







This indicates that flavored cigar preferences are 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. *Preventive Medicine*, 141:106284, 2020. <https://doi.org/10.1016/j.ypmed.2020.106284>.

<sup>17</sup> Odani S, et al. Flavored Tobacco Use and Nicotine Dependence Among Youth, United States, 2017–2018. *Preventive Medicine*, 141:106284, 2020. <https://doi.org/10.1016/j.ypmed.2020.106284>.

## 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 550,00 of them (58.3%) used flavored cigars, making cigars the most commonly used combustible tobacco product among youth.<sup>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. 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.#MID: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. Parns TA, et al. Characteristics of Past 30 Day Cigar Smoking, U.S. Adolescents 2020. *American J. Public Health*. 2021; 111(10):1603-1609. doi: 10.2196/20175

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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



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>



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 Cigarettes, Filtered Cigarettes, and/or Traditional Cigarettes 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*

55.3% of Black adolescents 12-19 years, and 45% 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.

### 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)

their mortality calculations to exclusive cigarmokers; 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>

### 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, 32,488 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

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> Parns 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

had ever used hookah used flavored hookah the first time they used the product. 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

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



history of exploiting any loopholes. Therefore, we strongly encourage the FDA to consider ways to strengthen and apply the proposed fact

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

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.



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>14</sup> According to the Agency, "FDA cannot and will not enforce against individual consumers for possession or use of flavored cigars."<sup>15</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

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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

### 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:

- x Expand the FDA's "The Real Cost" campaign to educate youth about the health consequences and risks of smoking cigars
- x Expand the 1-800-QUIT-NOW quit lines and include new options for smokers to access cessation resources, such as including online cessation services
- x Expand and adapt the CDC's Tips from Former Smokers campaign to maximize its impact on the populations most affected by flavored cigars
- x Expand coverage of tobacco cessation treatments and ensure that non-grandfathered

## 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 so 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 add 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:

- x Apply the product standard to all combustible tobacco products, including all cigars, hookah, and pipe tobacco
- x Apply the product standard to all cigar, hookah, and pipe tobacco components and parts, including those that are sold separately to consumers
- x Strengthen the factors used to identify a “characterizing flavor” to eliminate loopholes
- x Clarify how the FDA will distinguish between prohibited characterizing flavors and flavor additives allowed in “tobacco-flavored” products
- x 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
- x Work with federal and state agencies to expand cessation resources
- x Launch a public education campaign
- x 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 the 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.

