product is in fact flavored.
Beyond the deterrent effects of a tax on flavored tobacco products for those jurisdictions without flavored tobacco restrictions, the presence of a flavored tax stamp would make enforcement of flavored tobacco restrictions a simple visual check for enforcement personnel in jurisdictions with restrictions. In the absence of legislative action, based on the success of Proposition 56 in 2016 and the flavored tobacco epidemic, it is likely the voters would approve this approach if presented as an initiative measure. [See Appendix 1.B for model policy language for a flavored tobacco tax.]
III. Assessing the Suitability of Repurposing Existing Tobacco Directories to Establish a Non-Flavored Tobacco Products Directory

A. Manufacturer Supplied Information of Flavor Additives

Many manufacturers voluntarily publish ingredient information on their websites, including Phillip Morris/Altria and R. J. Reynolds.\textsuperscript{172} Additionally, the Australian Department of Public Health annually publishes a comprehensive list of ingredients for all products manufactured by British American Tobacco.\textsuperscript{173} In addition to product ingredients, manufacturer listings of tobacco products commonly contain characterizing descriptions.

From a legal perspective, overreliance on ingredient information could contravene the federal government’s unique role in monitoring tobacco product standards under the TCA.

The ingredients in, and descriptions of, tobacco products could assist tobacco regulators in constructing flavored or non-flavored tobacco lists; however, this effort would be exceedingly difficult, time-consuming and inconclusive. Many “unflavored” tobacco products contain significant amounts of cocoa, licorice and other flavor additives, and yet the additives do not characterize the end user’s experience as a flavored product. In addition, a variety of other flavor additives such as benzyl salicylate and isobutyl salicylate are chemical in composition, and not easily intuited as a flavor additives from product lists.\textsuperscript{174} From a legal perspective, overreliance on ingredient information could contravene the federal government’s unique role in monitoring tobacco product standards under the TCA. In order to avoid preemption in this context, the city of San Carlos, among others, follows model policy language produced by ChangeLab Solutions and caveats its definition of flavored tobacco products with the language that “[a] Tobacco Product shall not be determined to have

a Characterizing Flavor solely because of the use of additives or flavorings or the provision of ingredient information.\textsuperscript{175} Any ingredient based ban would have to qualify that these ingredients are banned to the extent that they impart a characterizing flavor on the product. Thus, any ingredient-based list must address ingredients in conjunction with an end-user test as to the presence of a “characterizing flavor.”

B. Government Produced Flavored Tobacco Lists

California Tobacco Directory (Revenue and Taxation Code § 30165.1)

On November 23, 1998, leading U.S. tobacco product manufacturers, Philip Morris Inc., R.J. Reynolds, Brown & Williamson and Lorillard (“Original Participating Manufacturers” or “OPMs”), entered into a settlement agreement (“Master Settlement Agreement” or “MSA”) with 46 states, the District of Columbia, and five territories, to settle more than 40 pending lawsuits seeking recovery for Medicaid and other health care costs. Four states, Mississippi, Florida, Texas and Minnesota, settled with the OPMs prior to the MSA.

The MSA also called for states to enact qualifying or escrow statutes, requiring manufacturers not participating in the MSA to make annual payments based on sales into an escrow account. These payments are intended to pay for any future judgments and to ensure that the state can recover healthcare related costs from cigarette manufacturers regardless of whether they signed onto the MSA.

Thereafter, the states began enacting directory statutes requiring the state to establish a directory listing all tobacco manufacturers that may sell tobacco products in the state. To be listed on the directory, tobacco product manufacturers must certify in part that they are either a participating member of the MSA or are a Non-Participating Tobacco Product Manufacturer (NPM) that is in compliance with the state’s qualifying or escrow statute. Every state that was party to the MSA has a directory statute.

Following the MSA, the California legislature enacted California Health and Safety Code §§ 104555-104558. To lawfully sell cigarettes or roll-your-own tobacco products in California, tobacco product manufacturers must either sign onto the MSA and perform under its financial obligations or establish and fund a Qualified Escrow Fund that reflects the number of each manufacturer’s cigarettes sold in California as an NPM (The California Reserve Fund Statute, Health and Safety Code §§ 104555-104557).

Pursuant to Revenue and Taxation Code § 30165.1, the California AG is required to develop and publish a directory of cigarettes approved for stamping and sale within California. The directory lists all tobacco product manufacturers and their cigarette brand families that the AG has determined has complied with § 30165.1.

\textsuperscript{175} Ordinance No. 1544, section 8.02.020(a) (April 8, 2019).
Given that the existing directory only lists FDA compliant cigarette products, all of which presumably lack any characterizing flavor (other than mint/menthol), significant alterations would need to be made to make the directory suitable for the purpose of enforcing local flavored tobacco bans.

**Products Included and Excluded**

All cigarettes and roll-your-own tobacco products and their manufacturers must be included on the California Tobacco Directory before such products may be lawfully distributed, sold, offered for sale, or possessed for sale in California. Little cigars are not required to be listed on the California Tobacco Directory in order to be sold lawfully in California, although the AG has the power to impose this requirement in the future. The existing California Tobacco Directory, maintained and published by the AG, contains a list of all “tobacco product manufacturers” and their cigarette or roll-your-own tobacco product brand families that have provided current, timely, and accurate annual certifications and other required information in compliance with section 30165.1 of the Revenue and Taxation Code.

**Assessment**

The California Tobacco Directory currently only contains the following categories of information: Brand Family, Styles, Manufacturer, and Participating/Non-Participating Manufacturer Status. Given that the existing directory only lists FDA compliant cigarette products, all of which presumably lack any characterizing flavor (other than mint/menthol), significant alterations would need to be made to make the directory suitable for the purpose of enforcing local flavored tobacco bans. In order to effectively list flavored tobacco products in a way that is conducive to enforcement activities, the following categories would likely have to be added, product type (e.g., cigarillo, e-liquid), characterizing flavor description, ingredients, company descriptions, and product labeling/depiction. In short, the state directory in its current form could not aid local flavored tobacco enforcement activities.

**Litigation Note**

Our research did not find any cases in which the legitimacy of the MSA directories was ruled against. Most significantly, none of the state tobacco directories have been challenged based on federal preemption in section 387p of Title 21.

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176 Calif. Rev. & Tax. Code, Sec. 30165.1, subd. (e).
177 California Dept. of Justice, California Tobacco Directory, available at: [https://oag.ca.gov/tobacco/directory](https://oag.ca.gov/tobacco/directory).
The following 41 states maintain a tobacco directory:

- Arizona: [https://www.azag.gov/consumer/tobacco/directory](https://www.azag.gov/consumer/tobacco/directory)
- Arkansas: [https://arkansasag.gov/arkansas-lawyer/public-protection/column-two/tobacco/](https://arkansasag.gov/arkansas-lawyer/public-protection/column-two/tobacco/)
- California: [https://oag.ca.gov/tobacco/directory](https://oag.ca.gov/tobacco/directory)
- Delaware: [https://attorneygeneral.delaware.gov/fraud/cpu/tobacco-litigation/](https://attorneygeneral.delaware.gov/fraud/cpu/tobacco-litigation/)
- Georgia: [https://law.georgia.gov/key-issues/consumer-information/tobacco-manufacturer-and-brand-compliance](https://law.georgia.gov/key-issues/consumer-information/tobacco-manufacturer-and-brand-compliance)
- Idaho: [https://www.idaho.gov/consumer-protection/tobacco-settlement/](https://www.idaho.gov/consumer-protection/tobacco-settlement/)
- Kansas: [https://ag.ks.gov/licensing/tobacco-enforcement/directories](https://ag.ks.gov/licensing/tobacco-enforcement/directories)
- Kentucky: [https://revenue.ky.gov/Business/Tobacco-Tax/Pages/Tobacco-Directories.aspx](https://revenue.ky.gov/Business/Tobacco-Tax/Pages/Tobacco-Directories.aspx)
- Louisiana: [https://www.ag.state.la.us/Tobacco](https://www.ag.state.la.us/Tobacco)
- Maryland: [http://www.marylandattorneygeneral.gov/Pages/Tobacco/brandsearch.aspx](http://www.marylandattorneygeneral.gov/Pages/Tobacco/brandsearch.aspx)
- Nebraska: [http://www.revenue.nebraska.gov/cig/manufacturer.html](http://www.revenue.nebraska.gov/cig/manufacturer.html)
- New Jersey: [https://www.nj.gov/oag/oag_tobacco.html](https://www.nj.gov/oag/oag_tobacco.html)
- New Mexico: [https://www.nmag.gov/tobacco-manufacturers-directory.aspx](https://www.nmag.gov/tobacco-manufacturers-directory.aspx)
- North Carolina: [https://www.ncdoj.gov/getdoc/3b96da5a-6384-4bfc-bd2f-3636a5bb8711/2-6-4-3-6-Tobacco-Lists.aspx](https://www.ncdoj.gov/getdoc/3b96da5a-6384-4bfc-bd2f-3636a5bb8711/2-6-4-3-6-Tobacco-Lists.aspx)
- Oklahoma: [http://www.oag.ok.gov/tobacco-enforcement-unit](http://www.oag.ok.gov/tobacco-enforcement-unit)
- Oregon: [https://www.doj.state.or.us/oregon-department-of-justice/publications-forms/tobacco-legislation/](https://www.doj.state.or.us/oregon-department-of-justice/publications-forms/tobacco-legislation/)
The California Fire Safety and Firefighter Protection Act, Health and Safety Code §§14950-14960

This statute prohibits a person from selling, offering, or possessing for sale in California any cigarettes not in compliance with its fire safety testing, performance standard, marking and certification requirements. Cigarettes sold in California must meet the following criteria:

- The cigarettes must be sold in packaging marked with the letters “FSC” for “Fire Standards Compliant” and approved by the State Fire Marshal.
- A certification must be submitted by the manufacturer to the State Fire Marshal certifying that each cigarette listed was tested and satisfies the performance requirements of ASTM E2187-04.

While all cigarettes sold in California must comply with these provisions prior to being authorized for sale in the state, neither Cal Fire nor the State Fire Marshal publishes any list of compliant cigarettes. Our researchers did not receive responses to our inquiries about the certification process or the suitability of the list for purposes of a banned product list or non-flavored list.

Flavored Tobacco Lists from other Jurisdictions

Given the vast quantity of available flavored tobacco products, should California decide to create its own banned product lists, it would likely start with one of the many lists already available. Most notable of these lists include those from the cities of Chicago, San Francisco, and Minneapolis, and the state of Massachusetts. The Massachusetts Association of Health Boards’ Guidance Flavored Product List contains 1,795 different flavored tobacco products179 and seven different categories of flavored tobacco

179 Last updated Dec. 18, 2017, available at: https://mahb.org/wp-content/uploads/2018/03/MAHB-Product-List-3.12.18.pdf; in addition, according to an unpublished 2018 update by the Public Health and Tobacco Policy Center, there were another 1,069 flavored tobacco products not captured in that list (not including flavored e-cigarette solutions). Email from Ilana Knopf (Oct. 25, 2019).
products. Of comparable quality is the list generated by the City of Chicago’s Department of Health and Human Services, containing 1,857 different flavored tobacco products, including menthol cigarettes. Additionally, the list provides a set of 827 flavored tobacco terms to assist with enforcement activities. The primary criticism of the list is that it has not been updated since December of 2015.

Another notable list, despite its relative brevity and recent removal from the official website, is the list of flavored tobacco products produced by the San Francisco Department of Public Health. While only containing 58 different tobacco products, the list possesses two unique features that are particularly helpful with remedying enforcement related issues. The first unique feature is a column in the list for a photograph of the product to assist the process of identifying and verifying items offered for sale by retailers and the corresponding entry on the flavored tobacco list. The second unique feature worthy of adoption by a new California non-flavored tobacco directory is a category for how the product was determined to contain a characterizing flavor. Usually this latter category utilizes the company’s own product description complete with a link for citation.

These lists each contain less than 2,000 products, well short of the total number of flavored tobacco products given that there are an estimated 17,000 available flavored e-cigarette liquids alone.

**FDA Tobacco Products Directory**

The TCA’s adding section 905 to the Food, Drug and Cosmetic Act requires the owners and operators of domestic manufacturing establishments engaged in manufacturing tobacco products to register with FDA and submit product listings. Initially, only cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were covered by these reporting requirements. Subsequently the FDA invoked its authority under 21 U.S.C. 387a(b) to deem other tobacco products subject to its authority (“the deeming rule”). Accordingly, “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” must register and submit product listings with the FDA. Following the initial registration, every person must register annually by December 31st of each year.

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180 The seven various product types listed include: smokeless/dissolvable tobacco, pipe tobacco, hookah/shisha, e-cig/ nicotine liquid, cigar, cigarillo (little cigar), and blunt wraps.
181 In line with this approach, is the recently enacted Senate Bill 538 (Rubio), which would require, commencing April 1, 2020, a manufacturer of an electronic cigarette sold in this state to submit a written physical description and a photograph of each electronic cigarette it sells to CDPH. Additionally, this bill would require CDPH, commencing July 1, 2020, to post the physical description and photograph of each electronic cigarette in a prominent location on its website.
182 Codified at 21 U.S.C. 387e.
183 U.S. Food & Drug Admin., “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and TCA; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,” May 10, 2016 (81 FR 28974) (hereinafter “the Deeming Rule”). The FDCA’s requirements concerning manufacturer and product registration, submission of ingredient listings, marketing, and premarket review applies to e-liquids and other tobacco products. Id. at 28976.
The FDA maintains a searchable database of tobacco products registered with FDA and tobacco products. It includes cigarettes, as well as the spectrum of tobacco products captured by the deeming rule, such as electronic cigarette products. There are currently 3692 products on the list. If a state agency has to build a non-flavored tobacco list from the ground up, this could be a starting point for an arduous effort.

For purposes of creating either a banned list of flavored tobacco products, the FDA product list is unsuitable for two simple reasons. First, while many of the flavored tobacco products are clearly identified as flavored (e.g. “Swisher Sweets Little Cigars Sweet Cherry”), as we have discussed, the enforcement issue crops up with respect to concept flavors, whose incidence and resistance to enforcement issues has been documented. Second, the information on the FDA product list is confined to the name of the product itself, e.g., “Swisher Sweets Filtered Cigars Silver” and its product category. From this information alone, it cannot be intuited whether the product is flavored or not, necessitating further research on the part of local enforcement officers. While the FDA itself may be apprised of the presence of flavorants in these tobacco products pursuant to 21 U.S.C. § 387d(a)(1), the mere presence of flavored ingredients in the composition of a tobacco product is not enough to trigger the definitions of “characterizing flavor” used in most flavored tobacco restrictions. Ingredients such as licorice and cocoa are used in cigarettes for a variety of non-flavoring purposes, such as smoothing the harshness of the smoke.

A more fundamental issue arises with the fact that even if the ingredient information is useful to local enforcement officers of flavored tobacco restrictions, the disclosure of ingredient information to the FDA is protected both by the TCA itself, as well the trade secret exemption in the federal Freedom of Information Act (FOIA). While the FDA is required to “place on public display” the quantities of certain “harmful” ingredients in tobacco products, flavorants are typically not encompassed by the definition. 21 § U.S.C. 387d(d)(1). Hence, as the Rozema court noted, most information that tobacco product manufacturers provide “shall be considered confidential and shall not be disclosed.”

184 FDA, supra note 35.
185 U.S. FDA Tobacco Product Establishment Registration & Listing Requirements, available at: https://ctpcerl.fda.gov/rlapp/home.html?jsessionid=uiUGd1NLvYG205GoqaT7wec0_pBNXx6zbUL8mSfMYUgivVz07GqKi!-1896525340.
186 Email from DJ Wilson, Tobacco Control Director and Public Health Liaison, Massachusetts Municipal Association (October 23, 2019).
187 21 U.S.C. § 387d(a)(1) requires the submission of “a listing of all ingredients, including tobacco, substances, compounds, and additives that are ... added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand.”
188 Sokol, supra note 53. “Tobacco manufacturers continue to add flavors at levels that may elicit a detectable difference in cigarette flavor that may not be recognizably attributable to a known and identifiable flavor. Although chocolate and cocoa flavored cigarettes are specifically banned in the TCA, the PM (www.philipmorrisusa.com) Web site lists cocoa and cocoa products as flavors in its cigarettes (Philip Morris USA, 2012), and the RJ Reynolds (RJR) (www.rjrt.com) and Lorillard (www.lorillard.com) Web sites list cocoa and cocoa products as cigarette ingredients (Lorillard, 2011; RJ Reynolds, 2010).”
190 Rozema, 167 F.Supp.3d at 329, citing 21 U.S.C. 387(f); see also 21 C.F.R. § 20.61(c) (“Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.”).
C. California Ab 1625 (Rivas): Potential Legal Issues And Politics

As previously discussed, California and national tobacco control experts agree that the preferred approach to enforcing flavored tobacco bans could be requiring a tobacco manufacturer by statute to certify their product is flavor free. This approach is taken by AB 1625.\textsuperscript{191} AB 1625 would require the AG to maintain a list of unflavored tobacco product brands. The bill would allow tobacco manufacturers or importers to submit a list of all brands of tobacco products they manufacture or import certified to lack a “characterizing flavor.”\textsuperscript{192} A product the AG reasonably determines has a characterizing flavor may not be listed. Manufacturers are liable for perjury for false certifications, likely falling under California Penal Code Section 131 which governs perjuries relating to business activities and punishable up to one-year imprisonment or by a $25,000 fine.

While the bill was introduced on February 22, 2019, it did not receive a hearing in any legislative committee during the first year of the biennial session. The bill is still in committee and has not advanced to the floor in the Assembly. It must be passed by the Assembly on or before January 31, 2020 to remain in play, then must be passed by the Senate and signed by the Governor.

AB 1625 is drafted in a way that falls short of requiring tobacco manufacturers and importers to report their unflavored tobacco products to the state. However, once the initial disclosure of a brand family is made, the tobacco importer or manufacturers comes under a broad variety of mandatory requirements, including requirements to update the list to remove unflavored products that are no longer sold. The certification of compliance that the AG’s list would provide to listed products would incentivize retailers to only sell those products, which would in turn incentivize manufacturers to voluntarily comply with the provisions of AB 1625. It is likely that AB 1625 avoids being a state “requirement” that might trigger preemption under section 387p of the TCA, as the Supreme Court has

\textsuperscript{191} AB 1625 (Rivas), available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB1625.

\textsuperscript{192} AB 1625, section 2, adding section 104559.1 to the California Health & Safety Code.
held that mere incentivization does not amount to a “requirement,” in interpreting a similar preemption clause. This sidesteps the secondary preemption analysis regarding whether the requirement might be “different from, or in addition to” federal requirements.193

Should a manufacturer submit a product to the AG having certified that the product is unflavored, and the AG then disagree with the manufacturer’s certification, AB 1625 provides a model remedy. In such a situation, the manufacturer would have the ability to challenge the AG’s determination, and to “seek to rebut any presumption relied upon by the Attorney General, and seek relief from the determination, by filing a writ of mandate pursuant to Section 1085 of the Code of Civil Procedure in the Superior Court of the County of Sacramento, or as otherwise provided by law.”194 Critical to this framework is that the manufacturer’s challenge would not necessarily stay the AG’s determination to deny or remove a product from the unflavored tobacco products list.195

In the preemption section of this report that follows, we analyze the legality of reporting requirements that resemble the registration requirements under the TCA. Based on that analysis, we conclude the provisions of AB 1625 can and should be mandatory. Separately, AB 1625 allows for a characterizing flavor to be based on ingredient information, which is in distinction to the litigated definitions of “flavored tobacco,” increasing the manufacturing standard preemption issue.196 As “ingredient information” requirements are of little use in assessing whether the finished product has a characterizing flavor, and might stray into “tobacco manufacturing standards,” we recommend that the definition be altered to comport with litigation-tested definitions of “flavored tobacco products.”197 [See Appendix 1.A for a mandatory version for creating a California non-flavored list.]

193 The Bates v. Dow Agrosciences case examined the preemptive significance of a state common law right of action which might lead pesticide manufacturers to change their federally controlled labels. As Justice Stevens wrote, “[t]he proper inquiry calls for an examination of the elements of the common-law duty at issue … it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action [i.e., changing the federally compliant label].” Bates v. Dow Agrosciences LLC, 544 U.S. 431, 445 (2005). This case is discussed below under the registration preemption subsection.
194AB 1625, section 2, adding section 104559.1 to the California Health & Safety Code.
195 Under California Code of Civil Procedure Section 1094.5 the court in which proceedings under this section are instituted may stay the operation of the administrative order or decision pending the judgment of the court, or until the filing of a notice of appeal from the judgment or until the expiration of the time for filing the notice, whichever occurs first.
196 Telephone interview with Derek Carr (June 12, 2019).
197 As the preemption’s registration section argues below, however, it is likely that even this would survive preemption challenge.
Also, refer to the discussion of flavorants above in section III. A. for a sense of how ubiquitous flavorants are, even in tobacco products that are marketed as unflavored tobacco products. Such ingredient information is of little use in assessing whether a tobacco product is unflavored or flavored.
IV. Legal Challenges to an Non-Flavored Tobacco List

A. Express Federal Preemption Under the Tobacco Control Act, and Theories of Implied Preemption

Of the possible legal impediments that confront a non-flavored list of unflavored tobacco products, the most noteworthy would be the TCA, specifically its express preemption clause in section 387p. This portion of the paper also discusses whether theories of implied preemption, in particular “field” preemption, might pose an impediment to the unflavored tobacco products non-flavored list. We should note as a preliminary matter that no court has ruled against the validity of a state or local flavor restriction on preemption grounds, nor do we expect a court to rule against the validity of a California non-flavored list. Additionally, all of the national and state experts we interviewed in the course of this paper were under the opinion that preemption would be, at worst, a mild threat to this less intrusive form of regulation, the production of an unflavored tobacco non-flavored list. In addition, it is firmly within the purview of a state’s power to support local enforcement efforts, as is already the occurring in California in the realm of tobacco control efforts. Research indicates that California is particularly adept at utilizing policy diffusion by allowing local jurisdictions to engage in a process of trial and error before adopting the most effective model regulation at the state level.

198 National Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I., 731 F.3d 71 (1st Cir. 2013); U.S. Smokeless Tobacco Mfg. Co. v. City of New York, 708 F.3d 428 (2d Cir. 2013); Independents Gas & Service Stations Associations, Inc. v. City of Chicago, 112 F.Supp.3d 749 (N.D. Ill. 2015); see also the more recent decision, GoodCat, LLC vs. Cook, 202 F.Supp.3d 896 (S.D. Ind. 2016) (holding no preemption, but a violation of the dormant commerce clause for an Indiana regime that imposed a variety of manufacturing requirements on out-of-state manufacturers).

199 Although AB 1625 (Rivas) was written without an explicit requirement to report unflavored tobacco products to the state of California, this section of the paper will be written as though it were, in part due to the fact that while the initial reporting is not mandatory, the AB 1625 does mandate annual updating on the part of tobacco manufacturers and importers that have voluntarily complied with its language. Accordingly, a court could construe the requirements of a bill structured this way, and it is possible that the tobacco industry would in any event argue that even the “soft” requirements of the AB 1625 could be viewed as a form of premarket review or annual registration requirements in the TCA, codified at 21 U.S.C. sections 387j or 387e.

200 “Local jurisdictions may have particular promise as pioneers of new policies for a variety of reasons, including their greater responsiveness to citizen concerns, the reduced influence of lobbyists (who are likely to focus resources at the state or national level), and the greater receptivity of citizens to local change.” Florey et al., “A Successful Experiment,” UCLA Law Review (2018), available at: https://www.uclalawreview.org/successful-experiment/.

201 See, e.g., California Health & Safety Code 104390, giving the California Department of Public Health the authority to assist local tobacco use prevention programs, including “data collection,” and “technical assistance.” Similar language in a California non-flavored list bill would help anchor the protections of the TCA’s savings clause, in terms of having “information reporting” “relate to” sales of tobacco products.

202 “To the extent that the state waited to adopt a broader regulatory policy until after similar local laws had gained in popularity, California appears to have followed a prudent approach to regulating electronic smoking devices. California’s experience suggests that state encouragement of local regulatory efforts can both facilitate the spread of sound policy and provide the groundwork for future state-level regulation.” Florey et al., supra note 201.
Background on the Family Smoking Prevention and Tobacco Control Act

The TCA has two explicit policy goals: curbing adolescent initiation of tobacco product consumption, while at the same time, preserving the rights of adults to access tobacco products. As the TCA’s Section 3 reads, “[t]he purposes of this division are … to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and … to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers.” The specific legislative intent underlying the tripartite preservation, preemption and savings clauses of the TCA are of weightier significance, but the general intent of the statute itself remains significant.

Consequently, a reviewing court will likely determine that any challenged state or local legislation aimed at curbing youth initiation of tobacco consumption is in line, and not in conflict, with the intent of the TCA, when performing a preemption analysis. Thus, a California non-flavored list with a primary purpose to assist local flavored tobacco bans, would likely be viewed as congruent with the legislative intent of the TCA. This congruence is particularly important as this issue is first impression. A reviewing court would likely be compelled to place great weight on legislative intent when conducting its preemption analysis. Moreover, if “there is any ambiguity as to whether the local and federal law can coexist, [a court] must uphold the ordinance.”

Preemption: The General Framework

The U.S. Constitution establishes 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.” A state or

203 “[T]here is no national consensus to abolish tobacco products altogether, particularly in light of the millions of adults who are addicted to them, see id. at 38 (noting that “prohibition of a product that is used regularly by a large number of heavily addicted adult users” would pose difficult questions of public health.” U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York, 708 F.3d 428, 433 (2d Cir. 2013).

204 Section 2 of the TCA, as well as comments made by Congress members during presentation on H.R. 1256 focus on issues such as: adolescents’ disproportionately high rate of tobacco initiation and level of susceptibility to tobacco advertisement in comparison to adults, the tobacco industry’s history of deceptive practices (including modified risk products), and the socio-economic benefits of reducing tobacco use initiation.


206 Somewhat surprisingly, it could be argued that a California unflavored tobacco non-flavored list could actually be seen as aligning with the second goal of the TCA, preserving the right of adults to continue their smoking habit, as the clarity of the list will provide a safe harbor for those adult smokers.

207 This report uses the term “California non-flavored list” to describe a list of unflavored tobacco products that may be sold within a jurisdiction banning flavored tobacco products, but this term is meant to be distinct from the “Unflavored Tobacco List” proposed in AB Bill 1625.

208 U.S. Smokeless Tobacco, 708 F.3d at 433.

209 U.S. Const. art. VI, cl. 2.
local law may be displaced because it either 1) expressly conflicts with the language of federal legislation; or 2) actually conflicts with federal law, or 3) implicitly conflicts with the structure and purpose of the federal legislation by entering a field completely occupied by Congress.\textsuperscript{210} However, when the state law aims to protect public health and safety (the police power), that law is not to be preempted unless that was clear and manifest purpose of Congress.\textsuperscript{211} This presumption against presumption does not apply when “the state law in question bears upon an area with a history of significant federal presence.”\textsuperscript{212} It may be argued (although no court has opined in this matter) that because the California non-flavored tobacco directory is aimed at protecting the health and safety of its people, if challenged, would be entitled to the presumption against preemption, based in part on the fact that the federal government’s regulation of tobacco was only clearly asserted in 2009 by the TCA.

### Express Preemption Issues under the TCA

Regardless of the preemption standard applied, a reviewing court would start with the text of the TCA’s three-part preservation, preemption, and savings clauses to determine whether the non-flavored tobacco directory would be preempted. The pertinent parts of the 21 U.S.C. section 387p are summarized as follows:

1. Preservation clause: expressly preserves state and local power to regulate tobacco products “in addition to, or more stringent than, requirements” of the TCA’s Chapter IX, including regulations “relating to or prohibiting the sale” of tobacco products. In other words, state and local jurisdictions are granted authority under the TCA’s preservation clause to regulate tobacco products post-production.\textsuperscript{213}

2. Preemption clause: prohibits state and local regulation “different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.”\textsuperscript{214}

3. Savings clause: explicitly states that the preemption clause will not apply to state and local regulations “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.”\textsuperscript{215}

\textsuperscript{210} Engine Mfrs. Ass’n v. South Coast Air Quality Management Dist., 498 F.3d 1031 (9th Cir. 2007) citing Tocher v. City of Santa Ana, 219 F.3d 1040, 1045–46 (9th Cir. 2000), abrogated on other grounds by City of Columbus v. Ours Garage & Wrecker Serv., Inc., 536 U.S. 424, 431–34 (2002).


\textsuperscript{212} United States v. Locke, 529 U.S. 89, 108 (2000) (holding that Washington’s tanker regulations regarding general navigation watch procedures, English language skills, training, and casualty reporting are preempted despite relating to public health and safety because, “The State has enacted legislation in an area where the federal interest has been manifest since the beginning of the Republic and is now well established,” having created “an extensive federal statutory and regulatory regime”).


\textsuperscript{215} 21 U.S.C. § 387p(a)(2)(B); the GoodCat court interpreted this section to mean that an otherwise preempted state or local law would be saved from preemption if it also related to sales or information reporting to the state. GoodCat, LLC v. Cook, 202 F. Supp. 3d 896 (S.D. Ind. 2016).
While the production/post-production distinction may seem to provide clear delineation between the exclusive jurisdiction of the FDA, and the shared jurisdiction of the FDA and the states/local governments, it does not provide much guidance in terms of the conditions which states are free to impose on the sale and distribution of tobacco products that may affect production itself.\textsuperscript{216} As a result, this regulatory scheme has effectively established a partially overlapping federal-state regulatory framework. Legislative intent is a useful guide to underscore the legitimacy of a California non-flavored list: it has been established that "[t]he purpose of Congress is the ultimate touchstone" in every preemption case.\textsuperscript{217}

Congressional Intent and the TCA

As a threshold matter, it is critical to note that despite the somewhat vague allocation of powers between the FDA and state/local government in the preemption clauses of the TCA, in at least one respect, the federal government’s powers are limited entirely. The FDA is expressly prohibited from banning entire categories of products, such as cigarettes or little cigars, whereas the TCA does not limit state and local government in this respect.\textsuperscript{218} In fact the preservation clause expressly saves the power to regulate the sale of tobacco products for state and local governments.

Furthermore, regarding Congressional intent, it might be argued that an unflavored tobacco non-flavored list runs counter to the purposes of the TCA, which explicitly targets the prevention of youth initiation of tobacco use. As noted above, it is flavored tobacco which is predominantly favored by the youth segment, and the unflavored tobacco non-flavored list does not target flavors, quite the contrary. Consequently, legislation establishing an unflavored tobacco non-flavored list in California should make clear the intention to use this list as a means of facilitating the enforcement of flavored tobacco bans at the local (and potentially, state) level.

In any event, it should be noted that throughout the U.S. (1) MSA states have all established tobacco directories comprised mostly of unflavored cigarettes, (2) none of these directories have been successfully challenged on preemption grounds, and (3) there have been no challenges to the MSA directories based on their being outside the scope of TCA powers.

Challengers of state tobacco regulation have relied on a broad swath of framing arguments to bring the state regulations under the ambit of federal preemption: for example, flavor bans in Providence and

\textsuperscript{216} As the \textit{U.S. Smokeless} court noted, not every sales ban amounts to a “backdoor” tobacco product standard even if the ban might affect manufacturing processes; in fact, such a broad reading would collapse the distinction between sales restrictions and manufacturing processes, and thereby undermine the structure and meaning of section 387p. \textit{U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York}, 708 F.3d 428, 434 (2d Cir. 2013).


\textsuperscript{218} The FDA may not “ban[] 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.” 21 U.S.C. § 387g(d)(3); as the court in \textit{U.S. Smokeless} noted, early versions of the TCA would have reserved the power to ban tobacco product categories to the FDA itself. 708 F.3d at 433, n.1.
New York City were challenged as impermissible (and preempted) tobacco manufacturing standards, even though the ordinances were silent as to the manufacturing processes involved. If the past is any prologue, section 387p challenges to an unflavored tobacco will also take the form of arguing that the non-flavored tobacco directory amounts to requirements “different from, or in addition to” those of the TCA regarding tobacco product standards, as well as other aspects of exclusively FDA responsibilities, such as registration and premarket review challenges. As we argue below, these challenges should similarly fail: we set them out in order to be comprehensive about potential litigation risks, however small.

**Express Preemption under the TCA: Registration Requirements**

Under 21 U.S.C 387i(a)(1), tobacco manufacturers are required to file with the FDA a list of all tobacco products which are being manufactured, prepared, compounded, or processed for commercial distribution. Further, manufacturers must submit the following information:

- All consumer information relating to each tobacco product, a representative sample of all advertisements for each product, a copy of all labeling for each product, a list of all components, ingredients, additives, and properties, and of the principle or principles of operation, a description of the content, delivery, and form of nicotine in each tobacco product, and all documents that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products.

Challengers of a California unflavored tobacco non-flavored list might point to the FDA registration requirements and argue that further reporting to the state would be duplicative and therefore preempted. However, this argument would likely be rejected by the courts.

The information reporting requirements of a California non-flavored tobacco non-flavored list would indeed result in duplicate registration requirements, however, the preemption clause only prohibits state registration requirements that are “different from, or in addition to” those required under the TCA itself. Interpreting similar federal preemption language in Bates v. Agrosciences LLC, the Supreme Court provided an example of a permitted “parallel” requirements: “A state regulation requiring the word “poison” to appear in red letters, for instance, would not be pre-empted if an EPA regulation imposed the same requirement. Bates, 544 U.S. at 444.”

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224 The phrase “different from, or in addition to” is a little problematic on its own, as it is somewhat difficult to intuit how a requirement could be “different from” but not “in addition to,” or vice versa.
Court safeguarded state “parallel requirements” from federal preemption. The Bates court held that the preemption clause prohibiting state requirements “in addition to or different from” the federal requirements must be interpreted to permit states to impose requirements parallel or identical to federal requirements, for to hold otherwise would be to read the phrase “in addition to or different from” out of the preemption provision.

“That Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not.” Given the broad sweep of federal registration and reporting requirements in the TCA, the overlap with the spartan requirements of a California non-flavored list are inevitable and immunizing, particularly as tobacco manufacturers are required to submit both ingredient information as well as marketing materials to the FDA.

Returning to the language of 387p itself, a broad reading of section 387p(a)(1)’s “different from, or in addition to” the registration requirements for the FDA could signal that no registration information can be provided to the states at all, for any disclosure to the states would automatically be “in addition” to the disclosure that was made to the FDA. This broad reading is undercut, however, by the last sentence of section 387(a)(2)(B) which states: “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.” This broad reading of the preemptive force of section 387p(a)(1) is further undercut by a federal court’s narrowing of similar preemption language of “different from, and in addition to.” The Bourbia court observed that the purpose of this language was to prevent “competing state labeling standards that would create significant inefficiencies for manufacturers, such as different labeling regimes prescribing the color, font size, and wording of warnings.” Similarly here, the thrust of section 387p’s preemption language is to prevent inefficiencies stemming from discrepant requirements of the fifty states. When the state requirements are in parallel to the federal requirements, no such inefficiency is possible.

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226 The Bates court noted that there was no “plausible alternative interpretation of ‘in addition to or different from’ that would give that phrase meaning…. Instead, they appear to favor reading those words out of the statute, which would leave the following: ‘Such State shall not impose or continue in effect any requirements for labeling or packaging.’ This amputated version of § 136v(b) would no doubt have clearly and succinctly commanded the pre-emption of all state requirements concerning labeling. That Congress added the remainder of the provision is evidence of its intent to draw a distinction between state labeling requirements that are pre-empted and those that are not.” Bates 544 U.S. at 448-449.

227 Id. at 449.


229 The Bates court observed that a concern lying underneath FIFRA’s preemption clause were the “hardships” imposed by a “crazy-quilt” of fifty states’ imposition of requirements in addition to the federal requirements. Bates, 544 U.S. at 451-452. Any “hardship” is undercut by the pre-existing breadth and depth of reporting to the FDA already performed by tobacco manufacturers and importers. Out of concern for creating “crazy-quilt” compliance issues, we recommend that the California non-flavored list rely on the tested (and federal) definition of flavored tobacco product to minimize any hardship that manufacturers might experience in reporting to the various states with flavored tobacco restrictions.
Hence, subparagraph (B) makes it plain that subparagraph (A), while nominally a preemption clause, is actually a parallel disclosure provision as well as a limitation on the scope of disclosures to state authorities. This reading of subparagraphs (A) and (B) helps explain why the TCA did not expressly protect state tobacco directories, as was the case with fire safety standards: because the information in the MSA directories is already captured in FDA registration requirements, subparagraph (A) does not preempt a state’s gaining access to that same information. Conversely, the failure to mention the MSA directories points to the fact that subparagraph (A) was designed to ensure a robust information flow to the states (this, notwithstanding its moniker as “preemption” clause).\(^{230}\)

For purposes of preemption analysis under subparagraph (A), the question becomes whether tobacco manufacturers or importers are disclosing “characterizing flavor” information to the FDA, similar to the sparse information in a California unflavored tobacco non-flavored list, viz., the brand style of the tobacco product, together with the certification that it lacks a characterizing flavor. The “brand style” (referred to in AB 1625), or similar reference to the name of the tobacco product, is reported to the FDA under the existing TCA requirements.\(^{231}\) And, given the broad contours of the registration information (including advertisements and “all consumer information”), registrants are in effect indicating to the FDA whether the product possesses characterizing flavors evident to the end user, albeit in a form that is the opposite of the certification requirement. That is, advertising information may identify the blueberry flavor of a tobacco product. By contrast, the information reported to the state under a non-flavored list requirement would be in the form of certifying that there is no blueberry flavor present.

Even if the language of subparagraph (A) were insufficient to protect the certification that the product lacks a characterizing flavor, the savings clause will serve to safeguard the reporting of that information to the state. That is, even if a court were to determine that “characterizing flavor” information is not required to be reported under the FDA’s registration process, that information is shielded from preemption by subparagraph (B), as it is a requirement “relating to … information reporting.”\(^{232}\)

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\(^{230}\) Pursuant to the Master Settlement Agreement (MSA), California, as well as many other states, had already required manufacturers of cigarettes to register with their state directory prior to introducing their products to market before the TCA was enacted. A court will be hard pressed to find that Congress enacted the TCA, with constructive knowledge of the existence of these state directories, and chose to implicitly preempt these directories. This is especially the case given the fact that preempting these directories would strip away a critical enforcement mechanism from the states, which is inconsistent with TCA’s findings which states, “…State governments have lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products.”

\(^{231}\) The FDA’s deeming rule provides further protection to a state non-flavored list, in that prior to its promulgations, the FDA’s registration requirements did not apply to tobacco products other than cigarettes. Now, the FDA requires product registration, ingredient submission and premarket review of all tobacco products; accordingly, state requirements of information reporting about non-cigarette tobacco products is duplicative of FDA requirements, and not “different from, or in addition to” those requirements. U.S. Food & Drug Admin. (FDA), Deeming Tobacco Products to be Subject to the FDCA, 81 Fed. Reg. 28,974 at 28,976 (May 10, 2016).

\(^{232}\) Our research into the legislative history around the savings clause did not unearth any clarification about its scope, but the plain language is unambiguous on its face. Also, given the TCA’s general intent to permit states to continue their role in regulating tobacco, the idea of an implied preemption of this vital mechanism in state’s protection of public health and safety.
A variant of this argument against the non-flavored list is rooted in the requirements of sections 387d and 387j. Challengers might argue that in order to disprove a “characterizing flavor” under the statute, they would need to reveal manufacturing processes and ingredient lists. This would increase the amount of duplication to the existing FDA reporting requirements and could implicate another aspect of express preemption: tobacco product standards (discussed at greater length below). As we note later, the absence of federal regulations implementing tobacco product standards undercuts the preemption argument even more fundamentally.233

In addition, in response to the tobacco product standard argument, California could argue that there are alternative means of disproving a “characterizing flavor” without resorting to ingredient disclosure or other argument that smacks of a product standard; the voluntary decision of a manufacturer to do so cannot reframe the requirements of an unflavored tobacco non-flavored list. Manufacturers are free to find other means to disprove the presence of characterizing flavor by other means. In addition to procedures set out in the California non-flavored list for rebutting a presumption of a “characterizing flavor,” California law sets out procedures for manufacturers to controvert adverse regulatory actions.234 For instance, abuse of discretion is established if the respondent has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence.235 Thus, manufacturers could prevail by simply arguing the inadequacy of the AG’s supporting findings, without getting into the zone of tobacco product standards.

**Express Preemption under the TCA: Premarket Review**

Under 21 U.S.C. 387j (of the TCA, as codified) a manufacturer of tobacco products not commercially marketed as of February 15, 2007 is required to submit those products for premarket review and approval by the FDA before placing them in interstate commerce.236 A challenge to the California non-flavored

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233 “But the text of the preemption clause does not limit the purpose of state or local regulations of tobacco products; it applies only to specific measures imposing different or additional requirements. See 21 U.S.C. § 387p(a)(2)(A) (“No State *912 ... may establish ... any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter ....”) (emphasis added). Thus, the clause does not operate unless the FDA regulates the adulteration of tobacco products, and GoodCat has not directed the court to any such regulations.” GoodCat, LLC v. Cook, 202 F. Supp. 3d 816, 911-12 (2016).

234 In accordance with California law governing writ of mandate, “[w]here the writ is issued for the purpose of inquiring into the validity of any final administrative order, evidence is required to be taken, and discretion in the determination of facts is vested in the inferior tribunal, corporation, board, or officer, the case shall be heard by the court sitting without a jury.” Calif. Code of Civil Procedure subd. 1094.5(a).

235 Calif. Code of Civil Procedure subd. 1094.5(b).

236 Deeming Tobacco Products to be Subject to the FDCA, 81 Fed. Reg. 28,974 (May 10, 2016); in addition, on 9/20/19, the FDA released its proposed rule, relating to new requirements for content, format, and FDA’s review and communications procedures in connection with premarket tobacco product applications (PMTAs), atop the existing requirements for premarket review in the TCA itself (21 U.S.C. 387j). U.S. Food & Drug Admin., “Premarket Tobacco Product Applications and Recordkeeping Requirements,” 84 Fed. Reg. 50,566 (Sept. 20, 2019). The proposed rule requires submitted PMTAs to contain details regarding the physical aspects of a tobacco product and information on the product’s potential public health benefits and harms. Section XII of the proposed rule signals that its promulgation might carry preemptive impact on the states. As the rule has not been finalized, it does not figure into our preemption analysis, however.
Challenges in Enforcing Local Flavored Tobacco Restrictions

The list might track the litigant’s argument in GoodCat, namely, that a manufacturer could meet all of the FDA’s premarket review requirements but be unable to sell in the California market because of a failure to comply with the requirements of a California’s unflavored tobacco non-flavored list. This argument would be particularly influential if the non-flavored list was either explicitly (or construed by a court as) a mandatory requirement as a precondition for sales in the California market. In short, a requirement of filing a certification as to the absence of “characterizing flavor” with the state would amount to a requirement “different from, or in addition to” the TCA’s premarket review requirements.\(^\text{237}\)

However, in response to this premarket review argument, the GoodCat court summarily rejected the plaintiff’s claim, observing that the argument “conflates the FDA’s review of specific tobacco products before they enter interstate commerce and the measures a manufacturer must implement at its facilities before selling any e-liquid in Indiana,” in holding that the Indiana security requirements were not subject to TCA preemption.\(^\text{238}\) Applying the GoodCat holding to California’s non-flavored list is on even stronger footing, as tobacco products actually need not be on the non-flavored tobacco list to be sold in the California market: California jurisdictions without flavor restrictions would not incorporate the non-flavored tobacco list in their local ordinances, and as a consequence, there would be no impediment to any tobacco products from being sold therein.\(^\text{239}\)

Challengers of a California non-flavored list might critique the GoodCat holding regarding premarket review by citing to section 387p(a)(2)(B), notably the explicit reference to protecting state fire standards. Fire safety standards in California and numerous other jurisdictions serve to ban the sale or possession of cigarettes not in compliance with California fire safety performance standards.\(^\text{240}\) So, the argument would go that if individual states’ premarket review/tobacco product standards were shielded from preemption by the fact that they only applied to that state, then there would have been no need to insulate state fire safety standards from preemption explicitly.

The response to this argument would be that “information reporting” has independently been protected in the savings clause, and typical information reporting requirements do carry penalties, in order to enforce compliance. That is, framing a requirement to supply information about unflavored tobacco products cannot be characterized as “premarket review”: a non-flavored list does not require additional testing or remanufacturing a tobacco product to meet a standard, rather, it only requires a certifica

\(^\text{237}\) Again, our position is that the non-flavored list does not function as a premarket review, but even so, litigation risk might trickle down to the local enforcement level, where the absence of a product on the non-flavored list would serve as a presumption that the product was in fact flavored. Retailers at that point could argue that the list is a precondition.

\(^\text{238}\) GoodCat, 202 F. Supp. 3d at 912.

\(^\text{239}\) A logical flaw obtains in the GoodCat holding: were every state in the union to similarly impose a premarket review condition, then notwithstanding FDA premarket approval, that tobacco product could not be sold in the United States.

\(^\text{240}\) The California Cigarette Fire Safety and Firefighter Protection Act; Cal. Health & Safety § 14951(a) (“A person shall not sell, offer, or possess for sale in this state cigarettes not in compliance . . . ”)
tation that a tobacco product lacks a characterizing flavor. But, even if this were the case, the California non-flavored list would fall under the Congressional protections afforded “information reporting” in subparagraph (B). Under this construction, the “fire safety standards” aspect of the savings clause simply protects state authority over tobacco product standards, jurisdiction which otherwise remains exclusively with the FDA.241

A comparison to the purposes and requirements of the existing premarket review process under section 387j underscores this point. The purpose of the premarket approval process is for the FDA to establish the safety/efficacy of a tobacco product, based on FDA-specified scientific studies and tests. Further, manufacturers must submit written documentation and reports which demonstrate the nature and results of these studies and tests. The TCA then requires the FDA to review the relevant records, documentation, and scientific test results242 and render a determination whether the cigarette manufacturer has demonstrated the safety and efficacy of the cigarette product. In comparison, the custodian of a California non-flavored list simply would require a certification from the manufacturer that the tobacco product lacks a characterizing flavor. This approach would not require further tests or other extensive submissions are required. While the non-flavored list’s custodian would likely engage in research as to the veracity of that submission (as is the case in AB 1625), its role could be purely ministerial in terms of adding products to the list (and leaving the purging of the list itself to a subsequent procedure). In any case, the purpose of the California non-flavored list, providing clarity for local jurisdictions about the distinction between flavored and unflavored tobacco products, is entirely orthogonal to the purposes of premarket review under the TCA, which aims at ensuring that tobacco products are safe.

One final note on this issue of the proper frame for the California non-flavored list: it is unlikely such a list would be characterized as “premarket review” because this characterization would also sweep up any precondition for sales into a US jurisdiction, including such matters at the California requirement that cigarettes sold in California bear a tax stamp,243 or even local tobacco retail license regulations.

241 Additionally, when reached for comment whether then-existing state directories were included under the TCA saving clause’s reference to “information reporting to the state” and whether future directories would be treated as an unauthorized state pre-market approval process, the office of Henry Waxman, author of the TCA, replied, “None of us ever dealt with or were asked to consider your question of whether allowable state information reporting could be considered premarket review. Having said that, none of us think there was any intention to consider state information reporting as premarket review. California definitely should treat as allowable information reporting the specific type of information regarding flavors.” (June 28, 2019) While a contemporaneous statement from the author of the statute will be accorded minimal weight, it is still useful to note that it was not explicitly the intention of the author to preempt existing state directories.

242 The following tests are performed during the premarket review process: Flammability and burn of the prepared cigarette wrapper paper, Flammability and burn of the cigarette filler, Use and effectiveness of the cigarette filter, cigarette draw, cigarette smoke taste and aroma, cigarette design defects. Additionally, cigarette smoking machine tests are utilized to measure the by-products of igniting and burning the cigarette’s ingredients and additives, identifying by products that are potentially harmful to the user.

243 The California Cigarette and Tobacco Products Tax Law requires that an appropriate stamp be affixed to, or that an appropriate meter impression be made upon, each package of cigarettes prior to distribution. California Rev. & Tax. Code §30001 et seq.
In sum, although it is highly likely that tobacco industry attempts to frame a California non-flavored list as a form of preempted premarket review will fail, in an abundance of caution, as is the case with AB 1625 the non-flavored list could be drafted as to be voluntary, with express language about how products may continue to be sold in the California market.\textsuperscript{244} The voluntary nature of AB 1625’s reporting may still be effective, given the numerous jurisdictions in California restricting flavored tobacco products. Should all those jurisdictions incorporate the AB 1625 non-flavored tobacco list in their local restrictions, there will be a strong incentive on tobacco manufacturers and distributors to comply voluntarily. Although if there is meager voluntary reporting, the effort of creating a non-flavored list would fall entirely onto the AG’s office, with all the attendant difficulties in distinguishing between flavored and unflavored products.

**Express Preemption under the TCA: Tobacco Product Standards and Good Manufacturing Practices**

A final express preemptive argument would be that a California non-flavored list would amount to a tobacco product standard, a power reserved exclusively to the FDA under 21 U.S.C. section 387g,\textsuperscript{245} or “good manufacturing practice” under 21 U.S.C. section 387f(e)(1)(A).\textsuperscript{246} This argument was raised in each of the cases challenging flavored tobacco restrictions (New York City, Chicago and Providence) as well as Indiana’s e-cigarette manufacturing standards. Tobacco retailers attempted to characterize local regulation of flavored tobacco as being a preempted attempt to create de facto tobacco product standards or good manufacturing standards, a realm of activity preempted under the TCA.

Federal courts have uniformly rejected these efforts. The court in *U.S. Smokeless Tobacco Mfg. Co. LLC. v. the City of New York* upheld New York City’s flavor ban as a sales ban and not an interference with manufacturing processes. The court reasoned: “[u]nlke the FSPTCA’s ‘special rule for cigarettes,’ which prohibits manufacturers from producing cigarettes that contain ‘an artificial or natural flavor’ as a constituent or additive, 21 U.S.C. § 387g(a)(1)(A), the city ordinance explicitly does not turn on ‘the use of additives or flavorings,’ but rather on whether the product itself imparts ‘a distinguishable taste or aroma.’”\textsuperscript{247} Of critical importance was that New York City’s ordinance did not focus on what goes into the tobacco or how the flavor is produced, but only whether final tobacco products are ultimately characterized by, or marketed as having, a flavor. If California’s non-flavored tobacco directory utilizes a similar definition of characterizing flavor, then it should not be preempted as an unauthorized attempt to regulate manufacturing standards.

\textsuperscript{244} In addition, the California non-flavored list should expressly save the authority of local jurisdictions to restrict tobacco products, beyond the definition of “flavored tobacco products” in the non-flavored list itself.

\textsuperscript{245} 21 U.S.C. section 387g sets out the special rule for cigarettes, banning flavored cigarettes, as well as confers the power to the FDA to adopt tobacco product standards. The FDA has not exercised the latter power to date.

\textsuperscript{246} Under 21 U.S.C. section 387f(e)(1)(A), the FDA is responsible for prescribing regulations “requiring that the methods used in, and the facilities and controls used for, the manufacture ... packing, and storage of a tobacco product conform to current good manufacturing practice.”

Another vital aspect of the court’s decision was its argument that even if the flavored tobacco sales restriction were construed as a tobacco product standard within the preemption provision, the savings clause would defeat preemption of the city’s sales restriction, as the regulation relates to the sale of tobacco products by limiting the business at which flavored tobacco might be sold.248

And even if a court improbably construed the non-flavored list as a product standard not “relating to” the sale and distribution of flavored tobacco products, the GoodCat court noted that a product standard itself would be rescued by the fact that the FDA has not promulgated any product standard regulations under the TCA.249 As the FDA has not promulgated any such regulation, then the preemption clause in Section 387p, which triggers only when a state or local measure “is different from, or in addition to, any federal requirement,” would not preempt any such state law. Similarly, in spite of the fact that the FDA has expressed its intent to regulate manufacturing standards eventually, it has yet to act upon that intent, indicating that even if the non-flavored tobacco directory were deemed a manufacturing standard it would nonetheless not be preempted.

The lesson for the drafters of a California non-flavored list statute would be to firmly link the utility of the non-flavored list to the efforts of state and local jurisdictions to restrict the sales of flavored tobacco products, by assisting in distinguishing between flavored and non-flavored tobacco products.

**Implied Preemption: Field Preemption**

If the California non-flavored list survives challenge under the express preemption clause in section 387p, the preemption analysis is not at its end.250 As the Supreme Court has made it clear, “a savings clause does not bar the ordinary working of conflict pre-emption principles.”251 That said, in determining whether a state or local law is preempted by federal law, where the federal statute contains an express preemption provision, courts begin with the wording of that provision. As much weight as a court will grant the language of the provision in question, it cannot be read in isolation as courts must also consider the statute as a whole to determine whether the local ordinance conflicts with the overall federal regulatory scheme. Where Congress has specifically addressed the preemption issue, the court’s task is primarily one of interpreting what Congress has said on the subject.252

248 Id.
249 The FDA has not issued product standards or good manufacturing practice regulations. See, e.g., 81 Fed. Reg. 28,974, at 29,003.
250 We have included this discussion of field preemption in the interests of comprehensively setting out the various preemption possibilities, although the likelihood of a finding of field preemption is very small.
252 U.S. Smokeless, 708 F.3d at 432.
Although the chances remain small, FDA developments in recent years increase the likelihood that a court may find that the FDA now occupies the field of tobacco regulation. Under the TCA, the FDA has the authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law.\(^\text{253}\) Effective August 8, 2016, the FDA expanded the scope of its authority to regulate a “tobacco product” to all other categories of products that meet the statutory definition of “tobacco product” in section 201(rr) of the Food, Drug and Cosmetic Act.\(^\text{254}\)

Additionally, on September 11, 2019, the FDA released a statement announcing the agency’s intention to implement a policy on the enforcement of premarket authorization requirements for non-tobacco-flavored e-cigarettes. The goal of the proposed rule is to target the influx of unauthorized e-cigarette products currently available on the market. Alex Azar, the Health and Human Services Secretary is quoted as saying, “The Trump Administration is making it clear that we intend to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools and communities.”\(^\text{255}\)

Also, in September of 2019, the FDA released their proposed rule concerning the premarket tobacco product applications (PMTAs). As currently drafted, the proposed rule establishes requirements related to the content, format, and FDA’s review and communications procedures for PMTAs, atop the existing requirements for premarket review in the TCA itself (21 U.S.C. 387j). The proposed rule requires submitted PMTAs to contain details regarding the physical aspects of a tobacco product and information on the product’s potential public health benefits and harms. That aim of including this information is to provide sufficient information for the FDA to effectively conduct a pre-market evaluation of an applicant’s product. In that same vein, the proposed rule would codify the procedures by which the agency would review PMTAs, and formalize record maintenance requirements for manufacturers relating to the FDA compliant marketing status of their tobacco products.\(^\text{256}\)

\(^{253}\) 21 U.S.C. 387a(b).

\(^{254}\) Under section 201(rr), the term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product.

The Deemining Rule is relatively silent in terms of state and local preemption. The Deemining Rule was codified in Title 21 in the Code of federal regulations in sections 1100, 1140, and 1143. Of these, only section 1140.16 mentions any explicit state carve out, Title 21 CFR 1140.16 which reads, “Paragraph (d)(2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.”


\(^{256}\) In October, the agency is hosting a public meeting to discuss policies, processes, and general scientific principles related to tobacco product marketing applications with a focus on deemed tobacco products such as cigars, waterpipes, and electronic nicotine delivery systems (ENDS). Per Administrative Procedure Act requirements, the proposed rule will be open to public input during the public comment period of 60 days, which will terminate after November 25, 2019.
An argument would follow that with these recent actions (particularly after the PMTA rule is made final), that the FDA has expanded its authority over tobacco products to the point where it now occupies the field of tobacco regulation. If a court were to come to this conclusion, then state and local regulation of tobacco products would be preempted. When faced with this argument, a court would look to both the federal statute granting the agency its authority, as well as the agency’s regulatory framework and whether that framework occupies the field or authorizes additional state and local regulation.

Even if a reviewing court were to hold that the FDA intended to occupy the field with its Deeming Rule and PMTA proposed rule, a reviewing court might still be guided by the language of the TCA and the Food, Drug and Cosmetic Act. The TCA still explicitly preserves and saves for states and local jurisdictions the authority to enact rules, “relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.” Thus, if the FDA attempted to preempt such state and local laws, they would be acting beyond the scope of authority delegated to them by Congress, and therefore said actions could not be relied on when making a field preemption argument. Further, the Deeming Rule and new PMTA proposed rule merely subject all tobacco products to the same regulations that cigarettes have been subject to since the passage of the TCA. Accordingly, the preemption analysis of state and local regulations of sale, distribution, and information reporting to the state should remain unaffected by the FDA’s Deeming Rule and PMTA proposed rule.

B. The Dormant Commerce Clause

The Commerce Clause of the federal Constitution vests Congress with authority to regulate commerce between and among the states. A longstanding judicial interpretation of the Commerce Clause prohibits states from discriminating against the commerce of another state. This prohibition is known as the dormant or negative Commerce Clause (DCC). The classic example of an activity barred by the DCC is a state imposing a tax on goods imported from another state, but not taxing similar goods produced in-state in order to protect an in-state industry. When a state facially discriminates against businesses from other states in this way it almost always fails.257

The proposed list does not make any distinctions between local and out-of-state producers. Thus, there is not likely to be a successful DCC challenge. Yet risks remain.

There are two additional – less central – strands in DCC jurisprudence that could be brought to bear in connection with the list. First, there is a DCC doctrine that prohibits extraterritorial state regulation. Under the extraterritoriality doctrine, states are forbidden from directly regulating commerce that occurs

257 United Haulers Ass’n v. Oneida-Herkimer Solid Waste Management Authority, 550 US 330, 338 (2007).
outside of the regulating state. On the one hand, this prohibition is just common sense. Of course, one state cannot impose its regulations upon another state’s citizens. Courts have primarily used this doctrine to strike down state laws that tie regulation of a multi-state enterprise to the regulations of another state. For example, in one key case, Connecticut required that importers of beer into the state affirm that their prices are no higher than what they charge in two neighboring states.258

Again, on its face, the proposed list has no extraterritorial reach. It imposes a requirement for making sales into California. The proposed list does not – and should not – impose rules for how a tobacco producer assembles its products.259 Similarly, the list does not – and should not – entangle itself with the list of any other jurisdiction. It might be tempting, and sensible, for one state’s non-flavored list to incorporate information from another, but it would be more prudent not to do so.

The final strand of DCC jurisprudence that could be relevant is known as the Pike balancing test. This test does not focus on whether the law discriminates against out-of-state commerce, but on whether “the burden imposed on [interstate] commerce [by the law] is clearly excessive in relation to the putative local benefits [provided by the law].”260 An example of a state law that failed this test was a state law requiring interstate trucks to use a particular – and unusual - kind of mudguard. On the one hand, there were (at most) minor benefits of using a particular kind of mudguard, but on the other were the vast costs imposed on interstate trucking firms if they were to really be required to use only one special kind of mudguard within a state while other states required different kinds of mudguards.261 The Supreme Court struck down the law because the burden on interstate commerce of complying with different mudguard rules clearly outweighed the minimal local benefits.

Certifying that a tobacco product is not flavored and paying a small fee does not appear to be clearly excessive, especially relative to health issues at stake. In addition, the non-flavored list requirement does not affect the ability or costs of tobacco manufacturers transporting their products across California territory, and provides substantial benefits to public health and safety, unlike the mudguards at issue in the Bibb case. That said, the easier the certification process, the better.

C. First Amendment

The tobacco industry raised First Amendment challenges to the ordinance at issue in Providence. The appeals court concluded that banning flavored cigarettes was not restricting speech, but restricting conduct and therefore not subject to First Amendment protection.262 It is possible that a court could construe the non-flavored list as a tool for local bans and therefore itself should be analyzed as conduct not subject to protection under the First Amendment.

259 Legato Vapors v. Cook, 847 F.3d 825 (7th Cir. 2017). Note that such a law would also likely be preempted.
262 National Ass’n of Tobacco Outlets, Inc. v. City of Providence, R.I., 731 F.3d 71, 76–78 (1st Cir. 2013).
Conversely, the Supreme Court has interpreted the zone of speech protected under the First Amendment as including commercial speech, even applying a form of heightened scrutiny. A court might view two aspects of the list as raising a First Amendment concern. First, there is the list itself. Second, there is the use of other speech, say an advertisement about the taste of the tobacco product, to establish a presumption that a certain product is, in fact, flavored.

As to the list itself, one argument that it should raise no First Amendment concerns is that no speech is compelled because, per the AB 1625, placing a product on the list is optional. Yet the list is clearly being offered as a tool for local jurisdictions to ban flavored tobacco, and so a court might see the permissiveness as a sham. As to mandatory speech, requiring information on a public list could be seen by the courts as subject to First Amendment scrutiny. For example, courts have considered the First Amendment rights of sex offenders as to sex offender registration lists.

The test for compelled commercial speech in the Ninth Circuit (and probably everywhere) asks “whether [a government required communication] is (1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome. A compelled disclosure accompanying a related product or service must meet all three criteria to be constitutional.” The disclosure about flavors would seem to be purely factual and easily justified. As with the dormant Commerce Clause analysis, it will be important that the burden on manufacturers not be too much. It is possible that disclosing the lack of flavor is “controversial” because people might disagree as to the policy or as to whether a product has flavor, but compelling the manufacturer to take a position on whether there is a flavor is not controversial like taking a position on abortion is controversial. It is more like forcing disclosure of an attorney’s pay structure, the original example a non-controversial disclosure.

As to a First Amendment challenge to the presumption, the argument would be that the speech of tobacco manufacturers is being restricted directly. That is, if a manufacturer makes certain public statements about the taste of its product, then the product will be taken off the non-flavored list and, in effect, banned from several local jurisdictions. This burden on free speech would likely receive some form of heightened scrutiny. Note that one aspect of the burden here will be that certain claims about taste are arguably ambiguous as to whether there is a characteristic flavor. Though use of the presumption could well pass constitutional muster, it should be considered how important it truly is as compared to some litigation risk – and the presumption is a current part of AB 1625. After all, a major advantage of

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264 See, e.g., *Delgado v. Swearingen*, 375 F. Supp. 3d 1251, 1258 (N.D. Fla. 2018) (“[B]y requiring registration of email addresses and internet identifiers, the statute burdens speech. This subjects the statute to scrutiny under the First Amendment”).
265 *Am. Beverage Ass’n v. City & Cty. of San Francisco*, 916 F.3d 749, 756 (9th Cir. 2019) (en banc). Note that the full Ninth Circuit, applying this test, struck down San Francisco’s soda warning label requirement.
268 Wellington (2016), *supra* note 15 reaches a similar conclusion.
the list is that it requires the manufacturers to reach a conclusion as to flavor. The presumption is helpful for enforcement personnel, but might be more trouble than it is worth. Note that the industry challenged a similar presumption in the litigation about Providence’s ordinance and the district court upheld the use of the presumption, but struck down using concept terms like “spicy” as indicating the presence of a flavor as “confus[ing] and void for vagueness considerations, although this discussion appeared in the First Amendment section of the opinion.”

D. Vagueness

Due process requires that ordinary citizens know what is required of them and thus laws can be found unconstitutionally vague. Laws that impose civil penalties are held to a lower standard than those that impose criminal penalties. A City of Chicago tobacco flavor ordinance was challenged on vagueness grounds. Interestingly, the challenge did not focus on the definition of “flavor” but on certain rules in the ordinance as to where flavored tobacco can be sold. (The court rejected those challenges.)

The definition of characterizing flavor used by Chicago, very similar to the one in AB 1625, would seem to give reasonable notice as to what is and is not flavored. AB 1625 also contains a mechanism for manufacturers to challenge adverse findings by the state. Note that the current approach, which focuses on the perception of flavor rather ingredients is not overly broad. Rather, as explained above, additional detail in the definition will only serve to cause problems for products that are not flavored (but might have a seemingly problematic, flavored ingredients), while giving a pass to products that are flavored but achieve that flavor without problematic ingredients. Indeed, by focusing on the ordinary experience of using the product, the statute is designed to give ordinary citizens notice of their obligations.

E. Funding Considerations

The state can, of course, choose to finance the list – and enforcement of the list – using general tax dollars. If the state chooses to do so, then there are no further issues. However, if the state were to choose to finance the list using fees generated by the tobacco product manufacturers registering on the list, additional complications arise because of various provisions of the state constitution. The concern is that excessive fees are really hidden taxes and should be subject to a vote (with a supermajority threshold). Fees however can be charged for “reasonable regulatory costs.”

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270 City of Chicago v. Morales, 527 U.S. 41, 56 (1999). Unconstitutionally vague laws can also be struck down because they “may authorize and even encourage arbitrary and discriminatory enforcement.” Id.


272 In particular, see Article XIII-A, sec. 3(b)(3). Note that the same rules would govern local governments. See XIII-C, sec. (1)(e)(3). Note that the phrasing of this section refers to regulatory costs “incident to issuing licenses and permits, performing investigations, inspections, and audits, enforcing agricultural marketing orders, and the administrative enforcement and adjudication thereof.” Placement on the non-flavored list is tantamount to a permit, but in the unlikely event that a court found that placement on the list did not qualify, then the State could likely impose a reasonable fee for a “privilege granted directly to the payor,” namely the privilege of not being considered flavored. See Article XIII-A, Sec. 3(b)(1). The same requirements would govern fees justified under this section.
The simple take-home message is that, if the state should wish to finance the list and its enforcement with fees, then it can do so, but must invest sometime in a process to make sure that the fees are reasonable and fair.

For a fee to be respected, there are two basic requirements. First, the overall level of fees must be reasonably related to the service being funded – in this case the list. Second, the methodology for allocating fees among participants must also be reasonable. If 99 percent of the fees were allocated to one registrant, then this would be a problem.

The simple take-home message is that, if the state should wish to finance the list and its enforcement with fees, then it can do so, but must invest sometime in a process to make sure that the fees are reasonable and fair.

It is important to observe that penalties are neither fees nor taxes, and they can be considerable in order to deter the targeted behavior. For example, corporate taxpayers who understate their tax liability by more than $1,000,000 are subject to a 20% underpayment penalty. Taxpayers sued, arguing that the high penalty amounted to a tax. They lost. Given the incentive a producer (or retailer) might have to bypass the list and the difficulty in enforcing it, considerable penalties for violations seems appropriate.

AB 1625 is silent on the issue of funding, an important consideration given the costs of researching/testing the veracity of tobacco manufacturer certifications. The bill could be amended to authorized reasonable fees to finance the list, with significant penalties for failure to comply. Senate Bill 538 authored by Senator Susan Rubio (2019-20 Regular Legislative Session) contains a provision permitting reasonable fees.

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273 City of San Buenaventura v. United Water Conservation Dist., 3 Cal. 5th 1191, 1214, 406 P.3d 733 (2017), as modified on denial of reh’g (Feb. 21, 2018).
274 Id.
275 Calif. Constitution, Article XIIIA, Sec. 3(b)(5).
276 Calif. Rev. & Tax Code § 19138.
Conclusion

The prevalence of flavored tobacco products has drastically increased youth tobacco usage rates. Flavored tobacco bans have proven to be effective in reducing youth usage rates; however, these bans have significant enforcement challenges. These challenges can be best addressed by the adoption of a non-flavored list, which is easier to build, maintain and use than a banned products list. In addition to the creation of a non-flavored list, state and local jurisdictions need to pay careful attention to their legislative drafting and to anticipate and avoid any unintended consequences and potential litigation.

Legislation implementing a California non-flavored list should clearly establish that the purpose and intent of the list is to facilitate the enforcement of flavored tobacco bans at the local level. This language could take the form of a modified version of AB 1625, which would state, “The State of California recognizes a vital need for a reliable and complete public list of unflavored tobacco products, to assist local jurisdictions in their flavored tobacco restrictions aiming, among other things, at preventing the youth initiation of tobacco usage.”

Additionally, the non-flavored list should include a column for a photograph of the product to assist the process of identifying and verifying items offered for sale by retailers and the corresponding entry on the flavored tobacco list. Equally conducive to optimal local enforcement is a non-flavored list determination of how a product was determined to lack a characterizing flavor. This product flavor determination could appear in a column and include the product manufacturer’s descriptions, marketing, promotions, labeling, advertising, or other official statements.

In an effort to proof the California non-flavored list against legal challenge, we recommend avoiding the use of ingredient or additive information as a tool for determining whether the tobacco product is flavored, out of a concern that this runs too close to tobacco manufacturing standards.

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278 AB 1625 (Rivas) Section 1 subd. (e).
279 SB 538 (Rubio) provides model language, “a manufacturer of an electronic cigarette sold in the state shall submit a written physical description and a photograph of each electronic cigarette sold by that manufacturer to the State Department of Public Health. For each new electronic cigarette manufactured for sale in the state after April 1, 2020, the manufacturer shall submit a written physical description and photograph of the electronic cigarette to the department within 30 days of making the electronic cigarette available for sale.”
280 Promotions should be defined expansively to cover statements made by third party promoters such as YouTube influencers.
Lastly, an ideal regulatory scheme would require a special tax stamp for flavored tobacco products making flavored products clearly identifiable.

To guide manufacturers in their process of certifying that their products are unflavored, “characterizing flavor” should be defined clearly. In an effort to proof the California non-flavored list against legal challenge, we recommend avoiding the use of ingredient or additive information as a tool for determining whether the tobacco product is flavored, out of a concern that this runs too close to tobacco manufacturing standards. A model definition would at least include the following: “characterizing flavor’ means a distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproducts of the tobacco product.

Characterizing flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. The presence of a distinguishable taste or aroma, or both, constitutes a characterizing flavor, which may be ascertained by reference to testing, sampling, or other procedures.281 If a tobacco product is suspected of having a characterizing flavor, manufacturers can rebut this presumption by supplying additional information.

Lastly, an ideal regulatory scheme would require a special tax stamp for flavored tobacco products making flavored products clearly identifiable. A distributor would be required to identify a flavored product and failure to do so would be a violation of tax law. The flavored product stamp has the dual benefits: 1) it would deter the usage of flavored tobacco products by changing price points to consumers; and, 2) the stamp itself could be used as an on-the-ground identifier for jurisdictions with flavored tobacco restrictions, facilitating compliance enforcement.

281 This definition modifies that of AB 1625 sec. 2, subd. (r)(3); some commentators expressed a concern that manufacturers might use genetically modified tobacco to impart a flavor; this practice would still be captured by this definition of “characterizing flavor.”
V. Acknowledgements

We thank the various national and state experts, listed below, who shared their insight, expertise, and passion with us as we crafted these materials. These contributions were critical in helping us better understand the nuances of the flavored tobacco market and the varied efforts at the local and state level to prevent flavored tobacco from continuing to cause premature death and disease. These efforts are particularly critical in communities that are targeted disproportionately by the tobacco industry, such as youth, women, ethnic minorities, and individuals living in poverty. We applaud your work!

The opinions and judgments in this paper remain those of the authors, however, unless the statements are directly cited to the interview subjects.

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* Our special thanks to those who reviewed our draft materials and provided us with the further comments and clarifications.
Appendix 1: Model Policy Language

Note: deletions from existing bill and statutory language is indicated by a strikethrough; new language is indicated by underlining.

A. The California Non-Flavored list (modeled extensively on AB 1625 (Rivas))

An act to add Article 5 (commencing with Section 104559.1) to Chapter 1 of Part 3 of Division 103 of the Health and Safety Code, relating to tobacco.

The People of the State of California do Enact as Follows:

Section 1.
The Legislature finds and declares all of the following:
(a) A large and increasing number of flavored tobacco products are available for sale in California, which appeal to minors and nonsmokers, initiate nonusers, and impede cessation.

(b) There is evidence that those products are disproportionately marketed to certain minorities and LGBTQ individuals.

(c) A growing number of cities and counties have restricted or banned the retail sale of flavored tobacco products.

(d) Because many tobacco manufactures do not disclose whether their products are flavored, it is difficult for government agencies, distributors, retailers and consumers to identify whether tobacco products are flavored without actually using the products.
(e) The State of California recognizes a vital need for a reliable and complete public list of unflavored tobacco products, to assist local jurisdictions in their flavored tobacco restrictions aiming, among other things, at preventing the youth initiation of tobacco usage.

Sec. 2.
Article 5 (commencing with Section 104559.1) is added to Chapter 1 of Part 3 of Division 103 of the Health and Safety Code, to read:

Article 5. Unflavored Tobacco
104559.1. (a) The Attorney General shall establish and maintain on the Attorney General’s internet website a list of tobacco product brand styles that lack a characterizing flavor. This list shall be known as the Non-Flavored Tobacco List.
(b) Every manufacturer and every importer of tobacco products may shall submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import for sale or distribution in or into California that lack a characterizing flavor. The Attorney General may deem each submission to be a request that the brand style be included on the Non-Flavored Tobacco List. Any submission under this section shall be accompanied by a certification by the manufacturer or importer, under penalty of perjury, that describes each brand style and states that it lacks a characterizing flavor.

(c) In determining whether or not a brand style has a characterizing flavor the Attorney General shall consider, among other factors, information received from the manufacturer or importer to the Attorney General regarding the brand style.

(d) The Attorney General shall presume a brand style has a characterizing flavor if the manufacturer, importer, distributor, wholesaler, or retailer of that brand style, or an employee, contractor, agent, or affiliate of that entity, makes a statement that the brand style has or produces a characterizing flavor. A statement includes, but is not limited to, text, color, or images on the brand style's labeling, packaging, marketing materials, social media, or advertising, or a submission to a government agency, that communicates explicitly or implicitly that the brand style has a characterizing flavor. This presumption may be rebutted by the manufacturer or importer.

(e) The Attorney General shall decline to list on the Non-Flavored Tobacco List any brand style that the Attorney General reasonably determines has a characterizing flavor.

(f) The Attorney General shall remove from the Non-Flavored Tobacco List any brand style that the Attorney General determines has a characterizing flavor. The Attorney General shall promptly provide the manufacturer or importer that submitted a certification regarding a brand style with written notice in the event that the Attorney General removes it from the Non-Flavored Tobacco List. This notice shall include the basis for the Attorney General's determination.

(g) A brand style not on the Non-Flavored Tobacco List shall be presumed to have a characterizing flavor. This presumption may be rebutted by the manufacturer or importer of that brand style. A manufacturer or importer that seeks to rebut this presumption shall notify the Attorney General, provide a certification by the manufacturer or importer that the brand style lacks a characterizing flavor, and, upon the request of the Attorney General, provide additional information and factual substantiation regarding the lack of a characterizing flavor.

(h) Every manufacturer and every importer that has made a submission under this section shall submit updated information to the Attorney General whenever it no longer manufactures or imports for sale or distribution in or into California a brand style listed on the Non-Flavored Tobacco List or when the brand style it manufactures or imports no longer lacks a characterizing flavor. This updated information shall be provided to the Attorney General by the manufacturer or importer prior to or on the date upon which the manufacture or importation of the brand style ceases, or prior to or on the date upon which the brand style no longer lacks a characterizing flavor.
(i) Every manufacturer or importer submitting a product pursuant to this section shall also do all of the following:

(1) Consent to the jurisdiction of the California courts for the purpose of enforcement of this section and for enforcement of any regulations adopted pursuant to this section.

(2) Appoint a registered agent for service of process in this state.

(3) Identify the registered agent to the Attorney General.

(4) Waive any sovereign immunity defense that may apply in any action to enforce this section or to enforce regulations adopted pursuant to this section.

(j) The Attorney General may require manufacturers or importers submitting products pursuant to this section to provide factual substantiation regarding the presence or lack of a characterizing flavor of a brand style that appears on the Non-Flavored Tobacco List, and may request manufacturers or importers to provide information regarding the presence or lack of a characterizing flavor of any brand style submitted to the Attorney General by the manufacturer or importer as a product that lacks a characterizing flavor.

(k) The Attorney General may require a manufacturer or importer of tobacco products sold or distributed in or into California, whether directly or indirectly through a distributor, wholesaler, or retailer, to submit to the Attorney General a list of all brand styles of tobacco products that they manufacture or import into California.

(l) Upon receiving notice from the Attorney General that a brand style is either removed from the Non-Flavored Tobacco List or that the Attorney General declines to include it on the list, the manufacturer or importer that provided the certification to the Attorney General that the brand style lacks a characterizing flavor may challenge the Attorney General’s determination as erroneous, seek to rebut any presumption relied upon by the Attorney General, and seek relief from the determination, by filing a writ of mandate pursuant to Section 1085 of the Code of Civil Procedure in the Superior Court of the County of Sacramento, or as otherwise provided by law. The filing of the petition shall not operate to stay the Attorney General’s determination except upon a ruling of a court of competent jurisdiction.

(m) The Attorney General shall publish the Non-Flavored Tobacco List on or before July 1, 2020.

(n) The Attorney General may recover reasonable attorney’s fees, investigation costs, and expert fees, or seek injunctive relief in the courts, against any entity or individual that makes a clearly frivolous submission to the Attorney General for inclusion on the Non-Flavored Tobacco List a brand style that has a characterizing flavor.

(o) Whenever the Attorney General prevails in a civil action to enforce this section, the court shall award to the Attorney General all costs of investigating and prosecuting the action, including expert fees,
reasonable attorney’s fees, and costs. Awards under this section shall be paid to the Public Rights Law Enforcement Special Fund established pursuant to Section 12530 of the Government Code.

(p) The Attorney General may adopt rules and regulations to implement the purposes of this section. The regulations adopted to implement this section are emergency regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code and shall be considered by the Office of Administrative Law to be necessary for the immediate preservation of the public health, safety, and welfare.

(q) This section does not preempt or otherwise prohibit the adoption of a local ordinance that is more restrictive than this provision, that references or incorporates the Non-Flavored Tobacco List, or that imposes standards or definitions for a characterizing flavor that are more restrictive than those in this section. A local standard for a characterizing flavor that imposes a more restrictive requirement shall control in the event of any inconsistency between this section and a local standard.

(r) For the purposes of this section, the following definitions apply:

(1) “Tobacco product” means a tobacco product as defined in paragraph (8) of subdivision (d) of Section 22950.5 of the Business and Professions Code.

(2) “Brand style” means a style of tobacco product within a brand that is differentiated from other styles of that brand by weight, volume, size, Universal Product Code, Stock Keeping Unit, nicotine content, characterizing flavor, logo, symbol, motto, labeling, marketing, materials, packaging, or other indicia of product identification.

(3) “Characterizing flavor” means a distinguishable taste or aroma, or both, other than the taste or aroma of tobacco, imparted by a tobacco product or any byproducts of the tobacco product. Characterizing flavors include, but are not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. The presence of a distinguishable taste or aroma, or both, constitutes a characterizing flavor, which may be ascertained by reference to testing, sampling, or other procedures.

(s) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

Sec. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.
B. Statewide Flavored Tobacco Tax

An act to amend Sections 30018, 30130.50, 31030.51, 30130.52, and 30130.57 of the Revenue and Taxation Code, relating to tobacco products, to take effect immediately, tax levy.

The People of the State of California do Enact as Follows:

Section 1.
The Legislature finds and declares all of the following:
(a) A large and increasing number of flavored tobacco products are available for sale in California, which appeal to minors and nonsmokers, initiate nonusers, and impede cessation.

(b) There is evidence that those products are disproportionately marketed to certain minorities and LGBTQ individuals.

(c) An increase in the tobacco tax is an appropriate way to decrease tobacco use among these vulnerable communities, and mitigate the costs of healthcare treatment and improve existing programs providing for quality healthcare and access to healthcare services for families and children. It will save lives and save state and local government money in the future.

Sec. 2. Section 30018 of the Revenue and Taxation Code is amended to read:
30018. (a) “Stamps and meter impressions” means the indicia of payment of tax, as required by Section 30161, and include, but are not limited to, stamps, meter impressions, or any other indicia developed using current technology.

(b) The board shall prescribe and approve the types of stamps and meter impressions, including a special distinctive stamp, meter impression, or any other indicia developed using current technology denoting that a tobacco product, as defined in subdivision (b) of Section 31030.50, has a characterizing flavor, as defined in subdivision (c) of Section 31030.50, and the methods of applying stamps and meter impressions to packages of cigarettes and other tobacco products.

Sec. 3. Section 30130.50 of the Revenue and Taxation Code is amended to read:30130.50. Definitions

For the purposes of this article:

(a) “Cigarette” has the same meaning as that in Section 30003.

(b) “Tobacco products” has the same meaning as that in subdivision (d) of Section 22950.5 of the Business and Professions Code.
“Characterizing Flavor” means a distinguishable taste or aroma, other than the taste or aroma of tobacco naturally occurring imparted by the tobacco or a byproduct produced by the tobacco. A characterizing flavor includes, but is not limited to, taste or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, menthol, mint, wintergreen, herb, or spice. If a tobacco product is suspected of having a characterizing flavor, there is a rebuttable presumption the tobacco product has a characterizing flavor unless the manufacturer demonstrates the flavor derives from the organic method used to grow the tobacco without genic modification to enhance flavor or sweetness.


(a) In addition to any other taxes imposed upon the distribution of cigarettes under this part, there shall be imposed an additional tax upon every distributor of cigarettes at the rate of one hundred mills ($0.100) for each cigarette distributed.

(b) The board shall adopt regulations providing for the implementation of an equivalent tax on electronic cigarettes as that term is defined in subdivision (c) of Section 30121, and the methods for collection of the tax. Such regulations shall include imposition of an equivalent tax on any device intended to be used to deliver aerosolized or vaporized nicotine to the person inhaling from the device when sold separately or as a package; any component, part, or accessory of such a device that is used during the operation of the device, whether sold separately or as a package with such device; and any liquid or substance containing nicotine, whether sold separately or as a package with any device that would allow it to be inhaled. Such regulations may include, but are not limited to, defining who is a distributor of electronic cigarettes pursuant to Section 30011 and the licensing requirements of any such person.

(c) The board shall adopt regulations providing for the implementation of an additional tax of ______ ($____) on a tobacco product specified in subdivisions (a) and (b) that contain a characterizing flavor.

(d) Notwithstanding any other provision of this part, all revenues resulting from the tax imposed by subdivision (a) and all revenues resulting from the equivalent increase in the tax on tobacco products, including electronic cigarettes, imposed by subdivision (b) of Section 30123, shall be deposited into the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund created by Section 30130.53.


(a) (1) In addition to any other tax, every dealer and wholesaler, for the privilege of holding or storing cigarettes for sale, use, or consumption, shall pay a floor stock tax for each cigarette in its possession or under its control in this state at the rate of one hundred mills ($0.100) for each cigarette.
(2) Every dealer and wholesaler shall file a return with the board on or before the first day of the first calendar quarter commencing more than 180 days after the effective date of this act on a form prescribed by the board, showing the number of cigarettes in its possession or under its control in this state. The amount of tax shall be computed and shown on the return.

(b) (1) Every licensed cigarette distributor, for the privilege of distributing cigarettes and for holding or storing cigarettes for sale, use, or consumption, shall pay a cigarette indicia adjustment tax for each California cigarette tax stamp that is affixed to any package of cigarettes and for each unaffixed California cigarette tax stamp in its possession or under its control at the following rates:

(A) Two dollars and fifty cents ($2.50) for each stamp bearing the designation “25.”

(B) Two dollars ($2) for each stamp bearing the designation “20.”

(C) One dollar ($1) for each stamp bearing the designation “10.”

(2) Every licensed cigarette distributor shall file a return with the board on or before the first day of the first calendar quarter commencing 180 days after the effective date of this act on a form prescribed by the board, showing the number of stamps described in subparagraphs (A), (B), and (C) of paragraph (1). The amount of tax shall be computed and shown on the return.

(c) Every licensed cigarette distributor, for the privilege of distributing a tobacco product with a characterizing flavor and for holding or storing these tobacco products for sale, use, or consumption, shall pay a flavored tobacco tax and affix a distinctive tax stamp on any tobacco product with a characterizing flavor in its possession or under its control.

(d) The taxes required to be paid by this section are due and payable on or before the first day of the first calendar quarter commencing 180 days after the effective date of this act. Payments shall be made by remittances payable to the board and the payments shall accompany the return and forms required to be filed by this section.

(e) Any amount required to be paid by this section that is not timely paid shall bear interest at the rate and by the method established pursuant to Section 30202 from the first day of the first calendar quarter, and shall be subject to determination, and redetermination, and any penalties provided with respect to determinations and redeterminations.

Sec 6. Section 30130.57 of the Revenue and Taxation Code is amended to read 30130.57. Implementation and Administrative Costs.

(a) Moneys from the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund shall be used to reimburse the board for expenses incurred in the administration, calculation, and collection of the tax imposed by this article and for expenses incurred in the calculation and distribution of funds.
and in the promulgation of regulations as required by this act, provided, however, that after deducting the necessary funds pursuant to subdivision (b) of Section 30130.54, not more than 5 percent annually of the funds remaining in the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund shall be used for such administrative costs.

(b) Moneys from the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund shall be used to reimburse the independent nonpartisan California State Auditor up to four hundred thousand dollars ($400,000) annually for actual costs incurred to conduct each of the audits required by Section 30130.56 for the purpose of providing public transparency and ensuring that the revenues generated by this article are used for healthcare, tobacco use prevention and research.

(c) Moneys from the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund in the amount of forty million dollars ($40,000,000) annually shall be used to provide funding to the University of California for the purpose and goal of increasing the number of primary care and emergency physicians trained in California. This goal shall be achieved by providing this funding to the University of California to sustain, retain, and expand graduate medical education programs to achieve the goal of increasing the number of primary care and emergency physicians in the State of California based on demonstrated workforce needs and priorities.

1. For the purposes of this subdivision, “primary care” means internal medicine, family medicine, obstetrics/gynecology, and pediatrics.

2. Funding shall be prioritized for direct graduate medical education costs for programs serving medically underserved areas and populations.

3. For the purposes of this subdivision, all allopathic and osteopathic residency programs accredited by federally recognized accrediting organizations and located in California shall be eligible to apply to receive funding to support resident education in California.

4. The University of California shall annually review physician shortages by specialty across the state and by region. Based on this review, to the extent that there are demonstrated state or regional shortages of nonprimary care physicians, funds may be used to expand graduate medical education programs that are intended to address such shortages.

(d) Moneys from the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund in the amount of thirty million dollars ($30,000,000) annually shall be used to provide funding to the State Department of Public Health state dental program for the purpose and goal of educating about, preventing and treating dental disease, including dental disease caused by use of cigarettes and other tobacco products. This goal shall be achieved by the program providing this funding to activities that support the state dental plan based on demonstrated oral health needs, prioritizing serving underserved areas and populations. Funded program activities shall include, but not be limited to, the following: education, disease prevention, disease treatment, surveillance, and case management.
The department shall have broad authority to fully implement and effectuate the purposes of this subdivision, including the determination of underserved communities, the development of program protocols, the authority to reimburse state-sponsored services related to the program, and the authority to contract with one or more individuals or public or private entities to provide program activities.

(e) Moneys from the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 Fund in the amount of forty-eight million dollars ($48,000,000) annually shall be used for the purpose of funding law enforcement efforts to reduce illegal sales of tobacco products, particularly illegal sales to minors; to reduce cigarette smuggling, the sale of a tobacco product with a characterizing flavor without the required tax stamp, tobacco tax evasion, the sale of tobacco products without a license and the sale of counterfeit tobacco products; to enforce tobacco-related laws, court judgments, and legal settlements; and to conduct law enforcement training and technical assistance activities for tobacco-related statutes; provided that these funds are not to be used to supplant existing state or local funds for these same purposes. These funds shall be apportioned in the following manner:

(1) Thirty million dollars ($30,000,000) annually to the California Department of Justice/Office of the Attorney General to be distributed to local law enforcement agencies to support and hire front-line law enforcement peace officers for programs, including, but not limited to, enforcement of state and local laws related to the illegal sales and marketing of tobacco to minors, and increasing investigative activities and compliance checks to reduce illegal sales of cigarettes and tobacco products to minors and youth.

(2) Six million dollars ($6,000,000) annually to the board to be used to enforce laws that regulate the distribution and retail sale of cigarettes and other tobacco products, such as laws that prohibit cigarette and tobacco product smuggling, counterfeiting, selling untaxed cigarettes and other tobacco products, and selling cigarettes and other tobacco products without a proper license.

(3) Six million dollars ($6,000,000) annually to the California Department of Public Health to be used to support programs, including, but not limited to, providing grants and contracts to local law enforcement agencies to provide training and funding for the enforcement of state and local laws related to the illegal sales of tobacco to minors, increasing investigative activities, and compliance checks, and other appropriate activities to reduce illegal sales of tobacco products to minors, including, but not limited to, the Stop Tobacco Access to Kids Enforcement (STAKE) Act, pursuant to Section 22952 of the Business and Professions Code.

(4) Six million dollars ($6,000,000) annually to the California Attorney General to be used for activities, including, but not limited to, enforcing laws that regulate the distribution and sale of cigarettes and other tobacco products, such as laws that prohibit cigarette smuggling, counterfeiting, selling untaxed tobacco, selling tobacco without a proper license and selling tobacco to minors, and enforcing tobacco-related laws, court judgments, and settlements.
(f) Not more than 5 percent of the funds received pursuant to this article shall be used by any state or local agency or department receiving such funds for administrative costs.

(g) The California State Auditor shall promulgate regulations pursuant to the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to define administrative costs for purposes of this article. Such regulations shall take into account the differing nature of the agencies or departments receiving funds.

(h) The board shall determine beginning two years following the effective date of this act, and annually thereafter, any reduction in revenues, following the first year after the effective date of this act, resulting from a reduction in the consumption of cigarettes and tobacco products due to the additional taxes imposed on cigarettes by this article, and the increase in the tax on tobacco products required by subdivision (b) of Section 30123. If the board determines there has been a reduction in revenues, the amount of funds allocated pursuant to subdivisions (c), (d) and (e) shall be reduced proportionately.

Sec. 7.
The Legislature finds and declares that this act furthers the purposes and intent of the California Healthcare, Research and Prevention Tobacco Tax Act of 2016.

Sec. 8.
This act provides for a tax levy within the meaning of Article IV of the California Constitution and shall go into immediate effect.