



**American
Heart
Association.**

Chairman of the Board

James J. Postl

President

Ivor J. Benjamin, MD, FAHA

Chairman-elect

Bertram L. Scott

President-elect

Robert A. Harrington, MD, FAHA

Immediate Past

Chairman of the Board

Alvin L. Royse, JD, CPA

Immediate Past President

John J. Warner, MD, FAHA

Treasurer

Raymond P. Vara, Jr.

Directors

Mary Ann Bauman, MD

Emelia J. Benjamin, MD, ScM, FAHA

Douglas S. Boyle

Keith B. Churchwell, MD, FAHA

Lloyd H. Dean

Mitchell S. V. Elkind, MD, MS, FAHA

J. Donald Fancher

Linda Gooden

Ron W. Haddock

Marsha Jones

Joseph Loscalzo, MD, PhD, FAHA

Lee Shapiro

David A. Spina

Bernard J. Tyson

Thomas Pina Windsor

Joseph C. Wu, MD, PhD, FAHA

Chief Executive Officer

Nancy A. Brown

Chief Operating Officer

Suzie Upton

Chief Science and Medical Officer

Rose Marie Robertson, MD, FAHA

*Chief Administrative Officer
and Corporate Secretary*

Larry D. Cannon

July 19, 2018

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. FDA-2017-N-6565

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and more than 40 million volunteers and supporters, we appreciate the opportunity to provide comments on the regulation of flavors in tobacco products.

AHA is pleased that the Food and Drug Administration (FDA) is considering potential regulatory actions for flavored tobacco products. However, we are disappointed that the Agency chose to address this issue by releasing an Advanced Notice of Proposed Rulemaking (ANPRM) – the earliest possible step in the rulemaking process. Moving from an ANPRM to a proposed rule and ultimately to a final regulation could take a year or longer. During that time, thousands of children and adolescents will try their first tobacco product, and many will become regular tobacco users. The 2014 Surgeon General's Report projects that if current trends continue, 5.6 million of today's youth under 18 will die prematurely in adulthood from smoking-related illness.¹ To protect this vulnerable population, the FDA needs to move quickly and ban the use of characterizing flavors, including menthol, from all tobacco products.

The evidence supporting a flavor ban is clear. As we discuss below, flavored tobacco products are highly attractive to youth and have led to increased initiation and use among children and adolescents. The number of flavored products on the market has also increased substantially in recent years with the tobacco industry marketing thousands of fruit, candy, and mint flavored products that appeal to children. Allowing these products to remain on the market puts a new generation at risk of a dangerous addiction.

While we understand that some adult tobacco users report using flavored products to transition or switch from combustible cigarettes, there is little evidence supporting their use as a cessation tool. In addition, there is some evidence that flavored tobacco products have enticed adult never smokers to try tobacco for the first time – just as they have with children.

We encourage the Agency to make protecting children its top priority when considering regulatory options for flavored tobacco. Accordingly, the FDA should move quickly to remove all characterizing flavors, other than tobacco, from the market.

Role of Flavors in Tobacco Products

Question 1: The role of flavors (other than tobacco) generally in tobacco products.

In general, characterizing flavors make tobacco products easier to use. Flavored tobacco products taste better because they are less harsh and less bitter, and the tobacco smoke is less astringent or irritating.^{2,3} Menthol products also produce a cooling and soothing effect.⁴ This makes flavored tobacco products a good “starter product” for youth or other inexperienced tobacco users.

Flavors also make tobacco products more attractive or marketable to certain populations. The sheer number of flavored tobacco products on the market illustrate their appeal. For example, between 2008 and 2015, the number of unique cigar flavors increased from 108 to 250.⁵ During that same period, sales of flavored cigars nearly doubled with flavored products accounting for 52% of all cigar sales. The number of e-cigarettes has also skyrocketed in recent years. One study examining e-cigarettes during 2013-2014, found there were more than 460 brands of e-cigarettes online, offering more than 7,700 unique flavors.⁶ The study authors found that more than 240 new flavors of e-cigarettes were introduced, on average, each month. When the authors updated their study for 2016-2017, they found that the number of e-cigarette brands had largely stayed the same, however, the number of distinct flavors had more than doubled to 15,586.⁷ The study also found that e-cigarette brands had “significantly decreased their proportions of tobacco, menthol, and alcohol/drink flavors”, and “significantly increased their proportion of dessert/candy flavors” which are known to be more appealing to youth and young adults.

¹ Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

² 83 Federal Register at 12296.

³ Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes. 2013.

⁴ Ibid.

⁵ Delnevo, CD, et al. Changes in Mass-Merchandise Cigar Market Since the Tobacco Control Act. Tobacco Regulatory Science, 3(2 Suppl 1): S8-S16, 2017.

⁶ Zhu SH, et al. Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation. *Tob Control* 2014; 23:iii3-iii9 doi:10.1136/tobaccocontrol-2014-051670.

⁷ Zhu SH, et al. Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites. *Med Internet Res* 2018;20(3):e80 doi:10.2196/jmir.8550.

The tobacco industry is well aware that flavored tobacco products appeal to youth. One major e-cigarette manufacturer even acknowledged, “Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, pina-colada and berry.”⁸ And the industry appears to be taking advantage of this, marketing products in a wide range of fruit and candy flavors, such as chocolate, cherry, strawberry, grape, and lemonade, as well as with catchy names that appeal to children such as Da Bomb Blueberry, Banana Split, Sour Gummy Worms, Cupcake Kisses, Blueberry Smurf, Deluxe Pancake Man, Banana Butt, and Marshmallow Man. Flavored tobacco products are also marketed in conjunction with children’s cartoon characters or associated with imagery that appeal to youth. A quick internet search, for example, found numerous unicorn flavored e-liquids, including unicorn tears, unicorn puke, unicorn burst, unicorn sprinkles, unicorn juice cloud, unicorn frappe, unicorn vomit, psycho unicorn, unicorn rainbow, unicorn cake, unicorn blend, unicorn 3D, unicorn de queso, unicorn’s roar, unicorn witch special, unicorn love special, and unicorn milk. And, as the FDA is well aware, some flavored tobacco products are marketed in ways that mimic kid-friendly food and beverage products, like Candy King Sour Worms or V’Nilla Cookies & Milk.⁹ We can only assume that products like unicorn cakes or twirly pop e-juice are intended for a younger audience.

The data show that these industry tactics work to draw youth to flavored tobacco products. The 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that a flavored tobacco product was the first tobacco product used by 81% of youth aged 12 to 17 years. Eighty-six percent of young adult (18-24 years) “ever users” also report that their first tobacco experience was with a flavored product.¹⁰ In addition, the overwhelming majority of young tobacco users continue to use flavored tobacco at high rates. Almost 80% of youth who currently use tobacco report using a flavored product within the past 30 days.¹¹ The PATH study also found that youth who start with a flavored tobacco product are more likely to progress from initiation to current established tobacco product use. According to the survey, 81.5% of young e-cigarette users and 73.8% of young cigar users say they use these products “because they come in flavors I like.”¹²

⁸ What You Need to Know About E-Cigarettes – Infographic. Real Parents Real Answers. Sponsored by Lorillard’s Youth Smoking Prevention Program, 2014. www.realparentsrealanswers.com. Website no longer available.

⁹E-Liquids Misleadingly Labeled or Advertised as Food Products.

<https://www.fda.gov/TobaccoProducts/NewsEvents/ucm605729.htm>.

¹⁰ Villanti, AC, et al. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013–2014), *American Journal of Preventive Medicine*, 53(2):139–151, 2017.

¹¹ Ibid.

¹² Ambrose, BK, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014, *Journal of the American Medical Association*, October 26, 2015.

Flavors and Initiation and Patterns of Tobacco Use, Particularly Among Youth and Young Adults

Question 2: The role of flavors in initiation and/or patterns of use of combusted tobacco products.

As described above, flavors contribute to tobacco initiation and continued use by youth. That pattern began with flavored combustible cigarettes and continues with other combustible products today.

After flavored cigarettes were banned in 2009, we saw a significant growth in the number of flavored cigars. Cigars became one of the most commonly used tobacco products among youth with high school males smoking cigars (10.5%) at a higher rate than cigarettes (9.8%).¹³ Much of this increase in cigar use can be attributed to the availability of flavored cigars. The Maryland Youth Tobacco Survey, for instance, found that over 76% of cigar users in high school smoke flavored cigars, while less than 2% of adults do.¹⁴ Another study found that 75% of the growth in cigar sales from 2008 to 2011 represents a growth in the sale of flavored cigars.¹⁵ By 2015, national sales data show that 26.1% of large cigars, 47.5% of cigarillos, and 21.8% of little cigars sold were flavored, and an additional 19.4% of little cigars sales were menthol.¹⁶

Unfortunately, flavored cigars, like other flavored products, serve as a gateway to tobacco use. Sixty-five percent of youth who have ever used a cigar report starting with a flavored cigar, and almost 72% of current cigar users smoked a flavored cigar in the past month.¹⁷ And, as noted above, almost 74% report using cigars “because they come in flavors I like.”¹⁸ Flavored cigars also appeal to adult never smokers and former smokers; 30.8% of never-cigarette smokers and 38.9% of former smokers report using flavored cigars.¹⁹ In addition, flavored cigars appear to encourage dual use with 43.8% of current cigarette smokers also smoking flavored cigars.²⁰

We see a similar pattern with hookah or waterpipe tobacco. Flavored hookah has increased in popularity in recent years with 1.02 million youth reporting use of the product in 2014;

¹³ Kann L, et al. Youth Risk Behavior Surveillance - United States, 2017. *MMWR Surveill Summ* 2018;67(No. SS-8):1–114. DOI: <http://dx.doi.org/10.15585/mmwr.ss6708a1>

¹⁴ Cigar Use Among Youth. Maryland Department of Health and Mental Hygiene. Nov 17, 2011.

¹⁵ Delnevo C, et al. Preference for Flavored Cigar Brands Among Youth, Young Adults and Adults in the USA. *Tob Control* 2014 April 10. doi: 10.1136/tobaccocontrol-2013-051408

¹⁶ Kuiper N, et al. Trends in Sales of Flavored and Menthol Tobacco Products in the United States during 2011–2015. *Nicotine Tob Res.* 20(6):698-706. <https://stacks.cdc.gov/view/cdc/50443>.

¹⁷ Ambrose BK, et al. 2015.

¹⁸ Ibid.

¹⁹ Bonhomme, MG, et al. Flavoured Non-Cigarette Tobacco Product Use Among US Adults: 2013–2014, *Tobacco Control*, 25(Suppl 2):ii4-ii13, 2016.

²⁰ Ibid.

second only to flavored e-cigarettes.²¹ And, of current hookah users, 89% report using a flavored product within the past month.²²

Finally, we must address the continued use of menthol in cigarettes and other combustible products. Menthol cigarettes, cigars, and pipe tobacco increased in popularity after the FDA implemented the flavored cigarette ban. More than half of all youth and young adult cigarette smokers now smoke menthol cigarettes,²³ and menthol cigarettes account for almost one-third of all cigarette sales.²⁴ According to the FDA's own 2013 scientific evaluation of menthol, younger populations have the highest rate of smoking menthol cigarettes. In fact, the FDA found that menthol is substantially more popular among newer smokers than the general population.²⁵ This is likely because "its pharmacological actions reduce the harshness of smoke and the irritation from nicotine".²⁶ The Agency and its Tobacco Products Scientific Advisory Committee (TPSAC) also found that menthol increases initiation and progression to regular smoking and enhances the addictiveness and dependence of tobacco.^{27,28}

Menthol's effects are not limited to cigarettes; menthol is also a popular flavor in other combustible products. Among adult users of flavored tobacco products, menthol was the preferred flavor for 12.9% of cigar users, 24.8% of pipe smokers, and 18.9% of hookah users.²⁹ Menthol was also popular among non-combustible tobacco products, including 76.9% of adult smokeless tobacco users.³⁰ Menthol flavor accounted for 57% of moist snuff and 88.5% of all snus sales in 2015.³¹

Menthol is also used to target the African American community. African American neighborhoods have a disproportionately high number of tobacco retailers and pervasive tobacco marketing, especially of menthol products.³² Menthol cigarettes are heavily marketed to and thereby quite popular with black smokers, 85% of whom use menthol products. Menthol is also popular with Latinos (45%) and Non-Hispanic Caucasians (30%) but at lower rates.³³

²¹ Corey, CG, et al. Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014, *Morbidity and Mortality Weekly Report*, 64(38):1066–1070, 2015.

²² Ambrose BK, et al. 2015.

²³ Villanti, A., et al. Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014, *Tobacco Control*, published online October 20, 2016.

²⁴ Kuiper N, et al. 2015.

²⁵ FDA Preliminary Scientific Evaluation.

²⁶ Tobacco Products Scientific Advisory Committee (TPSAC), *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, July 21, 2011

²⁷ FDA Preliminary Scientific Evaluation.

²⁸ TPASC Report.

²⁹ Bonhomme, et al. 2016.

³⁰ Ibid.

³¹ Kuiper N, et al. 2015.

³² Lee, JGL, et al. A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing, *American Journal of Public Health*, July 16, 2015.

³³ Villanti, AC, et al. 2016.

Question 3: The role of flavors in initiation and/or patterns of use of noncombusted tobacco products.

As with combustible tobacco, flavors also contribute to the initiation and continued use of noncombusted products, especially among youth.

This problem is most evident with e-cigarettes. Between 2011 and 2015, the number of youth using e-cigarettes increased dramatically from 1.5% to 16%.³⁴ While use dropped in 2016 to 11.3%,³⁵ it ticked back up slightly to 11.7% in 2017, and e-cigarettes remain the most commonly used tobacco product among high school and middle school students.³⁶ And prevalence rates are likely actually higher than they appear, because some youth are unaware that “vaping” or “JUULing” qualifies as an e-cigarette or electronic nicotine delivery system (ENDS).³⁷

Flavors are a major reason for e-cigarette use. Eighty-one percent of youth who have used an e-cigarette started with a flavored version, and 85.3% of current e-cigarette users report using a flavored e-cigarette in the past month.³⁸ Youth consistently say that the availability of flavors greatly influences their decision to use e-cigarettes. Almost one-third (31%) of students who responded to the National Youth Tobacco Survey reported that flavors are a main reason they use e-cigarettes,³⁹ while 81.5% of youth in the PATH survey said they use e-cigarettes “because they come in flavors I like.”⁴⁰

These surveys show that a large percentage of youth begin using e-cigarettes because they are attracted to the available flavors. Additional research indicates that some of these users are primarily focused on the flavors and are unaware that they are using a tobacco product or being exposed to nicotine. The 2016 Monitoring the Future study, for example, found that the majority of youth e-cigarette users believe they only vape flavoring, not nicotine, when they use an e-cigarette⁴¹ even though almost all e-cigarettes sold in retail outlets contain nicotine. Similarly, a study by the Truth Initiative found that 63% of young JUUL users were unaware that the product always contains nicotine.⁴²

³⁴ Corey CG, et al. 2015.

³⁵ Jamal A, et al. Tobacco Use Among Middle and High School Students — United States, 2011–2016. *MMWR Morb Mortal Wkly Rep* 2017;66:597–603. DOI: <http://dx.doi.org/10.15585/mmwr.mm6623a1>.

³⁶ Wang TW, et al. Tobacco Product Use Among Middle and High School Students – United States 2011–2017. *CDC Morbidity and Mortality Weekly Report*. Vol 67, No. 22. June 8, 2018.

³⁷ Willett JG, et al. Recognition, Use and Perceptions of JUUL Among Youth and Young Adults. *Tobacco Control* Published Online First: 18 April 2018. doi: 10.1136/tobaccocontrol-2018-054273.

³⁸ Ambrose BK, et al. 2015.

³⁹ Tsai J, et al. Reasons for Electronic Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2016. *MMWR Morb Mortal Wkly Rep* 2018;67:196–200. DOI: <http://dx.doi.org/10.15585/mmwr.mm6706a5>.

⁴⁰ Ambrose BK, et al. 2015.

⁴¹ See <http://www.monitoringthefuture.org/pubs/monographs/mtf-overview2016.pdf>.

⁴² Willett JG, et al. 2018.

Research conducted by AHA's Tobacco Regulation and Addiction Center (A-TRAC) reinforces that flavors are one of the most appealing aspects of vaping for teen e-cigarette users.⁴³ Thirty percent of respondents said that e-cigarettes taste better, have a bolder flavor, and less burnt taste than other tobacco products. Forty-two percent said that the ability to try many flavors sets e-cigarettes apart from other tobacco products. And 26% stated that the flavors in advertisements and marketing caught their attention. Interestingly, the survey also found that the majority of teen e-cigarette users prefer no nicotine (39%) or a low level of nicotine (20%) in their product suggesting that youth do not use e-cigarettes for the nicotine. The research also observed a correlation between flavor and ENDS initiation. The odds of youth using ENDS as their first tobacco product was about two times higher among those who selected fruit flavor as their favorite flavor.⁴⁴

These results are very concerning. They indicate that teens are not turning to e-cigarettes because they want to use a tobacco product or want to access nicotine. Instead, they are experimenting with e-cigarettes because they are attracted to the many available flavors. Unfortunately, the flavors lure kids into starting a very addictive and dangerous habit.

E-cigarette flavors also appear to attract adults. The 2013-2014 National Adult Tobacco Survey found that flavored tobacco products are popular with never smokers. Among users of non-cigarette tobacco products, adults who have never smoked combustible cigarettes had the highest proportion of flavored e-cigarette use (84.8%).⁴⁵ The rate dropped for individuals who recently quit smoking (78.1%) and current cigarette smokers (63.2%).⁴⁶ The National Health Interview Survey from 2014-2016 also found a significant increase in the number of adult never smokers who currently use e-cigarettes.⁴⁷

These data show that flavors are attracting new users to e-cigarettes. While this problem is most pronounced with children and adolescents, it is also concerning that adult never smokers are using e-cigarettes. As we stated above, we believe this warrants a flavor ban.

Question 4: The role of flavors in noncombusted tobacco products on initiation of tobacco product use or progression to use of other tobacco products

The evidence shows that flavors not only increase initiation, but also increase the likelihood of prolonged tobacco use. For example, the PATH Study found that youth whose first tobacco product was flavored had a 13% higher prevalence of current tobacco product use compared

⁴³ American Heart Association Teen Vaping Survey. Presentation to FDA, April 5, 2018. Unpublished.

⁴⁴ Groom A, Vu TH, Landry R, Kesh A, Hart J, Walker K, Sears C, Tompkins L, Mattingly D, Robertson RM, Payne T. Correlates of Youth Vaping Flavor Preferences. Poster Presentation at NIH Tobacco Regulatory Science meeting. June 18, 2018.

⁴⁵ Bonhomme, et al. 2016.

⁴⁶ Ibid.

⁴⁷ Bao W, et al. Changes in Electronic Cigarette Use Among Adults in the United States, 2014-2016. *JAMA*. 2018;319(19):2039-2041. doi:10.1001/jama.2018.4658.

<https://jamanetwork.com/journals/jama/article-abstract/2681181>

to youth who tried a non-flavored product. Adults who start with a flavored product have a 32% higher prevalence of current tobacco use.⁴⁸

An examination of e-cigarettes, which are typically flavored, yields similar results. An A-TRAC survey of teen e-cigarette users found that vapers tend to be dual or poly users of tobacco products; however, e-cigarettes were the first product tried by nearly half of them.⁴⁹ This indicates that many young e-cigarettes users – who overwhelmingly use flavored products – progress to other tobacco products. This conclusion is supported by a number of studies,^{50, 51, 52, 53, 54} as well as the National Academies of Sciences, Engineering, and Medicine’s (NASEM) recent report on the Public Health Consequences of E-Cigarettes.⁵⁵ The NASEM report found that there is *substantial evidence* that e-cigarette use increases the risk of ever using combustible cigarettes among youth and young adults. These findings mirror the 2016 Surgeon General’s Report: E-Cigarette Use Among Youth and Young Adults, which stated that “E-cigarette use is strongly associated with the use of other tobacco products among youth and young adults, including combustible tobacco products.”⁵⁶

Collectively, this research shows that eliminating characterizing flavors would help break the cycle of progressive tobacco use. Without flavors, teens and young adults would be less likely to initiate tobacco use. If we can prevent youth from trying e-cigarettes or other noncombusted products, we may be able to stop the cycle before it starts.

Flavors and Cessation, Dual Use, and Relapse Among Current and Former Tobacco Product Users

Question 5: The role of flavors in helping adult cigarette smokers reduce cigarette use and/or switch to potentially less harmful products

AHA is not aware of any studies that specifically examine the role that flavors may play in helping smokers reduce cigarette use or switch to other tobacco products. While there are

⁴⁸ Villanti AC, et al. 2017.

⁴⁹ American Heart Association Teen Vaping Survey. Presentation to FDA, April 5, 2018. Unpublished.

⁵⁰ Primack BA, Soneji S, et al. Progression to traditional cigarette smoking after electronic cigarette use among US adolescents and young adults. *JAMA Pediatrics*. 2015 Nov;169(11):1018-23.

⁵¹ Chaffee BW, et al. Trends in characteristics and multi-product use among adolescents who use electronic cigarettes, United States 2011-2015. *PLOS ONE*. 2017; 12(5).

⁵² Hammond D, et al. Electronic cigarette use and smoking initiation among youth: a longitudinal cohort study. *CMAJ*. 2017;189:E1328-36.

⁵³ Soneji S, et al. Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis. *JAMA Pediatr*. 2017;171(8):788–797.

⁵⁴ Watkins SL, et al. Association of Noncigarette Tobacco Product Use With Future Cigarette Smoking Among Youth in the Population Assessment of Tobacco and Health (PATH) Study, 2013-2015. *JAMA Pediatr*. 2018.

⁵⁵ National Academies of Sciences, Engineering, and Medicine. 2018. *Public health consequences of e-cigarettes*. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24952>.

⁵⁶ Department of Health & Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General, 2016.

studies that explore how e-cigarette users *feel about flavors*, those studies are not focused on flavors' role in reducing cigarette use or switching to other products. Likewise, there are studies that examine whether *e-cigarettes* have an impact on cessation or switching, but that research is not specific to *flavor's* role. Instead, reports that flavors help smokers switch to e-cigarettes or other potentially less harmful products appear to be based on anecdotes, which should not be the basis for FDA policy.

In addition, we do not see a role for flavors when the FDA has other, more effective means to encourage combustible cigarette smokers to quit or switch to less harmful products. If the Agency moves forward with its proposal to lower the nicotine content in cigarettes to non-addictive or minimally-addictive levels, current smokers will have a greater incentive to stop using combustible products. Smokers who are unable or unwilling to quit – and who want to maintain a certain level of nicotine – will have to switch to another tobacco product. We believe that smokers will make this switch in order to satisfy their nicotine addiction even if the FDA bans all flavored tobacco products.

Question 6: The role of flavors in noncombusted tobacco products on the likelihood of: (1) cessation of combusted tobacco products use, (2) cessation of all tobacco product use, and (3) uptake of dual use of combusted and noncombusted tobacco products among current and former tobacco product users

As noted above, we are not aware of any research that specifically examines the role of *flavors* in cessation, switching, or dual use. While the Federal Register notice contains two references to a focus group and an online survey, we note that the focus group was very small in size (11 e-cigarette users) and it was not centered on the role of flavors, but rather, whether *e-cigarettes* help participants quit combustible cigarettes and how they compare to nicotine replacement therapy (NRT). Additionally, the Agency has previously criticized the online survey⁵⁷ and several of its organizers appear to be associated with an institution that has accepted funding from e-cigarette companies for some of its studies.⁵⁸ Again, it would be inappropriate for the FDA to establish policy based on this limited, and potentially conflicted, information.

Additional Public Health Considerations

Question 9: The potential toxicity or adverse health effects to the user or others from any flavors in tobacco products

AHA is pleased that the FDA has asked this critical question. Thousands of flavors have been introduced to the market without undergoing FDA review, and it is unknown if these flavors

⁵⁷ Final Deeming Rule Redline Changes. Docket No. FDA-2014-N-0189-83193
<https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>.

⁵⁸ See <http://e-cigarette-summit.conference-websites.co.uk/speaker/dr-konstantinos-farsalinos-m-d/>.
“For some of the studies, the institution has received funding from e-cigarette companies. None of the researchers received any compensation for participating to the studies.”

have been tested for toxicity and teratogenicity and are safe for use in tobacco products. Recent evidence suggests that they are not.

Numerous toxins have been identified in the additives used to flavor some tobacco products. The type of toxin and the amount vary by flavor. A brief summary of results from a selection of studies follows:

- The addition of commonly added sugars (sucrose, glucose, and fructose) to burley tobacco lead to an increase in toxicants in tobacco smoke, including aldehydes acetaldehyde, acrolein, crotonaldehyde, propionaldehyde, and butanal.⁵⁹
- A review of unheated e-cigarette liquids identified the presence of sugars and related aldehydes. The level of glucose, fructose, and sucrose exceeded the limits of quantification in 22%, 53%, and 53% of the samples, respectively, as did the amount of formaldehyde, acetaldehyde, and acrolein in 72%, 84%, and 75% of the samples. Significant correlations were found between the amounts of formaldehyde and fructose and sucrose and acrolein and fructose and sucrose.⁶⁰
- 49 flavors of e-cigarettes were analyzed to determine the amount of free radicals produced. Approximately 43% of the flavors produced significantly higher levels of free radicals, including flavor additives that are used to produce citrus and floral flavors (dipentene, citral, linalool). While an additive for vanilla flavor (ethyl vanillin) decreased the production of free radicals.⁶¹
- Various flavors and brands of e-cigarette refills and do-it-yourself products were screened in both liquid and aerosol form for cytotoxicity. The study concluded that e-cigarette aerosols can produce cytotoxic effects in cultured cells; four patterns of cytotoxicity were found when comparing refill fluids and their corresponding aerosols; fluids accurately predicted aerosol cytotoxicity; stem cells were often more sensitive to aerosols that differentiated cells; and 91% of the aerosols made from fluids only containing glycerin were cytotoxic.⁶²
- The vapor from 24 e-cigarette flavors was analyzed for the presence of aldehydes and the presence of flavoring chemicals. Every sample contained at least one aldehyde and/or flavoring chemical on FEMA's High Priority Chemicals or FDA's Harmful and

⁵⁹ Cheah, et al. Effect of Adding Sugar to Burley Tobacco on the Emission of Aldehydes in Mainstream Tobacco Smoke. *Tobacco Regulatory Science*. 2018; 4(2): 61-72.

⁶⁰ Fagan, et al. Sugar and Aldehyde Content in Flavored Electronic Cigarette Liquids. *Nicotine & Tobacco Research*. 2017.

⁶¹ Zachary T, et al. Effect of Flavoring Chemicals on Free Radical Formation in Electronic Cigarette Aerosols. *Free Radical and Biology Medicine*. Volume 120, May 20, 2018, 72-79.

⁶² Behar, Rachel Z, et al. Comparing the cytotoxicity of electronic cigarette fluids, aerosols and solvents. *BMJ Tobacco Control*. June 2017; 0:1-9.

Potentially Harmful Constituents lists. More than 60% of the samples contained diacetyl, a known respiratory hazard linked to popcorn lung.⁶³

- The vapor from 51 types of flavored e-cigarettes deemed appealing to youth were analyzed for total mass of diacetyl, 2,3-pentanedione, and acetoin. At least one flavoring chemical was found in 47 of the flavors tested. 75% of the flavors contained diacetyl and 39 of the flavors contained diacetyl in amounts that exceeded the laboratory limit of detection. 46 of the flavors contained acetoin and 23 samples contained 2,3-pentanedione.⁶⁴
- The flavor chemicals in 30 e-cigarette fluids were identified and measured. Many of the samples contained 1-4% of total flavor chemicals. A significant number of the chemicals were aldehydes, which are recognized as “primary irritants” of the respiratory tract. The concentrations of some flavor chemicals “are sufficiently high for inhalation exposure by vaping to be of toxicological concern.”⁶⁵
- Human bronchial epithelial cells were exposed to cinnamon e-liquid and e-liquid aerosol. Both the e-liquid and aerosol rapidly suppressed cilia beat frequency. The effect lasted for approximately 60 minutes. Impaired cilia mobility can lead to diminished mucociliary clearance and lung damage.⁶⁶
- Saliva and urine samples collected from e-cigarette-only and e-cigarette-dual users 13-18 years of age were analyzed for eight volatile organic chemical compounds. The study found that e-cigarettes contain many of the same toxins as combustible cigarettes. In addition, among e-cigarette-only participants, the use of fruit flavored e-cigarettes produced significantly higher levels of the metabolites of acrylonitrile compared to users of other flavored e-cigarettes.⁶⁷
- Human cells were exposed to 148 e-liquid flavors and the cells’ growth rate was measured; reduced cell growth rates indicated higher toxicity. The study found that even e-liquids containing propylene glycol and vegetable glycerin, but without flavors, significantly reduced the growth of human cells, indicating toxicity. However,

⁶³ Klager, Skyler, et al. Flavoring Chemicals and Aldehydes in E-Cigarette Emissions. *Environmental Science and Technology*. 2017; 51(18): 10806-10813.

⁶⁴ Allen, Joseph 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*. Jun 2016; 124(6): 733-739.

⁶⁵ Tierney, Peyton A., et al. Flavour chemicals in electronic cigarette fluids. *BMJ Tobacco Control*. 2015; 0: 1-6.

⁶⁶ Clapp P, et al. The E-Cigarette Flavoring Cinnamaldehyde Suppresses Mitochondrial Function and Transiently Impairs Cilia Beat Frequency in Human Bronchial Epithelial Cells. *American Journal of Respiratory and Critical Care Medicine* 2018;197:A7626.

⁶⁷ Rubinstein M, et al. Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes. *Pediatrics*. April 2018, 141:4.

in general, the more ingredients the e-liquid contained, the higher the toxicity. The toxicity results remained the same when cells were exposed to e-liquid vapor.⁶⁸

- Human endothelial cells, which line the blood vessels and inside of the heart, were exposed to nine tobacco flavorings: menthol (mint), acetylpyridine (burnt flavor), vanillin (vanilla), cinnamaldehyde (cinnamon), eugenol (clove), diacetyl (butter), dimethylpyrazine (strawberry), isoamyl acetate (banana) and eucalyptol (spicy cooling). Researchers found all nine were dangerous to cells at the highest levels tested and all the flavorings impaired nitric oxide production in endothelial cells in culture. Several of the flavorings – menthol, clove, vanilla, cinnamon and burnt flavoring – were linked to higher levels of an inflammatory marker and lower levels of nitric oxide, a molecule that inhibits inflammation and clotting, and regulates vessels' ability to widen in response to greater blood flow. Increased inflammation and loss of nitric oxide can be early warning signs of future heart disease.⁶⁹

Question 11: Consumer perceptions of the health risks of tobacco products with flavors compared to other tobacco products, both with and without flavors

Two recent systematic reviews concluded that people have positive perceptions about flavored tobacco products. The first review, which included 40 studies published between 2010 and 2016, found that tobacco products with flavor descriptors were perceived to be better tasting, more appealing, and less harmful, and that younger respondents were more likely to believe flavored products were less harmful.⁷⁰ A second review, which examined 20 studies, found similar results. Participants, especially youth and young adults, reported positive perceptions about flavored tobacco. Flavors were cited as a reason for experimentation and/or initiation of flavored tobacco use, and flavored tobacco was viewed as less harmful than cigarettes.⁷¹

While neither of these reviews included menthol, a national Truth Initiative study found that respondents also have positive perceptions about menthol flavoring. According to the survey, 41% incorrectly believe that there are health benefits associated with menthol, compared with non-menthol cigarettes; and 61% believe that menthol makes it easier to quit smoking.⁷²

⁶⁸ Sassano MF, et al. Evaluation of E-liquid Toxicity Using an Open-Source High-Throughput Screening Assay. *PLoS Biol* 16(3):e2003904.

⁶⁹ Fetterman JL, et al. Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction. *Arteriosclerosis, Thrombosis, and Vascular Biology*. 2018;ATVBAHA.118.311156, originally published June 14, 2018. <https://doi.org/10.1161/ATVBAHA.118.311156>.

⁷⁰ Huang, L.-L., et al. Impact of Non-menthol Flavours in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review. *Tobacco Control*, 26(6):709-719, 2017.

⁷¹ Kowitt, S.D., et al. Perceptions and Experiences with Flavored Non-Menthol Tobacco Products: A Systematic Review of Qualitative Studies. *International Journal of Environmental Research and Public Health*, 14(4):338, 2017.

⁷² Truth Initiative. Menthol Cigarettes: Attitudes, Beliefs, and Policies. See <https://truthinitiative.org/research/menthol-cigarettes-attitudes-beliefs-and-policies>.

These results are very concerning because youth and young adults are more likely to use flavored tobacco if they perceive them as having a lower health risk.

Question 12: Consumer perceptions, if any, of the addictiveness of tobacco products with flavors

AHA is not aware of research that specifically examines the perceptions of addictiveness of flavored tobacco. However, as noted in our response to question three, many young e-cigarette users are unaware that ENDS, including JUUL, contain nicotine. Both the 2016 Monitoring the Future study and a Truth Initiative study found that the majority of e-cigarette or JUUL users believed they were vaping a flavor but were not aware that it contained nicotine. In addition, A-TRAC found that fewer adolescents (83%) believe addiction is a health risk associated with ENDS when compared to combustible tobacco use (92%).⁷³

This indicates that there are some misperceptions about the risk of addiction associated with ENDS use in general – regardless of whether it is flavored – particularly among youth.

Tobacco Product Standards

Question 13a: All flavors: Are there any specific flavors for which FDA should establish a tobacco product standard?

AHA encourages the FDA to establish a tobacco product standard that bans the use of all characterizing flavors, including menthol. A blanket flavoring ban is needed because a wide array of flavors appeal to youth and young adults, which increases the risk of initiation and continued tobacco use. Also, many of the flavorings, including some of the most popular, contain known toxins. We believe this would make it extremely difficult for the FDA to identify specific flavors to ban.

In addition, youth and adult tobacco users indicate that they prefer some of the same flavors. For example, a recent A-TRAC survey of teens found that fruit (30%) was the most popular flavor of ENDS. That was followed by menthol (10%), candy (8%), sweet (6%), chocolate (6%), and tobacco (6%).⁷⁴ Adult e-cigarette users exhibit similar preferences with fruit (44.9%), menthol (43.9%), and candy/chocolate/other sweet (25.7%) also reported as the top three most frequently used flavors, followed by clove/spice/herb (7%), other flavored (6.1%), and alcohol (4%).⁷⁵ It is unclear how the FDA could *both* ban flavors shown to appeal to children and allow flavors that appeal to adults, when some of those flavors – like fruit, menthol, and candy/sweet – are popular with both age groups.

⁷³ American Heart Association Teen Vaping Survey. Presentation to FDA, April 5, 2018. Unpublished.

⁷⁴ Groom A, et al. Poster Presentation at NIH Tobacco Regulatory Science meeting, June 18, 2018.

⁷⁵ Bonhomme, et al. 2016.

We also caution the FDA from simply banning the use of flavors with catchy names or child-appelling imagery like Sour Gummy Worms, Cupcake Kisses, or Hello Kitty. While tobacco products should not use names or imagery that are clearly geared toward a young audience, we do not believe that banning the use of such names will be sufficient. Teen use of JUUL in flavors, such as mango, cool mint, fruit medley, cool cucumber, crème brulee, and classic menthol indicate that flavors with more traditional sounding names are still highly popular with youth. Accordingly, a ban should cover all characterizing flavors, regardless of the flavor's name.

The only circumstance in which a characterizing flavor should be allowed is if the product manufacturer demonstrates to the FDA, and the Agency issues an order, finding that a specific flavor: 1) will help smokers quit tobacco products altogether or switch completely to a less risky noncombusted product, 2) that the flavor does not attract youth or lead to increased initiation, and 3) that the flavor is safe and has been tested for toxicity and teratogenicity.

Question 14: If FDA were to establish a tobacco product standard prohibiting or restricting flavors, to which types of tobacco products should the standard apply?

The FDA should establish a product standard that prohibits flavors in all types of tobacco products. We recommend a ban on all products for several reasons. First, as the FDA has acknowledged, the number of flavored tobacco products on the market increased substantially after flavored cigarettes were banned. After the 2009 ban took effect, the tobacco industry started producing different types of flavored tobacco products that were not subject to the prohibition. This led to the rise in flavored “little cigars” or “cigarillos” that mimic cigarettes but are not subject to the flavoring ban. At the same time, we saw an increase in the number of youth using flavored cigars and e-cigarettes. Both the tobacco industry and youth adjusted to the cigarette ban by moving to other tobacco products where flavors were still allowed. If the FDA were to extend the flavoring ban, but limit it to certain types of products, we are likely to see the same thing happen again.

Second, there is no need to allow flavors in combustible products. Flavors in combusted products attract youth and subject smokers to toxic chemicals. If the FDA wants to move people away from cigarettes and other combustible products, there is no benefit to allowing flavored combusted products to remain on the market. It is also our understanding that the Agency has already recognized the need to ban flavors from cigars; the FDA announced in 2016 that it would issue a product standard to eliminate flavored cigars.

Third, the availability of flavors is one of the main reasons youth and young adults use e-cigarettes and other noncombustible products. If the FDA wants to decrease youth tobacco use, removing flavors from noncombusted products is key. In addition, current smokers will be motivated to move to noncombusted products – even if they are unflavored – when the nicotine content in cigarettes is reduced.

Finally, as noted above, the only possible exemption to a flavor ban should be for e-cigarettes that have been proven to: 1) help smokers quit tobacco altogether or switch completely, 2) do not attract youth or increase initiation, and 3) are safe, non-toxic and non-teratogenic.

Question 15a: Menthol Flavor: The role of menthol in cigarettes, particularly regarding the role menthol plays in smoking initiation and in the likelihood of smoking cessation

The FDA has ample evidence to support a ban of menthol cigarettes. In 2011, the FDA Tobacco Products Scientific Advisory Committee (TPSAC) released the results of its year-long examination of menthol. And in 2013, the FDA's own scientists released the results of a separate "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes." Both the TPSAC report and the FDA evaluation concluded that banning menthol would benefit public health.

Since that time, additional studies have only added to the evidence base in support of a menthol ban. These studies show that menthol cigarettes increase initiation, especially among youth. Menthol cools and numbs the throat and reduces the harshness of cigarette smoke, making it a "starter product" for initiating tobacco use. Young menthol users report that menthol is easier to smoke and tastes and smells better than non-menthol versions; and menthol is perceived as "delivering more satisfaction with fewer cigarettes, being accessible as 'loosies', and being popular among their peers."⁷⁶ Menthol's popularity among this age group is clear: more than half of all youth smokers (54%) choose menthol. That number declines for older smokers to 32%.⁷⁷

Menthol is also associated with an increased progression to regular tobacco use and nicotine dependence, and a decreased likelihood that smokers can successfully quit:

- A 2013 cohort study using data from 83 middle and high schools found that initiating smoking with menthol was associated with greater odds of progressing to established smoking and higher dependence.⁷⁸
- A survey of 909 young adult smokers examining smoking behavior changes over the course of a year found that "menthol cigarette use nearly double[s] the odds of increased smoking behavior."⁷⁹

⁷⁶ Wackowski OA, et al. In Their Own Words: Young Adults' Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives. Nicotine & Tobacco Research. 2017.

⁷⁷ Villanti, AC, et al. 2016.

⁷⁸ Nonnemaker J, et al. Initiation with Menthol Cigarettes and Youth Smoking Updates. Addiction, 2013; 108(1):171-178.

⁷⁹ Delnevo C, et al. The Influence of Menthol, E-cigarettes, and Other Tobacco Products on Young Adults' Self-Reported Changes in Past Year Smoking." Tobacco Control. 2015;25(5).

- A systematic review of peer-reviewed literature identified one longitudinal and eight cross-sectional studies showing that “menthol smokers report increased nicotine dependence compared to non-menthol smokers”.⁸⁰
- A study examining the differences in dependency among menthol and non-menthol daily smokers aged 18-35, found that menthol smokers were more likely to have difficulty refraining from smoking in areas where it is prohibited. And, menthol smokers with higher levels of dependence were more likely to have tried to quit within the past 12 months but were less likely to have tried more than once.⁸¹

And as noted above, menthol also has a disproportionate impact on minorities, especially African Americans. Surveys show that menthol use is particularly high among African Americans, and that it more difficult for African Americans – even when highly motivated – to successfully quit.⁸² This may be the result of menthol’s pharmacological and physiological effects and their interaction with biological and genetic factors.⁸³

Finally, as the FDA acknowledged in the Federal Register notice, allowing menthol cigarettes to remain on the market has likely diminished the effect of the cigarette flavor ban. While overall cigarette consumption among youth decreased after the ban took effect in 2009, the number of menthol smokers increased, as smokers switched to the remaining available flavored product.^{84,85} It is time to correct this error. The evidence strongly supports a menthol ban.

Question 15b: Likelihood that smokers would completely switch to another tobacco product, or start dual use with another product, in the event of a tobacco product standard prohibiting or limiting menthol in cigarettes

This question considers how smokers would react to a menthol ban and provides two options: 1) switching to another tobacco product or 2) starting dual use. We question why the FDA is not considering a third option: how many smokers would quit tobacco altogether. Some studies indicate that menthol smokers would quit or try to quit rather than switch to a non-menthol version. For example, data from the 2011 National Young Adult Health Survey was examined to determine smoker status and behavioral intentions in the event of

⁸⁰ Villanti AC, et al. Menthol Cigarettes and the Public Health Standard: A Systematic Review. BMC Public Health. 2017; 17:983.

⁸¹ Fagan P, et al. Comparisons of Three Nicotine Dependence Scales in a Multiethnic Sample of Young Adult Menthol and Non-Menthol Smokers. Drug and Alcohol Dependence. April 2015; 149:203-211.

⁸² Keeler C, et al. The Association of Menthol Cigarette Use with Quit Attempts, Successful Cessation, and Intention to Quit Across Racial/Ethnic Groups in the United States. Nicotine & Tobacco Research. 2017; 19(12): 1450-1464.

⁸³ Alexander LA, et al. Why We Must Continue to Investigate Menthol’s Role in the African American Smoking Paradox. Nicotine & Tobacco Research. April 2016; 18(suppl 1): S91-S101.

⁸⁴ Courtemanche CJ, et al. Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use. American Journal of Preventive Medicine. 2017; 52(5);e-139-e146.

⁸⁵ Delnevo, CD, Trends in Menthol and Non-Menthol Cigarette Consumption in the USA: 2000-2011. Tobacco Control. 2014: 23(e2).

a menthol cigarette ban. Among current menthol smokers, a majority, “65.7% indicated they would quit tobacco use altogether if menthol cigarettes were no longer sold, while 18.4% said they would switch to non-menthol cigarettes, and 16% said they would switch to some other tobacco product.”⁸⁶ In addition, only one month after Ontario, Canada banned menthol cigarettes in January 2017, a small study found that 29.1% had already attempted to quit.⁸⁷ These data add to the evidence base in support of a menthol ban.

Question 15c: What is the role, if any, that menthol plays in use of tobacco products other than cigarettes, but not limited to, cigars and ENDS?

As noted in question two, menthol is a popular flavor in a number of tobacco products, not just cigarettes. A survey of sales data from convenience stores and other outlets found that in 2015, menthol products accounted for a significant portion of tobacco sales: 32.5% of cigarettes, 19.4% of little cigars, 57% of moist snuff, and 88.5% of snus.⁸⁸ According to the survey, sales of menthol versions of these products, along with chewing tobacco, increased between 2011 (the start date of the data collection) and 2015. Menthol is also a popular flavor among e-cigarette users. Almost 45% of adult e-cigarette users report using menthol/mint e-cigarettes.⁸⁹ Menthol was also identified as the second most popular e-cigarette flavor (10%) in A-TRAC’s survey of 1,549 teen e-cigarette users.⁹⁰

It is likely that menthol is popular in these tobacco products for the same reason it is in combustible cigarettes: menthol makes tobacco taste better and easier to use.

Sale or Distribution Restrictions

Question 16: What restrictions should FDA consider placing on the sale and distribution of flavored tobacco products, such as advertising and promotion of tobacco products with flavors; access to tobacco products with flavors; and/or on the label, labeling, and/or packaging of tobacco products with flavors?

We do not believe that sale and distribution restrictions alone are sufficient to keep youth from obtaining and using flavored tobacco products. Federal law already prohibits the sale of tobacco products to anyone under the age of 18, and several cities and states have raised the age limit to 21. Yet, children and adolescents who do not meet the age requirement still obtain and use tobacco. Youth evade the age restriction by purchasing from retail outlets and online retailers who do not require age identification.⁹¹ Retailer compliance with ID

⁸⁶ Wackowski OA, et al. Young Adults Behavioral Intentions Surrounding a Potential Menthol Cigarette Ban. *Nicotine Tob Res.* 2014 Jun;16(6):876-80. doi: 10.1093/ntr/ntu003. Epub 2014 Feb 10.

⁸⁷ Chaiton M, et al. Association of Ontario’s Ban on Menthol Cigarettes with Smoking Behavior 1 Month After Implementation. *JAMA Internal Medicine.* March 5, 2018.

⁸⁸ Kuiper N, et al. 2015.

⁸⁹ Bonhomme, et al. 2016.

⁹⁰ Groom A, et al. Poster Presentation at NIH Tobacco Regulatory Science meeting. June 18, 2018.

⁹¹ Williams RT, et al. Electronic Cigarette Sales to Minors Via the Internet. *JAMA Pediatrics.* 169(3):e1563. 2015.

checks in New York City, for example, was only 62% according to one recent study.⁹² While a Truth Initiative survey of 12-17 year olds who used JUUL in the past 30 days, found that 74% had obtained the product at a physical retail store despite being underage.⁹³ Other sources of JUUL for teens in the Truth Initiative Survey were social sources such as friends or family (52%) and online (6%). While the number of online purchasers was relatively low, 89% of those who attempted an online purchase succeeded, even though they were underage.

Youth are also drawn to flavored tobacco products because of the way they are advertised and marketed. Flavored products are heavily advertised in the mass media and on social media. Studies have shown that e-cigarette advertisements not only target adult smokers, they also reach significant numbers of youth. One study found that awareness of e-cigarette advertisements among youth and young adults is very high, “ranging from 89% for those ages 13-17 to 94% for young adults ages 18-21.”⁹⁴ Another study found youth exposure to e-cigarette advertisements on television increased 256% from 2011 to 2013 – reaching over 24 million youth – while young adult exposure increased 321% during the same time period.⁹⁵

Manufacturers are also using some of the same advertising techniques we saw the tobacco industry use to market cigarettes. Many advertisements include catchy names, cartoon characters or other child-appealing imagery, celebrity spokespeople, and sexual themes, or depict users as extremely masculine, glamorous, or rebellious. In addition, flavored tobacco products are often sold in brightly-colored packages alongside candy and toys; and as noted previously, some are marketed in ways that mimic well-known and kid-friendly candy and food products.

To combat these problems, we’d like to see the FDA and state officials increase enforcement of the age verification requirement and restrict online sales because of the difficulty enforcing age verification standards for non-face-to-face sales. The Agency should also place restrictions on how flavored products are marketed, to whom it is marketed, and how it is sold. However, we must reiterate that these actions alone are not sufficient. A flavor ban is the most effective way to address flavored tobacco’s impact on youth initiation and continued tobacco use.

⁹² Macinko SD, et al. Retailer Compliance with Tobacco Control Laws in New York City Before and After Raising the Minimum Purchase Age to 21. *Tobacco Control*. 2016; 25(6):624-627.

⁹³ Truth Initiative. Where Are Kids Getting JUUL? May 31, 2018. https://truthinitiative.org/news/where-are-kids-getting-juul?utm_source=Truth+Initiative+Mailing+List&utm_campaign=ccbf4c4db2-Newsletter_103_2018_05_31_06_15&utm_medium=email&utm_term=0_c91fd8a5c5-ccbf4c4db2-82380593.

⁹⁴ Truth Initiative. Vaporized: Youth and Young Adult Exposure to E-Cigarette Marketing. November 2015. <https://truthinitiative.org/sites/default/files/Vaporized-Youth-Exposure-To-E-Cigarette-Marketing.pdf>.

⁹⁵ Duke JC, et al. Exposure to Electronic Cigarettes Television Advertisements Among Youth and Young Adults. *Pediatrics*. Volume 134, Number 1, July 2014. Doi:10.1542/peds.2014-0269.

Question 17: To the extent that flavors may pose (1) potential benefits to adult smokers who might consider switching to a noncombusted flavor 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 products with higher individual risks, how should FDA assess and balance these benefits and risks?

We support the Agency's goal of helping smokers quit using tobacco altogether, or if they are unable or unwilling, to switch to a lower risk noncombusted product. And, we understand that some tobacco users may prefer a flavored noncombusted product. However, as discussed in question five, we believe there are other, more effective means to encourage smokers to quit or switch. Lowering the nicotine in combusted cigarettes to non- or minimally-addictive levels will provide a greater incentive to individuals who need to satisfy their nicotine addiction than the availability of a flavored product.

In addition, there is strong evidence that flavorings increase the appeal of tobacco products to youth and promote youth initiation. Given that the vast majority of smokers begin before the age of 18, it is critical that we keep kids from starting this dangerous habit. That should be the FDA's primary goal when considering this question: How do we keep children and adolescents from initiating tobacco use? To do that, the FDA must put youth first and ban characterizing flavors in all tobacco products.

Thank you for consideration of our comments. We look forward to continuing to work with you to combat the significant public health threat posed by tobacco.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Senior Regulatory Affairs Advisor, at 202-785-7908 or susan.k.bishop@heart.org.

Sincerely,

A handwritten signature in black ink that reads "Nancy A. Brown". The signature is written in a cursive, flowing style.

Nancy A. Brown
Chief Executive Officer
American Heart Association