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Dockets Management Staff [HFA-305]
 Food and Drug Administration
 5630 Fishers Lane, Room 1061
 Rockville, MD 20852

Re: Regulation of Flavors in Tobacco Products, Advance notice of proposed rulemaking, Docket No. FDA-2017-N- 6565

The undersigned organizations submit these comments in the above-designated docket regarding the regulation by FDA of flavored tobacco products.

INTRODUCTION

When Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA), it prohibited the use of characterizing flavors, other than menthol, in cigarettes because Congress concluded that flavors in cigarettes made the products appealing to adolescents. The TCA also directed FDA to consider the need for a prohibition on menthol as a characterizing flavor in cigarettes as well. The TCA’s elimination of flavors in cigarettes contributed to the reduction in youth usage of cigarettes.¹ However, the same kid-friendly flavors that had been prohibited in cigarettes—plus thousands more—have proliferated in other combusted and non-combusted tobacco products, enhancing the popularity of these

¹ Courtemanche, CJ, et al., “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use,” *American Journal of Preventive Medicine*, published online January 9, 2017.

products with kids. The presence of flavors in these other tobacco products is an important reason why, despite the steep decline in youth cigarette smoking, youth usage of tobacco products overall has not declined. Until the issuance of the deeming rule, these products were not subject to FDA jurisdiction, but now that FDA has asserted jurisdiction over all of them, the question of flavors in these products—and their effect on youth initiation—has become critically important.

In order to protect kids from these products, FDA should publish a proposed, and then final, rule prohibiting characterizing flavors in all combusted and smokeless tobacco products as soon as possible. That rule should also prohibit characterizing flavors in e-cigarettes unless the manufacturer demonstrates, for a specific flavor in a specific product, that the presence of the flavor helps smokers quit tobacco products entirely or at least switch completely to an e-cigarette, that the flavoring does not attract kids, and that the flavor is not toxic, carcinogenic or teratogenic.

It is also time for FDA to prohibit the use of menthol as a characterizing flavor in cigarettes. Despite a finding by the Tobacco Products Scientific Advisory Committee (TPSAC) that prohibiting menthol in cigarettes would benefit the public health, and despite an exhaustive independent study by FDA itself concluding that menthol as a characterizing flavor in cigarettes was contributing to youth smoking initiation and addiction and suppressing cessation, FDA has taken no action on menthol as a characterizing flavor in cigarettes. During these years, despite the reduction in non-menthol cigarette usage, sales of menthol cigarettes have remained robust and menthol cigarettes have continued to facilitate initiation of cigarette smoking by kids and retard cessation in adults, particularly in the African-American community.

The materials cited in FDA’s Advance Notice of Proposed Rulemaking (ANPRM)² provide an ample basis for these actions. The ANPRM recognizes that these flavored products, which have proliferated in recent years, play a critical role in attracting new tobacco users and increase the likelihood of long-term addiction.³ According to the 2012 Surgeon General Report, “Much of the growing popularity of small cigars and smokeless tobacco is among younger adult consumers (aged <30 years) and appears to be linked to the marketing of flavored tobacco products that, like cigarettes, might be expected to be attractive to youth.”⁴ Similarly, the 2016 Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons why youth and young adults use e-cigarettes.⁵

The widespread availability of flavored non-cigarette tobacco products and use of these products among youth presents a public health risk. Flavors increase the attractiveness of tobacco

² 83 Fed. Reg. 12294 (March 21, 2018).

³ ANPRM at 12295-96

⁴ U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012.

⁵ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*, 2016.

products to young people and are being introduced into the marketplace with no regard for their impact on youth. The young people who are lured to use tobacco products because of these flavors thus expose themselves to the risk of a lifetime of addiction.

The presence of flavors in e-cigarette products presents a more complex issue because some have argued that some flavorings might help smokers, who otherwise would not or could not stop smoking, to do so by completely switching to such products. Even if it were actually demonstrated that some flavorings could help individual smokers stop smoking, the net public health impact of such flavors would still depend on whether, and to what extent, the flavors cause non-users, especially young people, to initiate use. While there have been many assertions about the role of flavors in switching or quitting, most such reports are anecdotal and little information comes from well-conducted studies. Flavored e-cigarette products should be permitted only if the manufacturer has first demonstrated that the specific flavoring actually helps smokers quit or switch completely, that the marketing of the product does not cause young people to initiate tobacco use, and that the flavor is safe and non-toxic.

In the version of the deeming rule that it sent to the White House Office of Management and Budget (OMB) for review, FDA itself proposed to place the burden on manufacturers to demonstrate that flavored products benefit the public health. OMB, however, deleted this provision from the final rule. This key change was revealed in a “redline” version of the rule published on May 27, 2016, showing changes made by OMB. The deleted provisions proposed by FDA would have removed flavored e-cigarettes, cigars, hookah and other newly regulated products from the market by November 2016 and required those products to receive pre-market authorization from the FDA before re-entering the marketplace. This provision would also have applied to menthol-flavored products. The deleted portion of the rule provided 17 pages of scientific evidence to support removing flavored products from the market, concluding that these products should be removed “given the attractiveness of flavors, especially to youth and young adults, and the impact flavored tobacco products may have on youth initiation.”⁶ Moreover, when it issued the final deeming rule, FDA stated its intention to issue a proposed rule prohibiting characterizing flavors in cigars.⁷ Thus, the agency repeatedly has recognized the need for action against flavored products.

⁶ Deeming Final Rule Redline Changes in Docket No. FDA-2014-N-0189-83193, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products (May 27, 2016), <https://www.regulations.gov/document?D=FDA-2014-N-0189-83193>.

⁷ 81 Fed. Reg. at 29055.

I. ANPRM Questions 1-3. Non-Cigarette Tobacco Products are Available in Thousands of Flavors that Increase Youth Tobacco Use.

Despite the FDA’s ban on flavored cigarettes, the overall market for flavored tobacco products is growing rapidly. In every category of tobacco products, a substantial majority of youth users initiated with, and are using, flavored products. In recent years, tobacco companies have significantly increased the introduction and marketing of flavored other tobacco products (OTPs), particularly e-cigarettes and cigars, as well as smokeless tobacco and hookah (water pipes). From 2011-2015, sales increased for flavored cigarillos, flavored chewing tobacco and menthol cigarettes—at a time when cigarette sales have been gradually decreasing.⁸ The e-cigarette market also continues to grow, estimated to reach \$5.5 billion in 2018.⁹ Although tobacco companies claim that this proliferation of flavors is in response to adult tobacco users’ demand for variety, flavored tobacco products play a key role in enticing new users, particularly kids, to a lifetime of addiction. Tobacco companies market products in many kid-friendly flavors such as gummy bear, berry blend, chocolate, peach, cotton candy, strawberry and grape. In fact, the *same* flavor chemicals used in sweet-flavored cigars and smokeless tobacco products are also used in popular kid-friendly candy and drink products such as LifeSavers, Jolly Ranchers and Kool-Aid.¹⁰ A 2013 survey of internet tobacco retailers found that more than 40 percent of cigarette-sized cigars, machine-made cigars, moist snuff smokeless tobacco and dry snuff smokeless tobacco were flavored, including fruit, sweet and mint/menthol.¹¹

As FDA has noted, there is a robust research base supporting a stronger preference for sweet products among children, compared to adults. A systematic review of flavor preferences across all consumer products, spanning eight decades, concluded that, “Children have a strong, likely innate, preference for sweet tasting substances such as sugar and artificial sweeteners...Sweet tastes and sweet odours form a powerful sweet flavour mix that can be particularly attractive to children.”¹² The tobacco companies have manipulated this innate preference among young consumers to improve the taste and reduce the harshness of tobacco products, making these products more appealing and easier for beginners – often kids – to try the product and ultimately become addicted.

As FDA noted in the ANPRM (at 12296), internal tobacco industry documents show that tobacco companies have a long history of developing and marketing flavored tobacco products

⁸ Kuiper, NM, et al., “Trends in sales of flavored and menthol tobacco products in the United States during 2011-2015,” *Nicotine & Tobacco Research*, published online June 1, 2017.

⁹ Wells Fargo Securities. *Nielsen: Tobacco ‘All Channel’ Data 3/24*. Equity Research. San Francisco (CA): Wells Fargo Securities, April 3, 2018.

¹⁰ Brown, JE, et al., “Candy Flavorings in Tobacco,” *New England Journal of Medicine*, 370: 2250-2252, 2014.

¹¹ Morris, DS, Fiala, SC, “Flavoured, non-cigarette tobacco for sale in the USA: an inventory analysis of Internet retailers,” *Tobacco Control*, published online August 8, 2013.

¹² Hoffman, AC, et al., “Flavour preferences in youth versus adults: a review,” *Tobacco Control*, published online September 15, 2016.

as “starter” products that attract kids. For example, as early as 1972, advisors to Brown & Williamson reviewed new concepts for a “youth cigarette,” including cola and apple flavors, and a “sweet flavor cigarette,” stating, “It’s a well-known fact that teenagers like sweet products. Honey might be considered.”¹³ A 1974 RJR interoffice memo revealed this idea for new products: “Make a cigarette which is obviously youth oriented. This could involve cigarette name, blend, flavor and marketing technique....for example, a flavor which would be candy-like but give the satisfaction of a cigarette.”¹⁴

A. E-Cigarette Flavors

Sales of e-cigarettes have increased dramatically in recent years. The value of the e-cigarette market in the United States is estimated to have more than doubled from 2014 to 2018, from \$2.5 billion to \$5.5 billion.¹⁵ As of 2017, researchers had identified more than 15,500 unique e-cigarette flavors available online.¹⁶ An earlier study of e-cigarette flavors found that among the more than 400 brands available online in 2014, 84 percent offered fruit flavors and 80 percent offered candy and dessert flavors.¹⁷ In addition to the more traditional candy and fruit flavors like cherry and chocolate, the liquid nicotine solutions are also being sold in such kid-friendly options as cotton candy, gummy bear, root beer float and banana split (See Appendix at Exhibit A1). “Vape shops,” which are specialty e-cigarette retail stores, offer an even wider assortment of flavors. In addition to the pre-made options, these stores allow patrons to mix their own preferred flavor combinations.

One study uncovered over twenty different types of “unicorn-flavored” e-liquid, often paired with cartoon imagery, patently attempting to appeal to kids.¹⁸ Popular candy, cereal, and cookie companies—Wrigley, Ferrara Candy, Tootsie Roll Industries, General Mills, and the Girl Scouts of the USA—have sued or sent cease and desist letters to e-cigarette retailers for infringing their trademarks by selling e-liquids using their brand names and imagery.¹⁹ There is

¹³ Marketing Innovations, “Youth Cigarette - New Concepts,” Memo to Brown & Williamson, September 1972, Bates No. 170042014.

¹⁴ R.J. Reynolds Inter-office Memorandum, May 9, 1974, Bates No. 511244297-4298.

¹⁵ Wells Fargo Securities. *Nielsen: Tobacco ‘All Channel’ Data 3/24*. Equity Research. San Francisco (CA): Wells Fargo Securities, April 3, 2018. See also, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General* at 149.

¹⁶ Zhu, S-H, et al., “Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites,” *Journal of Medical Internet Research*, 20(3), published online March 12, 2018.

¹⁷ Zhu, S-H, et al., “Four Hundred and Sixty Brands of E-cigarettes and Counting: Implications for Product Regulation,” *Tobacco Control*, 23(Suppl 3):iii3-iii9, 2014.

¹⁸ Jackler, RK, and Ramamurthi, D. “Unicorn cartoons: marketing sweet and creamy e-juice to youth,” *Tobacco Control*, published online August 19, 2016.

¹⁹ Wohl, J., “Ferrara Candy sues e-cig seller,” *Chicago Tribune*, July 13, 2015, <http://www.chicagotribune.com/business/ct-fruit-stripe-lawsuit-0714-biz-20150713-story.html>. Channick, R., “Wrigley sues suburban vape firm that sells ‘Dbl Mint’ and ‘Joosy Fruit’ flavors, alleges trademark infringement,” *Chicago Tribune*, July 17, 2017, <http://www.chicagotribune.com/business/ct-wrigley-sues-vape-store-trademark-0718-biz-20170717-story.html>. Felberbaum, M., “Sweets makers work to keep names of e-cigs,” *USA Today*, May 25, 2014, <https://www.usatoday.com/story/money/business/2014/05/25/sweets-makers-work-to-keep-names-off-e-cigarettes/9568671/>.

no doubt whom these e-cigarette retailers are targeting with these flavors. In fact, even the tobacco companies acknowledge that flavored e-cigarettes appeal to youth. Lorillard Inc.’s Youth Smoking Prevention Program posted a page on e-cigarettes on its “Real Parents Real Questions” website that stated: “Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry.”²⁰

The top three cigarette manufacturers now sell e-cigarettes in a variety of flavors other than tobacco. Altria’s MarkTen brand e-cigarettes come in flavors such as Apple Cider, Strawberry Brulee, “Mardi Gras” and “Caribbean Oasis” varieties. Reynolds American’s Vuse product comes in flavors such as Melon, Nectar, Berry, Tropical and Chai, while ITG Brand’s blu e-cigarette features such flavors as Berry Cobbler, Blueberry, Cherry Crush, Strawberry Mint, Mango Apricot and Green Apple. JUUL, an independent company that has rapidly emerged as the market leader among tracked retailers as of late 2017, comes in eight flavors, including Mango, Fruit Medley and Cool Cucumber. Several of these companies have advertised certain flavors as “new” since August 8, 2016, without first seeking the required FDA authorization (See Appendix at Exhibit A2).²¹ Such flavors violate FDA’s Deeming Rule that extended the agency’s regulatory authority to additional tobacco products, including e-cigarettes, and prohibits the introduction of new or changed e-cigarettes after the August 8, 2016 effective date of the Rule without prior FDA review and authorization.

Flavors are not just a critical part of the product design, but are a key marketing ploy for the industry. The 2016 Surgeon General Report on e-cigarettes concluded, “E-cigarettes are marketed by promoting flavors and using a wide variety of media channels and approaches that have been used in the past for marketing conventional tobacco products to youth and young adults.”²² The use of flavors in e-cigarette products is of even greater concern because e-cigarettes are the subject of extensive advertising campaigns, and there is evidence that young people are exposed to significant amounts of e-cigarette advertising. The 2016 National Youth Tobacco Survey found that 78.2 percent of middle and high school students—20.5 million youth—had been exposed to e-cigarette advertisements from at least one source, an increase from 68.9 percent in 2014.²³

²⁰ Real Parents Real Answers, “What you need to know about e-cigarettes – Infographic,” April 23, 2014, accessed November 7, 2014, <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>. See also https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/What%20you%20need%20to%20know%20about%20e-cigarettes%20E2%80%93%20Infographic%20-%20Real%20Parents%20Real%20Answers_may31-2014.pdf.

²¹ See Appendix.

²² *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General.*

²³ Marynak, K., et al., “Exposure to Electronic Cigarette Advertising Among Middle and High School Students—United States, 2014-2016,” *MMWR* 67(10): 294-299, March 16, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6710a3-H.pdf>.

B. Cigar Flavors

Sales of all cigars (i.e., large cigars, cigarillos and small cigars) more than doubled between 2000 and 2017, from 6.1 billion cigars to 13.3 billion cigars, and sales have been generally increasing at a time when cigarette sales have been declining.²⁴ Much of the growth in cigar sales can be attributed to smaller types of cigars, many of them flavored. There has been explosive growth in flavor options for cigars, such as candy, fruit, chocolate and various other kid-attracting tastes. 2015 Nielsen convenience store market scanner data show that sales of flavored cigars increased by nearly 50 percent since 2008. As a proportion of all cigar sales in these stores, the share of flavored cigars rose from 43.6 percent in 2008 to 52.1 percent in 2015. Among flavored cigars sold in these stores in 2015, the most popular flavors were fruit (38.8 percent), sweet or candy (21.2 percent), and wine (17.0 percent). Further, the number of unique cigar flavor names more than doubled from 2008 to 2015, from 108 to 250.²⁵ Including additional store types, Nielsen data showed that flavored cigars made up 43 percent of cigar sales in 2015, an increase from 2011.²⁶ A 2013 survey of licensed tobacco retailers in Washington, D.C. found that 95 percent of stores that sold little cigars and cigarillos sold them in flavors like fruit, candy and wine.²⁷

The top five most popular cigar brands among 12- to 17-year olds who have used cigars – Black & Mild, Swisher Sweets, White Owl, Backwoods, and Dutch Masters – all come in flavor varieties.²⁸ For example, Black & Mild cigars come in flavors such as apple and cherry; Swisher Sweets comes in a huge variety of flavors such as tropical fusion, Maui pineapple, twisted berry, cherry dynamite and banana smash and White Owl has flavors such as mango, tropical twist, strawberry kiwi and peach (See Appendix at Exhibit A3). An industry publication stated, “While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers.”²⁹ These products are also often colorfully packaged and much cheaper than cigarettes; for instance, cigarillos can be priced as low as 3 or 4 for 99 cents, making them even more appealing to price-sensitive youth. They also typically are sold in shiny, colorful packages that reinforce the appeal of fruit and candy flavors that appeal to kids.³⁰ With their

²⁴ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics. December 2000 & December 2017, <https://www.ttb.gov/tobacco/tobacco-stats.shtml>.

²⁵ Delnevo, CD, et al., “Changes in the mass-merchandise cigar market since the Tobacco Control Act,” *Tobacco Regulatory Science*, 3(2 Suppl 1): S8-S16, 2017.

²⁶ Kuiper, NM, et al., “Trends in sales of flavored and menthol tobacco products in the United States during 2011-2015,” *Nicotine & Tobacco Research*, published online June 1, 2017.

²⁷ Cantrell, J, et al., “Marketing Little Cigars and Cigarillos: Advertising, Price and Associations with Neighborhood Demographics,” *American Journal of Public Health* 103(10):1902-9, October 2013.

²⁸ SAMHSA's public online data analysis system (PDAS). National Survey on Drug Use and Health, 2015, https://pdas.samhsa.gov/#/survey/NSDUH-2015-DS0001/crosstab/?row=CGR30BR2&column=CATAG2&weight=ANALWT_C&results_received=true.

²⁹ Niksic, M, “Flavored Smokes: Mmmmm...More Profits?” *Tobacco Retailer*, April 2007.

³⁰ Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar*, at 10, March 13, 2013, https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf.

colorful packaging and sweet flavors, flavored cigar products are often hard to distinguish from the candy displays in retail outlets (See Appendix at Exhibit A4).³¹

C. Flavored Smokeless Tobacco

Between 2005 and 2011, sales of moist snuff, the most popular smokeless tobacco product, increased by more than two-thirds; increases in the sale of *flavored* moist snuff accounted for about 60 percent of this growth.³² In 2015, flavored products made up more than half of all smokeless tobacco sales. Menthol and mint flavors were by far the most popular.³³ U.S. Smokeless Tobacco Company (UST, owned by Altria) increased the number of its sub-brands – including flavored products – by 140 percent from 2000 to 2006 in order to “cast a wide net” and appeal to as many potential users as possible.³⁴ In 2011, more than 80 percent of Skoal smokeless tobacco sold in convenience stores was flavored and more than one out of five (21.1%) were fruit-flavored.³⁵ Current Skoal flavors include kid-friendly peach, citrus, cherry, berry, and apple. Although cigarette smoking among youth in the U.S. has declined rapidly since the Tobacco Control Act went into effect, use of smokeless tobacco among youth has not followed that same trend, and among boys the prevalence of smokeless tobacco use is now slightly higher than that of cigarettes (7.7% vs. 7.6%).³⁶

D. Flavored Hookah (Water Pipe) Tobacco

Hookahs originate from Middle Eastern countries, but their use has rapidly increased in the U.S. The tobacco used in hookah often has flavorings or sweeteners added to enhance the taste and aroma. In the U.S., even more kid-friendly flavors are available, such as watermelon, tropical fruit, orange cream, caramel, chocolate, tutti frutti, vanilla and strawberry.³⁷ The online retailer, www.hookah-shisha.com, lists the most popular flavors from their best-selling brands in 2015, including:³⁸

- Al Fakher: Mint, Two Apples, Blueberry with Mint

³¹ *Not Your Grandfather's Cigar*, at 11.

³² Delnevo, CD, et al., “Examining market trends in the United States smokeless tobacco use: 2005-2011,” *Tobacco Control*, 23: 107-112, 2014.

³³ Kuiper, NM, et al., “Trends in sales of flavored and menthol tobacco products in the United States during 2011-2015,” *Nicotine & Tobacco Research*, published online June 1, 2017.

³⁴ Alpert, HR, et al., “Free nicotine content and strategic marketing of moist snuff tobacco products in the United States: 2000-2006,” *Tobacco Control* 17:332-338, 2008.

³⁵ Delnevo, C, et al., 2014.

³⁶ CDC, “Tobacco Use Among Middle and High School Students—United States, 2011-2017,” *MMWR*, 67(22): 629-633, June 7, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6722a3-H.pdf>. CDC, “Tobacco Use Among Middle and High School Students—United States, 2000-2009,” *MMWR*, 59(33): 1063-1068, <https://www.cdc.gov/mmwr/pdf/wk/mm5933.pdf>.

³⁷ American Lung Association, *An Emerging Deadly Trend: Waterpipe Tobacco Use*, February 2007, http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf.

³⁸ Hookah-Shisha, “Best Hookah Flavors of 2015,” <https://www.hookah-shisha.com/hookahlove/20489-best-hookah-flavors-of-2015.html>.

- Al Fakher Special Edition: Rich Crème, Banana Montana, Hookah Matata
- Fumari: White Gummi Bear, Ambrosia, Spiced Chai
- Haze: What-A-Mint, Cucumberita, Double Bubble

II. ANPRM Questions 2-4: Flavored Tobacco Products in Both Combusted and Non-combusted Tobacco Products Increase Initiation and Tobacco Product Use Among Youth and Young Adults

Research shows that no matter what the tobacco product, flavors appeal to youth and young adults. As summarized in FDA’s ANPRM (at 12296), data from the government’s 2013-2014 Population Assessment of Tobacco and Health (PATH) study found that 80.8 percent of 12-17 year olds who had ever used a tobacco product initiated tobacco use with a flavored product and 79.8 percent of current tobacco users had used a flavored tobacco product in the past month. Moreover, for each tobacco product, at least two-thirds of youth report using these products “because they come in flavors I like.”³⁹

Additional national data from the 2014 NYTS found that 70 percent of current middle and high school tobacco users – a total of over 3.2 million youth (12 percent of all youth) – had used a flavored tobacco product in the past month.⁴⁰ Another national study found that 18.5 percent of young adult (18-34 years old) tobacco users currently use a flavored tobacco product, with younger age being a predictor of flavored tobacco product use. In fact, the study found that those aged 18-24 years old had an 89 percent increased risk of using a flavored tobacco product compared to those aged 25-34 years old.⁴¹ Across all products, use of flavors declines with age, reflecting their primary appeal among youth and young adults who are initiating tobacco use.

Although there has been significant progress in reducing youth cigarette smoking in recent years, overall use of tobacco products remains high, with over 3.6 million middle and high school students reporting current tobacco product use.⁴² The proliferation of flavored tobacco products, particularly e-cigarettes, the continued popularity of cigars, and the continued availability of menthol cigarettes, has hindered progress in reducing overall tobacco product use among youth.

³⁹ Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.

⁴⁰ Corey, CG, et al., “Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014,” *MMWR* 64(38):1066-1070, 2015.

⁴¹ Villanti, AC, et al., “Flavored Tobacco Product Use Among U.S. Young Adults,” *American Journal of Preventive Medicine* 44(4):388-391, 2013.

⁴² CDC, “Tobacco Use Among Middle and High School Students—United States, 2011-2017,” *MMWR*, 67(22): 629-633, June 7, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6722a3-H.pdf>.

A. ANPRM Question 2. The availability of flavored combusted tobacco products increases youth initiation.

1. Flavored Cigars Increase Youth Initiation.

Cigars continue to be popular among youth, and are more popular than cigarettes among high school students, especially among high school boys, with 9.0 percent of high school boys reporting current cigar use in 2017, compared to 7.6 percent for cigarettes.⁴³ In 33 states, prevalence of cigar use equals or surpasses use of cigarettes among high school boys.⁴⁴ Using data from the 1999-2013 Youth Tobacco Surveys, a 2017 study analyzed the impact of the 2009 statutory prohibition of characterizing flavors in cigarettes on youth tobacco use. The researchers found that cigarette use declined significantly after 2009, whereas cigar and pipe tobacco use significantly increased.⁴⁵

Flavors play a key role in the popularity of cigars among youth and young adults. The 2013-2014 PATH study found that 65.4 percent of 12-17 year olds who had ever smoked cigars smoked a flavored cigar the first time they tried the product, and 71.7 percent of current cigar smokers had used a flavored product in the last month. Additionally, 73.8 percent of current youth cigar smokers said they smoked cigars “because they come in flavors I like.”⁴⁶ The 2014 NYTS found that 63.5 percent of middle and high school cigar smokers – a total of 910,000 youth – had smoked a flavored cigar in the past month.⁴⁷

Youth and young adults prefer brands that come in a variety of flavors, and that preference declines significantly with age. In one national study, 95 percent of 12-17-year-old cigar smokers reported a usual brand that makes flavored cigars compared with 63 percent of cigar smokers aged 35 and older.⁴⁸ Data from the 2013-2014 National Adult Tobacco Survey indicate that use of flavored cigars decreases with age. Flavored cigar use among cigar smokers was 48.3 percent among 18-24 year olds, 41.0 percent among 25-29 year olds, 37.1 percent among 30-44 year olds, 28.8 percent among 45-64 year olds and 17.8 percent among those ages 65 and older.⁴⁹

The cigar industry itself acknowledges that flavors attract new users. The vice president of marketing for the international division of Swedish Match, which sells White Owl cigars and

⁴³ CDC, “Tobacco Use Among Middle and High School Students—United States, 2011-2017,” MMWR, 67(22): 629-633, June 7, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6722a3-H.pdf>.

⁴⁴ Data from YRBS, YTS and other state-specific surveys. 33 states include AL, AZ, AR, DE, FL, GA, IL, IN, KS, LA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NM, NY, PA, RI, SC, SD, TN, TX, VT, VA, WI, WY.

⁴⁵ Courtemanche, CJ, et al., “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use,” *American Journal of Preventive Medicine*, published online January 9, 2017.

⁴⁶ Ambrose, BK, et al., 2015.

⁴⁷ Corey, CG, et al., 2015.

⁴⁸ Delnevo, C, et al., “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” *Tobacco Control* 24(4):389-94, 2015.

⁴⁹ Bonhomme, MG, et al., 2016.

Game cigars in the U.S., stated, “It is mainly new recruits to cigar smoking who take to the new flavors, while long-time consumers still prefer the more traditional cigars.”⁵⁰ Tobacco companies strategically added flavors to little cigars and cigarillos, to cover up the harshness of the tobacco, while also modifying those products to resemble cigarettes in order to appeal to new users.⁵¹ Industry insiders also recognize the use of flavors for the uninitiated. The luxury lifestyle magazine, *Cigar Aficionado*, stated in an article, “More likely, flavored cigars serve as a bridge to premium cigars for the uninitiated, something to be smoked as an entryway into the world of cigar smoking. For the novice, a simple, sweet and easily identifiable flavor (honey or cherry, for example) is an easier step than moving into a box marked Cuban-seed Corojo.”⁵²

2. Flavored Hookah Increases Youth Initiation.

The appeal of flavored hookah undoubtedly contributes to its popularity among youth and young adults. The 2013-2014 PATH study found that 88.7 percent of 12-17 year olds who had ever smoked hookah used flavored hookah the first time they tried the product, and 89 percent of current hookah users had used a flavored product in the last month.⁵³ According to the PATH study, use of flavored tobacco is highest for users of hookah than for any other tobacco product, and more than three-quarters (78.9 percent) of youth hookah users reported that they use hookah “because they come in flavors I like.”⁵⁴ The 2014 NYTS found that 60.6 percent of middle and high school hookah users – a total of over 1 million youth – had used flavored hookah in the past month.⁵⁵

B. ANPRM Question 3. Flavors in non-combusted tobacco products increase youth initiation.

1. Flavored E-Cigarettes Increase Youth Tobacco Initiation.

Given the dramatic growth in the availability and marketing of flavored e-cigarettes, it is no surprise that e-cigarettes continue to be the most popular tobacco product among youth. Among high school students, e-cigarette use increased from 1.5 percent in 2011 to 11.7 percent in 2017, peaking at 16.0 percent in 2015.⁵⁶ In at least 43 states, prevalence of e-cigarette use

⁵⁰ Swedish Match, “No. 2 worldwide in cigars,” March 7, 2007,

<http://www.swedishmatch.com/en/Media/Articles/No-2-worldwide-in-cigars/>.

⁵¹ Kostygina, G, Glantz, SA, & Ling, PM, “Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos,” *Tobacco Control* 25(1):66-74, 2016.

⁵² Savona, D, “Cigars of a Different Flavor,” *Cigar Aficionado*, July/August 2005.

⁵³ Ambrose, BK, et al., 2015.

⁵⁴ *Id.*

⁵⁵ Corey, CG, et al., 2015.

⁵⁶ CDC, “Tobacco Use Among Middle and High School Students—United States, 2011-2017,” *MMWR*, 67(22): 629-633, June 7, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6722a3-H.pdf>.

equals or surpasses use of cigarette smoking among high school students.⁵⁷ The 2016 Surgeon General Report on e-cigarettes stated that, “The widespread availability and popularity of flavored e-cigarettes is a key concern regarding the potential public health implications of the products. The concern, among youth, is that the availability of e-cigarettes with sweet flavors will facilitate nicotine addiction and simulated smoking behavior—which will lead to the use of conventional tobacco products.”⁵⁸ In recent months, the surging popularity of JUUL in high schools across the country, a product that features fruit flavors such as Mango, has caused widespread concern among both school officials and regulators.⁵⁹

The 2016 Surgeon General Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.⁶⁰ The 2013-2014 PATH study found that 81 percent of 12-17 year olds who had ever smoked an e-cigarette used a flavored e-cigarette the first time they tried the product, and 85.3 percent of current users used a flavored product in the last month. Additionally, 81.5 percent of current youth e-cigarette users said they used e-cigarettes “because they come in flavors I like.”⁶¹ A national telephone survey found that youth (ages 13-17) were more likely to report interest in trying an e-cigarette offered by a friend if it were flavored like fruit, candy or menthol, compared to tobacco.⁶²

Flavored e-cigarettes are more popular among youth and young adults than older adults. One study found that compared to college students, high school students were more likely to report experimenting with e-cigarettes because of appealing flavors (47 percent vs. 33 percent).⁶³ The 2013-2014 National Adult Tobacco Survey found that use of flavored e-cigarettes was highest among young adults (ages 18-24), compared to those over age 25, and that flavored e-cigarettes were most popular among adults who were never cigarette smokers.⁶⁴

⁵⁷ Data from YRBS, YTS and other state-specific surveys. 43 states include: AL, AK, AZ, AR, CA, CO, DE, FL, HI, ID, IL, IN, KA, ME, MD, MA, MI, MN, MS, MO, MT, NE, NV, NH, NJ, NM, NY, NC, ND, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI, WY.

⁵⁸ *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General* at 11.

⁵⁹ FDA Center for Tobacco Products, “Statement from FDA Commissioner Scott Gottlieb, M.D., on new enforcement actions and a Youth Tobacco Prevention Plan to stop youth use of, and access to, JUUL and other e-cigarettes,” April 24, 2018, <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm>. Hafner, J. “Juul e-cigs: The controversial vaping device popular on school campuses,” USA Today, October 31, 2017, <https://www.usatoday.com/story/money/nation-now/2017/10/31/juul-e-cigs-controversial-vaping-device-popular-school-campuses/818325001/>. Chen, A. “Teenagers Embrace JUUL, Saying It’s Discreet Enough to Vape in Class,” NPR, December 4, 2017, <https://www.npr.org/sections/health-shots/2017/12/04/568273801/teenagers-embrace-juul-saying-its-discreet-enough-to-vape-in-class>.

⁶⁰ *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General* at 88.

⁶¹ Ambrose, BK, et al., 2015.

⁶² Pepper, JK, et al., “Adolescents’ interest in trying flavoured e-cigarettes,” *Tobacco Control*, 25: ii62-ii66, published online September 15, 2016.

⁶³ Kong, G, et al., “Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults,” *Nicotine & Tobacco Research* 17(7):847-54, July 2015.

⁶⁴ Bonhomme, MG, et al., “Flavoured non-cigarette tobacco product use among US adults: 2013-2014,” *Tobacco Control*, 25: ii4-ii13, 2016.

2. Flavored Smokeless Tobacco Increases Youth Initiation.

As with cigarettes, characterizing flavors in smokeless products mask the tobacco flavor and can make the products appealing to youth. Tobacco industry documents indicate that smokeless tobacco companies knew that “sweeter milder flavours could increase appeal to starters by potentially lowering the pH of tobacco.”⁶⁵ In particular, mint flavoring in smokeless tobacco plays an important role in smokeless tobacco use initiation and dependence, by making the product more tolerable to new users.⁶⁶ The 2013-2014 PATH study found that 68.9 percent of 12-17 year olds who had ever used smokeless tobacco used flavored smokeless tobacco the first time they tried the product, and 81 percent of current smokeless tobacco users had used a flavored product in the last month.⁶⁷ The 2014 NYTS found that 58.8 percent of middle and high school smokeless tobacco users – a total of nearly 700,000 youth – had used flavored smokeless tobacco in the past month.⁶⁸

C. ANPRM Question 4. Flavors in Non-Combusted Tobacco Products Contributes to Progression to Use of Combusted Tobacco Products.

The dramatic increase in youth use of e-cigarettes is also concerning because research shows that use of e-cigarettes by youth may increase the risk of later use of more dangerous, combustible tobacco products. In 2016, the Surgeon General concluded that while more research is needed, evidence from several longitudinal studies suggests that e-cigarette use is “strongly associated” with the use of other tobacco products among youth and young adults, including conventional cigarettes.⁶⁹ Reviewing a more recent and larger evidence base, the 2018 NASEM Report found the effect of e-cigarette use on cigarette smoking initiation to be causal, concluding that “There is substantial evidence that e-cigarette use increases risk of ever using combustible tobacco cigarettes among youth and young adults.” In addition, several studies find that the link

⁶⁵ Kostygina, G & Ling, PM, “Tobacco industry use of flavourings to promote smokeless tobacco products,” *Tobacco Control* 25(Suppl 2):ii40-ii49, November 2016.

⁶⁶ Kostygina, G & Ling, PM, 2016.

⁶⁷ Ambrose, BK, et al., 2015.

⁶⁸ Corey, CG, et al., 2015.

⁶⁹ HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. See also, Leventhal, AM, et al., “Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence,” *Journal of the American Medicine Association*, 314(7): 700-707, 2015. Wills, Thomas A, et al., “Longitudinal study of e-cigarette use and onset of cigarette smoking among high school students in Hawaii,” *Tobacco Control*, published online first January 25, 2016. Wills, TA, et al., “E-cigarette use is differentially related to smoking onset among lower risk adolescents,” *Tobacco Control*, published online August 19, 2016. Barrington-Trimis, JL, et al., “E-Cigarettes and Future Cigarette Use,” *Pediatrics*, 138(1), published online July 2016.

⁶⁹ Barrington-Trimis, JL, et al., “E-Cigarettes and Future Cigarette Use,” *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., “E-cigarette use is differentially related to smoking onset among lower risk adolescents,” *Tobacco Control*, published online August 19, 2016.

between e-cigarette use and smoking initiation was stronger for those who had *lower* risk factors for smoking at baseline.⁷⁰

III. ANPRM Questions 5-7. There is Insufficient Evidence that Flavors in E-Cigarettes Help Adult Smokers Stop Smoking.

E-cigarette manufacturers contend that certain flavors may enhance the effectiveness of e-cigarettes in assisting smokers to stop smoking; however this assertion is unproven and proponents of this theory have not produced any significant scientific evidence to identify which flavors, if any, do so. No U.S. scientific body has yet concluded that e-cigarettes are effective cessation devices, nor that flavored e-cigarettes are more effective than non-flavored or tobacco-flavored e-cigarettes in helping adult smokers quit. Studies demonstrating adult *preference* for certain flavors are not valid evidence of their role in promoting *cessation*. This paucity of evidence, weighed against the conclusive body of evidence demonstrating the role of flavors in youth initiation of tobacco products (particularly e-cigarettes), indicates that the benefits of continued availability of flavored e-cigarettes do not outweigh the risks.

Many of the existing studies on this issue have significant limitations, and ultimately contribute little to our knowledge of the impact of flavors on cessation. In its review of the evidence on the impact of e-cigarette flavors on cessation among adult cigarette smokers, the FDA only cited two studies (ANPRM at 12298), both of which have serious flaws. The first study is a focus group study of only eleven e-cigarette users—the sample size and self-reported nature of this data alone deem this study insufficient to draw conclusions about the role of e-cigarette flavors for adult smokers. While the authors conclude that “having a variety of flavors, devices, and nicotine levels available reinforces the motivation to quit smoking and helps prevent relapse,” the supporting quotes from focus group participants solely revolve around *liking* flavors, not their role in cessation. Self-reported appeal and impact on cessation are not interchangeable constructs. Moreover, the two highlighted participants who are quoted as liking flavors also noted that they view e-cigarette use as a hobby and not as a means of quitting smoking. As the authors conclude, “Most of them didn’t necessarily see e-cigarettes as a means to quit nicotine altogether but liked the experience in addition to mixing and matching different types of e-cigarette parts and ‘juice’ flavors.”⁷¹

The second study cited by FDA is a 2013 survey that examined the impact of flavorings on the e-cigarette experience of dedicated e-cigarette users used a convenience sample of

⁷⁰ Barrington-Trimis, JL, et al., “E-Cigarettes and Future Cigarette Use,” *Pediatrics*, 138(1), published online July 2016. Wills, TA, et al., “E-cigarette use is differentially related to smoking onset among lower risk adolescents,” *Tobacco Control*, published online August 19, 2016.

⁷¹ Barbeau, A.M., et al., “Perceived Efficacy of E-cigarettes Versus Nicotine Replacement Therapy Among Successful E-cigarette Users: A Qualitative Approach,” *Addiction Science & Clinical Practice*, 8(1):5, 2013.

participants recruited from popular e-cigarette user forums and e-cigarette advocate websites.⁷² In a convenience sample, the respondents are not representative of the population, and in this study the authors acknowledge that participants were primarily dedicated e-cigarette users who had positive experiences with e-cigarettes. In addition, this internet-based survey just asked participants to rate the importance of flavor variability in reducing or quitting smoking, but did not actually assess if having access to a variety of flavors leads to reduced consumption or quitting, or if those who said they had quit stayed quit over time. In the redline version of the deeming rule, FDA also criticized this study, noting that it “did not address the question of whether study participants would have increased cigarette use if there were no available flavored ENDS or if the variety of flavored ENDS were limited.”⁷³

Separate from whether flavors in e-cigarettes have been shown to increase the effectiveness of e-cigarettes in assisting smokers to quit or switch completely, based upon the existing evidence, e-cigarettes benefit public health only if they help significantly reduce the number of people who use combustible cigarettes to quit or switch completely. However, the currently available data indicate that most e-cigarette users report using *both* e-cigarettes and cigarettes. A 2015 survey found that the majority of current e-cigarette users (58.8 percent) were also current smokers.⁷⁴ Earlier data from 2014 found that nearly half (47.6 percent) of current smokers reported having ever tried e-cigarettes, with 15.9 percent of smokers reporting that they also currently use e-cigarettes. The same survey found that 20.3 percent of smokers who had tried to quit smoking in the past year and 22 percent of recent former cigarette smokers (those who quit smoking within the past year) currently used e-cigarettes.⁷⁵ Data from the PATH study found that among adults who were dual users of e-cigarettes and cigarettes at Wave 1 (2013-2014), 44.3 percent maintained dual use, 43.5 percent discontinued e-cigarette use but maintained cigarette smoking, and only 12.1 discontinued cigarette use (5.1% discontinued cigarette use but continued e-cigarette use and 7.0% discontinued use of both products) at Wave 2 (2014-2015).⁷⁶

Some e-cigarette users report that they believe that e-cigarettes will help them quit or reduce the number of cigarettes they smoke.⁷⁷ However, there is not enough evidence to conclude whether e-cigarette use actually helps smokers quit cigarettes by switching to exclusive

⁷² Farsalinos, K, et al., “Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey,” *International Journal of Environmental Research and Public Health* 10:7272-7282, 2013.

⁷³ Deeming Final Rule Redline Changes.

⁷⁴ CDC, “*Quick Stats*: Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group—National Health Interview Survey, United States, 2015,” *Morbidity and Mortality Weekly Report*, 65(42): 1177.

⁷⁵ Schoenborn, CA & Gindi, RM, “Electronic Cigarette Use Among Adults: United States, 2014,” National Center on Health Statistics (NCHS) Data Brief, No. 217, October 2015.

⁷⁶ Coleman, B., et al., “Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013-2015),” *Tobacco Control*, published online April 25, 2018.

⁷⁷ Grana, R, et al., “E-Cigarettes: A Scientific Review,” *Circulation* 129(19):1972-86, 2014.

e-cigarette use or no tobacco product use.⁷⁸ The U.S. Preventive Services Task Force, which makes recommendations about the effectiveness of specific preventive care services after a thorough assessment of the science, concluded that, “the current evidence is insufficient to recommend electronic nicotine delivery systems for tobacco cessation...”⁷⁹ The NASEM report concluded, “[o]verall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation.”⁸⁰ According to researchers from the CDC, “There is currently no conclusive scientific evidence that e-cigarettes promote long-term cessation, and e-cigarettes are not included as a recommended smoking cessation method by the U.S. Public Health Service.”⁸¹ No e-cigarette product has been FDA-approved as a safe and effective cessation device.

Given the current lack of reliable scientific evidence about the potential for any specific flavoring to increase the effectiveness of e-cigarettes in helping smokers to quit or switch completely and the potential of flavored products to increase the number of kids using tobacco products, FDA should prohibit e-cigarettes with characterizing flavors except in specific cases in which the manufacturer has first submitted, and FDA has reviewed and concluded, that there is sufficient, valid scientific evidence for each non-tobacco flavored product that the flavor (1) enhances the efficacy of the product in increasing the number of smokers who stop smoking, (2) does not contribute to initiation of tobacco product use, including e-cigarette use, particularly among youth, or relapse into tobacco product use, (3) does not result in continued use of tobacco products by those who otherwise would have quit and (4) does not itself increase the toxicity of the product. Such an approach is consistent with recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM) committee in its 2018 report, *Public Health Consequences of E-Cigarettes*, which concluded that, “If evidence were to identify certain flavors that increased toxicity and appeal to youth, but did not enhance appeal or efficacy as a cessation aid, the development of product standards to prohibit the use of such additives would likely have net improvement on the health of the population.”⁸²

⁷⁸ King, BA, et al., “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011,” *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service Clinical Practice Guideline*, May 2008, NASEM, *Public Health Consequences of E-Cigarettes*, 2018.

⁷⁹ U.S. Preventive Services Task Force, *Behavioral and Pharmacotherapy Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Women: U.S. Preventive Services Task Force Recommendation Statement*, *Annals of Internal Medicine*, Vol. 163, No. 8, October 2015.

⁸⁰ NASEM, *Public Health Consequences of E-Cigarettes*, 2018.

⁸¹ King, BA, et al., “Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011,” *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., “Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013,” *Nicotine & Tobacco Research*, first published online September 19, 2014 and Fiore, MC, et al., *Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service Clinical Practice Guideline*, May 2008.

⁸² National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, p. 21-2, 2018, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

IV. ANPRM Question 10. Prohibiting Flavors in Tobacco Products Will Reduce Tobacco Use

The evidence is clear that flavors play a key role in initiation and continued use of tobacco products among youth. Emerging evidence confirms that prohibiting these kid-friendly products from the market will have a positive public health impact. After New York City restricted sales of flavored tobacco products (excluding e-cigarettes and menthol cigarettes) in November 2010, the sale of all flavored products declined significantly. In addition, the percent of New York City teens who reported ever use of flavored tobacco products or use of any tobacco products declined significantly after the policy was implemented. Together, these findings indicate that not only are flavored products not being sold in New York City, but the ordinance is effectively reducing youth access to and use of these products.⁸³

V. ANPRM Question 9. Some E-Cigarette Flavors Contain Toxic Chemicals

Despite some users' perceptions that flavored tobacco products are less risky, these products can contain chemicals that can increase the risk of harm for users. As FDA described in the ANPRM (at 12298), flavored tobacco products can contain or form toxic compounds when combusted or heated.

FDA has previously recognized the potential dangers from flavor additives in the version of the deeming rule sent to OMB. In a section entitled, "Some Chemical Flavorings in Newly Deemed Products Contain Toxic Compounds," the agency concluded that, "The potential dangers associated with chemical flavorings in newly deemed tobacco products provides additional supporting evidence not to extend the premarket review compliance policy to such products." This finding was redlined by the OMB in the final version of the deeming rule.⁸⁴ Research released since the final deeming rule has added to the evidence that e-cigarettes can contain toxic flavor additives.

While flavorings used in e-cigarettes have been labeled as "generally recognized as safe," some researchers, as well as the Flavor and Extract Manufacturers Association of the United States, the organization primarily responsible for granting that designation, have noted that it applies to ingestion in food,⁸⁵ not for other exposures such as inhalation. The NASEM report committee expressed concern about flavor additives because even to-date, they "have not been widely tested for sensitizing, toxic, or irritating potency."⁸⁶ NASEM concluded that,

⁸³ Farley, SM and Johns, M, "New York City flavored tobacco product sales ban evaluation," *Tobacco Control*, 26: 78-84, 2017.

⁸⁴ Deeming Final Rule Redline Changes.

⁸⁵ Flavor and Extract Manufacturers Association of the United States (FEMA), *Safety Assessment and Regulatory Authority to Use Flavors – Focus on Electronic Nicotine Delivery Systems and Flavored Tobacco Products*, Revised September 26, 2016, <https://www.femaflavor.org/safety-assessment-and-regulatory-authority-use-flavors-focus-electronic-nicotine-delivery-systems>.

⁸⁶ NASEM, *Public Health Consequences of E-Cigarettes*, p. 5-31, 2018.

“Independent of nicotine, exposure to particulates and flavorings in e-cigarette aerosols could also potentially impair lung function.”⁸⁷ The 2016 Surgeon General’s report stated that, “while some of the flavorings used in e-cigarettes are generally recognized as safe for ingestion as food, the health effects of their inhalation are generally unknown,” and noted that some of the flavorings found in e-cigarettes have been shown to cause serious lung disease when inhaled.⁸⁸ An article in the *Journal of the American Medical Association* raised concerns that the chemical flavorings found in some e-cigarettes and e-liquids could cause respiratory damage when the e-cigarette aerosol is inhaled deeply into the lungs.⁸⁹

Given there are over 15,500 e-cigarette flavors and over 250 cigar flavors, the differential health harms of each flavor toxicant are yet unknown. Some e-cigarette flavors contain aldehydes, which can cause respiratory irritation and airway constriction, at unacceptable levels.⁹⁰ One study, analyzing thirty e-cigarette flavors, found that kid-friendly cotton candy and bubble gum contained aldehydes, and that the aldehyde exposure from dark chocolate and wild cherry flavors was double the recommended workplace safety limit.⁹¹ Another study from atmospheric scientists found that, “thermal decomposition of flavoring compounds is the main source of aldehydes in vapors produced by e-liquids tested” and that, “aldehyde concentrations increase exponentially with the concentration of flavoring compounds.” The authors further stated, “one puff of any of the tested flavored e-cigarette liquids exposes the smoker to unacceptably dangerous levels of these aldehydes.”⁹²

Multiple studies have found cinnamaldehyde in e-cigarette flavors, primarily, but not exclusively in cinnamon-flavored e-liquids. According to the NASEM committee, these studies find that, “even at low concentrations, cinnamaldehyde in e-cigarette products is cytotoxic, genotoxic, and adversely affects cell processes and survival.”⁹³ For example, one study found that the Cinnamon Ceylon flavor was the most cytotoxic of the 36 e-liquids tested,⁹⁴ and a follow-up study specifically testing cinnamon-flavored e-liquids found that most of them were cytotoxic, with the level of cytotoxicity linked with the amount of cinnamaldehyde in the product.⁹⁵

⁸⁷ NASEM, *Public Health Consequences of E-Cigarettes*, p. 11-2, 2018.

⁸⁸ *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General* at 184.

⁸⁹ Barrington-Trimis, JL, et al., “Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?” *JAMA*, published online November 10, 2014.

⁹⁰ Klager, S, et al., “Flavoring chemicals and aldehydes in e-cigarette emissions,” *Environmental Science & Technology* 51(18):10806-10813, September 2017.

⁹¹ Tierney, P., et al. “Flavour chemicals in electronic cigarette liquids.” *Tobacco Control*, published online April 15, 2015.

⁹² Khlystov, A & Samburova, V, “Flavoring compounds dominate toxic aldehyde production during e-cigarette vaping,” *Environmental Science & Technology* 50(23):13080-13085, 2016.

⁹³ NASEM, *Public Health Consequences of E-Cigarettes*, p. 5-19, 2018.

⁹⁴ Behar, RZ, et al., “Identification of toxicants in cinnamon-flavored electronic cigarette refill fluids,” *Toxicology in Vitro* 28:198-208, 2014.

⁹⁵ Behar, R., et al., 2014.

In another study of 125 e-liquids manufactured by seven European manufacturers, benzaldehyde was found in 70 percent of the products and its concentration in aerosol generated from cherry-flavored samples was significantly higher than in products of other flavors. Exposure to benzaldehyde vapors has been shown to cause eye pain, conjunctiva redness, burning sensations in the nose and throat, cough and breathing difficulty.⁹⁶ Similarly, a study of 145 flavored e-liquids from International online retailers found benzaldehyde in 74.5 percent of them, with the highest levels measured in cherry-flavored liquids.⁹⁷

Another harmful chemical found in some e-cigarette flavors is diacetyl, used to give food a buttery or creamy flavor. High doses of diacetyl, deemed safe for ingestion by FEMA, have been shown to cause severe and irreversible obstructive lung disease, when inhaled by workers exposed to particulate aerosolized flavorings containing diacetyl.⁹⁸ A recent evaluation of 159 sweet-flavored e-nicotine solutions found diacetyl in 69.2 percent of samples and, in at least one sample, from 91.6 percent of manufacturers.⁹⁹ In another study of 51 flavored e-liquids, 46 contained acetoin, 39 contained diacetyl, and 23 contained acetylpropionyl.¹⁰⁰ Similar to diacetyl, acetoin and acetylpropionyl are also used to add a creamy flavor to products and are associated with adverse respiratory health outcomes.

A study looking at youth e-cigarette and dual users (e-cigarette and cigarette) found higher levels of acrylonitrile, a volatile organic compound, in the urine of youth using fruit flavored e-cigarettes compared to users of other flavored e-cigarettes. This is one of the first studies showing not only that adolescent e-cigarette users are being exposed to dangerous chemicals, but that the flavors impact the user. In this study, more than half of e-cigarette-only users and more than two-thirds of dual users reported using fruit flavors most often in the past month.¹⁰¹

A recent study has found that some flavoring chemicals in e-cigarette liquids could enhance the formation of free radicals in the aerosol. Free radicals can play a part in inducing

⁹⁶ Goniewicz, M, *Toxicants in E-Cigarette Refill Solutions and Vapor*, Presentation at the FDA “Electronic Cigarettes and the Public Health: A Public Workshop,” December 10, 2014.

⁹⁷ Kosmider, T, et al., “Cherry-flavoured electronic cigarettes expose users to the inhalation irritant, benzaldehyde,” *Thorax* 71(4):376-7, 2016.

⁹⁸ Barrington-Tremis, JL, Samet, JM, & McConnell, R, “Flavorings in Electronic Cigarettes: An Unrecognized Respiratory Health Hazard?,” *JAMA*, published online November 10, 2014.

⁹⁹ Farsalinos, KE, et al., “Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins,” *Nicotine & Tobacco Research* 17(2):168-174, February 2015.

¹⁰⁰ Allen, J. G., et al., “Flavoring chemicals in e-cigarettes: Diacetyl, 2,3-pentanedione, and acetoin in a sample of 51 products, including fruit-, candy-, and cocktail-flavored e-cigarettes.” *Environmental Health Perspectives* 124(6):733-739, 2016.

¹⁰¹ Rubenstein, ML, et al., “Adolescent Exposure to Toxic Volatile Organic Chemicals from E-Cigarettes,” *Pediatrics* 141(4):e20173557, 2018.

oxidative stress, which contributes to the development of cardiovascular diseases and other tobacco-related diseases.¹⁰²

Another recently published study of nine commonly used flavor additives, including menthol, found that “acute exposure to flavoring additives used in tobacco products include characteristics of endothelial dysfunction at potentially physiologically relevant concentrations.”¹⁰³ The authors of the study concluded that their results “provide quantitative support for the regulatory prohibition or the establishment of limits on the allowable level of flavors in e-cigarettes and other tobacco products.”

The impact of flavors on health risk is not limited to exposure to dangerous chemicals. One study has found that flavors can affect nicotine pharmacology among users, including nicotine absorption.¹⁰⁴ Flavors also make tobacco products more tolerable by masking the harshness of the product¹⁰⁵ to make the products easier to consume.

Although flavorings are added to other tobacco products, including smokeless tobacco, cigars, hookah, pipe tobacco, and menthol cigarettes, little research is available on the health impact of those additives, other than their role in increasing the appeal and tolerance for the products. One study found that little cigars, whether flavored or not, have similarly high levels of cytotoxicity, indicating they are equally as harmful to lung cells. In addition, some little cigar flavors may be more harmful than other flavors.¹⁰⁶ Another study found “measurable levels” of benzaldehyde in wild cherry-flavored cigar filler.¹⁰⁷

VI. ANPRM Questions 11 and 12. Flavored Tobacco Products are Widely—but Incorrectly—Believed to be Less Harmful and Less Addictive than Unflavored Tobacco Products.

With flavors that mimic popular kid-friendly candies and snacks, and the tobacco industry’s history of marketing menthol cigarettes as a cooling and healthier alternative, it’s no surprise that many believe that flavored tobacco products are safer. A 2016 systematic review of perceptions of flavored tobacco products included five studies that assessed harm perceptions,

¹⁰² Bitzer, ZT, et al., “Effect of flavoring chemicals on free radical formation in electronic cigarette aerosols,” *Free Radical Biology and Medicine* 120:72-79, 2018.

¹⁰³ Fetterman, JL, et al., “Flavorings in Tobacco Products Induce Endothelial Cell Dysfunction,” *Arteriosclerosis, Thrombosis, and Vascular Biology*, published ahead of print, June 14, 2018

¹⁰⁴ St.Helen, G, et al., “Impact of e-liquid flavors on nicotine intake and pharmacology of e-cigarettes,” *Drug and Alcohol Dependence* 178:391-398, 2017.

¹⁰⁵ Kostygina, G, Glantz, SA, & Ling, PM, “Tobacco industry use of flavours to recruit new users of little cigars and cigarillos,” *Tobacco Control* 25(1):66-74, January 2016. Wayne, GF & Connolly, GN, “Application, function, and effects of menthol in cigarettes: A survey of tobacco industry documents,” *Nicotine & Tobacco Research* 6(Supplement 1):S43-54, February 2004.

¹⁰⁶ Ghosh, A, et al., “Flavored little cigar smoke induces cytotoxicity and apoptosis in airway epithelia,” *Cell Death Discovery* 3:17019, 2017

¹⁰⁷ Lisko, JG, Stanfill, SB, & Watson, CH, “Quantitation of Ten Flavor Compounds in Unburned Tobacco Products,” *Analytical Methods* 6(13):4698-4704, 2014.

concluding that flavored tobacco products were, “perceived as less risky or harmful, and these perceptions potentially interact with age, with younger participants appearing more likely to believe that flavoured products were less harmful compared with non-flavoured products.”¹⁰⁸ A 2017 systematic review of qualitative studies on perceptions of flavored tobacco products found, based on six studies, that participants believe flavored tobacco products are less harmful than cigarettes.¹⁰⁹ A national phone survey conducted in 2014-2015 found that youth (ages 13-17) believed that fruit-flavored e-cigarettes were less harmful than tobacco-flavored e-cigarettes.¹¹⁰ An analysis of data from the 2014 National Youth Tobacco Survey found that use of flavored e-cigarette use was associated with lower odds of perceived harmfulness of tobacco use.¹¹¹ These findings are particularly concerning given that, as the FDA notes in the ANPRM (at 12296), “adolescents who perceive lower harms from using tobacco products are more likely to initiate use.” Prohibiting flavored tobacco products will help to send a clear message that sweet doesn’t mean safe and correct the misperception that these products are less harmful.

There is also evidence of misperceptions regarding the nicotine content and addictiveness of non-cigarette tobacco products, which are predominantly flavored. For example, e-liquid “pods” for the JUUL device, whose popularity among youth and young adults has been documented by news stories across the country, are reported by the company to contain a nicotine content equivalent to a pack of cigarettes.¹¹² However, a 2017 study found that 63 percent of youth and young adult current JUUL users did not know that JUUL pods always contain nicotine.¹¹³ Data from the 2014 National Youth Tobacco Survey found that 47.1 percent of middle and high school students believe e-cigarettes are less addictive than cigarettes and 31.5 percent believe cigars are less addictive than cigarettes. Youth who used these products were more likely to report that they believed them to be less addictive than cigarettes.¹¹⁴ Another 2014

¹⁰⁸ 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.

¹⁰⁹ 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.

¹¹⁰ Pepper, JK, et al., “Adolescents’ interest in trying flavoured e-cigarettes,” *Tobacco Control*, 25: ii62-ii66, published online September 15, 2016.

¹¹¹ Dai, H, et al., “Flavored electronic cigarette use and smoking among youth,” *Pediatrics*, 138(6): November 2016.

¹¹² JUUL Website, FAQ: JUULpods & JUULpod Liquid, accessed May 17, 2018. “What is the nicotine concentration? Each JUULpod is designed to contain approximately 0.7mL with 5% nicotine by weight at time of manufacture which is approximately equivalent to 1 pack of cigarettes or 200 puffs.” <https://support.juul.com/home/learn/faqs/juulpods-juulpod-liquid>.

¹¹³ Willet, J, et al., “Recognition, use and perceptions of JUUL among youth and young adults,” *Tobacco Control*, published online April 18, 2018.

¹¹⁴ Amrock, SM, et al., “Perceptions of e-cigarettes and noncigarette tobacco products among US youth,” *Pediatrics*, 138(5).

online survey of young adults found that only 57 percent knew that some e-cigarettes contain nicotine.¹¹⁵

VII. ANPRM Questions 13 and 14. There is No Rationale for Continuing to Permit Characterizing Flavors in Any Combusted Tobacco Product.

Question 13 asks whether there are specific flavors for which FDA should establish a product standard. In addressing this question it is important to note that flavors can only benefit the public health if they facilitate cessation from combusted tobacco products. Flavors in combusted products themselves quite clearly do not facilitate cessation from such products. Given the role flavors play in attracting young people to use combusted tobacco products, there is no rationale for continuing to permit *any* characterizing flavors in any combusted tobacco product.

After the TCA prohibited characterizing flavors in cigarettes, tobacco product manufacturers responded by introducing a host of kid-friendly flavors in other tobacco products and youth usage of these products boomed even while the prevalence of cigarette smoking by young people fell. With respect to flavors in combusted tobacco products, there is no reason for FDA to spend resources deciding which of the flavors in combusted tobacco products are the most egregious: none of them can possibly provide a net benefit to the public health. Now that FDA has asserted jurisdiction over all such products, including cigars and hookah, it should act promptly to eliminate characterizing flavors in all combusted tobacco products. There is no reason to wait until August 2021 to take such action because nothing in the applications that FDA will receive then could demonstrate that any such products have a positive impact on public health. The prohibition should apply to all combusted tobacco products regardless of when they were introduced or whether they are substantially equivalent to a product that has long been on the market. No such distinction can justify the continued marketing of any combusted tobacco product because no such product can play a constructive role in reducing smoking initiation or encouraging cessation.

VIII. ANPRM Question 13. FDA Should Prohibit Characterizing Flavors in E-Cigarettes Except Where the Manufacturer Has Demonstrated to the FDA, and the FDA has Issued an Order Finding, That the Specific Characterizing Flavor in the Specific Product (1) Helps Smokers Quit Tobacco Products Altogether or Switch Completely to e-Cigarettes; (2) Does Not Increase Initiation by Non-Users; and (3) is Safe and Non-Toxic.

Given the current lack of reliable scientific evidence about the potential for any specific flavoring to increase the effectiveness of e-cigarettes in helping smokers to quit or switch completely and the potential of flavored products to increase the number of kids using tobacco

¹¹⁵ Sanders-Jackson, AN, et al., “Knowledge about e-cigarette constituents and regulation: results from a national survey of U.S. young adults,” *Nicotine & Tobacco Research*, 2014, 17(1): 1247-1254.

products, FDA should prohibit e-cigarettes with characterizing flavors except in specific cases where the manufacturer has first submitted and FDA has reviewed and concluded that there is sufficient valid scientific evidence for each non-tobacco flavored product that the flavor (1) enhances the efficacy of the product in increasing the number of smokers who stop smoking, (2) does not contribute to initiation of tobacco product use, including e-cigarette use, particularly among youth, or relapse into tobacco product use, (3) does not result in continued use of tobacco products by those who otherwise would have quit and (4) does not itself increase the toxicity of the product. In applying such a standard, the burden of making this demonstration should be on the manufacturer with respect to each product. In the absence of such a showing, no characterizing flavor should be permitted.

With thousands of flavored products on the market, it would not be reasonable to leave all such products on the market unless FDA establishes that the benefits of cessation for smokers, who otherwise would not switch, exceed the risk of youth initiation. Given the high level of youth usage of flavored e-cigarette products, the uncertainty about the degree to which e-cigarettes actually facilitate smoking cessation, and the additional uncertainty about whether flavors in e-cigarettes enhance their ability to facilitate cessation, FDA should prohibit flavors in e-cigarette products unless the manufacturer demonstrates that the benefits from increased smoking cessation attributable to a flavored e-cigarette product actually exceed the risks from youth initiation.

IX. ANPRM Question 15. FDA Should Prohibit the Use of Menthol as a Characterizing Flavor in Cigarettes

For years, FDA has had sufficient scientific evidence—including its own analysis and that of the Tobacco Product Scientific Advisory Committee (TPSAC)—to prohibit menthol as a characterizing flavor in cigarettes. FDA should promptly issue a proposed rule extending the ban on characterizing flavors in cigarettes to menthol, followed by a final rule as soon as possible. Among the actions FDA can take that would both reduce the death and disease caused by tobacco use and reduce health inequities caused by tobacco use, none is more important than prohibiting the use of menthol in cigarettes and other tobacco products.

As the only remaining flavored cigarette, menthol cigarettes have greatly increased their share of the cigarette market. Data from the Federal Trade Commission (FTC) show that in 2016 (the most recent year for which data are available), menthol cigarettes comprised 35 percent of the market, the highest proportion on record since FTC began collecting this data in 2001.¹¹⁶

¹¹⁶ U.S. Federal Trade Commission (FTC), Cigarette Report for 2016, 2018, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2016-federal-trade-commission-smokeless-tobacco-report/ftc_cigarette_report_for_2016_0.pdf [data for top 5 manufacturers only].

FDA should also include menthol flavors in the prohibition on characterizing flavors in all other tobacco products. According to Nielsen data, from 2011-2015, menthol products represented 18.0% of little cigar sales and 55.3% of moist snuff sales.¹¹⁷

A. Menthol Cigarettes Increase Youth Initiation

Menthol cools and numbs the throat, reducing the harshness of cigarette smoke, thereby making menthol cigarettes more appealing to youth who are initiating tobacco use.¹¹⁸ Further, FDA's own scientific analysis concluded that menthol cigarettes lead to increased smoking initiation among youth and young adults.¹¹⁹ Additionally, according to FDA's Tobacco Products Scientific Advisory Committee (TPSAC):¹²⁰

- Menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking.
- Young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.
- The availability of menthol cigarettes reduces smoking cessation, especially among African Americans, and increases the overall prevalence of smoking among African Americans.

Since FDA's scientific analysis in 2013 and the 2011 TPSAC report, the evidence base supporting the role of menthol in youth smoking initiation and the greater preference for menthol cigarettes among younger populations has only continued to build:

- Using data from the 1999-2013 Youth Tobacco Surveys, a 2017 study analyzed the impact of the 2009 ban on characterizing flavors in cigarettes on youth tobacco use. The researchers found that use of menthol cigarettes increased significantly after the ban on other characterizing flavors in cigarettes.¹²¹ As the

¹¹⁷ Kuiper, NM, et al., "Trends in sales of flavored and menthol tobacco products in the United States during 2011-2015," *Nicotine & Tobacco Research*, published online June 1, 2017.

¹¹⁸ FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

¹¹⁹ FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

¹²⁰ Tobacco Products Scientific Advisory Committee (TPSAC), *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, July 21, 2011 <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.

¹²¹ Courtemanche, CJ, et al., "Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use," *American Journal of Preventive Medicine*, published online January 9, 2017.

only flavored cigarette left on the market, it is no surprise that menthol cigarettes are popular among youth.

- Over half (54 percent) of youth smokers ages 12-17 use menthol cigarettes compared to nearly one-third (32 percent) of older adult smokers.¹²² Prevalence of menthol use is even higher among African Americans: seven out of ten African-American youth smokers smoke menthol cigarettes.¹²³
- The popularity of menthol flavored cigarettes is also evidenced by brand preference among youth. According to data from the 2015 National Survey on Drug Use and Health, one in five smokers ages 12-17 prefers Newport cigarettes, a heavily marketed menthol cigarette brand. Preference for Newport is even higher among African-American youth smokers (69.1 percent) because of targeted marketing by the tobacco industry.¹²⁴
- Using data from the 3-wave American Legacy Longitudinal Tobacco Use Reduction Study, a 2013 study found that initiating smoking using menthol cigarettes was associated with greater odds of progressing to established smoking and higher nicotine dependence.¹²⁵
- Data from the Tobacco Use Supplement to the Current Population Survey shows that the proportion of young adult smokers using menthol cigarettes has increased from the 2003 to 2014-2015 survey waves. This includes an increase from 30.7 percent to 41.3 percent of 18-24 year-old smokers and from 23.5 percent to 39.7 percent of 25-34 year-old smokers.¹²⁶

¹²² Villanti, A., et al., 2016.

¹²³ *Id.*

¹²⁴ SAMHSA's public online data analysis system (PDAS), National Survey on Drug Use and Health, 2015. http://pdas.samhsa.gov/#/survey/NSDUH-2015-DS0001/crosstab/?row=CIG30BR2&column=CATAG3&control=NEWRACE2&weight=ANALWT_C&results_received=true and https://pdas.samhsa.gov/#/survey/NSDUH-2015-DS0001/crosstab/?column=CATAG3&results_received=true&row=CIG30BR2&weight=ANALWT_C.

¹²⁴ FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

¹²⁵ Nonnemaker, J, et al., "Initiation with menthol cigarettes and youth smoking update," *Addiction*, 2013;108(1):171-178.

¹²⁶ National Cancer Institute, The 2014-2015 Tobacco Use Supplement to the Current Population Survey, November 2017, https://cancercontrol.cancer.gov/brp/terb/tus-cps/TUS-CPS_2014-15_SummaryDocument.pdf.

B. Menthol Increases Addiction and Reduces Cessation

FDA's own scientific analysis concluded that menthol cigarettes lead to greater addiction and decreased success in quitting smoking.¹²⁷ Additionally, according to TPSAC:¹²⁸

- Menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking.
- Young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.
- The availability of menthol cigarettes reduces smoking cessation, especially among African Americans, and increases the overall prevalence of smoking among African Americans.

Since FDA's scientific analysis in 2013 and the 2011 TPSAC report, the evidence base supporting the role of menthol in inhibiting cessation has continued to build:

- An analysis of data from the 2003 and 2006-2007 waves of the Tobacco Use Supplement to the Current Population Survey found that menthol smokers were less likely to have quit smoking, with a more pronounced impact on minority populations, including African American and Puerto Rican smokers.¹²⁹
- A nationally representative survey conducted in 2010 found that 38.9% of all menthol smokers, including 44.5% of African American menthol smokers say they would try to quit smoking if menthols were banned.¹³⁰

The difficulty menthol smokers have in quitting is also documented by sales trends. Between 2009 and 2016 sales of non-menthol cigarettes have declined by 25.8% nationally while sales of menthol cigarettes have declined by only 2.2% during the same period.¹³¹

¹²⁷ FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

¹²⁸ TPSAC Report, 2011.

¹²⁹ Delnevo CD, Gundersen DA, Hrywna M, Echeverria SE, Steinberg MB. Smoking-cessation prevalence among U.S. smokers of menthol versus nonmenthol cigarettes. *American Journal of Preventive Medicine*, 41(4):357-365, 2011.

¹³⁰ Pearson JL, Abrams DB, Niaura RS, Richardson A, Vallone DM. A Ban on Menthol Cigarettes: Impact on Public Opinion and Smokers' Intention to Quit. *American Journal of Public Health*. 102(11):e107-e114, 2012.

¹³¹ Estimate based on market share data from FTC, *Cigarette Report for 2014, 2016*. [Data for top 5 manufacturers only] and pack sales data from the Alcohol and Tobacco Tax and Trade Bureau (TTB), <https://www.ttb.gov/tobacco/tobacco-stats.shtml>.

C. Menthol Cigarettes Disproportionately Harm the Health of African American Communities

The FDA and TPSAC concluded that African Americans are disproportionately burdened by the health harms of menthol cigarettes. TPSAC, in its 2011 report to the FDA, estimated that by 2020 (less than two years away now), 4,700 excess deaths in the African American community will be attributable to menthol cigarettes, and over 460,000 African Americans will have started smoking because of menthol cigarettes.¹³²

TPSAC also concluded that menthol cigarette marketing increases the prevalence of smoking for African Americans. Since FDA's scientific analysis in 2013 and the 2011 TPSAC report, research has continued to document how the tobacco industry targets African American communities with marketing for menthol cigarettes, perpetuating existing health disparities:

- A 2013 study found that census tracts in St. Louis with a higher proportion of black residents had more menthol and total tobacco product marketing, and that census tracts with a higher proportion of black children had a higher proportion of menthol marketing near candy.¹³³
- The 2011 California Tobacco Advertising Survey reports that there were significantly more menthol advertisements at stores in neighborhoods with a higher proportion of African-American residents and in low-income neighborhoods.¹³⁴
- Another 2011 California study found that as the proportion of African-American high school students in a neighborhood rose, the proportion of menthol advertising increased, the odds of a Newport promotion were higher, and the cost of Newport cigarettes was lower.¹³⁵
- An assessment of menthol cigarette ads run from June 2012 to February 2013 found that the tobacco industry spent an estimated \$31 million on menthol cigarette direct mail, email, print and online advertisements in just a 9-month period. During this time, 61 percent of Newport print ads featured at least one

¹³² TPSAC Report, 2011.

¹³³ Moreland-Russell, S, et al., "Disparities and Menthol Marketing: Additional Evidence in Support of Point of Sale Policies," *International Journal of Environmental Research and Public Health*, 10: 4571-4583, 2013.

¹³⁴ Schleicher, N, et al., "Tobacco Marketing in California's Retail Environment (2008-2011), Final report for the California Tobacco Advertising Survey. Stanford, CA: Stanford Prevention Research Center, July 2013.

¹³⁵ Henriksen, L., et al., "Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods," *Nicotine & Tobacco Research*, June 24, 2011.

African-American model. These ads ran in twenty publications including *Jet*, *Ebony*, and *Essence*, which have predominantly African-American readership.¹³⁶

It is also essential that FDA include other combusted tobacco products in any action that it takes to restrict the sale of menthol products. The experience after the ban on other characterizing flavors in cigarettes demonstrates that tobacco manufacturers will try to use little cigars as cigarette substitutes unless FDA includes all combusted tobacco products in any rule governing menthol.

XI. ANPRM Question 10. Impact of Regulatory Actions by State and Local Jurisdictions.

Preliminary evidence of the impact of Ontario, Canada’s January 2017 ban on menthol cigarettes shows a positive impact on cessation. A small study of menthol smokers ages 16 and older found that 29.5 percent had made a quit attempt in the first month following the ban, nearly double the proportion (14.5%) who expected they would try to quit smoking in response to the ban. Additionally, 12.1 percent of menthol smokers remained quit at one month follow-up.¹³⁷

XII. ANPRM Question 16. If FDA Does Not Prohibit Flavored Tobacco Products, it Should Place Limitations on Their Sales, Advertising and Marketing.

As noted above, FDA should prohibit characterizing flavors in combusted tobacco products and smokeless tobacco and permit any characterizing flavors in e-cigarettes only where the manufacturer has demonstrated and FDA has reviewed and concluded that the particular flavoring in the particular product actually helps smokers, who would not otherwise stop smoking, to quit altogether or switch completely, without deterring cessation or increasing youth initiation, and is non-toxic. If, contrary to our recommendation, flavored products continue to be sold, sales should be permitted only in places where access is strictly limited to adults.

Moreover, if FDA permits the sale of any flavored product, in order to prevent sales of these products to underage users, non-face-to-face sales of the newly deemed products should be prohibited because of the difficulty of enforcing age verification standards for such sales. Research has shown that it remains easy for underage consumers to buy tobacco products—particularly e-cigarettes—over the internet without effective age verification.¹³⁸

The advertising and promotion of flavored tobacco products makes it abundantly clear that many flavored products are being advertised and marketed to children. The attached

¹³⁶ Richardson, A, et al., “How the industry is marketing menthol cigarettes: the audience, the message, and the medium,” *Tobacco Control*, 24: 594-600, 2015.

¹³⁷ Chaiton, M, et al., “Association of Ontario’s ban on menthol cigarettes with smoking behavior 1 month after implementation,” *JAMA Internal Medicine*, published online March 5, 2018.

¹³⁸ Williams, RT, et al., “Electronic cigarette sales to minors via the internet.” *JAMA Pediatrics* 169(3):e1563, published online March 2, 2015.

Appendix (at Exhibit A4) shows just a sample of the advertising and in-store placement of flavored tobacco products. An examination of these materials makes clear the audience for which they are intended and graphically illustrates that tobacco product manufacturers are still marketing tobacco products to children. Rising use of flavored tobacco products by children is no accident: it is the result of marketing designed to achieve this very result. Therefore, even if FDA were to approve a flavored product because it helps smokers to quit or switch completely, the agency should place restrictions on how it is marketed, to whom it is marketed and how it is sold. The evidence demonstrates that, absent marketing or sales restrictions, manufacturers will market their products in ways that appeal to youth and/or undermine cessation efforts.

It is important that the FDA define characterizing flavor in a way that makes the prohibition clear to manufacturers and retailers, protects public health, and prevents tobacco companies from evading the intent of the provision. In the redline version of the deeming rule, FDA noted that, “Among the factors that FDA would consider in determining whether a product has characterizing flavor are: whether the manufacturer or retailer is representing, through product labeling, advertising, or other means that the product has a characterizing flavor; whether the product elicits a characterizing flavor sensory perception; or whether the product contains chemicals or additives that produce a characterizing flavor for the tobacco product.”¹³⁹ To this end, the definition of characterizing flavor must include at least the following:

- The flavor must not be found in any component of the product, including tobacco, paper, filter, etc.
- The flavor need not have to be the single or primary characterizing flavor, but simply a characterizing flavor.
- The flavor may include the taste or the smell of the product.
- The flavor cannot be either in the product, the smoke, or the aerosol.
- Neither the product itself, nor any component of its marketing (e.g., the pack in pictures or words, advertising, public relations, etc.), communicate a characterizing flavor in any fashion

Thus, any definition should include:

“A tobacco product shall be deemed to have a characterizing flavor if the product or any component (including but not limited to the tobacco, paper, or filter) or its smoke or aerosol imparts a distinguishable taste or aroma other than tobacco either prior to consumption or during consumption.”

It should also make clear that a product will be deemed to have a characterizing flavor:

¹³⁹ Deeming Final Rule Redline Changes.

“if it or any component part thereof is advertised or marketed as having or producing a flavor, taste, or aroma other than tobacco.”

FDA should also make clear that products with flavor additives sufficient to produce a recognizable flavor in the average consumer are considered to have characterizing flavors even where the name of the flavor does not suggest an actual flavor. Nielsen convenience store market scanner data show an increasing number of “other” options have emerged in the past few years, using names that do not explicitly identify a flavor such as Swisher’s “Wild Rush” and Altria’s “Jazz,” even though they are flavored. This practice could reflect an attempt by cigar manufacturers to circumvent local sales restrictions on characterizing flavors, which rely on definitions that describe flavors.¹⁴⁰

XIII. ANPRM Question 23. Prohibition of Characterizing Flavors in Tobacco Products is Technologically Feasible.

Imparting a characterizing flavor to a tobacco product is accomplished by adding materials to the product. A prohibition on the use of characterizing flavors could be accomplished by a manufacturer’s simply refraining from introducing the additive that produces the flavor and thus presents no technological issue.

Respectfully submitted,

¹⁴⁰ Viola, AS, et al., “A cigar by any other name would taste as sweet,” *Tobacco Control*, published online October 1, 2015. See also Delnevo, CD, et al., 2017.

Action on Smoking and Health
 American Academy of Family Physicians
 American Academy of Oral and
 Maxillofacial Pathology
 American Academy of Oral Medicine
 American Academy of Pediatrics
 American Association for Dental Research
 American Association for Respiratory Care
 American Cancer Society Cancer Action
 Network
 American College of Cardiology
 American College of Obstetricians and
 Gynecologists
 American College of Physicians
 American College of Preventive Medicine
 American Heart Association
 American Medical Student Association
 American Psychological Association
 American Public Health Association
 American School Health Association
 American Society of Addiction Medicine
 American Society of Clinical Oncology
 Americans for Nonsmokers' Rights
 Association of State and Territorial Health
 Officials
 Association of Women's Health, Obstetric
 and Neonatal Nurses
 Big Cities Health Coalition
 Campaign for Tobacco-Free Kids
 Community Anti-Drug Coalitions of
 America
 Counter Tools
 Eta Sigma Gamma - National Health
 Education Honorary
 International Association for the Study of
 Lung Cancer
 Lung Cancer Alliance
 Mesothelioma Applied Research Foundation
 National African American Tobacco
 Prevention Network
 National Association of County and City
 Health Officials
 National Association of Pediatric Nurse
 Practitioners
 National Hispanic Medical Association
 National Network of Public Health Institutes
 Oncology Nursing Society
 Oral Health America
 Prevention Institute
 Public Health Solutions
 Society for Cardiovascular Angiography and
 Interventions
 Society for Public Health Education
 Students Against Destructive Decisions
 The Society for State Leaders of Health and
 Physical Education
 The Society of Thoracic Surgeons
 The University of Texas MD Anderson
 Cancer Center
 Trust for America's Health
 Truth Initiative