

July 19, 2018

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6565, Advance Notice of Proposed Rulemaking: Regulation of Flavors in Tobacco Products

The Attorney General of California submits this comment in response to the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking titled "Regulation of Flavors in Tobacco Products." (83 Fed. Reg. 12294 (Mar. 21, 2018) (Notice).

This comment is based on the unique position of state attorneys general – including the Attorneys General of California over the previous two decades – in relation to the regulation of tobacco products. This position is founded on our securing and enforcing the 1998 Tobacco Master Settlement Agreement (MSA), as well as our enforcement of numerous state laws regulating the sale, distribution, marketing, licensing, use, and taxation of tobacco products.

From this position, state attorneys general have on several occasions requested and recommended that FDA take additional steps to protect the public, particularly youth, from the dangers of tobacco use. For instance, on November 8, 2013, 27 State Attorneys General submitted comments to FDA supporting a ban on menthol-flavored cigarettes. This letter cited the findings of FDA report, "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes"<sup>1</sup> as evidence for the conclusion that sales of menthol cigarettes undermine State attempts to curb smoking, particularly by youth and African-Americans and other minorities.<sup>2</sup> Then, on August 8, 2014, 29 State Attorneys General submitted comments to FDA regarding the proposed deeming rule and urged FDA to prohibit all characterizing flavors other than tobacco and menthol in the newly deemed tobacco products (which included cigarillos, little cigars, electronic cigarettes and other products).

I am in general agreement with the comment submitted by the Attorney General of New York and other states on this topic, noting in particular that comment's summation of scientific evidence pointing to the role of flavors in initiation of use of tobacco products, and the paucity of evidence regarding the efficacy of flavors for purposes of cessation of use of tobacco products by established smokers. I also refer to and am in agreement with the comment submitted by the California Department of Public Health on April 13, 2018, reflecting the use of flavored tobacco

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<sup>1</sup> *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*, FOOD AND DRUG ADMIN. (2013), available at <http://www.fda.gov/downloads/UCM361598.pdf> .

<sup>2</sup> The FDA Menthol Report's conclusions confirmed the findings made by FDA's Tobacco Product Scientific Advisory Committee, which in 2011 concluded that removing flavors from cigarettes would benefit public health. See U.S. Food and Drug Admin., Tobacco Prod. Sci. Advisory Committee, *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, 22-23 (2011), available at <https://www.fda.gov/downloads/ucm361598.pdf>.

products by minors in California and the attitudes and perceptions of the citizens of California towards flavored tobacco products. I am also informed by the passage and implementation of ordinances in a growing number of cities and counties in California that either restrict or prohibit sale of flavored tobacco products. In one instance where the ordinance was challenged by popular referendum – San Francisco – the flavor restriction was supported by over two-thirds of the electorate.<sup>3</sup>

Section 907 of the Federal Food, Drug, and Cosmetic Act permits FDA to adopt a product standard to prohibit flavored tobacco products, if it “finds that a tobacco product standard is appropriate for the protection of the public health.” (Section 907(a)(3)(A).) The Act more specifically instructs FDA to “consider scientific evidence concerning the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard; the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.” (Section 907(a)(3)(B)(i)(I)-(III).)

Under the terms of the statute, and given the state of the art of evidence referenced in the comments cited above about the potential for any specific flavoring to increase the effectiveness of electronic cigarettes to helping smokers to quit or switch completely and the potential of flavored products to increase the number of kids using tobacco products, FDA should propose and adopt a rule prohibiting flavored tobacco products, including electronic cigarettes and other non-combusted tobacco products, other than those with the characterizing flavor of tobacco.

The Act also provides for a procedure for FDA to approve a flavored tobacco product if it does meet the statutory determinants of the public health standard. For this purpose FDA should propose and adopt a rule setting forth such a procedure and the conditions that a manufacturer would have the burden of satisfying. These conditions are where the manufacturer has first submitted and FDA has reviewed and concluded that there is sufficient valid scientific evidence for each flavored product that the flavor (1) enhances the efficacy of the product in increasing the number of smokers who stop smoking combustible tobacco products, (2) does not contribute to initiation of tobacco product use, including use of non-combustible products such as electronic cigarettes, particularly among youth, or relapse into tobacco product use, (3) does not result in continued use of tobacco products by those who otherwise would have quit and (4) does not itself increase the toxicity, carcinogenicity or teratogenicity of the product. In applying such a standard, the burden of making this demonstration should be on the manufacturer with respect to each product. In the absence of such a showing, no characterizing flavor should be permitted.

With thousands of flavored products on the market,<sup>4</sup> it is unreasonable and contrary to the public health standard articulated in the Act to leave all such products on the market, unless FDA establishes that the benefits of cessation for smokers, who otherwise would not switch, exceed the risk of youth initiation. Given the high level of youth usage of flavored electronic cigarettes

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<sup>3</sup> <https://sfelections.sfgov.org/june-5-2018-election-results-summary>

<sup>4</sup> For example, as of 2017, researchers identified over 15,500 unique e-cigarette flavors available online. Zhu, S-H, et al., “Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites,” *Journal of Medical Internet Research*, 20(3), published online March 12, 2018.

and other non-combustible products such as flavored chewing tobacco, the uncertainty about the degree to which electronic cigarettes in particular actually facilitate smoking cessation, and the additional uncertainty about whether flavors in electronic cigarettes facilitate cessation, FDA should prohibit flavors in all tobacco products, including non-combustible products such as electronic cigarettes, unless the manufacturer demonstrates that the benefits from increased smoking cessation attributable to a flavored e-cigarette product or other non-combustible product actually exceed the risks from youth initiation.

I turn now to address certain questions posed by FDA in the Notice, to the extent my office has experience and expertise in the field:

*D. 9. Provide studies or information regarding the potential toxicity or adverse health effects to the user or others from any flavors . . . in tobacco products.*

Since the State Attorneys General’s prior letter of August 8, 2014, I have learned that some flavorants used in tobacco products are themselves harmful.<sup>5</sup>

Although tobacco manufacturers of flavored products generally advertise their flavors as “generally recognized as safe,” or “GRAS,” that designation was created by the Flavor and Extract Manufacturers Association of the United States to apply solely to the ingestion of flavors in food, not for other exposure such as inhalation.<sup>6</sup> The National Academies of Sciences, Engineering, and Medicine (NASEM) 2018 report committee expressed concern about flavor additives because even to-date, they “have not been widely tested for sensitizing, toxic, or irritating potency.”<sup>7</sup> NASEM concluded that, “Independent of nicotine, exposure to particulates and flavorings in e-cigarette aerosols could also potentially impair lung function.”<sup>8</sup> Additionally, the 2016 Surgeon General’s report stated that, “while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are

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<sup>5</sup> See, e.g., Jessica L. Fetterman et al., *Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction*, 38 ARTERIOSCLEROSIS, THROMBOSIS, & VASCULAR BIOLOGY 1607, 1610 (2018) (finding that exposure to certain flavorants induced both inflammation and impaired A23187-stimulated nitric oxide production); see generally M. Flori Sassano et al., *Evaluation Of E-Liquid Toxicity Using an Open-Source High-Throughput Screening Assay* 16 PLOS BIOLOGY 1 (2018) (measuring toxicity of flavorants found in commercially available e-liquids); Mark L. Rubinstein, Kevin Delucchi, Neal L. Benowitz, & Danielle E. Ramo, *Adolescent Exposure to Toxic Volatile Organic Chemicals From E-Cigarettes*, 141 PEDIATRICS 1, 7 (2018) (finding that urine of teenagers who used fruit-flavored e-cigarettes had significantly higher levels of the metabolites of acrylonitrile, a highly poisonous compound used widely in the manufacture of plastics, adhesives, and synthetic rubber).

<sup>6</sup> Flavor and Extract Manufacturers Association of the United States (FEMA), *Safety Assessment and Regulatory Authority to Use Flavors – Focus on Electronic Nicotine Delivery Systems and Flavored Tobacco Products*, Revised September 26, 2016, <https://www.femaflavor.org/safety-assessment-and-regulatory-authority-use-flavors-focus-electronic-nicotine-delivery-systems>.

<sup>7</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, p. 5-31, 2018, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx> [hereinafter NASEM Report].

<sup>8</sup> NASEM Report, p. 11-2.

generally unknown,” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.<sup>9</sup>

Specific flavorants that have been found to be toxic include cinnamaldehyde (found in cinnamon flavors),<sup>10</sup> diacetyl and its frequent substitutes, acetoin and acetylpropionyl (found in creamy flavors),<sup>11</sup> benzaldehyde (found in cherry flavors),<sup>12</sup> vanillin (found in vanilla flavors), menthol (found in mint flavors), eugenol (found in clove flavors), and acetylpyridine (found in burnt flavors).<sup>13</sup>

*D. 10. Provide studies or information on the impact, whether intended or unintended, of public health efforts by local jurisdictions, States, and members of the international community to impose restrictions on the manufacture, marketing, sale or distribution of all or a subset of tobacco products with flavors (other than tobacco), including but not limited to cigars, ENDS, menthol cigarettes, and smokeless tobacco products.*

Some local jurisdictions, including several in California, have implemented sales restrictions on flavored tobacco products. These local sales restrictions are challenging to enforce, for several reasons. For instance, some manufacturers use colors or designs, rather than names of explicit flavors, to signify flavors, e.g., green signifies menthol or mint, purple signifies grape. Other manufacturers use concept descriptors, rather than flavor descriptors, for products that are nonetheless flavored, e.g., French sunrise, arctic wolf, unicorn poop, mermaid tears, and angry munchkins.<sup>14</sup> Further, there are now many thousands of flavors on the market, making it exceedingly difficult to create or maintain an accurate and current list of flavored tobacco

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<sup>9</sup> U.S. DEP’T. OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, 184 (2016), [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf).

<sup>10</sup> NASEM Report, p. 5-19, 2018; Behar, RZ, et al., “Identification of toxicants in cinnamon-flavored electronic cigarette refill fluids,” *Toxicology in Vitro* 28:198-208, 2014.

<sup>11</sup> Barrington-Tremis, JL, Samet, JM, & McConnell, R, “Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?,” *JAMA*, published online November 10, 2014; Farsalinos, KE, et al., “Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins,” *Nicotine & Tobacco Research* 17(2):168-174, February 2015; Allen, J. G., et al., “Flavoring chemicals in e-cigarettes: Diacetyl, 2,3-pentanedione, and acetoin in a sample of 51 products, including fruit-, candy-, and cocktail-flavored e-cigarettes.” *Environmental Health Perspectives* 124(6):733-739, 2016.

<sup>12</sup> Goniewicz, M, *Toxicants in E-Cigarette Refill Solutions and Vapor*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014; Kosmider, T, et al., “Cherry-flavoured electronic cigarettes expose users to the inhalation irritant, benzaldehyde,” *Thorax* 71(4):376-7, 2016.

<sup>13</sup> Jessica L. Fetterman et al., *Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction*, 38 *ARTERIOSCLEROSIS, THROMBOSIS, & VASCULAR BIOLOGY* 1607 (2018) (finding that exposure of human aortic endothelial cells to lower concentrations of flavorants vanillin, menthol, cinnamaldehyde, eugenol, and acetylpyridine induced both inflammation and impaired A23187-stimulated nitric oxide production consistent with endothelial dysfunction).

<sup>14</sup> <https://www.lighterusa.com/products/dream-e-juice-10-french-sunrise-70-vg> ; [https://www.vaporgod.com/VaporGod-Arctic-Wolf-Eliquid\\_p\\_248.html](https://www.vaporgod.com/VaporGod-Arctic-Wolf-Eliquid_p_248.html) ; <https://slimsejuice.com/Mermaid's-Tears-Ejuice-Eliquid-for-Vaping> ; <https://breazy.com/products/the-angry-munchkins-e-liquid-food-fighter-e-liquid> ; <https://www.eliquid.com/products/unicorn-poop-by-dripstar-vapor?variant=16370577729> .

products. The complexity and expense of doing so is beyond the means and capacities of local jurisdictions. Setting a national product standard, at the point of manufacture, would be a considerably more straightforward and efficient method of regulating flavored products.

Another enforcement challenge arises from the lack of an affordable, convenient and reliable field test to detect flavors in tobacco products. Inspectors and decision-makers have to rely, on occasion, on their own senses of smell. This gap sometimes places enforcement officers in a difficult position. I recommend that FDA, when setting a flavor product standard, at the same time provide funds for development of a field device capable of detecting (non)compliance with the proposed standard.

Ultimately, however, despite enforcement challenges, local flavor restrictions have led to increased quit attempts overall as well as declining youth tobacco use. For example, in a 2017 study analyzing the effect of New York City's ban on flavored cigars, cigarillos, little cigars, chew, snuff, snus, tobacco, pipe tobacco, roll-you-own tobacco, and dissolvables (as measured by retail tobacco sales), the researchers found that sales of such products, as well as the odds of ever using such products, declined significantly among teens after the flavor ban went into effect.<sup>15</sup> Moreover, following enforcement of New York City's flavor ban, teens had lower odds of using *any* type of tobacco product, including those that are not flavored.<sup>16</sup> Similarly, in another study examining the effect of the Canadian province of Ontario's ban on menthol in tobacco products (among a random sampling of approximately 1,000 menthol smokers), researchers determined that the menthol ban was associated with quitting behavior, as well as a sharp contrast in self-predicted behavior. Prior to Ontario's flavor ban, only 10% of participants predicted that they would quit smoking—however, 40% of menthol smokers attempted to quit smoking shortly after the ban's implementation.<sup>17</sup>

*E. 13. All Flavors:*

*a. Are there any specific flavors for which FDA should establish a tobacco product standard? If so, which flavors (e.g., flavor additives, compounds, or ingredients) and why?*

*b. With respect to your response to the previous question, what level (e.g., maximum, minimum, prohibition) should FDA establish to protect the public health, and why?*

I draw FDA's attention to prior comment submitted by state attorneys general supporting a prohibition on menthol-flavored cigarettes in particular. I also urge FDA to ban all flavorants that have been or are found to be toxic, such as cinnamaldehyde, diacetyl and its frequent substitutes, acetoin and acetylpropionyl, benzaldehyde, vanillin, eugenol, and acetylpyridine.

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<sup>15</sup> S.M. Farley & M. Johns, *New York City Flavoured Tobacco Product Sales Ban Evaluation*, 26 TOBACCO CONTROL, 78 (2017). The New York City ban excludes menthol. *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> Ontario Tobacco Research Unit, *Evaluation of Ontario's Menthol Ban* (Mar. 2018), [https://otru.org/wp-content/uploads/2018/03/update\\_march2018a.pdf](https://otru.org/wp-content/uploads/2018/03/update_march2018a.pdf).

*E. 14. If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply (e.g., combusted, noncombusted, both), and why?*

Because both combusted and noncombusted flavored tobacco products are associated with youth initiation, the standard should apply to both. Even if FDA approves modified risk applications for noncombusted tobacco products because they offer a harm reduction pathway for smokers to quit, it is not clear at present that it is the flavored nature of the noncombusted products that has that cessation effect. The mere showing that adults like flavors is insufficient and, even if it were established and sufficient, that would also be a factor against approval of flavored noncombusted products because the flavors would induce non-smoking adults to initiate use of noncombusted products.

The standard should also apply to combusted products, where there is no countervailing argument at all. I draw FDA's attention to the fact that the majority of state attorneys general are already on record in support of a prohibition on menthol-flavored cigarettes. The need to regulate flavored cigars, little cigars and cigarillos is urgent. Numerous flavored products proliferated on the market after flavored cigarettes were prohibited in 2009, and the cigar segment has grown rapidly since then. This is detailed in my comment submitted to FDA regarding the proposed premium cigar exemption.

*F. 16. FDA may consider restrictions on the sale and distribution of flavored tobacco products. Possible restrictions could include restrictions on the advertising and promotion of tobacco products with flavors; on access to tobacco products with flavors; and/or on the label, labeling, and/or packaging of tobacco products with flavors. These restrictions could include requirements to bear warnings or disclosure statements. What such restrictions, if any, should FDA consider and why?*

I urge FDA to propose and adopt a rule imposing sale and distribution restrictions, as well as a flavored product standard. Enforcement is most effective when it can be exercised at multiple points in the production and supply chain. Here, a product standard could be implemented at the manufacturing level (where states do not regulate but where FDA regulation is strong), and also at the distribution and sales levels (where states and local jurisdictions tend to regulate, as well as FDA, e.g., retailer compliance inspections by federal, state and local authorities, state and local licensing requirements at the distributor and retail levels, state excise taxes levied and stamps applied at the distribution level.)

Sales restrictions alone can be challenging to enforce. As discussed above, the use of concepts and colors rather than explicit statements of flavors has proliferated. Thus, it would be more effective if a sales restriction was coupled with a product standard. Further, enforcement at the point of sale or at the distribution level would be facilitated if FDA required that products meeting the product standard appear distinctive, e.g., distinctive packaging, size, labels, etc. Such a requirement would be synergistic with consumer preferences: a consumer seeking a flavored (non-compliant) product would be unlikely to purchase a product that had no obvious indicia that

it was in fact flavored. Those indicia of flavor – and thus of non-compliance – would be as obvious to regulators as to would-be consumers.

An enforcement challenge at the point of sale arises from the fact that some tobacco products are marketed not so much through traditional advertising as through use of influencers on social media who seek to create and propagate memes and so-called organic user content. It is difficult to discern whether a comment, image or video was posted on social media by an agent of a manufacturer, distributor, retailer or trade group, or by an independent consumer. Making the situation even more complex, some manufacturers have affiliate programs; a post on social media may be placed by an individual who is actually an affiliate who is rewarded with discounted product or monetary compensation for customer referrals. Advertising and disclosure rules and restrictions have little effect on such types of marketing and are difficult to monitor or enforce. Once again, a national product standard in combination with sales and distribution restrictions is likely to be more effective and enforcement will be more efficient.

Another enforcement challenge at the point of sale arises from the lack of an affordable, convenient and reliable field test to detect flavors in tobacco products. As discussed earlier, I recommend that FDA, whether setting a flavor product standard or a sales and distribution restriction, provide funds for development of a field device capable of detecting (non)compliance with the proposed standard.

I also draw FDA's attention to the fact that many electronic smoking devices are decorated or accessorized with "skins" and other covering materials. The effect of these accessories is to cover the exterior of the device. Thus any rule about warning, disclosure or labeling on the product may easily be rendered ineffective because consumers will cover the product with a "skin." Again, this points to the importance of having both a product standard and a sales and distribution restriction.

*G. 17. To the extent that flavors may pose both (1) potential benefits to adult smokers who might consider switching to a noncombusted flavored tobacco product with lower individual risk and (2) potential risks to nonusers who might initiate use of tobacco products through flavored tobacco products or to current users who might progress to flavored tobacco products with higher individual risks, how should FDA assess and balance these benefits and risks?*

As referenced above, the Act provides FDA with a framework for making this assessment. In this specific content, FDA should propose and adopt a rule setting forth the conditions that a manufacturer would have the burden of satisfying prior to selling a flavored tobacco product. These conditions are where the manufacturer has first submitted and FDA has reviewed and concluded that there is sufficient valid scientific evidence for each flavored product that the flavor: (1) enhances the efficacy of the product in increasing the number of smokers who stop smoking combustible tobacco products, (2) does not contribute to initiation of tobacco product use, including use of non-combustible products such as electronic cigarettes, particularly among youth, or relapse into tobacco product use, (3) does not result in continued use of tobacco products by those who otherwise would have quit, and (4) does not itself increase the toxicity, carcinogenicity or teratogenicity of the product. In applying such a standard, the burden of

making this demonstration should be on the manufacturer with respect to each product. In the absence of such a showing, no characterizing flavor should be permitted.

Further, it is important not to rely excessively on a product standard and/or sales and distribution restriction, in the belief that pharmacology and flavors are the only determinants of smoking, addiction or quitting. Rather, the fundamental elements of successful tobacco control programs are well-known and beyond dispute, e.g., smoke-free laws, taxation of tobacco products, regulation of promotions, ongoing media campaigns, well-funded cessation programs, etc. Unlike proposals to permit or even promote flavored noncombusted products, none of these strategies place non-users at risk of initiating smoking. Thus, tobacco control efforts and funding should focus on those tried and trusted strategies.

Further, where those strategies have been implemented diligently over time – as they have in my state – the results are impressive, if uneven. I am aware of no evidence that flavored noncombusted products are effective in reducing smoking among those groups among whom smoking is most prevalent, e.g., Native Americans, older blue collar workers, certain immigrant groups.<sup>18</sup> In other words, in one of the areas where need is greatest, there is no evidence that flavors promote cessation.

In light of substantial evidence of the effectiveness of other strategies that carry no risk of harm, it is counter-productive for FDA to allow continued production and sale of flavored noncombusted products that appeal to non-users, in particular, minors and young adults,<sup>19</sup> simply because they may offer a tool for some smokers to switch.<sup>20</sup> In this regard I also note the telling fact that **none** of the noncombusted tobacco products have sought or received approval from FDA as a cessation device, even though many have been on the market for years and have made such cessation and health claims.

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<sup>18</sup> A recent study found no evidence that flavors in e-cigarettes helped *any* population group quit smoking. Scott R. Weaver, et al., *Are electronic nicotine delivery systems helping cigarette smokers quit? Evidence from a prospective cohort study of U.S. adult smokers, 2015–2016*, PLOS ONE (July 9, 2018). (Year-long survey evaluation of adult cigarette users and dual users, finding, among other things, that there was no instance where e-cigarette users were more likely to quit than non- e-cigarette users. Tobacco-flavored or unflavored e-cigarette users and users of other flavors (e.g., fruit, dessert, spice) had significantly lower adjusted odds of quitting than non-users.)

<sup>19</sup> James Tsai et al., *Reasons for Electronic Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2016*, 67 MORBIDITY MORTALITY WEEKLY REP. 196, 196 (2018) (among middle school and high school students who ever used e-cigarettes in 2016, the most commonly selected reasons for use were “use by a friend or family member” and “availability of flavors”); Li-Ling Huang et al., *Impact of Non-Menthol Flavors in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review*, 26 TOBACCO CONTROL 709, 717 (2017) (“Flavours in tobacco products seem to have a universal and rather strong appeal to youth and young adults interested in initiating tobacco use or experimenting with different products due to the variety and availability of flavours [and] are reported as a reason for using most tobacco products...”); Nicholas I. Goldenson et al., *Effects of Sweet Flavorings and Nicotine on the Appeal and Sensory Properties of E-Cigarettes Among Young Adult Vapers: Application of a Novel Methodology*, 168 DRUG & ALCOHOL DEPENDENCE, 176, 176 (2016) (discussing how flavoring tobacco enhances the appeal of e-cigarettes and vaping); Hyoshin Kim, et al. *Role of Sweet and Other Flavours in Liking and Disliking of Electronic Cigarettes*, 25 TOBACCO CONTROL 1, 1 (2016) (Supp. 2).

<sup>20</sup> As the NASEM Report concluded, “[t]here is insufficient evidence from randomized controlled trials about the effectiveness of e-cigarettes as cessation aids compared to no treatment or to FDA-approved smoking cessation treatments.” NASEM Report, at p. S-7.



*G. 21. Discuss any other tobacco product standard, regulatory action, or other activity that FDA could pursue that would complement or increase the effectiveness of the potential tobacco product standards or other regulatory actions discussed in the preceding questions.*

FDA should propose and adopt a product standard for a maximum nicotine level in tobacco products. For further information on this topic I refer you to the comment I filed on this topic on July 16, 2018, with five other State Attorneys General.

FDA should also investigate setting a product standard for the pH level of combustible tobacco products so that smokers are less likely to inhale and/or are likely to inhale less frequently and less deeply.

*G. 24. If FDA were to establish a tobacco product standard prohibiting or restricting flavors in tobacco products, what evidence is there, if any, that consumers would start to flavor their own tobacco products?*

It is likely that some consumers will switch to purchase other products that are flavored and/or to flavor their own tobacco products.

Some users of electronic smoking devices, specifically vape mods using flavored e-liquids, already mix their own flavors and flavor their own tobacco products. There is at present, however, little incentive for such conduct because innumerable flavored products are readily available in convenient sizes and forms.

I am not aware of evidence that individual smokers started to flavor their own cigarettes after Congress prohibited cigarettes with flavors other than menthol or tobacco. However, many consumers, particularly youth, switched to flavored little cigars and cigarillos, many of which were and are functionally cigarettes. The market for these flavored combusted products continues to increase even as sales of cigarettes decline year upon year. Similarly, purchases of flavored noncombusted products have increased rapidly. This suggests that consumers will seek out flavored products, if available on the market. However, the ready, convenient and cheap availability of these flavored products also caused little incentive for consumers to start to flavor their own products.

Thus it is likely that if FDA restricts flavors in certain tobacco products (e.g., all combusted products) then consumers, including youth, will switch to other flavored, noncombusted, products. It is also possible that some consumers will flavor their own products, e.g., rolling cigarettes with flavored rolling papers, adding flavored e-liquid to non-flavored cigarettes or cigarillos, using flavored tobacco from premium cigars if they are exempted from regulation. This suggests that FDA should adopt a uniform product standard for flavors across all categories of tobacco products.

*G. 25. What data may be used to assess and analyze the range and variety of flavored tobacco products that are currently available to consumers? How can available sources of information, such as manufacturer registrations and/or product listings with FDA, be used in this assessment?*

I am aware of the City of Chicago's database of flavored products, available at <http://www.flavoredtobaccosearchengine.org/>

Additionally, researchers at the University of North Carolina at Chapel Hill have created a publicly available searchable website containing data on e-liquid flavors, their chemical composition, and toxicity, available at <https://eliquidinfo.org/>.<sup>21</sup> While this database does not contain all e-liquid flavors currently on the market, it is a valuable resource and may serve as a model for future data collection and dissemination.

### **Conclusion**

I applaud FDA for soliciting public comments on this question of supreme importance to the health and well-being of the American public and urge FDA to exercise its full statutory authority to regulate flavored tobacco products.

Respectfully submitted,



Xavier Becerra  
California Attorney General

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<sup>21</sup> See discussion in M. Flori Sassano et al., *Evaluation Of E-Liquid Toxicity Using an Open-Source High-Throughput Screening Assay* 16 PLOS BIOLOGY 1 (2018).