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Massachusetts, New Mexico, Oregon, Pennsylvania, Rhode Island**

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Via Federal eRulemaking Portal

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

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

The undersigned State Attorneys General submit these comments in response to the Advance Notice of Proposed Rulemaking titled “Regulation of Flavors in Tobacco Products” (the “ANPRM”).¹ It is well settled that tobacco companies use flavors to mask the harshness of tobacco and nicotine, thereby making it easier for new and younger users to become addicted.² Congress acknowledged this fact when it passed the Family Smoking Prevention and Tobacco Control Act banning cigarettes with characterizing flavors except for tobacco and menthol flavors. The ANPRM also acknowledges this fact and cites much of the evidence demonstrating that first use of flavored tobacco products, including e-cigarettes, is more likely to lead to continued use of tobacco products and nicotine dependence than first use of non-flavored tobacco products. The ANPRM also recognizes the deleterious impact that menthol continues to have in the cigarette market. Based on the substantial evidence supporting the conclusion that flavors in tobacco products damage the public health and the scant evidence of any benefit derived from them, we urge the Food and Drug Administration (FDA) to ban the use of flavors, including menthol, in all tobacco products. Parts II and III of this letter respond to Questions 1–4 of the ANPRM. Part III also responds to Question 15 of the ANPRM. Part IV.A of this letter responds to Questions 5–10 and Question 17 of the ANPRM. Part IV.B and Part V respond to Questions 13–14 and Question 16 of the ANPRM.

State Attorneys General have long fought to protect their citizens, particularly youth, from the hazards of tobacco products. Though States have had considerable success in doing so with regard to cigarettes, barriers to this goal still exist. In particular, flavors in tobacco products, including menthol—the one non-tobacco characterizing flavor still allowed in cigarettes—are an impediment to States’ public health goals. Flavors have an outsized attraction

¹ Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12294 (Mar. 21, 2018).

² See Daniel S. Morris & Steven C. Fiala, *Flavoured, Non-Cigarette Tobacco for Sale in the USA: An Inventory Analysis of Internet Retailers*, 24 TOBACCO CONTROL 101, 101 (2015) (“Flavors like menthol, cherry, grape and chocolate mask the harshness of tobacco, making it easier to become addicted.”).

towards youth, have a disparate impact on minority populations, and, when present in e-cigarettes, have only a speculative positive effect on the rate of adult cigarette use. At a time when State efforts have decreased cigarette consumption, we face a new scourge caused in large part by the combination of flavors and tobacco products other than cigarettes, including e-cigarettes.

As officials of States entrusted with the power to protect the health, safety, and welfare of the public, we urge that the FDA ban the use of flavors in tobacco products.

I. States have Substantial Interests in Decreasing Tobacco Use.

State Attorneys General have been at the forefront of the fight against tobacco products for decades. In the nineteen nineties, every State Attorney General sued the major tobacco companies for the harm their products cause and reached settlement agreements that, among other things, include restrictions on the advertising, marketing, and promotion of cigarettes. The most famous of these agreements, the 1998 Master Settlement Agreement, specifically banned youth targeting by tobacco manufacturers.³ Thanks in part to this agreement, youth cigarette use has declined significantly over the past twenty years.⁴

On several occasions, State Attorneys General have also recommended that the FDA take additional steps to protect the public, particularly youth, from the dangers of tobacco use. Many of these recommendations are still relevant today. In October 2013, for example, 41 State Attorneys General wrote to the FDA, urging the agency to promptly issue regulations regarding the advertising, ingredients, and sale to minors of e-cigarettes. At that time—now five years ago—the Attorneys General noted the rapidly increasing advertising and sales of e-cigarettes; their increased use by youth; the appeal of their flavors in sales to youth; and the use of advertising methods reminiscent of past cigarette campaigns that targeted youth, among other things. Now, FDA notes that e-cigarettes are “the most commonly used tobacco product” among youth.⁵ Additionally, in November 2013, 27 State Attorneys General submitted comments to FDA supporting a ban on menthol-flavored cigarettes. These Attorneys General cited the findings of an FDA report, “Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes”⁶ (the “FDA Menthol Report”) as evidence

³ Master Settlement Agreement § III(a) (Nov. 1998), available at <http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf>.

⁴ Lloyd D. Johnston et al., *Monitoring the Future National Survey Results on Drug Use, 1975–2015: Overview, Key Findings on Adolescent Drug Use*, INST. FOR SOC. RES., U. OF MICH. (2015), <http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2015.pdf>.

⁵ 83 Fed. Reg. at 12296.

⁶ *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes*, FOOD AND DRUG ADMIN. (2013), <http://www.fda.gov/downloads/UCM361598.pdf> (hereinafter, “FDA Menthol Rept.”).

for the conclusion that sales of menthol cigarettes undermine State attempts to curb smoking, particularly by youth and African-Americans and other minorities.⁷

Each of these actions by State Attorneys General has been motivated by their duty to protect their citizens from the well-documented dangers of tobacco use. The continued availability of menthol cigarettes and other flavored tobacco products has the potential to undermine the progress made in protecting those citizens by reducing tobacco use and its dangers.

II. Flavors Lead Youth to Tobacco Use and Nicotine Dependence.⁸

Research has shown that flavors in tobacco products increase the appeal of tobacco products to youth and promote youth initiation of tobacco use.⁹ Results from the 2014 National Youth Tobacco Survey on flavored tobacco product use among middle and high school students show that an estimated 3.26 million youth tobacco product users (12 percent of all youth) reported using a flavored tobacco product within 30 days of the survey. By product, an estimated 1.58 million reported using a flavored e-cigarette, 1.02 million reported using flavored waterpipe tobacco, 910,000 reported using flavored cigars, 900,000 reported using menthol cigarettes, 690,000 reported using flavored smokeless tobacco (defined as chewing tobacco, snuff, dip, snus, or dissolvables), and 120,000 reported using flavored pipe tobacco.¹⁰ In New York, the majority of middle and high school students who currently use e-cigarettes, cigars, or hookah reported using flavored products.¹¹

Unsurprisingly, research has shown that the availability of flavored tobacco products at these developmental stages may result in lifelong tobacco use.¹² Use of tobacco products puts youth and young adults at greater risk for future health issues, such as coronary artery disease, cancer, and other known tobacco-related diseases.¹³ In part to counter these effects, Congress

⁷ 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>

⁸ Part II responds to Questions 1-4 of the ANPRM.

⁹ 83 Fed. Reg. at 12295; see also Li-Ling Huang et al., *Impact of Non-Menthol Flavours 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 ...”).

¹⁰ 83 Fed. Reg. at 12296.

¹¹ *Flavored and Menthol Tobacco Use Among New York Youth*, NEW YORK STATE DEP'T OF HEALTH (2018).

¹² 83 Fed. Reg. at 12295, 12298.

¹³ *Id.* at 12295.

passed the 2009 Family Smoking and Prevention Tobacco Control Act banning the use of characterizing flavors other than menthol in cigarettes.¹⁴ Recent studies have shown that rates of use of the still-allowed flavored tobacco products, including e-cigarettes, however, continue to rise in young adults.¹⁵

Flavors in tobacco products other than cigarettes, including e-cigarettes and cigars, appeal to youth and young adults.¹⁶ For example, a 2014 study reported that there are more than 7,000 unique flavors of e-cigarettes, including tobacco, menthol, and others with the flavors of desserts and candies.¹⁷ Sweet flavors can play an important role in e-cigarette use, especially for youth and young adults.¹⁸ More than half of middle and high school students who smoke e-cigarettes prefer to do so with sweet flavors.¹⁹ In one New York study, nearly half of adolescent e-cigarette users surveyed reported liking fruit flavors the best, followed by menthol or mint, and a combined category of chocolate, candy, or other sweets.²⁰ E-cigarette users exhibit a preference for sweetness, even in menthol flavored tobacco products.²¹ Additionally, young

¹⁴ Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 21 U.S.C.). Notably, Congress did not give a free pass for menthol flavors in cigarettes. Instead, Congress directed FDA to form a Tobacco Products Scientific Advisory Committee that would study menthol and its effect on public health, including children and African-Americans. See 21 U.S.C. § 387g(e)(1) (2012).

¹⁵ Jessica Miller Rath et al., *Correlates of Current Menthol Cigarette and Flavored Other Tobacco Product Use Among U.S. Young Adults*, 62 ADDICTIVE BEHAV. 35, 36 (2016); see generally Charles J. Courtemanche, Makayla K. Palmer, & Michael F. Pesko, *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, 52 AM. J. PREVENTATIVE MED. e139 (2017) (estimating the association between the ban on flavored cigarettes and tobacco use among adolescents).

¹⁶ 83 Fed. Reg. at 12296; see also Reinskje Talhout, Suzanne van der Nobelen, & Anne S. Kienhuis, *An Inventory of Methods Suitable to Assess Additive-Induced Characterising Flavours of Tobacco Products*, 161 DRUG & ALCOHOL DEPENDENCE 9, 10 (2016) (noting that younger smokers are more likely to have tried or to smoke flavored cigarettes); 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”).

¹⁷ Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3, iii4 (2014). Zhu and colleagues found that between August 2012 and January 2014, “242 new flavours were [being] added per month.” *Id.* at iii5–iii6.

¹⁸ See generally 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); see also Sarah D. Kuwitt et al., *Perceptions and Experiences with Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies*, 14 INT. J. ENVIRON. RES. & PUB. HEALTH 1, 16 (2017) (“[I]n nearly all 20 studies included in our review, participants reported positive perceptions of flavored tobacco products and mentioned how flavors led to their experimentation and/or initiation of flavored tobacco products.”).

¹⁹ 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).

²⁰ A. Henes et al., *2017 Adolescent E-Cigarette Survey*, RTI INT’L (2017) (unpublished data).

²¹ Kim, *supra* note 19, at 5.

adult cigar smokers have a clear preference for flavored cigars.²² In 2010-11, youth and young adults in addition to African-Americans were “significantly more likely” to report a usual or well-known cigar brand that was flavored.²³

This data regarding tobacco products other than cigarettes is consistent with the experience of the State Attorneys General in the regulation of flavors in cigarettes. Documents from the tobacco industry show that the industry used food flavors, such as fruit and candy, to attract new, primarily youth, cigarette smokers.²⁴ The use of these flavors in other tobacco products endangers state tobacco control efforts and impedes the benefits that could, and should, be derived from the ban on cigarettes with characterizing flavors other than menthol.

Even controlling for other factors associated with tobacco product use, youth who first used flavored tobacco products had a higher prevalence of current tobacco use compared to youth whose first product was not flavored.²⁵ There is increasing evidence that “flavoring enhances the rewarding and reinforcing value of e-cigarettes with nicotine, and thus their abuse liability in young adult smokers.”²⁶ That evidence also demonstrates that flavoring may “result in higher levels of nicotine dependence.”²⁷ Situational experiences may also make it even easier for youth and young adults to continue using tobacco products other than cigarettes. For example, youth and young adult e-cigarette users “may learn that e-cigarettes can be used in place of combustible cigarettes in situations in which smoking is prohibited, minimizing the inconvenience of being a smoker, and diminishing motivation to quit smoking.”²⁸

In sum, flavors in tobacco products entice youth and young adults to try those products, to continue using those products, and ultimately to become dependent on them.

²² Adrienne S. Viola et al., *A Cigar by Any Other Name Would Taste as Sweet*, 25 TOBACCO CONTROL, 66, 67 (2016). In fact, cigars are the most popular tobacco product among African-American youth, and young adult cigar smokers have a clear preference for flavored cigars. *Id.*

²² 83 Fed. Reg. at 12297.

²³ Ganna Kostygina, Stanton A. Glantz, & Pamela M. Ling, *Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos*, 25 TOBACCO CONTROL 66 (2016).

²⁴ 83 Fed. Reg. at 12296.

²⁵ *Id.* at 12297.

²⁶ Janet Audrain-McGovern, Andrew A. Strasser, & E. Paul Wileyto, *The Impact of Flavoring on the Rewarding and Reinforcing Value of E-Cigarettes With Nicotine Among Young Adult Smokers*, 166 DRUG & ALCOHOL DEPENDENCE 263, 265 (2016).

²⁷ *Id.* at 266.

²⁸ *Id.* (citing Rass et al., *Characterizing Use Patterns and Perceptions of Relative Harm in Dual Users of Electronic and Tobacco Cigarettes*, 23 EXP. CLINICAL PSYCHOPHARMACOLOGY 494, 494 (2015)).

III. Menthol Use is Higher in Youth Tobacco Users and Tobacco Users From Minority Populations.²⁹

In 2013, FDA concluded it “likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes.”³⁰ Nothing that has occurred in the past five years would alter that conclusion.

Tobacco companies add menthol to cigarettes in part because menthol is known to be an attractive feature to inexperienced smokers who perceive menthol cigarettes as less harsh and easier to smoke.³¹ In fact, these newer smokers prefer menthol cigarettes at levels substantially above that of the general population, and younger populations have the highest rate of smoking menthol cigarettes.³² In New York, the majority of youth smokers smoke menthol cigarettes.³³ The general decline in youth and young adult cigarette smoking has not been mirrored in youth and young adult menthol cigarette smoking, which is disproportionately higher than older adult menthol cigarette smoking.³⁴ Moreover, youth who initiate smoking with menthol cigarettes may be at a greater risk to progress to established smoking and nicotine dependence than youth who initiate smoking with nonmenthol cigarettes.³⁵ The data regarding youth use of menthol cigarettes extends to non-cigarette tobacco products with the same flavor and is consistent with the widespread appeal of flavored products in this demographic.³⁶

Research has shown that certain discrete segments of the population prefer menthol. For example, one study indicates that “African-American smokers are nearly 11 times more likely to use menthol than White smokers”³⁷ Among New York adults who smoke, 88.5% of non-

²⁹ Part III responds to Questions 1–4 and Question 15 of the ANPRM.

³⁰ FDA Menthol Rept., *supra* note 6, at 6.

³¹ Kim Klausner, *Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective*, 20 TOBACCO CONTROL, ii12, ii13 (2011) (Supp. 2).

³² FDA Menthol Rept., *supra* note 6, at 5; Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004-2014*, 25 TOBACCO CONTROL ii14, ii16 (2016).

³³ J. Pepper, J. Nonnemaker, & K. Watson, *Flavored and Menthol Tobacco Use Among New York Youth*, NEW YORK STATE DEP’T OF HEALTH (2018) (unpublished data).

³⁴ 83 Fed. Reg. at 12296 (citing Andrea C. Villanti et al., *Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004–2014*, 25 TOBACCO CONTROL ii14, ii16 (2016)); *see also* Rath, *supra* note 15, at 36.

³⁵ Denise Kandel et al., *On the Measurement of Nicotine Dependence in Adolescence: Comparisons of the mFTQ and a DSM-IV-Based Scale*, 30 J. OF PEDIATRIC PSYCHOL. 319, 322-24 (2005); Joseph R. DiFranza et al., *Symptoms of Tobacco Dependence After Brief Intermittent Use*, 161 ARCHIVES OF PEDIATRICS & ADOLESCENT MED. 704, 707–09, 2007; 83 Fed. Reg. at 12297; FDA Menthol Rept., *supra* note 6, at 96, 113.

³⁶ 83 Fed. Reg. at 12296.

³⁷ Rath, *supra* note 15, at 40. In addition, the FDA Menthol Report showed that the majority of African-American smokers smoke menthol cigarettes and that other groups of racial minorities are more likely to use them as well. FDA Menthol Rept., *supra* note 6, at 5.

Hispanic African Americans smoked menthol cigarettes, analogous to national percentages.³⁸ The FDA Menthol Report also showed that menthol cigarettes are associated with increased dependence on smoking and reduced success in smoking cessation in African-Americans.³⁹ The Report's finding that use of menthol cigarettes is more prevalent among this group is unsurprising given its acknowledgment that tobacco companies have marketed menthol cigarettes in ways to promote their use by African-Americans.⁴⁰

Moreover, since the FDA last solicited comments on the use of menthol in 2013, evidence has also demonstrated that menthol in e-cigarettes may put both youth and African-Americans at risk for greater rates of e-cigarette initiation and use.⁴¹ In 2018, even more evidence suggests that it is "likely that menthol cigarettes pose a public health risk above that seen with nonmenthol cigarettes."⁴²

IV. FDA Should Ban Flavors in All Tobacco Products.

Given this evidence, FDA should use its authority⁴³ to ban flavors in all tobacco products, including flavors in e-cigarettes. This is especially true where the evidence for any public health benefit from flavored tobacco products is extremely weak, and where developing and enforcing a flavor product standard is unworkable.

A. The Evidence That Flavors In Non-Combustible Tobacco Products Help Adult Cigarette Smokers Reduce Combustible Cigarette Use is Extremely Weak.⁴⁴

As noted by the Surgeon General's 2016 report on e-cigarettes, "the evidence supporting the effectiveness of e-cigarettes as an aid for quitting conventional cigarettes remains **extremely weak for adults and untested and nonexistent among youth.**"⁴⁵ Similarly, the National Academies of Sciences, Engineering, and Medicine's 2018 comprehensive and in-depth review of the scientific literature surrounding e-cigarettes reached the following conclusion: "For youth

³⁸ *New York Adult Tobacco Survey*, NEW YORK STATE DEP'T OF HEALTH, available at <https://health.data.ny.gov/Health/Adult-Tobacco-Survey-Beginning-2003/ckfz-a669>.

³⁹ FDA Menthol Rept., *supra* note 6, at 6, 113, 130.

⁴⁰ *Id.* at 68-69.

⁴¹ Kim, *supra* note 19, at 5.

⁴² FDA Menthol Rept., *supra* note 6, at 6.

⁴³ See Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 906(d)(1) (1970) (authorizing FDA to restrict the sale and distribution of tobacco products by regulation if the Agency determines that such regulations would be appropriate for the protection of the public health).

⁴⁴ Part IV.A responds to Questions 5–10 and Question 17 of the ANPRM.

⁴⁵ U.S. DEP'T. OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, 124 (2016), available at https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf (emphasis added).

and young adults, there is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes. For e-cigarette users who have also ever used combustible tobacco cigarettes, there is moderate evidence that e-cigarette use increases the frequency and intensity of subsequent combustible tobacco cigarette smoking.”⁴⁶ And significantly, “[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.”⁴⁷

Recent studies have further shown that banning flavors in tobacco products has led to increased quit attempts overall, as well as declining tobacco use among teens—a clear public health benefit.⁴⁸ 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.⁴⁹ Moreover, following the 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.⁵⁰ Similarly, in another study examining the effect 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.⁵¹

In contrast, FDA’s two cited cessation studies—i.e., for the suggestion that flavors in e-cigarettes “may help some adult users decrease their cigarette use and transition away from combusted products to potentially less harmful products”—are deeply flawed and should not be relied on to form the basis of FDA’s future actions concerning flavors.⁵² Neither study appeared

⁴⁶ National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes, Consensus Study Report Highlights*, at 3 (Jan. 2018), <https://www.nap.edu/resource/24952/012318ecigaretteHighlights.pdf>.

⁴⁷ *Id.*

⁴⁸ See, e.g., S.M. Farley & M. Johns, *New York City Flavoured Tobacco Product Sales Ban Evaluation*, 26 TOBACCO CONTROL, 78 (2017) (describing the decline of sales of flavored tobacco, cigars, and pipes); Ontario Tobacco Research Unit, *Evaluation of Ontario’s Menthol Ban* (Mar. 2018), https://otru.org/wp-content/uploads/2018/03/update_march2018a.pdf.

⁴⁹ 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.*

⁵⁰ *Id.*

⁵¹ Ontario Tobacco Research Unit, *Evaluation of Ontario’s Menthol Ban* (Mar. 2018), https://otru.org/wp-content/uploads/2018/03/update_march2018a.pdf.

⁵² 83 Fed. Reg. at 12298 (citing Amanda M. Barbeau, Jennifer Burda & Michael Siegel, *Perceived Efficacy of E-Cigarettes Versus Nicotine Replacement Therapy Among Successful E-Cigarette Users: A Qualitative Approach*, 8 ADDICTION SCI. & CLINICAL PRAC., 5 (2013); and K.E. Farsalinos, G. Romagna, & D. Tsiapras., *Impact of Flavour*

to use a group of participants that could be said to represent the views of the over 37 million adult smokers, or roughly 11 million e-cigarette users, in the United States.⁵³ One study based its findings on the views of nine men and two women recruited from an e-cigarette web forum and www.vapersclub.com.⁵⁴ The other study consisted of an online survey study in English and Greek; included an unknown number of respondents from Europe, Asia, and Australia; as well as a large number of participants that had some level of university or college education—a quality the survey’s researchers found to be “not representative of the general population of smokers [in the United States], who are generally less educated compared to the population evaluated here.”⁵⁵ Both studies, furthermore, drew their respondents from popular e-cigarette websites, ensuring that “dedicated users with positive experience with [e-cigarettes] would mainly participate[.]”⁵⁶ Per the Federal Judicial Center’s Reference Manual on Scientific Evidence, however, such self-selected participants are “very likely to self-select on the basis of the nature of the topic.” As a result, “[t]hese self-selected pseudosurveys resemble reader polls published in magazines and **do not meet standard criteria for legitimate surveys admissible in court.**”⁵⁷

In addition to the debate regarding whether flavors aid in smoking cessation, there is a growing body of literature concluding that the flavorings used in tobacco products are in and of themselves unsafe.⁵⁸ Given the scientific uncertainty surrounding these serious issues, the FDA should ban flavors in all tobacco products, including e-cigarettes.

Variability on Electronic Cigarette Use Experience: An Internet Survey, 10 INT. JOURNAL OF ENV. RES. AND PUB. HEALTH 7272, 7278 (2013)).

⁵³ Centers for Disease Control and Prevention, *Smoking & Tobacco Use, Current Cigarette Smoking Among Adults in the United States*, https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm (last visited July 19, 2018); Charlotte A. Schoenborn & M. Gindi, *Electronic Cigarette Use Among Adults: United States, 2014*, NCHS DATA BRIEF NO. 217 (Oct. 2015), <https://www.cdc.gov/nchs/data/databriefs/db217.pdf> (noting that approximately 3.7% of the U.S. Population use e-cigarettes every day or some days); see U.S. and World Population Clock, UNITED STATES CENSUS BUREAU, <https://www.census.gov/popclock/> (noting that on December 31, 2014, there were nearly 320 million persons living in the United States).

⁵⁴ See Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28973, 29055 (2016) (noting that the study “did not consider whether either the self-selection or the demographic profile of the respondents might affect the applicability of its results to any larger population. Moreover the study did not address the question of whether study participants would have increased cigarette use if there were no available flavored ENDS [i.e., electronic nicotine delivery devices] or if the variety of flavored ENDS were limited.”).

⁵⁵ K.E. Farsalinos, G. Romagna, & D. Tsiapras, *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*, 10 INT. JOURNAL OF ENV. RES. AND PUB. HEALTH 7272, 7279 (2013).

⁵⁶ *Id.*; see also Amanda M. Barbeau, Jennifer Burda, & Michael Siegel, *Perceived Efficacy of E-Cigarettes Versus Nicotine Replacement Therapy Among Successful E-Cigarette Users: A Qualitative Approach*, 8 ADDICTION SCI. & CLINICAL PRAC. 5, 7 (2013) (noting that youth often reported positive social benefits of e-cigarettes).

⁵⁷ Shari Seidman Diamond, *Reference Guide on Survey Research*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 358, 407–08 (3d ed. 2011) (emphasis added).

⁵⁸ 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

B. Developing And Enforcing A Flavor Product Standard—Much Less a Nicotine Standard—Appears Unworkable.⁵⁹

FDA has requested comments concerning the advisability of a product standard with respect to flavor additives, compounds, and ingredients.⁶⁰ For several reasons, developing and enforcing a product standard (e.g., prohibiting no more than x milliliters / milligrams of menthol or other flavorant per tobacco product) appears unworkable:

First, as noted by the Surgeon General in its 2016 report, there is a dearth of research concerning the characteristics of e-cigarette devices, the constituents of e-liquids, and “the user behaviors that can influence the yield of nicotine and other toxicants.”⁶¹ This current lack of research concerning e-cigarettes and their effects makes the development of a potential product standard extremely challenging.

In January 2014, one study estimated there were over 7,700 unique e-cigarette flavors on the market, with over 240 new flavors added each month.⁶² In addition, the “huge variety of products of different origin and design, the rapid emergence of new products, and the varied ways in which consumers use these products makes the development of standard measurement conditions challenging.”⁶³ Developing such a standard would further require a close focus on the details of each device (e.g., the voltage of the power supply, heating element resistance) and components of e-liquids (e.g., propylene glycol, vegetable glycerin, other additives), and measuring user puff topography.⁶⁴ Standardizing procedures for producing and delivering the aerosol would likely be a necessary component of some in vivo and in vitro work.⁶⁵ More

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).

⁵⁹ Part IV.B responds to Questions 13-14 and Question 16 of the ANPRM.

⁶⁰ 83 Fed. Reg. at 12299.

⁶¹ U.S. DEP'T. OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, 124 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

⁶² Shu-Hong Zhu et al., *Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation*, 23 TOBACCO CONTROL iii3, iii5 (2014).

⁶³ U.S. DEP'T. OF HEALTH & HUMAN SERVS., E-CIGARETTE USE AMONG YOUTH AND YOUNG ADULTS: A REPORT OF THE SURGEON GENERAL, 124 (2016), https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf.

⁶⁴ *See id.*

⁶⁵ *See id.*

research would also be needed to understand how each design feature related to potential toxicity.

Thus, additional time would be required to develop such a standard—time that could be better spent enforcing a complete flavor ban. Such a standard would also be extremely difficult to enforce. Unless there was a reliable field test to determine the chemical constituents and concentration of particular flavorings, law enforcement personnel would be unable to determine whether a particular product was compliant with the standard.

Second, any developed product standard—and any testing protocol for ensuring compliance with such standard—can be gamed.⁶⁶ Indeed, it was the tobacco companies' complete and utter subversion of the Federal Trade Commission's testing protocols for tar, nicotine, and carbon monoxide⁶⁷ that eventually led the Commission to withdraw its guidance and reliance on such testing protocols.⁶⁸

As FDA may recall, beginning in 1967, the Federal Trade Commission (FTC) operated a laboratory to test the tar and nicotine content of cigarettes. At the time, the agency believed that “reducing the amount of ‘tar’ in a cigarette could reduce a smoker’s risk of lung cancer,” and that “giving consumers uniform and standardized information about the tar and nicotine yields of cigarettes would help smokers make informed decisions about the cigarettes they smoked.”⁶⁹ In 1980, FTC modified its protocol to include testing for carbon monoxide.⁷⁰ In 1987, however, FTC closed its testing laboratory, “in part because of insufficient expertise within the agency to carry out an increasingly complex and costly testing program.”⁷¹ Testing was then conducted by

⁶⁶ See, e.g., *Volkswagen Violations*, ENVMTL. PROTECTION AGENCY (2017), <https://www.epa.gov/vw/learn-about-volkswagen-violations> (describing how Volkswagen installed defeat mechanisms to EPA’s emissions testing protocols).

⁶⁷ See, e.g., Lynn T. Kozlowski & Richard J. O’Connor, *Official Cigarette Tar Tests Are Misleading: Use a Two-Stage, Compensating Test*, 355 THE LANCET 2159, 2159 (2000) (describing how cigarette manufacturers knew their designed cigarettes were “cheating the official system”). “Although publicly resisting the official smoking-machine tests, manufacturers have designed cigarettes to capitalise on the testing system. Industry documents describe an awareness of cheating the official system by designing ‘elastic’ cigarettes that give low numbers to the machine and high numbers to smokers.” *Id.* In essence, because FTC’s testing protocol relied on machine tests that were inconsistent with human smoking behavior, the smoking machine tests systematically underestimated human smoking behavior. *Monograph No. 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*, NAT’L. CANCER INST. (Nov. 19, 2001, 11:26 AM), <https://cancercontrol.cancer.gov/brp/tcrb/monographs/13/>, at 146.

⁶⁸ Rescission of FTC Guidance Concerning the Cambridge Filter Method, 75 Fed. Reg. 74500, 74503 (Dec. 8, 2008).

⁶⁹ Rescission of FTC Guidance Concerning the Cambridge Filter Method, 75 Fed. Reg. at 74501.

⁷⁰ *Monograph No. 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes*, NAT’L. CANCER INST., https://cancercontrol.cancer.gov/brp/tcrb/monographs/7/m7_1.pdf, at 2.

⁷¹ *Id.* at v; see also *Monograph No. 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes*, NAT’L. CANCER INST., https://cancercontrol.cancer.gov/brp/tcrb/monographs/7/m7_1.pdf, at 5 (“No two human smokers smoke in the same

the Tobacco Institute—the trade organization and lobbying arm for the tobacco industry⁷² whose primary functions included “disputing statements from health organizations about smoking and disease ... denying that cigarette smoking was addictive; minimizing the difficulties of quitting smoking; and denying that the industry marketed to youth.”⁷³ In fact, it was only until the States’ 1998 Tobacco Master Settlement Agreement that the tobacco industry agreed to dissolve its trade group.⁷⁴ Notably, during this same period of time, FTC asked FDA’s parent agency (i.e., the Department of Health and Human Services) for recommendations concerning whether and how to change its testing protocol.⁷⁵ But finding no scientific consensus on these issues, FTC continued to endorse its flawed testing protocol before finally revoking the protocol in 2008.⁷⁶

Given FTC’s tortured and failed history of attempting to apply a testing protocol as well as the cost, the practical considerations concerning the use and implementation of any such standard weigh in favor of a complete ban on flavors. FDA does not have unlimited resources. FDA furthermore has all the information it needs to support a flavor ban.

V. Recommendations⁷⁷

In light of the above, FDA should take the step of banning flavored tobacco products and join the several countries taking a strong stand for public health. Just this year, Brazil’s highest court upheld that a ban on all flavors and additives in tobacco products.⁷⁸ Canada last year finalized a ban on menthol tobacco products.⁷⁹ By 2020, the EU will have phased out all

way. No individual smoker always smokes in the same fashion ... [and] no test [can] accurately duplicate human smoking”).

⁷² See *Monograph No. 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes*, NAT’L. CANCER INST., https://cancercontrol.cancer.gov/brp/tcrb/monographs/7/m7_1.pdf, at v.

⁷³ *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 65 (D.D.C. 2006).

⁷⁴ See Master Settlement Agreement § III(o) (Nov. 1998), available at <http://www.naag.org/assets/redesign/files/msa-tobacco/MSA.pdf>.

⁷⁵ Rescission of FTC Guidance Concerning the Cambridge Filter Method, 75 Fed. Reg. at 74503.

⁷⁶ See *id.*

⁷⁷ Part V responds to Questions 13-14 and Question 16 of the ANPRM.

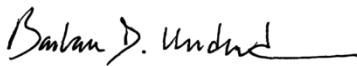
⁷⁸ *Brazil’s Highest Court Upholds Ban on Flavored Tobacco Products*, CAMPAIGN FOR TOBACCO-FREE KIDS (Feb. 1, 2018), https://www.tobaccofreekids.org/press-releases/2018_02_01_brazil-court-upholds-flavor-ban.

⁷⁹ *How Other Countries Regulate Flavored Tobacco Products*, TOBACCO CONTROL LEGAL CONSORTIUM (2015), <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-2015.pdf>; see also *Leading from Up North: How Canada is Solving the Menthol Tobacco Problem*, TOBACCO CONTROL LEGAL CONSORTIUM (2017), <http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-Canadian-Menthol-CaseStudy-2017.pdf>.

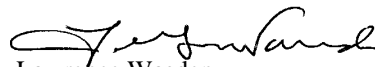
flavored tobacco products and most additives.⁸⁰ And most recently, San Francisco voters approved a proposition that would ban the sale of flavored tobacco products, including menthol cigarettes and flavored vaping liquids.⁸¹ The scientific evidence supports FDA's and others' findings that removing menthol from cigarettes will improve public health. Removing flavors from e-cigarettes, little cigars, and other non-combustible tobacco products will further reduce the appeal of such tobacco products to youth.

Here, the evidence that flavors in e-cigarettes will benefit public health is extremely limited to say the least. And to date, the tobacco and e-cigarette companies have failed to show how flavors in tobacco products may improve the public health. In short, FDA must act on its responsibility to the public. The mission of the Department of Health and Human Services is to enhance and protect the health and well-being of all Americans. The cost of doing nothing—whether measured in dollars saved or lives lost—is too great a price to pay.

Respectfully submitted,



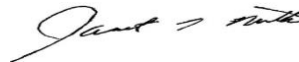
Barbara D. Underwood
New York Attorney General



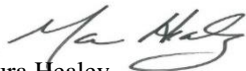
Lawrence Wasden
Idaho Attorney General



Lisa Madigan
Illinois Attorney General



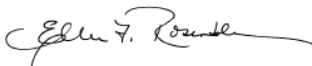
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Oregon Attorney General



Josh Shapiro
Pennsylvania Attorney General



Peter F. Kilmartin
Rhode Island Attorney General

⁸⁰ Zlata Rodionova, *Menthol Cigarettes To Be Phased Out Within Weeks Ahead of Complete Ban*, INDEPENDENT (Mar. 9, 2017, 3:42 PM), <https://www.independent.co.uk/news/business/news/menthol-cigarettes-ban-date-availability-a7620901.html>.

⁸¹ Madison Park and Roni Selig, *San Francisco Bans Sales of Flavored Tobacco Products*, CNN (June 6, 2018, 3:19 AM), <https://www.cnn.com/2018/06/06/health/san-francisco-flavored-cigarettes-proposition-e/index.html>.