



August 2nd, 2022

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

**Re: Docket No. FDA-2021-N-1309 for “Tobacco Product Standard for Characterizing Flavors in Cigars.”**

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the proposed rule to establish a product standard for characterizing flavors in cigars. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society’s (ACS) nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer.

Tobacco use is the leading cause of preventable death in the U.S., with more than 480,000 deaths each year caused by cigarette smoking and costs more than \$300 billion in medical costs and lost productivity.<sup>1</sup> This includes 30% of all cancer deaths and 80% of lung cancer deaths.<sup>2</sup>

People who smoke cigars are four to ten times more likely to die from laryngeal, oral or esophageal cancers than people who do not smoke cigars.<sup>3</sup> Heavy cigar smoking also increases the risk of developing lung diseases, such as emphysema and chronic bronchitis.<sup>4</sup> Regular cigar smoking increases the risk of cancers of the lung, oral cavity, larynx, and esophagus.<sup>5</sup>

The American Cancer Society has documented the lethal consequences of smoking and its detrimental effects on almost every organ of the body; and ACS CAN has advocated for comprehensive public policies to effectively reduce tobacco use and exposure to secondhand smoke in the U.S. In fact, the

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<sup>1</sup> US Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Washington, DC: US Department of Health and Human Services, CDC; 2014. Available at <http://www.surgeongeneral.gov/library/reports/50-years-ofprogress/full-report.pdf>.

<sup>2</sup> Islami F, Goding Sauer A, Miller KD, Siegel RL, Fedewa SA, Jacobs EJ, McCullough ML, Patel AV, Ma J, Soerjomataram I, Flanders WD, Brawley OW, Gapstur SM, Jemal A (2018) Proportion and number of cancer cases and deaths attributable to potentially modifiable risk factors in the United States. *CA Cancer J Clin* 68: 31-54

<sup>3</sup> Oral Cancer and Tobacco. Johns Hopkins Medicine. <https://www.hopkinsmedicine.org/health/conditions-and-diseases/oral-cancer-and-tobacco#:~:text=Smokers%20are%20also%20at%20a,60%20known%20cancer%2Dcausing%20agents.>

<sup>4</sup> Cigars. Centers for Disease Control and Prevention. [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/cigars/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/cigars/index.htm)

<sup>5</sup> American Cancer Society. Cancer Facts & Figures 2022. Atlanta: American Cancer Society; 2022.

national reductions in overall cancer mortality over the past few years can be partially attributed to our work in tobacco control to prevent youth from starting to use tobacco products and helping current people who use tobacco quit.

Despite this progress, tobacco-related disparities exist and continue to grow. These disparities are not by accident, but rather a direct result, in part, of the tobacco industry's marketing directly to these communities.<sup>6</sup>

Cigars pose a real danger to the long-term health of all Americans – and to young people especially – yet government regulation of cigars lags behind that of cigarettes and e-cigarettes. In January 2020, the FDA prohibited the sale of most flavors in cartridge-based e-cigarettes.<sup>7</sup> Flavored cigarettes, except for menthol, have been largely illegal since 2009. However, similar regulations do not exist for flavored cigars, something that has helped the cigar industry stay attractive to younger customers.

Eliminating characterizing flavors in all cigars is a critically important action the Food and Drug Administration (FDA) can take to reduce initiation of smoking, promote cessation, and reduce tobacco-related health disparities. ACS CAN supports the swift finalization and implementation of the rule to prohibit characterizing flavors in cigars with no exemptions and to expand the rule to all other tobacco products. Critically important, ACS CAN recommends the FDA implement outreach education and cessation services to people who smoke flavored cigars and other tobacco products now, in anticipation of when the rule becomes effective. Additionally, ACS CAN supports the equitable enforcement of tobacco control laws and that no law enforcement agency has the authority to enforce this rule against individual consumers.

We have added our name to a comprehensive comment letter on the proposed rule submitted by the Campaign for Tobacco-Free Kids and signed by dozens of tobacco control and health partners. We submit these additional comments to contribute to the record in support of the tobacco product standard for menthol in cigarettes.

### **Addressing Cancer Disparities**

Innovations in cancer prevention, detection, treatment and survivorship have come a long way, but not everyone has benefited equally.<sup>8</sup> While overall cancer mortality rates in the U.S. are dropping, populations that have been marginalized are bearing a disproportionate burden of cancer.

For example, Black people have the highest death rates and shortest survival rates of any racial or ethnic group in the U.S. for most cancers.<sup>9</sup> Lung cancer is the most common cause of cancer death among Black

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<sup>6</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>7</sup> FDA Finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint. U.S. Food and Drug Administration. Published January 2, 2020. Accessed December 9, 2020. <https://www.fda.gov/news-events/press-announcements/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes-appeal-children>

<sup>8</sup> <https://www.cancer.org/about-us/what-we-do/health-equity.html>

<sup>9</sup> American Cancer Society. Cancer Facts & Figures for African American/Black People 2022-2024. Atlanta: American Cancer Society, 2022.

men, despite Black men having overall lower lifetime smoking rates.<sup>10</sup> More than 25,000 Black people will be diagnosed with lung cancer and more than 14,000 will die from it in 2022. Additionally, Black individuals also experience more illness, worse outcomes, and premature death compared to white individuals.

People who identify as lesbian, gay, bisexual, transgender or queer (LGBTQ) may have a higher risk of getting cancer than those who people identify as heterosexual or cisgender. The American Cancer Society estimates there will be 1.9 million newly diagnosed cancer cases and nearly 609,000 cancer deaths in 2022 with national estimates that 5-10% of the general population identify as LGBTQ, this means there could be approximately 143,900 new cancer cases and more than 45,702 cancer deaths in the LGBTQ+ population this year.<sup>11</sup>

These cancer disparities are largely driven by social mechanisms like structural racism and discrimination against historically marginalized groups, but also the direct actions of the tobacco industry in designing products and targeting its marketing to specific communities, like Black and LGBTQ communities. To reduce deaths from tobacco-related cancers, everyone must not only have the ability to benefit from the advances in prevention and treatment of cancer, but also be protected from the predatory actions of the tobacco industry. Taking actions that protect those individuals that are bearing the disproportionate burden of cancer by the design of the tobacco industry meets the FDA’s standard for the protection of public health.

### **Current Use and Trends in Cigar Prevalence and Sales**

Cigars are tobacco wrapped in tobacco leaf or wrapped in a substance containing tobacco leaf. Cigars sold in the United States include large cigars, cigarillos, and little cigars. Large cigars usually contain at least a half an ounce of tobacco, while cigarillos tend to be shorter and contain 3 grams or less of tobacco. Some cigarillos and little cigars are similar in size and shape to cigarettes.

Flavored cigars make up a substantial portion of the cigar market, particularly after the 2009 prohibition on characterizing flavors in cigarettes (excluding menthol). In 2020, cigarillos also constituted the largest market share (94.2%) of cigars sold in the U.S., followed by little cigars (3.1%), and large cigars (2.7%).<sup>12</sup> From 2016-2020, share of annual unit sales of flavored tobacco products was 48-51% for cigarillos, 46-49% for little cigars, and 13-17% for large cigars. Several studies have documented the increase in flavored cigars sales over the course of the last two decades.<sup>13,14</sup> The prohibition on characterizing flavors in cigarettes (excluding menthol) without a prohibition on cigars opened the door for cigar manufacturers to recruit new users to its products.

### *Adults:*

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<sup>10</sup> American Cancer Society. Cancer Facts & Figures for African American/Black People 2022-2024. Atlanta: American Cancer Society, 2022.

<sup>11</sup> <https://www.cancer.org/content/dam/cancer-org/cancer-control/en/booklets-flyers/lgbtq-people-with-cancer-fact-sheet.pdf>

<sup>12</sup> Xu Wang, PhD, Yoonsang Kim, PhD, Mateusz Borowiecki, BA, Michael A Tynan, BA, Sherry Emery, PhD, Brian A King, PhD, Trends in Cigar Sales and Prices, by Product and Flavor Type—the United States, 2016–2020, *Nicotine & Tobacco Research*, Volume 24, Issue 4, April 2022, Pages 606–611, <https://doi.org/10.1093/ntr/ntab238>

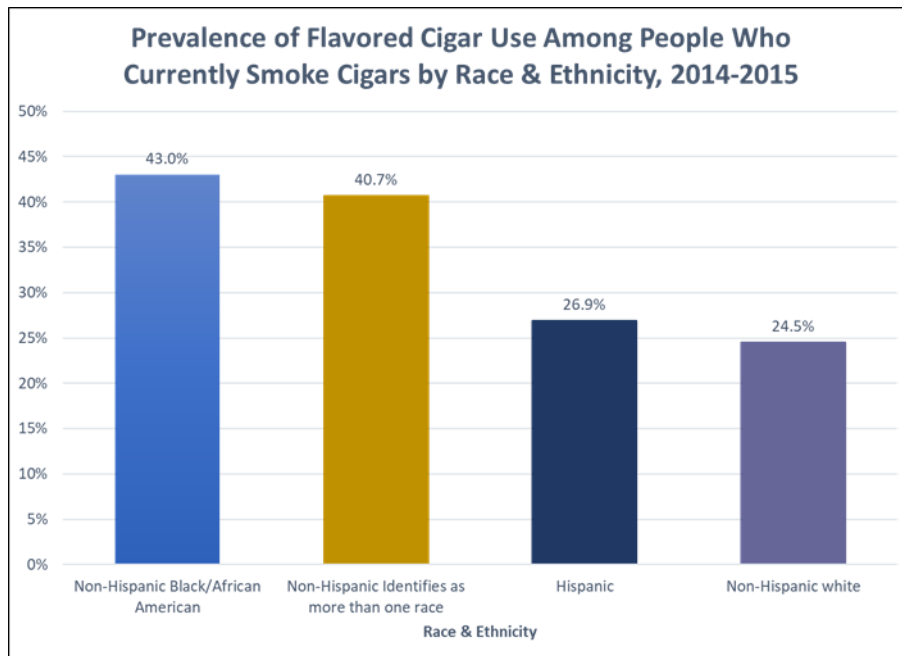
<sup>13</sup> Delnevo, CD, et al., “Cigar Sales in Convenience Stores in the US, 2009-2020,” *JAMA* 326(23):2429-2432, 2021.

<sup>14</sup> Delnevo, CD, Giovenco, DP, & Miller, EJ, “Changes in the Mass-merchandise Cigar Market since the Tobacco Control Act,” *Tobacco Regulatory Science* 3(2 Suppl 1):S8-S16, 2017.

In 2020, 3.5% of U.S. adults reported current cigar use.<sup>15</sup> Cigar use was higher among men (6.3%) than women (0.8%) and higher for non-Hispanic Black adults (4.6%) than white non-Hispanic adults (3.8%), Hispanic adults (2.2%) or non-Hispanic Asian adults (0.9%). Cigar use was higher for adults who identified as gay, lesbian or bisexual (4.3%) than adults who identified as heterosexual (3.5%).

Among adults who currently smoke cigars, those who used flavored products were more likely to be non-Hispanic Black individuals, younger, and have lower household incomes.<sup>16</sup>

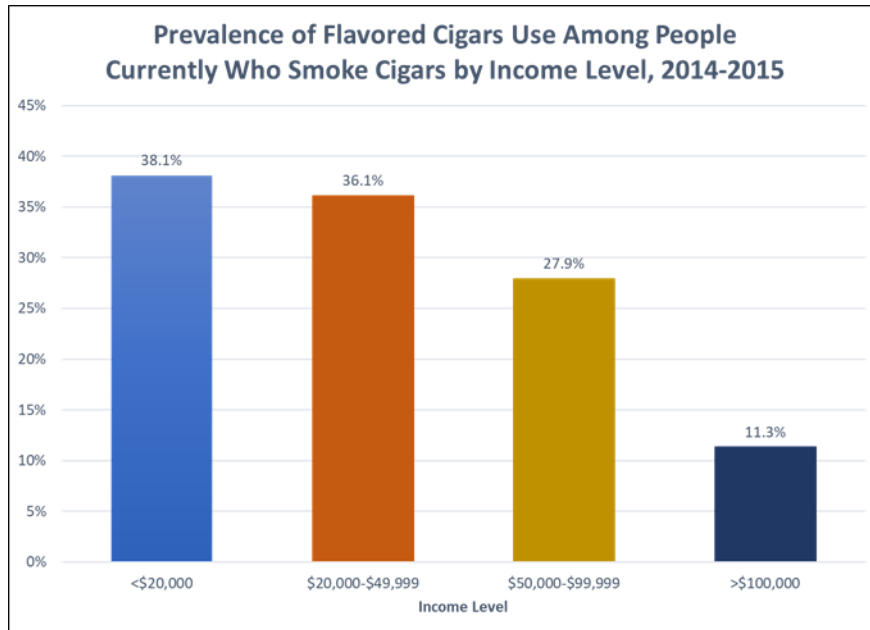
Among individuals who currently smoke cigars, non-Hispanic Black Americans were nearly twice as likely to smoke a flavored cigar compared to non-Hispanic white Americans.



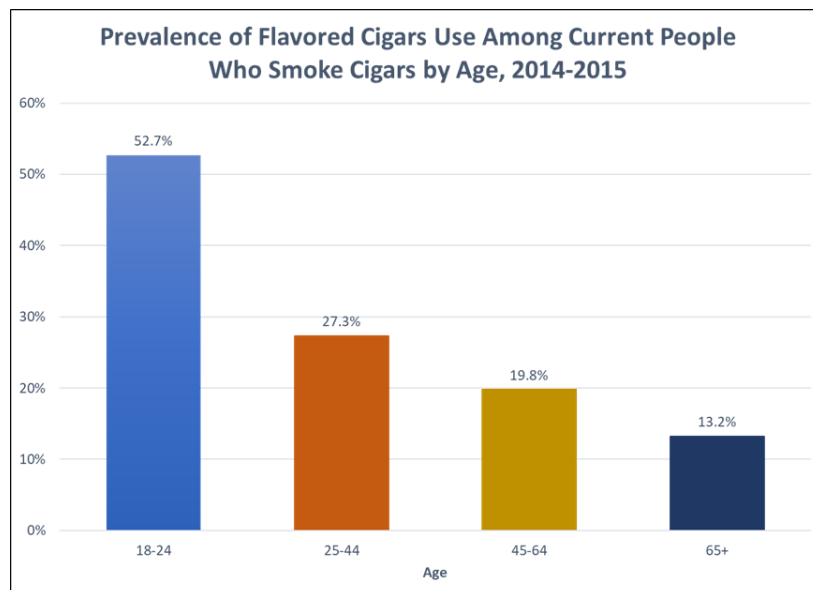
Among individuals who currently smoke cigars, those with household incomes below \$20,000 were more than three times as likely to use a flavored cigar than individuals with household incomes of more than \$100,000.

<sup>15</sup>Cornelius ME, Loretan CG, Wang TW, Jamal A, Homa DM. Tobacco Product Use Among Adults — United States, 2020. *MMWR Morb Mortal Wkly Rep* 2022;71:397–405. DOI: <http://dx.doi.org/10.15585/mmwr.mm7111a1>

<sup>16</sup> Odani S, Armour B, Agaku IT. Flavored Tobacco Product Use and Its Association With Indicators of Tobacco Dependence Among US Adults, 2014–2015. *Nicotine & Tobacco Research*. 2020;22(6):1004-1015. doi:10.1093/ntr/ntz092



Among adults who currently smoke cigars, younger adults (aged 18-24) were 4 times as likely to smoke flavored cigars than older adults (aged 65+).



**Youth:**

An estimated 380,000 U.S. students were current cigar users in 2021, making cigars the second most popular tobacco product overall and the most popular combustible tobacco product among youth.<sup>17</sup> Black students are more than twice as likely to use cigars than their peers. In 2021, 3.1% of surveyed Black middle and high school students reported using cigars in the past 30 days, compared to 1.4%

<sup>17</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Surveill Summ 2022;71(No. SS-5):1–29.

among all students. Male high school students are also more likely than female high school students to be current cigar users (2.6% vs 1.5%).

Flavored cigars are very popular among children and young adults. In 2021, 44.4% of students who currently use cigars reported using flavored cigars in the past 30 days (41.1% for high school students and 59.9% for middle school students).<sup>18</sup> Importantly, flavored cigars can also serve as a gateway for new tobacco users. A 2019 longitudinal study found that, among youth aged 12-17 who began using cigars during the study period, 45.2% reported that their first product was flavored.<sup>19</sup> This same study found that young adults aged 18-24 who start with flavored cigars are more likely to become regular users compared to those who start with unflavored cigars.

### **Prohibiting All Characterizing Flavors in All Cigars is for the Protection of Public Health**

*All cigars can cause cancer and are addictive.*

Cigar smoke has higher levels of cancer-causing substances and there is no safe level of exposure to cigar smoke for users or nonusers. As stated earlier, regular cigar smoking is associated with increased risk of cancers of the lung, oral cavity, larynx, esophagus, and probably pancreas. People who smoke cigars have a 4 to 10 times greater risk of dying from laryngeal, oral, or esophageal cancer compared to people who don't smoke. Additionally, regardless of whether they inhale, people who smoke cigars directly expose their lips, mouth, tongue, throat, and larynx to cigar smoke.<sup>20</sup> Moreover, a long-term study of over 130,000 men found that even men who smoke cigars who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked.<sup>21</sup>

*Characterizing flavors in cigars are attractive to new users, particularly youth, promoting initiation.*

The FDA's own report concluded that "the addition of characterizing flavors to tobacco products, including cigars, increases product appeal and makes tobacco products easier to use, particularly among youth" and that "characterizing flavors in cigars are associated with increased likelihood of youth and young adult experimentation, as well as progression to more regular patterns of use."<sup>22</sup>

Flavors are a marketing weapon the tobacco manufacturers use to target youth and young people to a lifetime of addiction and premature death. Knowing that youth who experience less negative physiological effects of tobacco use are more likely to continue using, the tobacco industry has spent decades using flavors to appeal to youth. Altering tobacco product ingredients and design, like adding flavors, can improve the ease of use of a product by masking harsh effects, facilitating nicotine uptake,

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<sup>18</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ* 2022;71(No. SS-5):1–29.

<sup>19</sup> Villanti AC, Johnson AL, Glasser AM, et al. Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015. *JAMA Netw Open*. 2019;2(10):e1913804. doi:10.1001/jamanetworkopen.2019.13804

<sup>20</sup> Shanks TG, Burns DM. Disease consequences of cigar smoking. National Cancer Institute, Smoking and Tobacco Control, Monograph 9: Cigars – Health Effects and Trends. Washington, DC: National Institutes of Health; 1998.

<sup>21</sup> Shapiro, JA, et al., "Cigar Smoking in Men and Risk of Death from Tobacco-Related Disease," *Journal of the National Cancer Institute*, 92(4):333-337, 2000, at 334.

<sup>22</sup> FDA. Scientific Assessment of the Impact of Flavors in Cigar Products. March 2022.

[https://www.fda.gov/media/157595/download#:~:text=An%20analysis%20of%20survey%20data,et%20al.%2C%202018\).](https://www.fda.gov/media/157595/download#:~:text=An%20analysis%20of%20survey%20data,et%20al.%2C%202018).)

and increasing a product's overall appeal.<sup>23</sup> Candy, fruit, mint and menthol flavorings in tobacco products are aggressively marketed with creative campaigns by tobacco companies.<sup>24</sup> Cigars, cigarillos and little cigars are sold in many flavors such as banana, mango, chocolate and grape that are clearly not aimed at established, adult tobacco users and years of tobacco industry documents confirm the intended use of flavors to target youth.<sup>25</sup> Furthermore, youth report flavors as a leading reason why they use tobacco products and perceive flavored products as less harmful.<sup>26,27</sup>

*The cigar industry targeting of communities of color has led to tobacco-related health disparities.* For decades, the tobacco industry has target specific communities - youth, communities of color, LGBTQ+ communities, women and limited income communities – with its products.<sup>28</sup> Tobacco companies disproportionately market cigars and flavored cigars in Black neighborhoods, magazines popular with Black Americans, and events that are aimed for Black Americans. Studies have found greater tobacco retailer density nationwide in census tracts with a higher proportion of Black residents.<sup>29</sup> The more tobacco retailers, the more exposure to tobacco marketing individuals face. In fact, retail marketing, including in-store advertising, product displays, and discounts accounts for a large portion of the tobacco industry's marketing budget.<sup>30</sup>

As stated in the proposed rule, the proposed product standard is for the protection of public health because it will “reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death.”

### **The Product Standard Should Eliminate All Characterizing Flavors in all Cigars**

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<sup>23</sup> FDA Guidance for Industry and FDA Staff, “General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) (“FDA Guidance on Characterizing Flavors”).

<sup>24</sup> Delnevo, C, et al., “Preference for flavoured cigar brands among youth, young adults and adults in the USA,” Tobacco Control, epub ahead of print, April 10, 2014. King, BA, et al., “Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students,” Journal of Adolescent Health 54(1):40-6, January 2014.

<sup>25</sup> Carpenter CM, Wayne GF, Pauly JL, Koh HK, Connolly GN. New cigarette brands with flavors that appeal to youth: tobacco marketing strategies. Health Affairs. 2005; 24(6): 1601-1610.

<sup>26</sup> Ambrose et al. Flavored tobacco product use among U.S. youth aged 12-17 years, 2013-2014. JAMA, 2015; 314(17): 1871-3.

<sup>27</sup> Huang L-L, Baker HM, Meernik C, Ranney LM, Richardson A, Goldstein AO. Impact of non-menthol flavours in tobacco products on perceptions and use among youth, young adults and adults: a systematic review. Tobacco Control 2016.

<sup>28</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>29</sup> U.S. National Cancer Institute. A Socioecological Approach to Addressing Tobacco-Related Health Disparities. National Cancer Institute Tobacco Control Monograph 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute; 2017.

<sup>30</sup> U.S. Federal Trade Commission (FTC), Cigarette Report for 2020, 2021 <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2020-smokeless-tobacco-report2020/p114508fy20cigaretterepreport.pdf> [data for top 5 manufacturers only].; FTC, Smokeless Tobacco Report for 2020, 2021, <https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2020-smokeless-tobacco-report2020/p114508fy20smokelesstobacco.pdf> [Data for top 5 manufacturers only].

ACS CAN supports a comprehensive product standard that eliminates all characterizing flavors in all cigars. Such a product standard should give the FDA appropriate discretion to determine whether a product has a characterizing flavor.

*The product standard should include all cigars.*

All cigars should be included in the rule. Cigars, cigarillos, and little cigars are all sold in many flavors that are appealing to young people, such as banana, mango, chocolate, and grape. All cigars expose users to hazardous levels of cancer-causing toxins and addictive levels of nicotine. As stated earlier, regular cigar smoking increases the risk of cancers of the lung, oral cavity, larynx, and esophagus. Black teens are twice as likely to smoke cigars than their white peers, and half smoke a flavored cigar. People, especially youth, misperceive cigars, and especially flavored cigars, as less harmful than cigarettes.

*The product standard should include products that have already received marketing orders.*

The product standard should apply to all cigars without any exemptions. This should include those products that have already received marketing orders. If the manufacturer of a current flavored cigar wants to sell a non-flavored version of their product that is not currently on the market, they should be required to undergo the appropriate marketing pathway. If the non-flavored product raises new questions of public health it must submit to the requirements of premarket review applications.

*The product standard should include any analog products and tobacco product flavor components and parts.*

The product standard should include any flavor analogs or components and parts that can turn a cigar into a flavored cigar. As one example, tobacco product manufacturers use flavor capsules as a way to deliver one or more flavors, which can potentially help them avoid flavor prohibitions that have been imposed in other countries.<sup>31</sup> Limited data from the U.S. suggest flavor capsule products are more popular with young adults than older adults, and part of their appeal is the taste and perceived less risk.<sup>32,33</sup> In addition to taste, those younger adults who use menthol flavored capsule cigarettes report package design and low-cost as primary reasons for using them – all indications that manufacturers are targeting young people with the advertising of these products.

*The product standard should include explicit and implicit flavor representations, including descriptors, colors, “concept flavors” or other flavor representations in the product packaging and advertising.*

Cigars sold in “concept” flavors has increased as a way for the tobacco industry to circumvent local and state sales restrictions on cigars with characterizing flavors.<sup>34</sup> In fact, U.S. sales of concept flavors increased from 2.2% of flavored cigar sales in 2009 to 21.4% in 2020.<sup>35</sup>

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<sup>31</sup> Kyriakos CN, Zatoński MZ, Filippidis FT. Flavour capsule cigarette use and perceptions: a systematic review. *Tobacco Control*. Published Online First: 04 October 2021. doi: 10.1136/tobaccocontrol-2021-056837

<sup>32</sup> Thrasher JF, Abad-Vivero EN, Moodie C, et al. Cigarette brands with flavour capsules in the filter: trends in use and brand perceptions among smokers in the USA, Mexico and Australia, 2012–2014. *Tobacco Control* 2016;25:275–283.

<sup>33</sup> Emond JA, Soneji S, Brunette MF, et al. Flavour capsule cigarette use among US adult cigarette smokers. *Tobacco Control* 2018;27:650–655.

<sup>34</sup> Gammon, DG, et al., “National and state patterns of concept-flavoured cigar sales, USA, 2012–2016,” *Tobacco Control* 28(4):394–400, 2019; Delnevo, CD, supra note 11.

<sup>35</sup> Delnevo, C. D., E. Miller Lo, D. P. Giovenco, et al., “Cigar Sales in Convenience Stores in the US, 2009–2020.” *Journal of the American Medical Association*, 326(23):2429–2432, 2021. Available at <https://doi.org/10.1001/jama.2021.19692>.



Similarly, after the federal prohibition on the false and misleading descriptors of “light,” “low,” and “mild,” tobacco manufacturers substituted the descriptors with colors on packaging and advertising to allow consumers to continue to identify these so-called “light,” “low,” and “mild” cigarettes. Evidence shows that use of these colors on packaging perpetuated the incorrect belief among consumers that these products posed less harm or less risk than other cigarettes, thereby undermining the intent of the prohibition on the descriptors.<sup>36</sup> Several studies from provinces in Canada show that cigarette manufacturers reacted similarly in response to a menthol cigarette prohibition by replacing menthol with other descriptors, such as “smooth,” and colors on packaging.<sup>37,38</sup>

### **The Product Standard Should be Extended to at least All Combustible Tobacco Products**

A comprehensive prohibition on characterizing flavors in at least all combustible tobacco products is necessary for the protection of public health. There is no scientific rationale for permitting any flavored tobacco product to remain on the market. Only a comprehensive prohibition can counter the scientifically proven effects of flavors on initiation, progression to regular use, dependence, and cessation, and eliminate any potential loopholes for the tobacco industry to exploit to continue to sell flavored tobacco products.

#### *Other tobacco products cause harm to users.*

Waterpipe or hookah tobacco increases the risk of lung, oral, and esophageal cancers, as well as noncancer respiratory illnesses.<sup>39</sup> Waterpipe smoking results in significant exposure to toxicants, including many carcinogens such as tar, aldehydes, and polycyclic aromatic hydrocarbons.<sup>40</sup> Smoke inhaled during a typical session of waterpipe smoking contains similar or higher amounts of many toxicants and carcinogens than smoke inhaled during the smoking of a cigarette.<sup>41</sup> Waterpipe smoking also results in substantial nicotine intake, considered sufficient to sustain nicotine addiction.<sup>42</sup>

Pipe smoking also exposes users to tobacco carcinogens. A comprehensive review by the International Agency for Research on Cancer (IARC) in 2004 concluded that pipe smoking (as well as cigar smoking) was “strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx and oesophagus, the magnitude of risk being similar to that from cigarette smoking” and also concluded that pipe smoking is causally associated with lung cancer.<sup>43</sup> Further evidence was provided by analyses from a cohort of 138,307 U.S. men enrolled in an American Cancer Society prospective cohort study (the Cancer Prevention Study II) which found that exclusive pipe smoking, compared with never use of tobacco, was

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<sup>36</sup> Connolly GN, Alpert HR. Has the tobacco industry evaded the FDA's ban on ‘Light’ cigarette descriptors? *Tobacco Control* 2014;23:140-145.

<sup>37</sup> Brown J, DeAtley T, Welding K, et al. Tobacco industry response to menthol cigarette bans in Alberta and Nova Scotia, Canada. *Tobacco Control* 2017;26:e71-e74.

<sup>38</sup> Borland T, D’Souza SA, O’Connor S, et al. Is blue the new green? Repackaging menthol cigarettes in response to a flavour ban in Ontario, Canada. *Tobacco Control* 2019;28:e7-e12.

<sup>39</sup> American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2021-2022*. Atlanta: American Cancer Society; 2021.

<sup>40</sup> Maziak, W. The waterpipe: An emerging global risk for cancer. *Cancer Epidemiology*. 2013;37: 1–4.

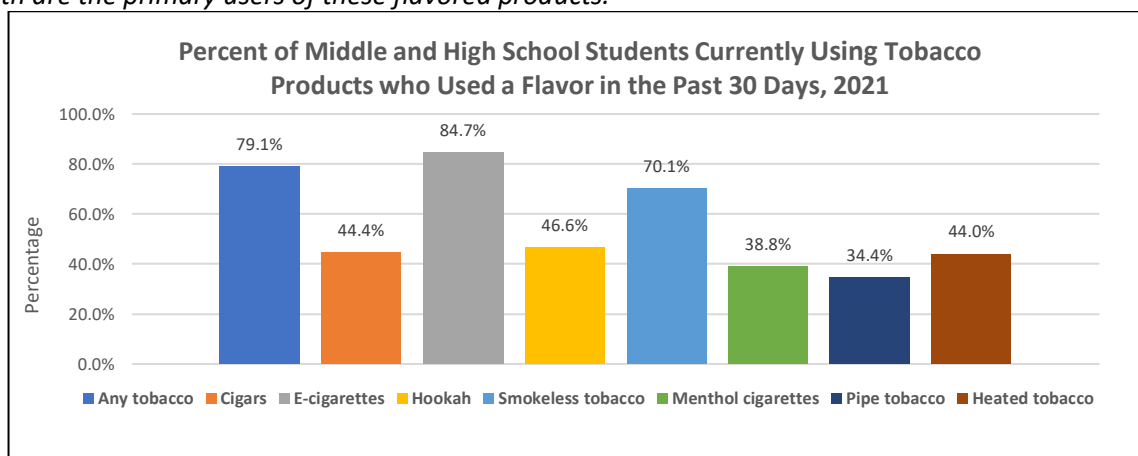
<sup>41</sup> Eissenberg, T, Shihadeh, A. Waterpipe Tobacco and Cigarette Smoking Direct Comparison of Toxicant Exposure. *Am J Prev Med*. 2009 December ; 37(6): 518–523. Maziak, W. The waterpipe: An emerging global risk for cancer. *Cancer Epidemiology*. 2013;37: 1–4.

<sup>42</sup> Eissenberg, T, Shihadeh, A. Waterpipe Tobacco and Cigarette Smoking Direct Comparison of Toxicant Exposure. *Am J Prev Med*. 2009 December ; 37(6): 518–523. Jacob, P et al. Comparison of Nicotine and Carcinogen Exposure with Water Pipe and Cigarette Smoking. *Cancer Epidemiol Biomarkers Prev* 2013;22:765-772.

<sup>43</sup> World Health Organization. *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Tobacco Smoke and Involuntary Smoking*. Vol 83. International Agency for Research on Cancer, Lyon 2004.

associated with significantly increased risk of death from cancers of the lung, oropharynx, esophagus, colon and rectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and chronic obstructive pulmonary disease.<sup>44</sup> Importantly, the “relative risks of lung cancer showed statistically significant increases with number of pipes smoked per day, years of smoking, and depth of inhalation, and decreases with years since quitting.” These results were consistent with prior prospective and case-control studies that have found positive associations between exclusive pipe smoking and tobacco-related diseases.

*Youth are the primary users of these flavored products.*



Waterpipe or hookah tobacco comes in hundreds of flavors. It increases the likelihood of hookah initiation among those who do not smoke and would never smoke, as well as the continued use of hookah among regular users.<sup>45</sup> Just under one percent or 222,000 current middle and high school used a waterpipe or hookah in 2021, and of those students, 46.6% used a flavored product.<sup>46</sup> Another survey found that almost 90% of those youth who had ever smoked hookah used a flavored product the first time in 2014.<sup>47</sup> Additionally, while there is no nationally representative survey of hookah use among college students, smaller studies have found that estimates of past year hookah use range from 22-40%.<sup>48</sup>

What is troubling, is that the flavorings used in waterpipe tobacco, the sweet aromas and use of water, make users misperceive this practice as safer than cigarette smoking.<sup>49</sup> In fact, hookah tobacco and

<sup>44</sup> Henley SJ, Thun MJ, Chao A, Calle EE. Association between exclusive pipe smoking and mortality from cancer and other diseases. *J Natl Cancer Inst.* 2004;96(11):853-861.

<sup>45</sup> Owens, V. L., Ha, T., & Soulakova, J. N. Widespread use of flavored e-cigarettes and hookah tobacco in the United States. *Preventive medicine reports*, 2019; 14, 100854.

<sup>46</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ* 2022;71(No. SS-5):1–29. DOI: <http://dx.doi.org/10.15585/mmwr.ss7105a1>

<sup>47</sup> Ambrose et al. Flavored tobacco product use among U.S. youth aged 12-17 years, 2013-2014. *JAMA*, 2015; 314(17): 1871-3.

<sup>48</sup> CDC. Hookahs. April 22, 2021.

[https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/tobacco\\_industry/hookahs/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/hookahs/index.htm)

<sup>49</sup> Morris DS, Fiala SC, Pawlak R. Opportunities for Policy Interventions to Reduce Youth Hookah Smoking in the United States. *Prev Chronic Dis* 2012;9:120082. Akl EA, Gaddam S, Gunukula SK, Honeine R, Jaoude PA, Irani J. The Effects of Waterpipe Tobacco Smoking on Health Outcomes: A Systematic Review External Web Site Icon.

smoke are as dangerous as cigarettes, and contain carcinogens and other substances that can cause cancer and other diseases.<sup>50</sup> An hour-long waterpipe or hookah session typically involves 200 puffs of smoke, whereas smoking a single cigarette typically involves 20 puffs of smoke. In addition, unlike cigarettes, hookah smoke may also contain charcoal or wood cinder combustion products from the heat source used to burn the tobacco, increasing the cancer- and heart-disease causing agents in the smoke.<sup>51</sup>

Pipe tobacco is reported to be used by 80,000 youth in 2021, and among these youth, one-third report using a flavored product.<sup>52</sup> This may be an underestimate as it likely does not account for youth who use pipe tobacco to roll their own cigarettes and cigars, therefore it may be more appropriate to look at the number of youth who use combustible tobacco overall to understand the potential impact of excluding pipe tobacco from a prohibition on characterizing flavors. In 2021, 860,000 youth used any combustible tobacco product, and non-Hispanic Black youth were more likely to use any combustible product (5.2%) than their peers (2.8%-3.2%).<sup>53</sup> Excluding pipe tobacco from this rule will create a loophole for tobacco manufacturers to continue to target youth with flavored tobacco products.

#### *Youth will initiate or switch to the tobacco products with flavors.*

To understand the consequences of only including certain products or flavors in a flavor prohibition, a study looked at what happened to youth smoking after the federal prohibition on flavors in cigarettes, except for menthol, went into effect. While there was an overall decrease in the likelihood of teens smoking, there was an increase in the chance they would use menthol cigarettes and there were increases in both cigar and pipe use – which were still permitted to have flavors. This suggests that teens who smoked, in the absence of flavored cigarettes, were substituting with menthol cigarettes or cigars and pipe tobacco.

There is simply no rationale for permitting any flavored product on the market given the role of flavors in increasing youth initiation and use, decreasing quitting success, and generating tobacco-related health disparities. Furthermore, it is important that this rule and the rule to prohibit menthol as a characterizing flavor in cigarettes are implemented at the same time.

#### **Dispute Countervailing Effects**

ACS and ACS CAN previously provided comments regarding an ANPRM for *Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard*. In

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International Journal of Epidemiology 2010;39:834–57. Smith JR, Edland SD, Novotny TE, et al. Increasing hookah use in California. *Am J Public Health*. Oct 2011;101(10):1876-1879.

<sup>50</sup> Knishkowsky, B., Amitai, Y. Water-Pipe (Narghile) Smoking: An Emerging Health Risk Behavior. *Pediatrics*. 2005;116:113–119. WHO study group on tobacco product regulation. Advisory note on water pipe tobacco smoking: health effects, research needs and recommended actions by regulators, 2005. El-Hakim Ibrahim E., Uthman Mirghani AE. Squamous cell carcinoma and keratoacanthoma of the lower lips associated with "Goza" and "Shisha" smoking. *International Journal of Dermatology*. 1999;38:108-110.

<sup>51</sup> World Health Organization. Advisory note: waterpipe tobacco smoking: health effects, research needs and recommended actions by regulators, 2nd edition. April 15, 2015. <https://www.who.int/publications/i/item/advisory-note-waterpipe-tobacco-smoking-health-effects-research-needs-and-recommended-actions-by-regulators-2nd-ed>.

<sup>52</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ* 2022;71(No. SS-5):1–29. DOI: <http://dx.doi.org/10.15585/mmwr.ss7105a1>

<sup>53</sup> Gentzke AS, Wang TW, Cornelius M, et al. Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. *MMWR Surveill Summ* 2022;71(No. SS-5):1–29. DOI: <http://dx.doi.org/10.15585/mmwr.ss7105a1>

our letter we argued that any risk of illicit trade is overstated by the tobacco industry and would be extremely challenging due to geographical coverage of the policy and current manufacturing in the U.S. Additionally, any potential for illicit trade can be mitigated by the FDA implementing an effective track and trace system.

### **Effective Dates**

We support an effective date of no more than one year from final publication, and there should be no “sell-off” period for retailers after the effective date. This is more than sufficient time for retailers to remove flavored cigars from their inventory.

### **Enforcement Should Target Manufacturers, Retailers and Distributors, not Individuals**

ACS CAN endorses the joint statement on principles for addressing systemic racism in the enforcement of commercial tobacco control and would encourage FDA to use the principles in its own enforcement and in the education and training of state and local law enforcement.<sup>54</sup> The principles recommend entrusting to public health officials or other non-law enforcement personnel the enforcement of tobacco control laws and eliminating laws, policies and enforcement practices that target individuals, especially youth or communities of color, rather than businesses and industry actors.

FDA has reiterated in the proposed rule that:

“FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. In addition, state and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf.”

This is a critical statement from FDA and FDA must follow through with appropriate education and training of federal, state, local and tribal law enforcement and public health partners in order to ensure communities that have already been targeted by the tobacco industry are not also targeted by law enforcement for compliance of the rule.

As disparities in tobacco product advertising and access persist, so do disparities in the enforcement of commercial tobacco control laws and policies. FDA must ensure its enforcement practices occur in a data-driven, evidence-based, and equitable manner. Enforcement practices should not unfairly target communities that have been marginalized. If businesses in certain communities have a greater number or rate of violations, FDA should seek to identify compliance barriers and offer technical assistance to help businesses comply with the law. Law enforcement should not approach, harass, or arrest communities that have been historically marginalized because they have a tobacco product in their possession. Tobacco control partners can work with the FDA and others to address where and how public health laws contribute to systemic racism and discrimination.

Lastly, ACS CAN recognizes the important role of ceremonial tobacco for many indigenous communities. This letter is intended to address commercial tobacco, not the provision, possession, or use of tobacco

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<sup>54</sup>[https://www.fightcancer.org/sites/default/files/Tobacco%20Control%20Enforcement%20for%20Racial%20Equity\\_FINAL\\_20201011.pdf](https://www.fightcancer.org/sites/default/files/Tobacco%20Control%20Enforcement%20for%20Racial%20Equity_FINAL_20201011.pdf)

products as part of an indigenous practice or other recognized religious or spiritual ceremony or practice. All references to tobacco and tobacco products in this letter refer to commercial tobacco.

### **Outreach and Cessation Services**

As summarized above, there are millions of people in the U.S. who currently smoke flavored cigars and use other flavored products, most of whom want to quit and many of whom may have less access to resources to quit. Efforts must be made to offer free, accessible, confidential, and culturally appropriate cessation and counseling services. There are evidence-based proven resources available, including medications, counseling and quitlines. What's lacking are strategies specifically designed to support and provide education to individuals who smoke flavored cigars and use other flavored products, including people who are Black, LGBTQ+, have limited incomes and youth. The FDA should immediately implement new and improved outreach to these populations with evidence-based cessation resources in anticipation of a finalized rule.

FDA has run highly successful campaigns designed to reduce youth initiation and to promote cessation. FDA should consider restarting these campaigns with messages about flavored cigars and other flavored products. FDA has previously partnered with the National Cancer Institute (NCI) on the "Every Try Counts" campaign and should consider other partners for collaborations on education campaigns, including the Centers for Disease Control and Prevention (CDC). The "Tips from Former Smokers" campaign has been highly successful at promoting quit attempts and successful quitting. The FDA should work with the NCI and CDC to develop messaging and cessation resources most appropriate for people who smoke flavored cigars and use other flavored products.

The FDA should consider partnering with healthcare systems to reach people who smoke flavored cigars and use other flavored products. Such systems can include behavioral health clinics, federally qualified health centers, Veteran Affairs hospitals and clinics, and Indian Health Services hospitals and clinics. Even for people with health insurance, it can be difficult to know what services are available. Additionally, as stated earlier, people who use tobacco are more likely to be uninsured or underinsured. FDA should consider opportunities to reach those individuals with cessation services, such as through quitlines or other programs that can provide such resources free of charge.

The FDA should look at opportunities to partner with non-tobacco control programs both at the federal and state level, such as offices of health equity, women and maternal health, and minority health, as well as non-government health organizations that focus on supporting populations that have been marginalized and are often the target of tobacco industry marketing.

To maximize the public health impact of this effort, FDA should also consider including messaging on lung cancer screening for those individuals who may be eligible. The U.S. Preventive Services Task Force recommends lung cancer screening for individuals who are aged 50 or older, with a 20-year pack history, and are currently still smoking or quit in the last 15 years.<sup>55</sup> These individuals would benefit from information on screening as well as cessation message.

ACS CAN believes FDA currently has the capacity to support people who want to quit and does not need to delay the rule.

### **Conclusion**

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<sup>55</sup> <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>

Thank you for the opportunity to provide input on this important topic. If we can provide additional information, please contact Katie McMahon, MPH, Policy Principal, at ACS CAN at 202-869-3876 or [katie.mcmahon@cancer.org](mailto:katie.mcmahon@cancer.org). Thank you.