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August 2, 2022

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

Re: Docket No. FDA-2021-N-1309

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), and more than 40 million volunteers and supporters, we appreciate the opportunity to provide comments on the proposed product standard for characterizing flavors in cigars.

AHA strongly supports the Food and Drug Administration's (FDA) proposal to prohibit characterizing flavors (other than tobacco) in cigars. For decades, AHA has worked to combat the tremendous toll of tobacco use. Tobacco use is a leading preventable cause of death, disease, and disability in the U.S., and smoking is a major risk factor for cardiovascular disease, including stroke. More than 16 million Americans are living with a disease caused by smoking, and it is responsible for over 480,000 deaths in the U.S. each year.<sup>1</sup> Tobacco use is also the leading cause of premature death (before the age of 70) from cardiovascular disease.<sup>2</sup>

AHA would like to see an end to all tobacco and nicotine addiction in the U.S. We are particularly concerned about combustible products, like cigars, because they pose significant risk to users and to those exposed to secondhand smoke. Removing flavored cigars from the market would help minimize the use of combustible products and help us reach the tobacco endgame, which AHA defines as reducing the use of tobacco products to less than 5% in the U.S. by 2035, prioritizing less than 5% prevalence of combustible tobacco use by 2030 while continuing to ensure that other products do not addict the next generation of youth and adolescents. This ambitious, lifesaving goal is likely only achievable through the implementation of equity-focused public policies, such as this proposed rule.

The evidence supporting the proposed rule is clear. As we discuss below, characterizing flavors make cigars easier to use and more appealing to new users, increasing initiation among youth and young adults. Flavors also increase the likelihood that new users will continue to experiment with cigars and progress to regular tobacco use. Flavored cigars also contribute to tobacco-related health disparities and the resulting disparities in health outcomes. Removing flavored cigars from the market would have substantial benefits for public health, including reduced initiation, increased cessation, and lower rates of tobacco-related death and disease. The rule would also lower health care costs and advance health equity.

There is no question that prohibiting flavored cigars is “appropriate for the protection of public health.” We urge the FDA to move forward without delay.

### **Impact of Flavored Cigars on Tobacco Use**

#### ***Flavored Cigars Appeal to New Users and Increase Initiation***

Characterizing flavors increase the appeal of cigars and other combustible products and make them easier to use, resulting in increased initiation. Flavored cigars taste better because they are less harsh and less bitter, and the tobacco smoke is less astringent or irritating.<sup>3</sup> This makes flavored cigars a “starter product” for youth or other inexperienced tobacco users.

The flavors in cigars and other tobacco products are familiar to youth. One study found that candy-flavored tobacco products taste like candy because these tobacco products contain the same flavor chemicals used in candy and children’s drink mixes. According to the study’s authors, there is “great overlap in the flavor chemicals used.”<sup>4</sup> For example, benzaldehyde, benzyl alcohol, or both were found in “cherry” Jolly Rancher candies, Life Savers, Zotz Candy, Kool-Aid drink mix, and all cherry-flavored tobacco products.<sup>5</sup> The researchers also found overlap in grape and apple flavored candy and tobacco products and analogous patterns for peach and berry flavored products.

The sheer number of flavored cigars on the market also illustrate their appeal. After flavored cigarettes (other than menthol) were banned in 2009, we saw significant growth in the

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<sup>1</sup> U.S. Department of Health & Human Services. Smoking Cessation by the Numbers. Smoking Cessation: A Report of the Surgeon General. 2020.

<sup>2</sup> Roy A, et al. Tobacco and Cardiovascular Disease: A Summary of Evidence (in) Cardiovascular, Respiratory, and Related Disorders. 3<sup>rd</sup> edition. Washington, DC: The International Bank for Reconstruction and Development. The World Bank; 2017.

<sup>3</sup> 87 FR at 26405.

<sup>4</sup> Brown JE, et al. Candy Flavorings in Tobacco. N Engl J Med 2014; 370:2250-2252. June 5, 2014: DOI: 10.1056/NEJMc1403015.

<sup>5</sup> Ibid.

number of flavored cigars. Between 2008 and 2015, the number of unique cigar flavors increased from 108 to 250.<sup>6</sup> During that same period, sales of flavored cigars nearly doubled. A more recent examination found that flavored cigar sales continue to increase. In 2009, flavored cigars represented 45% of convenience store sales, but increased to 53.3% of the market share in 2020.<sup>7</sup> According to sales data from that study, the most popular cigar flavors are sweet/candy (30.6%), fruit (29.5%), concept (21.4%), and wine (9.0%).<sup>8</sup>

The appeal that flavored cigars have for youth is evident. Every day, more than 1,200 youth try a cigar for the first time,<sup>9</sup> and cigars have become one of the most commonly used tobacco products among youth. High school students now smoke cigars (2.1%) at a rate comparable to cigarettes (1.9%), and high school boys smoke cigars (2.6%) at a slightly higher rate than cigarettes (2.0%).<sup>10</sup> Much of their interest in cigars can be attributed to the availability of flavored cigars. Approximately 60% of youth who have ever used a cigar started with a flavored version, and between 44 and 58.3% of current users smoked a flavored cigar in the past month. Notably, almost 74% report using cigars “because they come in flavors I like.”<sup>11</sup>

Flavored cigars are also popular with young adults. Each day, more young adults try cigars (3,100) for the first time than cigarettes (2,600).<sup>12</sup> Like youth, more than 60% of young adults start smoking cigars with a flavored version, and 38.3% smoked a flavored cigar in the past month.<sup>13</sup> While some older adults also use flavored cigars, data from the 2013-2014 National Adult Tobacco Survey show that use of flavored cigars decreases with age:<sup>14</sup>

- 18-24 year-olds – 48.3% of cigar users
- 25-29 year-olds – 41.0%
- 30-44 year-olds – 37.1%
- 45-64 year-olds – 28.8%
- 65 and older – 17.8%

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<sup>6</sup> Delnevo, CD, et al. Changes in Mass-Merchandise Cigar Market Since the Tobacco Control Act. *Tobacco Regulatory Science*, 3(2 Suppl 1): S8-S16, 2017.

<sup>7</sup> Delnevo CD, et al. Cigar Sales in Convenience Stores in the US, 2009-2020. *JAMA*. 2021 Dec 21;326(23):2429-2432. doi: 10.1001/jama.2021.19692. PMID: 34932088; PMCID: PMC8693219.

<sup>8</sup> Ibid.

<sup>9</sup> Substance Abuse and Mental Health Services Administration. Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health, 2020.

[https://store.samhsa.gov/sites/default/files/SAMHSA\\_Digital\\_Download/PEP20-07-01-001-PDF.pdf](https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-07-01-001-PDF.pdf).

<sup>10</sup> Gentzke AS, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. *MMWR*. 2022; 71(5):32.

<sup>11</sup> Ambrose, BK, et al. Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014. *JAMA*. October 26, 2015.

<sup>12</sup> Substance Abuse and Mental Health Services Administration. 2020.

<sup>13</sup> 87 FR at 26404. PATH Study Data Tables and Figures. Inter-University Consortium for Political and Social Research, 2021. <https://www.icpsr.umich.edu/web/pages/NAHDAP/path-studytables-home.html>.

<sup>14</sup> Bonhomme, MG, et al. Flavoured Non-Cigarette Tobacco Product Use Among US Adults 2013-2014. *Tobacco Control*, 25: ii4-ii13, 2016.

This indicates that flavored cigar preference is strongest among youth and young adults.

***Flavored Cigars Encourage Experimentation and Continued Use***

In addition to enticing young people to initiate cigar use, flavored cigars also increase the likelihood that users will continue to experiment and progress to regular tobacco use. As the FDA explains in the proposed rule, “The process of becoming a regular cigar smoker includes stages of experimentation, development of nicotine dependence, and progression to regular use.”<sup>15</sup> Characterizing flavors contribute to this process by making cigar smoking a more enjoyable experience and facilitating repeat experimentation.

Flavors also appear to enhance dependence on nicotine. For example, youth who use flavored tobacco products are more likely to report strong cravings and a desire to use tobacco within 30 minutes of waking – both signs of nicotine dependence – compared to use of a non-flavored tobacco product.<sup>16</sup> Similarly, flavored cigar use among adults is associated with greater odds of daily cigar smoking and smoking within 30 minutes of waking.<sup>17</sup> Research has also shown that flavors “activate the brain’s reward circuit and produce rewarding effects on their own.”<sup>18</sup> This suggests that flavors and nicotine interact to reinforce nicotine’s effects.<sup>19</sup>

Flavored cigar smokers are also more likely to continue use and become frequent, regular users. According to an analysis of Population Assessment of Tobacco and Health (PATH) data, youth and young adults who initiate cigar use with a flavored cigar have greater odds of continuing cigar use in the future compared to those who initiate with a non-flavored version.<sup>20</sup> The analysis found that youth who start with a flavored cigar are 72% (menthol or mint) and 47% (other flavor) more likely to continue to use at follow-up one year or more later. Among young adults, the increased likelihood of continued use was 71% (menthol or mint) and 52% (other flavor) higher than adults who start with non-flavored cigars.

Taken together, this shows that flavored cigar users exhibit signs of greater nicotine dependence and are more likely to continue tobacco use.

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<sup>15</sup> 87 FR at 26406.

<sup>16</sup> Gomez Y, et al. Patterns of Tobacco Use and Nicotine Dependence Among Youth, United States, 2017–2018. *Preventative Medicine*, 141:106284, 2020. <https://doi.org/10.1016/j.ypmed.2020.106284>.

<sup>17</sup> Odani S, et al. Flavored Tobacco Product Use and Its Association with Indicators of Tobacco Dependence Among US Adults, 2014–2015. *Nicotine & Tobacco Research* 22(6):1004–1015, 2020. <https://doi.org/10.1093/ntr/ntz092>.

<sup>18</sup> Food and Drug Administration. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

<sup>19</sup> *Ibid.*

<sup>20</sup> 87 FR at 26407. Villanti, AC, et al. Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1–4 of the PATH Study, 2013– 2017.’ *Nicotine & Tobacco Research*, 23(8):1318–1326, 2021. <https://doi.org/10.1093/ntr/ntaa224>

## **Flavored Cigars Have a Disproportionate Impact on Certain Population Groups**

### ***Cigar Use is Highest Among Vulnerable Population Groups***

Cigar use varies by a number of factors, including age, race and ethnicity, income, education, gender identity, and disability status.<sup>21</sup> However, cigar use is most prevalent among youth, young adults, communities of color, and vulnerable or marginalized population groups.

Cigar smoking in the U.S. was traditionally a behavior in older men, however aggressive targeted marketing has increased their use among youth.<sup>22,23</sup> According to the 2020 National Youth Tobacco Survey (NYTS), 960,000 middle and high school students (3.5%) were current cigar smokers, and 550,000 of them (58.3%) used flavored cigars, making cigars the most commonly used combustible tobacco product among youth.<sup>24,25</sup> But cigar use varies significantly among youth of different racial and ethnic groups. Black students smoke cigars at disproportionately higher rates (6.5%) than White students (2.8%) and are more likely to initiate cigarillo or filtered cigar use at an earlier age.<sup>26</sup> Black youth are also more likely to have smoked a cigar in the past 30 days, more likely to smoke cigars (9.2%) than cigarettes (2.8%), and 111% more likely than non-Hispanic White youth to be “fairly regular” users of cigarillos or filtered cigars.<sup>27,28</sup> Black youth who smoke cigars are also disproportionately more likely to start smoking cigarettes.<sup>29</sup>

Similar disparities are seen among adult cigar users. In 2020, 8.6 million adults (3.5%) reported using cigars some or every day.<sup>30</sup> But Black adults were significantly more likely to report current cigar use, be a “fairly regular” cigar smoker, or use cigars every day.<sup>31</sup> In addition, prevalence of cigar use has not decreased among Black smokers as it has with other

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<sup>21</sup> Food and Drug Administration. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

<sup>22</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Centers for Disease Control and Prevention, Office on Smoking and Health, 2012.

<sup>23</sup> Harrell MB, et al. Flavored Tobacco Product Use Among Youth and Young Adults: What if Flavors Don't Exist? *Tob Regul Sci.* 2017 Apr;3(2):168-173. doi: 10.18001/TRS.3.2.4. PMID: 28775996; PMCID: PMC5536860.

<sup>24</sup> Gentzke, AS, et al. Tobacco Product Use Among Middle and High School Students—United States, 2020. *Morbidity and Mortality Weekly Report*, 69(50):1881–1888, 2020.

<sup>25</sup> 87 FR at 26397. Parms TA, et al. Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020. *American Journal of Preventive Medicine*, 62(1):e39–e44, 2022. <https://doi.org/10.1016/j.amepre.2021.06.011>.

<sup>26</sup> Gentzke, AS, et al. 2020.

<sup>27</sup> Ibid.

<sup>28</sup> Chen B, et al. Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars Among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017.” *PLoS ONE*, 15(12):e0243372, 2020. <https://doi.org/10.1371/journal.pone.0243372>.

<sup>29</sup> 87 FR 26414. Stokes AC, et al. Racial/Ethnic Differences in Associations of Non- Cigarette Tobacco Product Use with Subsequent Initiation of Cigarettes in US Youths. *Nicotine & Tobacco Research*, 23(6):900–908, 2021. <https://doi.org/10.1093/ntr/ntaa170>.

<sup>30</sup> Cornelius ME, et al. Tobacco Product Use Among Adults - United States, 2020. *MMWR Morb Mortal Wkly Rep.* 2022 Mar 18;71(11):397-405. doi: 10.15585/mmwr.mm7111a1.\$

<sup>31</sup> Food and Drug Administration. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

racial and ethnic groups.<sup>32</sup> Almost half of Black youth and 70% of Black young adult cigar smokers use flavored cigars.<sup>33,34</sup>

Disparities are also seen in the LGBTQ population. According to 2020 NYTS data, youth who identify as lesbian, gay, or bisexual are nearly twice as likely (6.0%) to use cigars compared to heterosexual youth (3.1%).<sup>35</sup> Ever or current cigar use is also higher among adults who identify as lesbian, gay, or bisexual; and transgender adults are significantly more likely (26.8%) to be past 30-day-users of cigars compared to cisgender adults (9.3%).<sup>36</sup>

As the FDA found in its Scientific Assessment, cigar use is also higher among youth with disabilities, adults experiencing a chronic physical or mental health condition, individuals experiencing poor mental health, and those with less education or lower household income.<sup>37</sup>

Notably, while cigarette smoking has declined to all-time lows, cigar smoking has increased.

### ***The Cigar Industry Targets Underserved Communities***

The popularity of flavored cigars among youth, young adults, Black Americans, and others is the result of intentional targeting by the tobacco industry. The tobacco industry has used a combination of appealing flavors, inexpensive pricing, and a variety of advertising and marketing tactics to increase flavored cigar use in underserved communities.

Tobacco companies use characterizing flavors to make cigars more attractive or marketable to certain populations. Cigars are marketed in a wide range of candy and fruit flavors, such as chocolate, cherry, strawberry, and grape, which are attractive to youth, as well as with catchy names that appeal to young people such as Da Bomb Blueberry, Pinkberry, and Banana Split. Studies have shown that the popularity of cigars among youth and young adults can largely be attributed to the availability of flavored products. As one study discussed by the FDA found, nearly half of youth and young adult focus group participants believe that “the most appealing component of cigar packaging were aspects that indicated

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<sup>32</sup> Ibid.

<sup>33</sup> Gentzke AS, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021. MMWR. 2022; 71(5):32.

<sup>34</sup> National Academies of Sciences, Engineering, and Medicine. Premium Cigars: Patterns of Use, Marketing, and Health Effects; 2022.

<sup>35</sup> Gentzke AS, et al. Tobacco Product Use Among Middle and High School Students – United States, 2020. MMWR. 2020; 69(1881-1888).

<sup>36</sup> Food and Drug Administration. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

<sup>37</sup> Ibid.

the flavor (e.g., a flavor name or image)” and that “words describing the flavor (e.g., “sweet”) were a reason to buy the product.”<sup>38</sup>

Tobacco companies also developed flavored “cigars” that mimic cigarettes. These “little cigars” are similar in shape, size, filters, and packaging to the flavored cigarettes that were popular with youth until the Tobacco Control Act removed them from the market.<sup>39,40</sup> Tobacco companies simply rebranded their flavored cigarettes as “little cigars” to circumvent the flavored cigarette ban. As the Surgeon General noted, after the ban, “Djarum clove cigarettes re-emerged in the market as clove flavored cigars, and Sweet Dreams flavored cigarettes re-emerged as Sweet Dreams flavored cigars.”<sup>41</sup> This led to the rise in flavored “little cigars” or “cigarillos” and the resulting increase in the number of youth using flavored cigars.

Similarly, cigar manufacturers have recently been offering an increasing number of so called “concept” cigars that utilize color names or sensory descriptors like Summer Twist, Moontrance, or Jazz where the flavor is not immediately recognizable based on the product name alone.<sup>42</sup> These products still appeal to youth and young adults and may successfully evade local or state flavor prohibitions if they are not easily identifiable as a flavored tobacco product.

Tobacco companies also use small pack sizes and low pricing to make cigars attractive to certain populations. Cigars, unlike cigarettes, may be sold individually or in small quantities. After the flavored cigarette ban took effect, there was a shift in cigar pack sizes with sales of cigars in packs of two or three increasing 140%.<sup>43</sup> More recently, sales of individually wrapped cigars have also grown substantially.<sup>44</sup> These small pack sizes are designed to appeal to price sensitive youth. As one wholesale distributor put it, the most popular cigars are those priced at “two-for-99-cents, three-for-\$1.29 and save-on-two.”<sup>45</sup> And, as the FDA

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<sup>38</sup> 87 at FR 26405. Liu J, et al. Inside the Adolescent Voice: A Qualitative Analysis of the Appeal of Different Tobacco Products. *Tobacco Induced Diseases*, 19:15, 2021. <https://doi.org/10.18332/tid/132856>.

<sup>39</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults. A Report of the Surgeon General. 2012.

<sup>40</sup> Delnevo CD, et al. A whole ‘nother smoke” or a cigarette in disguise: How RJ Reynolds reframed the image of little cigars. *Am J Public Health* 2007;97:1368–75.

<sup>41</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults. 2012.

<sup>42</sup> Henriksen L, et al. Marijuana as a 'concept' flavour for cigar products: availability and price near California schools. *Tobacco Control*. 2018 Sep;27(5):585-588. DOI: 10.1136/tobaccocontrol-2017-053961.

<sup>43</sup> Delnevo CD, et al. Changes in the mass-merchandise cigar market since the Tobacco Control Act. *Tob Regul Sci*. 2017;3(2)(suppl 1):S8-S16. doi:10.18001/TRS.3.2(Suppl1).2.

<sup>44</sup> Riell H. Cigars Face New Challenges, CStore Decisions, 2021. <https://cstoredecisions.com/2021/06/23/cigars-face-proposed-federal-flavor-ban/>

<sup>45</sup> Ibid.

discusses in the proposed rule, an analysis of proprietary sales data suggests that flavored cigars are generally priced lower than tobacco-flavored cigars.<sup>46</sup>

Flavored cigars are also marketed heavily in communities of color. Retailers in Black, Hispanic, Korean, and low-income communities are more likely to carry and advertise inexpensive tobacco products, such as flavored cigars, little cigars, and 99-cent cigarillos.<sup>47,48,49,50,51,52</sup> One study conducted in Washington, DC also found that retailers in neighborhoods with a greater proportion of Black residents had more outdoor advertisements and price promotions for little cigars and cigarillos.<sup>53</sup> Advertisements of little cigars and cigarillos in Black markets highlight the perceived attributes of these products while downplaying or failing to mention their harms.<sup>54</sup>

Cigar companies also distribute coupons or free samples in Black communities, advertise in Black publications, sponsor music festivals, and try to associate their products with an urban lifestyle, hip hop, and rock music – the same tactics used by the tobacco industry to market menthol cigarettes. Cigar companies have also enlisted popular Black performers to serve as spokespeople<sup>55</sup> and use influencers – many from communities of color – to promote cigars on social media.<sup>56</sup>

### ***Cigars Have a Disproportionate Health Impact***

As discussed above, flavored cigar use is most prevalent among young people, communities of color, and other underserved populations. Unfortunately, these disparities in use translate to unequal health outcomes.

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<sup>46</sup> 87 FR at 26403.

<sup>47</sup> Giovenco DP, et al. Neighborhood Differences in Alternative Tobacco Product Availability and Advertising in New York City: Implications for Health Disparities. *Nicotine Tob Res.* 2019;21(7):896-902. doi:10.1093/ntr/nty244.

<sup>48</sup> Smiley SL, et al. Disparities in retail marketing for little cigars and cigarillos in Los Angeles, California. *Addict Behav Rep.* 2018;9:100149. Published 2018 Dec 5. doi:10.1016/j.abrep.2018.100149

<sup>49</sup> Cantrell J, et al. Marketing little cigars and cigarillos: advertising, price, and associations with neighborhood demographics. *Am J Public Health.* 2013;103(10):1902-1909. doi:10.2105/AJPH.2013.301362.

<sup>50</sup> Ribisl KM, et al. Disparities in tobacco marketing and product availability at the point of sale: Results of a national study. *Prev Med.* 2017;105:381-388. doi:10.1016/j.yjpm.2017.04.010.

<sup>51</sup> Roberts ME, et al. Point-of-sale tobacco marketing in rural and urban Ohio: Could the new landscape of Tobacco products widen inequalities? *Prev Med.* 2015;81:232-235. doi:10.1016/j.yjpm.2015.08.024

<sup>52</sup> Rose SW, et al. Inequitable Distribution of FTP Marketing by Neighborhood Characteristics: Further Evidence for Targeted Marketing. *Nicotine Tob Res.* 2022;24(4):484-492. doi:10.1093/ntr/ntab222

<sup>53</sup> Cantrell J, 2013.

<sup>54</sup> Rosario C, et al. Tobacco Advertisements: What Messages Are They Sending in African American Communities?. *Health Promot Pract.* 2020;21(1\_suppl):54S-60S. doi:10.1177/1524839919882390

<sup>55</sup> Sterling KI. Exposure to Celebrity-Endorsed Small Cigar Promotions and Susceptibility to Use Among Young Adult Cigarette Smokers. *Journal of Environmental and Public Health.* 2013:520286, 2013.

<sup>56</sup> Navarro MA, et al. Influencer Prevalence and Role on Cigar Brand Instagram Pages. *Tobacco Control.* , October 12, 2020. doi: 10.1136/tobaccocontrol-2020-055994



The disparities are most evident among Black tobacco users. Research has shown that Black Americans are more likely to initiate cigar use at an earlier age, smoke cigars more regularly, and have lower odds of discontinuing cigar use.<sup>57,58</sup> In addition, the prevalence of cigar use among Black smokers has, depending on the study, remained steady or increased over time, despite decreasing in other racial and ethnic groups.<sup>59,60</sup> This means that Black cigar smokers may be exposed to harmful tobacco constituents for a longer period of time, increasing their risk for tobacco-related death and disease.

Black communities already suffer some of the greatest burden of tobacco-related death of any racial or ethnic group in the U.S.<sup>61</sup> Tobacco use is a major contributor to three of the leading causes of death among Black Americans: heart disease, cancer, and stroke.<sup>62</sup> Tobacco use is an independent risk factor for heart disease and is linked to nearly one-half of all premature deaths due to cardiovascular disease.<sup>63</sup> Black adults are 30% more likely to die from heart disease, and 50% more likely to die from stroke.<sup>64,65</sup> Smoking is also responsible for one-third of all cancer deaths and approximately 85% of all lung cancer deaths.<sup>66</sup> Tobacco use also increases the risk of developing diabetes, another leading cause of death in Black Americans, by 30-40% compared to non-smokers.<sup>67</sup>

Black children and adults are also more likely to be exposed to secondhand smoke than any other racial and ethnic groups.<sup>68</sup> In 2013-2014, 66.1% of all Black children aged 3-11 years,

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<sup>57</sup> Chen B, et al. Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars Among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017." PLoS ONE, 15(12):e0243372, 2020. <https://doi.org/10.1371/journal.pone.0243372>.

<sup>58</sup> Kasza K.A, et al. Correlates of Tobacco Product Cessation Among Youth and Adults in the USA: Findings from the PATH Study Waves 1–3 (2013–2016). Tobacco Control, 29:s203–s215, 2020. <https://doi.org/10.1136/tobaccocontrol-2019-055255>.

<sup>59</sup> Weinberger AH, et al. Trends in Cigar Use in the United States, 2002–2016: Diverging Trends by Race/Ethnicity.' Nicotine & Tobacco Research, 22(4):583–587, 2020. <https://doi.org/10.1093/ntr/ntz060>.

<sup>60</sup> Rostron BL, et al. Cigar Smoking Prevalence and Morbidity Among US Adults, 2000– 2015. Preventive Medicine Reports, 14:100821, 2019. <https://doi.org/10.1016/j.pmedr.2019.100821>.

<sup>61</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups. 1998.

<sup>62</sup> Centers for Disease Control and Prevention. <https://www.cdc.gov/tobacco/campaign/tips/groups/african-american.html>

<sup>63</sup> Bhatnagar A. Environmental Determinants of Cardiovascular Disease. Circ Res. 2017;121:162-180.

<sup>64</sup> U.S. Department of Health and Human Services. Office of Minority Health. Heart Disease and African Americans. <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlID=19>

<sup>65</sup> U.S. Department of Health and Human Services. Office of Minority Health. Stroke and African Americans. <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlID=28>

<sup>66</sup> Warren GW, et al. Tobacco and lung cancer: risks, trends, and outcomes in patients with cancer. Am Soc Clin Oncol Educ Book. 2013:359-64. doi: 10.14694/EdBook\_AM.2013.33.359. PMID: 23714547.

<sup>67</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/diabetes/library/features/smoking-and-diabetes.html>

<sup>68</sup> Centers for Disease Control & Prevention. <https://www.cdc.gov/tobacco/health-equity/african-american/secondhand-smoke.html>

55.3% of Black adolescents 12-19 years, and 45.5% of Black adults aged 20 and older were exposed to secondhand smoke.<sup>69</sup> Exposure to secondhand smoke can have devastating health effects. Children get sick more frequently, including more severe asthma attacks, respiratory infections, ear infections, and sudden infant death syndrome.<sup>70</sup> Secondhand smoke also causes cardiovascular disease and lung cancer.<sup>71</sup> It is important to note that large cigars may produce even more smoke than cigarettes because large cigars typically contain more tobacco, as much as a whole pack of cigarettes.<sup>72</sup>

### **Benefits of Removing Flavored Cigars**

#### ***Reduce Initiation and Use, Increase Cessation***

AHA agrees with the FDA's assessment that prohibiting characterizing flavors in cigars (other than tobacco) would reduce initiation and use. As discussed in this letter and the proposed rule, flavors significantly increase the appeal of cigars to youth and young adults, make cigars easier to use, and increase the likelihood that young cigar users will continue to experiment and progress to regular use. Removing flavors from these products will decrease cigars' appeal.

We also agree that prohibiting characterizing flavors would increase the number of smokers who stop using cigars. Real-world evidence suggests that many flavored tobacco product users do attempt to quit in response to flavor restrictions. For example, after Canada banned menthol cigarettes, many smokers attempted to quit.<sup>73</sup> Similarly, after flavor restrictions were implemented in several U.S. cities and states, sales of both flavored and non-flavored cigars declined.<sup>74,75</sup>

We expect that an FDA ban on characterizing flavors would have an even more significant impact. One study that examined the population health benefits of a nationwide flavored cigar ban estimated that it would result in 780 fewer cigar-smoking attributable premature deaths in the U.S. each year.<sup>76</sup> This is a conservative estimate as the study's authors limited

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<sup>69</sup> Ibid

<sup>70</sup> Centers for Disease Control & Prevention.

[https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/secondhand\\_smoke/health\\_effects/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/secondhand_smoke/health_effects/index.htm)

<sup>71</sup> Ibid

<sup>72</sup> 79 FR at 23151.

<sup>73</sup> Fong GT, et al. Summary of the ITC Project Evaluation of the Canada-Wide Ban on Menthol Cigarettes: Implications for Projected Increases in Quitting in the United States and California. April 8, 2021

<sup>74</sup> Farley SM, et al. New York City Flavoured Tobacco Product Sales Ban Evaluation. *Tobacco Control* 26(1):78-84, 2017.

<sup>75</sup> Rogers T, et al. Changes in Cigar Sales Following Implementation of a Local Policy Restricting Sales of Flavoured Non-Cigarette Tobacco Products. *Tobacco Control* 29(4):412-419, 2020.

<sup>76</sup> L Rostron B, et al. Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars throughout the US. *Int J Environ Res Public Health*. 2019 Sep 4;16(18):3234. doi: 10.3390/ijerph16183234

their mortality calculations to exclusive cigar smokers; they did not examine the impact that a flavored cigar ban may have on individuals who practice dual use.<sup>77</sup> The study also found that a flavored cigar ban would keep 112,000 people in each cohort of 18 year-olds from initiating cigar use or progressing to regular cigar use.

These data add to the evidence base in support of a flavored cigar ban.

### ***Improve Public Health***

If flavored cigars are removed from the market, it will have a substantial impact on public health, reducing tobacco-related morbidity and mortality. As the Agency is well aware, cigar smoking causes cancer of the oral cavity, larynx, esophagus, and lung; and increases risk for heart disease, chronic obstructive pulmonary disease, and aortic aneurysm.<sup>78</sup> Simply being exposed to secondhand cigar smoke, which contains the same harmful substances as cigarette smoke, increases risk for heart disease, cancer, and stroke, as well as a number of serious health conditions in children and adolescents. Each year, 9,000 premature deaths are attributed to regular cigar smoking, including 5,200 in cigar smokers who did not also use cigarettes.<sup>79</sup> In addition, the average cigar smoker loses approximately 15 life years.<sup>80</sup>

The good news is that quitting cigarette smoking has “immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general;”<sup>81</sup> we expect that those same benefits would apply to cigar cessation. For example, heart rate and blood pressure drop 20 minutes after finishing an acute episode of smoking.<sup>82</sup> As early as two weeks after quitting, circulation improves and lung function increases. One year after quitting, the excess risk of coronary heart disease drops to half that of someone who continued to smoke. Five to ten years after quitting, stroke risk decreases. And fifteen years after quitting, the risk of coronary heart disease reduces to that of a nonsmoker.

If, as a result of the proposed rule, even a small fraction of flavored cigar users quit, or youth or young adults do not start, it will have a substantial benefit on public health. According to the Regulatory Impact Analysis, if 30% of adults who currently smoke flavored cigars quit, there would be 25,000 fewer premature deaths over 40 years.<sup>83</sup> An additional 55,500 lives would be saved by reducing youth cigar initiation by an estimated 36%.

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<sup>77</sup> Food and Drug Administration. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

<sup>78</sup> Cigar Smoking and Cancer Fact Sheet. National Cancer Institute, National Institutes of Health.

<sup>79</sup> Nonnemaker J, et al. Mortality and Economic Costs from Regular Cigar Use in the United States, 2010. *American Journal of Public Health*, 104(9):e86–e91, 2014. <https://doi.org/10.2105/AJPH.2014.301991>.

<sup>80</sup> Ibid.

<sup>81</sup> HHS. The Health Consequences of Smoking. 2004.

<sup>82</sup> American Cancer Society. Health Benefits of Quitting Smoking Over Time. <https://www.cancer.org/healthy/stay-away-from-tobacco/benefits-of-quitting-smoking-over-time.html>

<sup>83</sup> Food and Drug Administration. Tobacco Product Standard for Characterizing Flavors in Cigars: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis.

### ***Lower Health Care Costs***

A reduction in flavored cigar use would also lead to lower health care costs. As described in the proposed rule, cigar smoking results in an estimated \$1.75 billion in health care expenditures each year, with \$284 million attributed to exclusive cigar smoking and \$1.5 billion attributed to dual use.<sup>84</sup> This same study found that exclusive cigar smoking results in “72,137 excess nights in the hospital, 32,748 excess ED visits, and 420,118 excess home-care visits.”<sup>85</sup>

While AHA is unable to quantify the specific cost savings that would result from a flavored cigar ban during this comment period, it is evident that fewer cigar smokers would result in lower health care costs.

### ***Advance Health Equity***

AHA agrees with the Agency that removing flavored cigars from the market is an important step to advance health equity. Flavored cigar initiation and use is higher in underserved and vulnerable populations, including youth, communities of color, the LGBTQ community, and communities with lower income or rates of educational attainment. This has resulted in tobacco-related health disparities within those communities.

One of the best ways to address these disparities is to eliminate flavored cigars because they are intentionally and aggressively marketed to these populations. Because flavored cigar use is higher in these communities, this policy is expected to have the greatest impact in these same population subgroups.<sup>86</sup> Flavored cigar use and adverse tobacco-related health effects in these populations would likely decrease significantly.

### **Scope of the Proposed Product Standard**

#### ***All Cigars Should Be Subject to the Product Standard***

Under the proposed rule, all tobacco products that meet the definition of a “cigar” would be subject to the new product standard prohibiting the use of characterizing flavors other than tobacco.

AHA strongly supports this proposal; the product standard should apply to all cigars. All cigars pose risk; all cigars expose users to nicotine, toxins, and carcinogens; and all cigars cause cancer and increase risk for heart and lung diseases. In addition, youth use of cigars is not limited to one specific type of cigar. Youth cigar smokers report using cigarillos (44.1%), regular cigars (33.1%), and little cigars (22.6%), while one-fifth of current youth cigar users

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<sup>84</sup> Wang Y, et al. Health Care Utilization and Expenditures Attributable to Cigar Smoking Among US Adults, 2000-2015. Public Health Rep. 2018 May/Jun;133(3):329-337. doi: 10.1177/0033354918769873.

<sup>85</sup> Ibid.

<sup>86</sup> 87 FR at 26403.

report not knowing the type of cigar they use (21.8%).<sup>87</sup> (It is important to note that the NYTS does not ask respondents how frequently they use “premium” cigars). We also know that flavored cigars of all types are particularly appealing to youth. More than one-third of all youth traditional cigar smokers (33.9%), 46% of youth cigarillo smokers, and one-half of youth filtered cigar smokers (50.2%) report smoking flavored versions.<sup>88</sup> Accordingly, there is no reason to exempt any subset of cigars from the proposed product standard.

If any cigars were exempt from the product standard, youth and youth adults would simply migrate to those flavored versions. As the Agency is aware, that is what occurred after flavored cigarettes (other than menthol) were removed from the market in 2009. The tobacco industry started producing different types of flavored tobacco products that were not subject to the prohibition, including flavored cigars. As a result, we saw a significant increase in both the number of flavored cigars on the market and the number of youth using them. If the FDA were to limit the characterizing flavor ban to certain types of cigars, we are likely to see the same product migration happen again. Both the tobacco industry and youth would adjust to the ban by moving to cigars where flavors are still allowed. We urge the FDA not to make that mistake. We also encourage the Agency to take immediate action against flavored cigarettes that are masquerading as “little cigars or “cigarillos” simply to circumvent the flavored cigarette ban.

We understand that the proposed product standard will not impact “premium” cigars to the extent that they meet the court’s definition as established in *Cigar Association of America, et al v. Food and Drug Administration, et al*. According to that definition, “premium” cigars do not have a characterizing flavor other than tobacco. We urge the FDA to carefully monitor the cigar market to ensure that manufacturers do not attempt to claim that they are “premium” cigars and are somehow not subject to the product standard.

### ***All Combustible Products Should be Subject to the Product Standard***

According to the proposed rule, the:

FDA is proposing to limit the scope of this proposed standard to cigars, given their well-documented harms and the fact that flavored cigars clearly appeal to youth and young adults in large numbers, while undertaking additional efforts to evaluate and determine whether to prohibit or otherwise limit characterizing flavors in other tobacco products.<sup>89</sup>

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<sup>87</sup> Parms TA, et al. Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020. *American Journal of Preventive Medicine*, 62(1):e39–e44, 2022. <https://doi.org/10.1016/j.amepre.2021.06.011>.

<sup>88</sup> PATH Study Data Tables and Figures, 2021.

<sup>89</sup> 87 FR at 26434.

The Agency then requests comments on whether the product standard should be extended to other combustible tobacco products, specifically waterpipe and pipe tobacco.

AHA strongly supports extending the product standard to all combustible tobacco products; there is no public health benefit to allowing characterizing flavors in combusted tobacco. Combustible products present the highest level of risk to the individual user and those exposed to secondhand smoke. As the Surgeon General concluded: “The burden of death and disease from tobacco use in the United States is *overwhelmingly caused by cigarettes and other combusted tobacco products*; rapid elimination of their use will dramatically reduce this burden” (emphasis added).<sup>90</sup>

We urge the FDA to extend the product standard to all combustible tobacco products, including hookah and pipe tobacco. We also encourage the Agency to move forward with its separate proposal to prohibit menthol as a characterizing flavor in cigarettes. Moving both standards forward in tandem will have the greatest public health benefit.

### ***Hookah/Waterpipe Tobacco***

The proposed product standard should be extended to include hookah or waterpipe tobacco. Like flavored cigars, waterpipe tobacco has “well-documented harms” and “clearly appeal[s] to youth and young adults in large numbers.”

Hookah has many of the same risks as cigarette or cigar smoking. Hookah users are exposed to toxins, carcinogens, carbon monoxide, tar, heavy metals, and nicotine.<sup>91</sup> Hookah users may be exposed to higher levels of these chemicals because hookah smoking sessions are typically longer (20-80 minutes) and involve more inhalations. According to the FDA, a one-hour hookah session “involves inhaling 100–200 times the volume of smoke from a single cigarette.”<sup>92</sup> Hookah users are at increased risk for cancer, heart disease, reduced lung function, and decreased fertility, and may give birth to babies with low birth weight and increased risk of respiratory disease.<sup>93</sup>

Hookah is also popular with youth and young adults. In 2020, 420,000 high school students and 160,000 middle school students reported using hookah in the past 30 days. Flavored hookah was particularly popular. One study found that 88.7% of all 12-17 year-olds who

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<sup>90</sup> U.S. Department of Health & Human Services. The Health Consequences of Smoking – 50 Years of Progress. A Report of the Surgeon General. 2014

<sup>91</sup> Bhatnagar A, et al. Waterpipe (Hookah) Smoking and Cardiovascular Disease Risk: A Scientific Statement from the American Heart Association. *Circulation*. 2019;139:e917–e936. 2019.  
<https://doi.org/10.1161/CIR.0000000000000671>

<sup>92</sup> Food and Drug Administration. Hookah Tobacco (Shisha or Waterpipe Tobacco)

<sup>93</sup> Ibid.

had ever used hookah used flavored hookah the first time they used the product.<sup>94</sup> According to the same study, use of flavored tobacco is higher for users of hookah than for any other tobacco product. In addition, youth hookah users overwhelmingly report (78.9%) using hookah “because they come in flavors I like.”<sup>95</sup>

Hookah use is particularly concerning because many users are unaware of the dangers associated with it. One study of adolescents found that 33% believe smoking hookah is less harmful than cigarettes, 38% believe hookah is less addictive, and almost half (48%) reported that hookah is socially acceptable among friends.<sup>96</sup>

According to the proposed rule, the FDA is hesitant to prohibit characterizing flavors in hookah because of limited data on how hookah tobacco might be used in the absence of characterizing flavors.<sup>97</sup> While we understand the Agency’s preference for additional data, we encourage the FDA to consider the information that is currently available. We already know that hookah presents significant health risks for users; that hookah is used by hundreds of thousands of young people; and that the availability of hookah in flavors such as strawberry lemonade, double apple, white gummi bear, and chocolate mint is a major reason why young people are drawn to this product. If the FDA allows hookah with characterizing flavors to remain on the market, youth and young adults will continue to use these dangerous products. In contrast, prohibiting flavored hookah would reduce the appeal to youth and young adults and reduce initiation and experimentation among this age group; adults would still have the option to use traditional, tobacco-flavored hookah.

### ***Pipe Tobacco***

The proposed product standard should also be extended to include pipe tobacco. Pipe tobacco, like all combustible tobacco products, poses risk.

According to the proposed rule, the FDA opted not to include pipe tobacco because fewer youth and young adults use pipe tobacco compared to cigars. While we understand the Agency’s rationale, we are concerned that youth and young adult pipe tobacco use will increase when other flavored combustible products are removed from the market. As discussed above, youth use of flavored cigars increased significantly when flavored cigarettes were removed from the market. We anticipate the same thing could happen in this situation; youth may migrate from flavored cigars to flavored pipe tobacco.

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<sup>94</sup> Ambrose BK, et al. Flavored Tobacco Product Use Among U.S. Youth Aged 12-17 Years, 2103-2014. *Journal of the American Medical Association*, published online October 26, 2015.

<sup>95</sup> *Ibid.*

<sup>96</sup> Fitzpatrick M, et al. Adolescent Beliefs About Hookah and Hookah Tobacco Use and Implications for Preventing Use. *Prev Chronic Dis* 2019;16:180093. DOI: <http://dx.doi.org/10.5888/pcd16.180093>

<sup>97</sup> 87 FR at 26434.

Allowing flavored pipe tobacco to remain on the market would also provide tobacco companies with an opportunity to evade the flavor restriction. As we've already described, the tobacco industry has a history of taking advantage of loopholes, such as rebranding flavored cigarettes as flavored "cigars" or relabeling roll-your-own tobacco as pipe tobacco to avoid higher excise tax rates. We are concerned that the tobacco industry would do the same here and exploit any loophole that remains.

If the Agency decides against prohibiting characterizing flavors in pipe tobacco, we ask the FDA to closely monitor the number of pipe tobacco products on the market, prevalence of pipe tobacco use, and pipe tobacco sales. The FDA must be prepared to act if youth and young adult use increases.

Again, we urge the FDA to make all combustible tobacco products subject to the proposed product standard.

### **Characterizing Flavor**

#### ***Factors to Identify a Characterizing Flavor***

According to the proposed rule, the FDA intends to use the following four factors to determine if a cigar has a characterizing flavor:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts
- The multisensory experience (i.e., taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packing) or advertising of a tobacco product
- Any other means that impart flavor or represent that a tobacco product has a characterizing flavor

We understand the Agency's decision to utilize these "specific, flexible factors"<sup>98</sup> rather than one rigid definition. It would be difficult to develop one definition that adequately covers all the methods the tobacco industry can utilize to produce a flavored product or the sensation of one. It would also be difficult to capture new ingredients or innovations that the tobacco industry may develop in the future. In addition, providing one specific definition might actually make it easier for the tobacco industry to evade the flavoring restriction.

However, we are still concerned that the tobacco industry will attempt to evade the four factors identified by the FDA. As we've noted repeatedly, the tobacco industry has a long

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<sup>98</sup> 87 FR at 26488.



history of exploiting any loopholes. Therefore, we strongly encourage the FDA to consider ways to strengthen and apply the proposed factors. This may include flagging ingredients that are not traditionally thought of as flavors but provide some of the same sensory effects, such as ingredients with anesthetic or cooling properties, sweeteners, the use of multiple flavor additives but each in small amounts to evade any specific flavor limits, the use of a small amount of a flavor additive in conjunction with other ingredients that amplify its flavor or effects, or flavor ingredients added to the product packaging.

The factors the FDA ultimately selects must be able to withstand the innovative, perpetual, and persistent efforts the tobacco industry will undoubtedly employ.

### ***Tobacco-Flavored Cigars***

Under the proposed rule, cigars with tobacco as their characterizing flavor would not be prohibited. According to the Federal Register notice, the tobacco flavor “need not be naturally inherent to the product to be considered ‘tobacco flavored’ but rather may result from the addition of ingredients or other measures by the manufacturer to produce the presence of tobacco as its characterizing flavor.”<sup>99</sup>

It is unclear how this provision will work. How will the FDA determine which ingredients or flavor additives impart a “tobacco” flavor? How will a “tobacco” flavor be described or defined? According to the Premium Cigar Association, “tobacco has a variety of natural flavor profiles” like oak, leather, hay, pepper, spice, coffee, and chocolate.<sup>100</sup> Will cigar manufacturers be allowed to add spice, chocolate, or similar additives to create that “natural tobacco flavor profile” if it does not rise to the level of a characterizing flavor?

We request that the FDA clarify this provision.

### ***Flavor Descriptors in Marketing***

In addition, we understand that cigar brands use terms like “chocolate,” “spice,” and “coffee” in their marketing materials to describe non-flavored cigars.<sup>101</sup> We find this concerning. Tobacco companies should not be allowed to use this type of flavor descriptor on product labeling or packaging or in advertising. Consumers – especially youth – are unlikely to understand the distinction between a cigar with a chocolate characterizing flavor and a tobacco-flavored cigar with a “natural” chocolate flavor profile; consumers will simply see a product advertised as a “chocolate” cigar.

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<sup>99</sup> 87 FR at 26437.

<sup>100</sup> Premium Cigar Association. Handout. E.O. 12866 Meeting with Office of Information and Regulatory Affairs. March 10, 2022.

<sup>101</sup> Ibid.

Any cigar that uses this type of flavor descriptor in their labeling, packaging, or advertising should be considered a flavored cigar and prohibited under the proposed product standard. We recommend that FDA explicitly prohibit the use of this type of flavor descriptor.

### **Pathways to Market**

#### ***Substantial Equivalence Pathway***

Under the Tobacco Control Act, manufacturers are required to submit new tobacco products for FDA review. This would include any flavored tobacco product that is modified to comply with the proposed product standard.

AHA agrees that manufacturers may be able to use the substantial equivalence (SE) exemption pathway to satisfy this requirement. This pathway would be appropriate if the *only* change to the product is the removal of flavor additives to comply with the prohibition against characterizing flavors. The SE exemption process would not be appropriate if the manufacturer adds new ingredients to the product, makes any major changes, or if the product was not legally marketed prior to the implementation of the product standard.

To show that a product meets the SE exemption criteria, the manufacturer must provide detailed information about the modification, demonstrate that the modification is, in fact minor, and explain why a more detailed substantial equivalence report is not necessary to ensure that the product is appropriate for the protection of public health. The FDA must rigorously review all SE exemption requests and make its own determination that a SE exemption is appropriate. Products that do not meet these requirements must be required to use another premarket pathway.

### **Possible Countervailing Effects**

#### ***Illicit Trade Market***

In the Federal Register notice, the FDA examines possible countervailing effects that may occur if the proposed product standard is adopted, including an illicit trade market. We agree with the FDA's assessment that if this were to occur, its impact would be minimal. It is unlikely that a large number of illicit flavored cigars would be available, or that a substantial number of smokers would utilize such products. We also agree that the risks of a potential illicit market do not outweigh the benefits created by this rule.

It is important to recognize that the argument that a flavored cigar ban will create an illicit market is largely driven by the tobacco industry itself. The tobacco industry has a history of using the threat of an illegal market to argue against tobacco regulations, such as flavor restrictions and increased tobacco taxes. The industry overstates the risks of an illicit market to create opposition to the proposed policy. That is the case again here.

It is unlikely that a large illicit market of flavored cigars would develop in the U.S. because the product standard would prohibit the manufacture, distribution, or sale of these products. Cigar manufacturers would no longer be producing flavored cigars for a U.S. market, and it is unlikely that manufacturers would be willing to engage in large scale manufacturing of illegal products. In addition, because the product standard would apply nationwide, would-be participants in an illicit market would not be able to obtain flavored cigars simply by crossing state lines. Therefore, it would be difficult for entities to secure large quantities of flavored cigars to distribute and sell in an illicit market.

In addition, we are unaware of any evidence that other flavor restrictions have led to a significant increase in illicit tobacco. For example, after flavored cigarettes (other than menthol) were removed from the market in 2009 as directed by the Tobacco Control Act, there was no surge in illicit flavored cigarettes. Instead, youth cigarette smoking decreased.<sup>102</sup> There is additional real-world evidence from other U.S. cities that have implemented flavor restrictions, as well as evidence from Canada and England. For example, after the Canadian province of Nova Scotia banned menthol cigarettes, a study found “there was no surge in illicit cigarettes after the 2015 ban on menthol cigarette sales.”<sup>103</sup> And, as the National Research Council and Institute of Medicine concluded in their 2015 report “Understanding the U.S. Illicit Tobacco Market,” if tobacco products are modified by regulation, such as eliminating flavors or reducing nicotine content, “the demand for illicit versions of them is likely to be modest.”<sup>104</sup>

The FDA and other enforcement agencies also have tools to combat an illicit market and minimize its effects. A recent letter from 23 Attorneys General in support of a menthol cigarette ban described several of those tools, which would also apply to flavored cigars, such as preventing the importation of prohibited products (U.S. Customs and Border Protection), inspecting cigarette manufacturers (Alcohol and Tobacco Tax and Trade Bureau), and inspecting tobacco retailers (FDA).<sup>105</sup> The FDA could also implement a track-and-trace system, as required by the Tobacco Control Act. A track-and-trace system would allow the FDA to track tobacco products from their manufacture or importation to the point of retail

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<sup>102</sup> 87 FR at 26470-26471.

<sup>103</sup> Stoklosa M. No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia. *Tobacco Control* 2019;28:702-704.

<sup>104</sup> National Research Council. 2015. *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/19016>.

<sup>105</sup> Attorney General of Connecticut, et al. Comments on Docket No. FDA-2013-P-0435. Citizen Petition to the Federal Food, Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes. Jan 22, 2021.

sale by use of a unique, counterfeit-resistant identification code.<sup>106</sup> Illegal cigars that lack the track-and-trace code could be easily identified.

We understand that some opponents of the proposed rule have argued that a flavored cigar ban would create an illicit market where underage youth could buy tobacco products. They argue it would be safer to keep flavored cigars on the market where they are sold by legitimate tobacco retailers who ID customers before purchase. While AHA strongly supports the 2019 federal law that raised the minimum sales age to 21, and we urge all retailers to comply with its requirements, we must note that underage youth are still able to obtain tobacco products. According to the 2021 NYTS, 2.55 *million* middle and high school students are current tobacco users.<sup>107</sup> This shows that age restrictions alone are not sufficient to keep youth from obtaining tobacco products. If flavored cigars are allowed to remain on the market, underage youth would still be able to access them from retail and social sources. The best way to curb youth use of flavored cigars is to remove them from the market.

Again, we do not believe a flavored cigar product standard will result in a significant illicit market, but, if an illicit market emerges, any potential adverse effects will be outweighed by the substantial public health benefit.

### **Potential Racial and Social Justice Implications**

#### ***Impact of a Flavored Cigar Ban on Minority Communities***

In the Federal Register notice, the FDA acknowledges concerns that a flavored cigar ban may result in illicit trade, increased policing, and criminal penalties in underserved communities, including Black communities. The Agency then requests comments on the “policy considerations related to potential racial and social justice implications of the rule.”<sup>108</sup>

AHA appreciates the FDA requesting comments on this important topic. Racial discrimination and the overpolicing of Black people and other communities of color is a critical issue and one that must be addressed urgently; we share the public’s concern. Unfortunately, the tobacco industry has taken this legitimate issue, twisted, and exploited it, and turned it into a tool to defeat tobacco regulations. The tobacco industry itself is largely responsible for fueling the claim that a flavored cigar and menthol cigarette ban will lead to increased policing in Black communities and mass incarcerations. Ironically, the tobacco

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<sup>106</sup> Action on Smoking and Health, et al. Comments on FDA-2018-N-0529. Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard. July 16, 2018.

<sup>107</sup> Centers for Disease Control and Prevention. Press Release: Approximately 2.55 Million Students Reported Currently Using a Tobacco Product in 2021. March 10, 2022.

<sup>108</sup> 87 FR at 26435.

industry aggressively pushes this talking point, while it continues to target these same communities with products that kill almost half-a-million people in the U.S. each year.

The tobacco industry has enlisted the help of community groups, influential leaders, social media influencers, politicians, and political organizations in its efforts to boost sales and fight tobacco restrictions. For decades, tobacco companies have aligned themselves with Black and Hispanic leaders and provided financial support that is meant to promote name recognition and engender goodwill among members of these communities and encourage trusted community figures to support the tobacco industry's position on tobacco regulation, such as opposing flavor restrictions.<sup>109,110</sup> The tobacco industry has, for example, recruited civil rights activists and other prominent Black leaders to host town halls on flavor bans and increased criminalization,<sup>111</sup> hosted events at law enforcement conferences, hired lobbyists to fight tobacco restrictions without acknowledging the source of their funding, and paid protestors to attend rallies.<sup>112</sup> The tobacco industry has also used television and social media ads to oppose local flavored tobacco restrictions, claiming that it will increase racial profiling by law enforcement.<sup>113</sup> Most recently, the industry has tried to associate itself with the Black Lives Matter movement and concerns about police brutality. While much of this work to date has focused on menthol cigarettes, the impact is widespread and has affected perceptions of a flavored cigar ban.

However, the proposed rule is specifically designed not to increase law enforcement interactions with the community. The FDA is clear that the rule will only apply to manufacturers, distributors, wholesalers, importers, and retailers; it will not include a prohibition of individual consumer possession or use.<sup>114</sup> According to the Agency, "FDA cannot and will not enforce against individual consumers for possession or use of flavored cigars."<sup>115</sup> In addition, the FDA has clarified that state and local law enforcement entities do not and cannot take enforcement action on FDA's behalf for violations of this restriction. Therefore, a federal ban on flavored cigars should not increase the risk of police abuse or racial discrimination within particular communities.

The important public health benefits of removing flavored tobacco products from the market have also been recognized by many members of the Black community. For example, the

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<sup>109</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups: A Report of the Surgeon General. Atlanta, 1998.

<sup>110</sup> National Cancer Institute. The Role of the Media in Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19. Bethesda, MD: NIH Pub. No. 07-6242, June 2008.

<sup>111</sup> Truth Initiative. Menthol: Facts, Stats and Regulations. April 22, 2022. <https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations>.

<sup>112</sup> Ibid.

<sup>113</sup> Truth Initiative. Menthol: Facts, Stats and Regulations.

<sup>114</sup> 87 FR at 26432.

<sup>115</sup> 87 FR at 26484.

African American Tobacco Control Leadership Council, Association of Black Cardiologists, Black Women’s Health Imperative, Center for Black Health and Equity, NAACP, National Black Nurses Association, National Caucus and Center on Black Aging, and National Medical Association, among others have all voiced strong support for removing menthol cigarettes from the market. In a letter to HHS Secretary Becerra in April 2021, the groups described how “The industry’s successful campaign to hook Black/African Americans on a more addictive cigarette has had devastating consequences” and noted that:

The tobacco industry’s spokespeople have attempted to stoke fears that prohibiting menthol cigarettes is discriminatory, but this could not be further from the truth. The industry has mischaracterized a prohibition on menthol cigarettes as criminalizing Black/African American smokers when the tobacco industry is directly responsible for this disparity in menthol use. Therein lies the true injustice. There are undoubtedly racial injustices in our criminal justice system, but FDA’s rulemaking process should clarify that just as it enforces other tobacco regulations, a prohibition of menthol cigarettes will focus enforcement efforts on manufacturers and retailers, not individual consumers.<sup>116</sup>

A flavored cigars and menthol cigarette ban is also supported by many Black policy makers. For example, in 2020, a majority of the Congressional Black Caucus (CBC) voted for legislation that would prohibit flavors in tobacco products, including flavored cigars and menthol cigarettes. And last year, the CBC Health Braintrust called on HHS to remove menthol cigarettes from the market, stating that “[t]he tobacco industry must no longer be permitted to use menthol cigarettes to profit at the expense of the health of Black Americans.”<sup>117</sup>

Finally, we do not view this proposed rule as an either/or choice where the FDA must choose between protecting people from flavored cigars or from biased policing. We must address both issues. We cannot let this opportunity pass us by, and we cannot allow the tobacco industry – the same industry that has spent decades aggressively marketing and advertising its products to communities of color – to falsely frame this debate. Removing flavored cigars and menthol cigarettes from the market is one of the most important public health actions the Agency can take to improve health, reduce tobacco-related health disparities, and advance health equity. We urge the FDA to move forward with this important public health action.

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<sup>116</sup> African American Tobacco Control Leadership Council, et al. Letter to HHS Secretary Becerra. April 14, 2021. [https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204\\_14\\_21.pdf](https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204_14_21.pdf)

<sup>117</sup> CBC Health Braintrust. Letter to HHS Secretary Becerra. April 15, 2021. [https://www.tobaccofreekids.org/assets/content/press\\_office/2021/CBCletter.pdf](https://www.tobaccofreekids.org/assets/content/press_office/2021/CBCletter.pdf)

## **Effective Date**

### ***Proposed Effective Date***

According to the proposed rule, the new tobacco product standard would take effect one year after a final rule is published. AHA agrees that one year is an appropriate timeline. A one-year effective date would be consistent with the statute, and it would give flavored cigar smokers time to access cessation services and attempt to quit. We know that smoking cessation can be very difficult, and, for many, it takes multiple attempts to permanently quit. We believe one year strikes the appropriate balance between giving current smokers an opportunity to quit and not delaying the effective date for too long and increasing the number of new youth and young adults who start using flavored cigars. We would strongly oppose extending the effective date beyond one year.

One year would also give the FDA and other federal and state agencies sufficient time to expand cessation resources and to educate the public about the types of services available. To provide flavored cigar smokers with adequate cessation support, the Agency should work with other departments within HHS to:

- Expand the FDA's "The Real Cost" campaign to educate youth about the health consequences and risks of smoking cigars
- Expand the 1-800-QUIT-NOW quit lines and include new options for smokers to access cessation resources, such as including online cessation services
- Expand and adapt the CDC's Tips from Former Smokers campaign to maximize its impact on the populations most affected by flavored cigars
- Expand coverage of tobacco cessation treatments and ensure that non-grandfathered group plans, individual insurance plans, and state Medicaid programs provide cessation services as required by the Affordable Care Act
- Launch a public education campaign to explain the nature of the flavored cigar product standard, the reasons for it, and the cessation resources available

We must also assure equitable access to comprehensive cessation therapies for those who want to quit.

### ***Sell-Off Period***

The FDA requests comment on whether it should include a sell-off period, such as 30 days after the effective date of a final rule, to give retailers time to sell through their current inventory of flavored cigars. AHA strongly opposes a separate sell-off period. A one-year effective date will provide retailers sufficient time to plan, adjust their orders for flavored cigars, and sell any remaining inventory by the time the rule takes effect. There is no justification for a separate sell-off period.

## **Regulatory Impact Analysis**

### ***Consumer Surplus***

AHA is disappointed that the Regulatory Impact Analysis (RIA) contains a discussion of “consumer surplus” or what is loosely defined as how much a consumer values or benefits from a product. As we have expressed to FDA previously, we do not believe that “consumer surplus” should be applied to tobacco use.

The concept of lost consumer surplus should only be considered when individuals are able to make fully rational and fully informed decisions. However, nearly nine out of 10 smokers start smoking before age 18 and 99% start before age 25.<sup>118</sup> Adolescents are not fully aware of the health consequences of tobacco use, have little concept of their own mortality, and heavily discount the threat of addiction, making their decisions neither fully informed nor rational. It is this premise – that youth may not be able to make fully rational decisions – that led policymakers to create and later raise the minimum sales age for tobacco products.

In addition, tobacco is addictive and once an individual becomes addicted, the decision to continue buying tobacco products is no longer rational. Addiction is not a pleasurable experience. Instead, addiction to a deadly product can lead to frustration and anger as individuals find it very difficult to quit using tobacco. Surveys have found that nearly 70% of adult smokers want to stop smoking and 56% have made a serious quit attempt;<sup>119</sup> most wish they had never started.

By applying consumer surplus, the Agency is also ignoring the role that decades of targeted marketing have played in enticing people to use flavored cigars. The tobacco industry has gone to great effort and expense to develop products that appeal to young people and other targeted populations and are designed to maximize addictiveness.<sup>120</sup> That means that smoking “is not as personal a ‘choice’ as some assume.”<sup>121</sup>

According to the RIA, the FDA recognizes some of the challenges of applying consumer surplus to cigar smoking, noting “it is difficult to disentangle consumption driven by addiction from that which may be driven by rational demand” and “some argue that most consumers do not experience losses from reduced use because they derive little to no pleasure from consumption,” yet the Agency still considers consumer surplus as

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<sup>118</sup> U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, 2012.

<sup>119</sup> Babb, S., et al. Quitting Smoking Among Adults—United States, 2000-2015. *Morbidity and Mortality Weekly Report*, 65(52):1457-1464. 2017.

<sup>120</sup> Public Health Law Center. Menthol Ban: Highlighting the Facts and Rebutting Tobacco Industry Misinformation.

<sup>121</sup> *Ibid.*



“appropriate impact to consider.”<sup>122</sup> We disagree and we urge the Agency to remove the concept of consumer surplus or consumer utility change from the RIA.

## **Conclusion**

In closing, we reiterate our strong support for the proposed rule. Prohibiting characterizing flavors in cigars is appropriate for the protection of public health. Removing flavored cigars from the market would reduce initiation, increase cessation, and lower rates of tobacco-related death and disease. This product standard would also lower health care costs, reduce health disparities, and advance health equity. Importantly, it would also eliminate one of the tobacco industry’s tools to attract and addict new smokers, especially among youth, communities of color, and other underserved populations. We applaud the FDA for taking this important step.

To keep the rule strong and maximize its public health benefit, we urge the FDA to:

- Apply the product standard to all combustible tobacco products, including all cigars, hookah, and pipe tobacco
- Apply the product standard to all cigar, hookah, and pipe tobacco components and parts, including those that are sold separately to consumers
- Strengthen the factors used to identify a “characterizing flavor” to eliminate loopholes
- Clarify how the FDA will distinguish between prohibited characterizing flavors and flavor additives allowed in “tobacco-flavored” products
- Prohibit the use of flavor descriptors such as chocolate, spice, and coffee in the labeling, packaging, or advertising of “tobacco-flavored” cigars, hookah, and pipe tobacco
- Work with federal and state agencies to expand cessation resources
- Launch a public education campaign
- Establish a one-year effective date with no sell-off period

AHA also encourages the Agency to work as expeditiously as possible to release the final rule. Six years have passed since FDA first announced that it would issue a product standard to eliminate flavored cigars. During that time, the market share for flavored cigars continued to increase and the number of youth, young adults, and people of color using these products remained high. We fear that any delay will have real, and continuing, public health consequences. Therefore, we urge you to release the final rule by the end of this calendar year.

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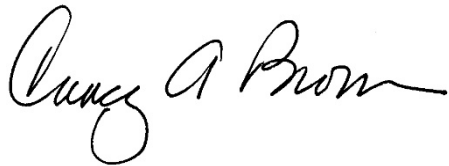
<sup>122</sup> FDA. Tobacco Product Standard for Menthol in Cigarettes: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis. 2022.

Prohibiting flavored cigars and menthol cigarettes is one of the most important actions the FDA can take “to ensure that tobacco-related disease and death is a part of America’s past, not America’s future.”<sup>123</sup> We look forward to continuing to work with you to achieve this mutual goal.

Thank you for your consideration of our comments.

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

Sincerely,

A handwritten signature in black ink that reads "Nancy A. Brown". The signature is written in a cursive style with a long horizontal flourish at the end.

Nancy A. Brown  
Chief Executive Officer  
American Heart Association

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<sup>123</sup> @FDATobacco. May 20, 2002. <https://twitter.com/FDATobacco/status/1527689609261506560>