

**Improving the Health  
of Pennsylvanians**

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**pahealthpolicy.org**

August 1, 2022

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Proposed Rule FDA-2021-N-1309: Tobacco Product Standard for  
Characterizing Flavors in Cigars**

The Pennsylvania Health Policy Coalition strongly supports the FDA's proposed tobacco product standard prohibiting characterizing flavors in all cigars and their components and parts.

The Pennsylvania Health Policy Coalition was established to represent the unified interests of Pennsylvania's local health departments and is recognized by the National Association of County and City Health Officials as Pennsylvania's state affiliate. The Coalition espouses a shared vision for improved public health and coordinated, sustained policy implementation at the local, state, and federal levels.

Prohibiting characterizing flavors in all cigars and their components and parts is an essential step in mitigating the harmful effects of tobacco in Pennsylvania. Tobacco products, including flavored cigars, create a tremendous burden of death and disease every year. A review of the Truth Tobacco Industry Documents Library, an archive of tobacco manufacturer documents, shows that some flavors in cigars (e.g., vanilla beans, peach, apricot, licorice, cocoa) mask the bitterness of tobacco leaves, throat burn, and heavy taste, thereby facilitating inhalation, making smoking more tolerable for current users, and increasing palatability for new users. These documents similarly suggest that tobacco manufacturers added flavors and changed design characteristics of little cigars and cigarillos to facilitate inhalation and make smoke more tolerable for current smokers, as well as more palatable for new users.<sup>1</sup>

In Pennsylvania, tobacco use prevalence is extraordinarily high and the disparate impact of tobacco-related diseases on low-income and underserved communities is simply staggering. The percentage of individuals who smoke in the Commonwealth is higher than the national average, while the average life expectancy at birth is lower.<sup>2</sup> Tobacco kills 22,000 adults in Pennsylvania every year. An estimated 244,000 youth, currently under the age of 18, will die prematurely from smoking.<sup>3</sup> While there have been some regulations on

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<sup>1</sup> Kostygina, G., Glantz, S.A., Ling, P.M. Tobacco industry use of flavors to recruit new users of little cigars and cigarillos. Tobacco control. 2016;25(1):66-74. 10.1136/tobaccocontrol-2014-051830.

<sup>2</sup> CDC, Behavioral Risk Factor Surveillance System, 2018.

<sup>3</sup> Campaign for Tobacco Free-Kids. The Toll of Tobacco in Pennsylvania. Available at: <https://www.tobaccofreekids.org/problem/toll-us/pennsylvania>

cigarettes have been put into place in order to reduce premature deaths, the same is not true of cigars. Cigars are cheaper, sold as singles, and made with sweet flavors to be more attractive to youth.

While evidence from national surveys, including the National Youth Tobacco Survey (NYTS), suggest cigar among youth use had been on the decline (2011 to 2017), beginning in 2019, cigars became the most reported combustible tobacco product used by youth.<sup>4</sup> In 2019, 26.7 percent of Pennsylvania high school youth reported currently using tobacco products. More high school students in Pennsylvania smoked cigars, cigarillos, or little cigars on at least one day in the past 30 days, compared to national statistics, and less students tried to quit using tobacco products in the past 12 months than did nationally.<sup>5</sup> Pennsylvania's FDA Retail Tobacco Compliance Program reported 231 sales to minors between July 2020 through April 2022. Out of those 231 sales, 73 percent were flavored tobacco products.<sup>6</sup>

Youth and young adults now use flavored tobacco products more than other age group and are often the first tobacco product they ever use. More than four out of five young adults, ages 18 to 24, report that their first product was flavored<sup>7</sup> and among current young adult non-cigarette tobacco users, 84 percent report using a flavored product.<sup>8</sup> Flavors, especially sweet and fruit flavors, play a role in influencing tobacco experimentation and progression to more regular patterns of use in youth and young adults.<sup>9</sup> The process of becoming a habitual cigar smoker includes stages of experimentation, development of symptoms of tobacco-use dependence, and progression to regular use. The U.S. Surgeon General noted that symptoms of nicotine dependence in cigar smokers can result from even a limited exposure to nicotine during adolescence.<sup>10</sup> Young people who start with a flavored cigar are more likely to continue smoking a year later,<sup>11</sup> often perceiving flavored products as less harmful than unflavored cigars<sup>12</sup> and cigarettes.<sup>13</sup>

Yet, while research indicates high levels of cigar smoking among youth, it is still likely an underrepresentation. Several studies have shown that youth tend to underreport cigar smoking if brand

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<sup>4</sup> Wang TW, Gentzke AS, Creamer MR, et al. (2019). Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019. *MMWR Surveill Summ* ;68(No. SS12):1–22.

<sup>5</sup> CDC, Youth Risk Behavioral Surveillance System, 2019.

<sup>6</sup> Pennsylvania Department of Health. FDA Retail Tobacco Compliance Program. Available at: <https://www.health.pa.gov/topics/programs/tobacco/Pages/FDA-Program.aspx>

<sup>7</sup> Villanti AC, Johnson AL, Ambrose BK, et al. Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013-2014). *American journal of preventive medicine*. 2017,

<sup>8</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>9</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>10</sup> U.S. Department of Health and Human Services. How tobacco smoke causes disease: The biology and behavioral basis for smoking-attributable disease - A Report of the Surgeon General. Rockville, MD: U.S. Dept. of Health and Human Services, Public Health Service, Office of the Surgeon General; 2010.

<sup>11</sup> Villanti AC, Johnson AL, Glasser AM, et al., *supra* note 8.

<sup>12</sup> Delnevo CD, Jeong M, Ganz O, Giovenco DP, Miller Lo E. The Effect of Cigarillo Packaging Characteristics on Young Adult Perceptions and Intentions: An Experimental Study. *Int J Environ Res Public Health*. 2021 Apr 19;18(8):4330. doi: 10.3390/ijerph18084330. PMID: 33921793; PMCID: PMC8073489.

<sup>13</sup> Sterling, K.L., Fryer, C.S., Fagan, P. The Most Natural Tobacco Used: A Qualitative Investigation of Young Adult Smokers' Risk Perceptions of Flavored Little Cigars and Cigarillos. *Nicotine Tob Res*. 2016;18(5):827-833. 10.1093/ntr/ntv151.

name identifiers are not provided.<sup>14</sup> In a study of Virginia high school students, for example, the reported prevalence of cigar use nearly doubled after accounting for students who reported smoking Black & Mild (a brand name of cigarillos); previously, the students had not acknowledged using cigars, cigarillos, or little cigars.<sup>15</sup>

We know youth find flavored tobacco products appealing based on the continued reporting of flavor as a reason for tobacco use, the selection of flavored products during first tobacco use, and the sustained prevalence of youth flavored tobacco. Flavors can activate the brain's reward circuit, producing rewarding effects that, when added to tobacco products, can reinforce the effects of nicotine. The use of sweet, candy, and other characterizing flavors popular among youth produces a strong reinforcing effect in young populations.<sup>16</sup>

Patterns of cigar use also differ by race and ethnicity, household income, education level, and among other vulnerable populations such as individuals who identify as LGBTQ+ and persons with disabilities. Black cigar smokers are nearly twice as likely to smoke a flavored cigar compared to White cigar smokers.<sup>17</sup> Among individuals who currently smoke cigars, those with household incomes below \$20,000 were more than three times more likely to use flavored cigars than individuals with household incomes of more than \$100,000.<sup>18</sup> LGBTQ+ adults have a higher prevalence of flavored cigar use than cisgender adults.<sup>19</sup> Lesbian, gay, and bisexual women have a significantly higher rate of cigar use than heterosexual women.<sup>20</sup> The proportion of little cigar use among students with at least one reported disability, defined as individuals with a visual, hearing, cognitive, mobility, self-care, and/or independent living disability, is higher than among students without a disability.<sup>21</sup> Mental health conditions are also associated with particularly high odds of cigar use, as adults with anxiety, depression, and substance abuse disorders have significantly higher rates of cigar use than individuals without a chronic condition.<sup>22</sup>

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<sup>14</sup> Nasim, A., Blank, M.D., Berry, B.M., Eissenberg, T. Cigar Use Misreporting Among Youth: Data from the 2009 Youth Tobacco Survey, Virginia. *Preventing chronic disease*. 2012;9: E42-E42. 10.5888/pcd9.110084.

<sup>15</sup> *Id.*

<sup>16</sup> Palmatier, M.I., Lantz, J.E., O'Brien, L.C., Metz, S.P. Effects of Nicotine on Olfactogustatory Incentives: Preference, Palatability, and Operant Choice Tests. *Nicotine & Tobacco Research*. 2013;15(9):1545-1554. 10.1093/ntr/ntt016

<sup>17</sup> American Cancer Society. Use of Flavored Cigars Higher for Black Americans, Youth, and Lower Income Individuals. *Cancer Action Center*. April 2022.

<sup>18</sup> American Cancer Society. Use of Flavored Cigars Higher for Black Americans, Youth, and Lower Income Individuals. *Cancer Action Center*. April 2022.

<sup>19</sup> King, B.A., Dube, S.R., Tynan, M.A. Flavored Cigar Smoking Among U.S. Adults: Findings From the 2009– 2010 National Adult Tobacco Survey. *Nicotine & Tobacco Research*. 2013;15(2):608-614. 10.1093/ntr/nts178.

<sup>20</sup> Emory K, Kim Y, Buchting F, et al. Intragroup Variance in Lesbian, Gay, and Bisexual Tobacco Use Behaviors: Evidence That Subgroups Matter, Notably Bisexual Women. *Nicotine Tob Res* 2016;18(6):1494-501. doi:10.1093/ntr/ntv208.

<sup>21</sup> Senders, A., Horner-Johnson, W. Disparities in E-Cigarette and Tobacco Use Among Adolescents with Disabilities. *Prev Chronic Dis*. 2020;17: E135. 10.5888/pcd17.200161.

<sup>22</sup> Stanton, C.A., Keith, D.R., Gaalema, D.E., et al. Trends in tobacco use among US adults with chronic health conditions: National Survey on Drug Use and Health 2005-2013. *Preventive medicine*. 2016; 92:160-168. 10.1016/j.ypmed.2016.04.008.

Cigar use is especially disproportionate among Black youth.<sup>23</sup> Black students are nearly twice as likely to smoke flavored cigars as White students<sup>24</sup> and Black college students who smoke cigars are three times more likely to smoke flavored cigars than their White counterparts.<sup>25</sup> Within six months of initiation, the average frequency of use among youth and young adults was higher by 2.21 days per month for Black youth compared to White youth.<sup>26</sup>

This increased prevalence of cigar smoking, spurred by initiation with flavored cigars, has created a disproportionate burden of tobacco-related morbidity and mortality within Black communities. Among Black Americans, tobacco use is a major contributor to the three leading causes of death - heart disease, cancer, and stroke.<sup>27,28</sup> The risk of developing diabetes, the fourth leading cause of death among Black Americans, is 30–40 percent higher for smokers over nonsmokers.<sup>29</sup>

Greater use among these communities is no accident, but the result of the predatory marketing of flavored tobacco products to specific groups. Communities with large Black, Latinx, and low-income populations tend to have more tobacco retailers located within them, creating greater exposure to tobacco advertising.<sup>30</sup> Tobacco manufacturers continue to target these communities with flavored cigar marketing, across diverse marketing platforms, ranging from traditional print media to online platforms.<sup>31</sup> Flavored cigars are inexpensive, mass-merchandised products often marketed at retail outlets in neighborhoods with large numbers of Black residents, youth, and young adults. Tobacco retailers in predominately Black neighborhoods are significantly more likely to sell cigars and cigarillos, are significantly more likely to have exterior advertisements for cigars and cigarillos, and to sell cigars and cigarillos at a lower price, compared to tobacco retailers in other neighborhoods.<sup>32</sup> While the 2009 Family Smoking Prevention and Tobacco Control Act requires that cigarettes and smokeless tobacco products be located behind the counter, the restriction does not apply to other tobacco products.<sup>i</sup> Exposure to flavored cigar marketing increases product

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<sup>23</sup> Gentzke, A.S., Wang, T.W., Jamal, A., et al. Tobacco Product Use Among Middle and High School Students - United States, 2020. Morbidity and mortality weekly report: MMWR /. 2020;69(50):1881-1888.

<sup>24</sup> American Cancer Society. Use of Flavored Cigars Higher for Black Americans, Youth, and Lower Income Individuals. Cancer Action Center. April 2022.

<sup>25</sup> Hinds, J.T., Xiaoyin, L., Loukas, A., Pasch, K.E., Perry, C.L. Flavored Cigars Appeal to Younger, Female, and Racial/Ethnic Minority College Students. *Nicotine & Tobacco Research*. 2018;20(3):347-354. 10.1093/ntr/ntx041.

<sup>26</sup> Cantrell, J., Xu, S., Kreslake, J., Liu, M., Hair, E. Cigar Use Progression Among New Cigar Initiators: A Two-part Growth Curve Analysis Among a Youth and Young Adult Cohort. *Nicotine & Tobacco Research*. 2022;24(1):28-36. 10.1093/ntr/ntab143.

<sup>27</sup> U.S. Department of Health and Human Services. Tobacco Use Among U.S. Racial/Ethnic Minority Groups—African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A Report of the Surgeon General. Centers for Disease Control and Prevention, Office on Smoking and Health, 1998.

<sup>28</sup> Kochanek KD, Murphy SL, Xu JQ, Tejada-Vera B. Deaths: Final Data for 2014. National Vital Statistics Reports, 2016; vol 65: no 4. Hyattsville, MD: National Center for Health Statistics.

<sup>29</sup> Heron, M. Deaths: Leading Causes for 2010. National Vital Statistics Reports, 2013;62(6).

<sup>30</sup> Cruz, T.B., Rose, S.W., Lienemann, B.A., et al. Pro-tobacco marketing and anti-tobacco campaigns aimed at vulnerable populations: A review of the literature. *Tob Induc Dis*. 2019; 17:68. 10.18332/tid/111397.

<sup>31</sup> Tan, A.S.L., Hanby, E.P., Sanders-Jackson, A., Lee, S., Viswanath, K., Potter, J. Inequities in tobacco advertising exposure among young adult sexual, racial, and ethnic minorities: examining intersectionality of sexual orientation with race and ethnicity. *Tobacco Control*. 2021;30(1):84- 93. 10.1136/tobaccocontrol-2019-055313.

<sup>32</sup> Cantrell J, Kreslake JM, Ganz O, Pearson JL, Vallone D, Anesetti-Rothermel A, Xiao H, Kirchner TR. Marketing little cigars and cigarillos: advertising, price, and associations with neighborhood demographics. *Am J Public Health*. 2013 Oct;103(10):1902-9. doi: 10.2105/AJPH.2013.301362. Epub 2013 Aug 15. PMID: 23948008; PMCID: MC3780734.

appeal and likelihood of use, and the disproportionate marketing and product exposure contributes to the ongoing disparities in flavored cigar use.

Several states and localities have also attempted to restrict the sale of tobacco products. To date, at least 345 localities nationwide have passed restrictions on the sale of flavored tobacco products, more than 160 of which also restrict the sale of menthol cigarettes.<sup>ii</sup> Pennsylvania, however, does not prohibit sales of flavored cigars and state preemption laws severely limit what measures local health departments and localities can take to restrict the sale of tobacco products.

The use of flavored tobacco products creates significant health and economic burdens for residents, families, businesses, and communities in Pennsylvania. While Pennsylvania's local health departments continue to fight against these deadly products, state preemption laws make evident the need for federal regulation of characterizing flavors in cigars.

We urge the FDA to enact the proposed regulation to prohibit characterizing flavors in all cigars and their components and parts as expeditiously as possible.

Sincerely,



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Health Department



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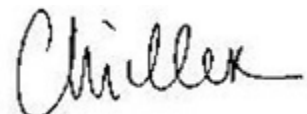
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**PENNSYLVANIA  
HEALTH POLICY  
COALITION**

Handwritten signature of Cheryl Bettigole in black ink.

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<sup>i</sup> Family Smoking Prevention and Tobacco Control Act. In. Public Law No: 111-31. Vol HR 12562009.

<sup>ii</sup> Bach, Laura. Campaign for Tobacco-Free Kids. States & localities that have restricted the sale of flavored tobacco products. June 2022. Available at: <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>