



August 2, 2022

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

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

The undersigned public health, medical, education, civil rights, and community organizations submit these comments in response to the Proposed Rule for a Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26,396 (May 4, 2022). These comments explain why the proposed rule is strongly supported by the scientific evidence and is “appropriate for the protection of the public health” under Section 907(a)(3)(A) of the Food, Drug and Cosmetic Act (FD&C Act) as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA). Issuance of this rule in final form will have a substantial impact in preventing tobacco-caused mortality, avoiding suffering from tobacco addiction and disease, and reducing persistent and tragic health disparities in the U.S.

## **I. SUMMARY OF REASONS SUPPORTING A PRODUCT STANDARD PROHIBITING CHARACTERIZING FLAVORS IN CIGARS**

- **Cigar makers have radically transformed the cigar market since 2009, using flavored<sup>1</sup> cigars to attract youth.**
  - Flavored cigars have come to dominate the cigar market, with great appeal to youth.
  - The tobacco industry has deliberately developed and marketed flavored cigars to appeal to youth.
  - Youth usage of flavored cigars is significant.
- **Cigar smoking is a significant public health concern, particularly for young people.**
  - All cigars increase health risks.
  - Characterizing flavors in cigars create added risks.
- **Flavored cigars disproportionately harm the health of Black Americans and other underserved populations.**
  - The tobacco industry targets Black youth with cheap, flavored cigars.
  - Cigars have a disproportionate impact on underserved populations.
- **Prohibiting flavored cigars will produce substantial public health benefits, including reducing health disparities.**
  - Prohibiting flavored cigars will likely reduce cigar initiation, particularly among young people.
  - Prohibiting flavored cigars will likely cause significant numbers of people who currently smoke cigars to stop smoking.
  - Prohibiting flavored cigars will promote health equity.
- **There is no public health rationale for continuing to permit characterizing flavors in any cigar, waterpipe, or pipe tobacco product.**
  - The public health impact of the flavored cigar product standard would be enhanced if implemented alongside the product standard on menthol cigarettes.
  - Flavored waterpipe tobacco products attract young users.
  - Exempting flavored pipe tobacco could create a loophole for manufacturers to circumvent the product standard.
  - As FDA proposes, the rule should apply to all cigars.

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<sup>1</sup> We use the terms “flavored,” “characterizing flavor(s),” and “flavor(s)” interchangeably throughout this comment to mean characterizing flavors other than tobacco.

- The substantial equivalence exemption pathway may be appropriate for certain unflavored cigars that come into compliance with the rule.
- **Any risks of unintended and adverse consequences from prohibiting flavored cigars can be ameliorated and will not outweigh the public health benefits.**
  - Prohibiting flavored cigars will not cause the emergence of an illicit market that will nullify the public health gains from such a policy.
  - Prohibiting flavored cigars will not increase the likelihood of police abuse in Black and other communities of color.

## **II. STATUTORY BACKGROUND FOR FDA CONSIDERATION OF A PRODUCT STANDARD PROHIBITING CHARACTERIZING FLAVORS IN CIGARS**

In enacting the Tobacco Control Act, Congress recognized that successful efforts to reduce the toll of tobacco-related death and disease require comprehensive measures directed at curbing smoking by young people, calling the tobacco plague a “pediatric disease of considerable proportions,”<sup>2</sup> and finding that “[v]irtually all new users of tobacco products are under the minimum legal age to purchase those products.”<sup>3</sup> Past efforts, Congress found, “have failed adequately to curb tobacco use by adolescents,” thus making necessary “comprehensive restrictions on the sale, promotion and distribution of such products.”<sup>4</sup>

As a key part of the TCA’s set of reforms directed at curbing youth smoking, Congress, in Section 907, prohibited the use of constituents or additives to impart any characterizing flavors in cigarettes, other than tobacco or menthol.<sup>5</sup> In addition, Section 907 gives FDA broad authority to adopt additional tobacco product standards, upon a finding that such action “is appropriate for the protection of the public health.”<sup>6</sup> In making such a finding, FDA is required to “consider scientific evidence concerning —

- (1) the risks and benefits to the population as a whole, including users and non-users of tobacco products, of the proposed standard;
- (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”<sup>7</sup>

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<sup>2</sup> Tobacco Control Act § 2(1), 123 Stat. at 1777.

<sup>3</sup> *Id.* § 2(4).

<sup>4</sup> *Id.* § 2(6).

<sup>5</sup> 21 U.S.C. § 387g(a)(1)(A).

<sup>6</sup> *Id.* § 387g(a)(3)(A).

<sup>7</sup> *Id.* § 387g(a)(3)(B)(i).

Thus, in considering a product standard prohibiting characterizing flavors in cigars, FDA is required to make a population-wide assessment of the impact of such a product standard, including not only its impact on those who currently smoke (including whether it may make it less difficult for them to stop smoking), but also its impact on those who do not smoke (including whether such a product standard may reduce initiation of smoking).

In making this population-wide assessment of a proposed product standard, FDA is not required by the TCA to make conclusions with scientific certainty. Section 907 therefore speaks in terms of *likelihoods*, not certainties. Section 907 requires FDA to assess “the increased or decreased *likelihood*” that existing users of tobacco products will cease their use and “the increased or decreased *likelihood*” that non-users will initiate use (emphasis added) if the product standard under consideration is adopted. A “likelihood” would exist, for example, if it is more likely than not that adoption of a product standard prohibiting characterizing flavors in cigars would reduce the number of people initiating smoking cigars or that it would increase the number of people who quit smoking cigars. The statute calls on FDA to make its best judgment, informed by the available science, as to the likely population-wide impact of a product standard prohibiting characterizing flavors in cigars.<sup>8</sup> Tobacco companies have insisted that FDA adopt a causal analysis for product standards similar to that used by the U.S. Surgeon General to determine the causal link between smoking and disease.<sup>9</sup> But because Section 907 necessarily requires FDA to make a predictive judgment about the impact of a proposal on human behavior, such a causal analysis is completely inapplicable and there is no indication in the TCA that Congress intended such an analysis to govern FDA’s approach to product standards.

As is apparent from the Preamble to the proposed rule, and as argued below, the available science strongly establishes that the proposed flavored cigar product standard is appropriate for the protection of the public health.

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<sup>8</sup> That Congress intended FDA to have maximum discretion to impose product standards without a requirement of scientific certainty is further confirmed by the judicial review section of the TCA. Section 912 of the TCA expressly subjects regulations establishing product standards to the lenient standard for judicial review under the Administrative Procedure Act, which empowers courts to set aside agency actions found to be “arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law.” 21 U.S.C. §3871(a)(1)(A) and (b), *incorporating by reference* 5 U.S.C. §706(2)(A). In other analogous regulatory contexts, courts have interpreted this judicial review standard to allow broad agency discretion to act even in the face of scientific uncertainty. *See, e.g., FCC v. Prometheus Radio Project*, 141 S.Ct. 1150, 1160 (2021) (agency acted lawfully when it “made a reasonable predictive judgment based on the evidence it had” despite that evidence being “[f]ar from” perfect.); *Indus. Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 656 (1980) (agency was “not required to support its findings . . . with anything approaching scientific certainty.”); *Coalition for Responsible Regulation, Inc. v. Environmental Protection Agency*, 684 F.3d 102,120 (D.C. Cir. 2012) (per curiam) (courts “give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.” Given that the Clean Air Act is “designed to protect the public health,” “the existence of some uncertainty does not, without more, warrant invalidation of an endangerment finding.”)

<sup>9</sup> *See, e.g.,* Altria Client Services, Comments in Docket No. FDA-2017-N-6565 (83 Fed. Reg. 12,294, March 21, 2018) “Advance Notice of Proposed Rulemaking on the Regulation of Flavors in Tobacco Products,” at 12-13, (Sep. 7, 2018), <https://www.regulations.gov/comment/FDA-2017-N-6565-23206>.

### **III. CIGAR MAKERS HAVE RADICALLY TRANSFORMED THE CIGAR MARKET SINCE 2009, USING FLAVORED CIGARS TO ATTRACT YOUTH.**

The cigar category has evolved dramatically over the past two decades, and today, cigars come in a wide variety of sizes, flavors, and price points. As a result, they appeal to a broader, more diverse market, including children.

Sales of cigars (i.e., large cigars, cigarillos, and small cigars) more than doubled between 2000 and 2020, from 6.2 billion cigars to 13.2 billion cigars; and this increase in cigar sales has come at a time when cigarette smoking has been declining.<sup>10</sup> Much of the growth in cigar sales is attributable to smaller types of cigars, many of them flavored, that are especially appealing to youth.

Cigar manufacturers have known that flavors help mask the harshness of cigars, making the products easier to smoke, and intentionally designing flavored cigars to serve as “starter” products for youth and young adults. This strategy has worked—many youth use flavored cigars and prefer brands that come in a variety of flavors.

#### **A. Flavored Cigars Have Come to Dominate the Cigar Market, with Great Appeal to Youth.**

Over the past two decades, and particularly after the TCA’s 2009 prohibition on non-menthol characterizing flavors in cigarettes, there has been explosive growth in flavor options for cigars, such as candy, fruit, chocolate, and various other kid-attracting flavors. Nielsen convenience store market scanner data show that the share of flavored cigars rose from 45% in 2009 to 53.3% in 2020, while the share of non-flavored cigars declined. Among flavored cigars sold in these stores in 2020, the most popular flavors were sweet or candy (30.6%), fruit (29.5%), concept (21.4%), and wine (9.0%).<sup>11</sup> Earlier data show that sales of flavored cigars in convenience stores increased by nearly 50% between 2008 and 2015, with the number of unique cigar flavor names more than doubling from 108 to 250 over the same time period.<sup>12</sup>

A separate study looking across all Nielsen-tracked channels found that cigarillos make up the vast majority (94.2%) of cigar sales and drove the increase in cigar sales during 2016 to 2020. In this study, 48.3% of cigarillo sales were flavored and 48.5% of little cigars were flavored in the first half of 2020.<sup>13</sup> These products can be priced as low as 3 or 4 for 99 cents, making them even more appealing to price-sensitive youth. They also typically are sold in shiny,

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<sup>10</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB), Tobacco Statistics. December 2000 & December 2020, <https://www.ttb.gov/tobacco/tobacco-stats.shtml>.

<sup>11</sup> Delnevo, CD, et al., “Cigar Sales in Convenience Stores in the US, 2009-2020,” *JAMA* 326(23):2429-2432, 2021.

<sup>12</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.

<sup>13</sup> Wang, X, et al., “Trends in Cigar Sales and Prices, by Product and Flavor Type—the United States, 2016–2020,” *Nicotine & Tobacco Research* 24(4):606-611, 2022.

colorful packages that reinforce the appeal of fruit and candy flavors that appeal to kids.<sup>14</sup> As FDA recognized, “Youth more commonly use cigarillos and little filtered cigars that are designed to be inhaled, which may increase their risk of poor health outcomes as well as addiction.” 87 Fed. Reg. 26,418.

We are pleased to see that FDA has proposed to include products that do not have explicit flavor names, also known as “concept” flavors. 87 Fed. Reg. at 26,404. Research shows that the availability of these types of cigars sold in “concept” flavors has grown as the industry attempts to circumvent local and state sales restrictions on cigars with characterizing flavors by exploiting confusion about what qualifies or can be identified as flavored cigars.<sup>15</sup> FDA should make it clear that the factors to be considered in determining whether a product has a characterizing flavor (at 26,437) do not require an explicit flavor name, although, under those factors, the use of such a name would be a flavor representation sufficient to establish that the product has a characterizing flavor. FDA also should make it clear that use of the term “sweet” in the labeling or advertising of a cigar is a flavor representation establishing that the product has a characterizing flavor.

#### **B. The Tobacco Industry Has Deliberately Developed and Marketed Flavored Cigars to Appeal to Youth.**

The tobacco industry continues to promote flavored cigars, despite knowing their appeal to youth. Historically, cigar manufacturers strategically added flavors to little cigars and cigarillos to cover up the harshness of the tobacco and make them more appealing to new, younger users. Cigarette companies also developed flavored little cigars that resembled cigarettes for similar reasons and to circumvent cigarette regulations.<sup>16</sup>

Cigars are sold in a range of flavors attractive to youth. “Candy-flavored” is an appropriate descriptor of these flavored cigars, given an analysis showing that the same flavor chemicals used in sweet-flavored cigars of various sizes are also used in popular candy and drink products such as LifeSavers, Jolly Ranchers, and Kool-Aid.<sup>17</sup> A systematic review of flavor preferences across all consumer products, spanning eight decades, concluded that, “Children have a strong, likely innate, preference for sweet tasting substances such as sugar and artificial sweeteners . . . Sweet tastes and sweet odours form a powerful sweet flavour mix that can be particularly attractive to children.”<sup>18</sup>

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<sup>14</sup> Campaign for Tobacco-Free Kids, *Not Your Grandfather’s Cigar*, at 10, 2013.

<sup>15</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>16</sup> Kostygina, G, Glantz, S, & Ling, PM, “Tobacco industry use of flavours to recruit new users of little cigars and cigarillos,” *Tobacco Control* 25(1):66-74, 2016.

<sup>17</sup> Brown, JE, et al., “Candy Flavorings in Tobacco,” *New England Journal of Medicine*, DOI: 10.1056/NEJMc1403015, 2014.

<sup>18</sup> Hoffman, AC, et al., “Flavour preferences in youth versus adults: a review,” *Tobacco Control* 25:ii32-ii39, 2016.

There is no doubt that flavored cigars attract youth. Research demonstrates that flavors play a key role in attracting youth to start using tobacco products, including cigars. 87 Fed. Reg. at 26,405. Flavors help to mask tobacco’s harshness and make cigars easier to smoke.<sup>19</sup> 87 Fed. Reg. at 26,405. A 2012 Surgeon General Report concluded that, “Much of the growing popularity of small cigars . . . is among younger adult consumers (aged <30 years) and appears to be linked to the marketing of flavored tobacco products that, like cigarettes, might be expected to be attractive to youth.”<sup>20</sup>

The cigar industry itself acknowledges that flavors attract new users. A tobacco industry trade publication stated, “While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers.”<sup>21</sup> The vice president of marketing for the international division of Swedish Match, which sells White Owl cigars and Game cigars in the U.S., stated, “It is mainly new recruits to cigar smoking who take to the new flavors, while long-time consumers still prefer the more traditional cigars.”<sup>22</sup> Industry insiders also recognize the use of flavors for inexperienced cigar smokers. The luxury lifestyle magazine, *Cigar Aficionado*, stated in an article, “More likely, flavored cigars serve as a bridge to premium cigars for the uninitiated, something to be smoked as an entryway into the world of cigar smoking. For the novice, a simple, sweet and easily identifiable flavor (honey or cherry, for example) is an easier step than moving into a box marked Cuban-seed Corojo.”<sup>23</sup>

Tobacco companies also continue to introduce new cigars in kid-friendly flavors despite FDA’s stated intention to advance this rulemaking. Last year, public health groups brought to FDA’s attention White Owl cigars in flavors such as “Chocolate & Vanilla Swirl” and “Jamaican Me Happy” that were brought to market by Swedish Match North America long after August 8, 2016 without any indication that they had received marketing orders from FDA.<sup>24</sup> Other companies have also introduced new flavors such as ITG Brands’ Backwoods Banana, advertised as “the latest rare edition” in the February 2022 issue of *Convenience Store News* magazine,<sup>25</sup> and Swisher Sweet’s Purple Swish.<sup>26</sup>

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<sup>19</sup> Kostygina, G, *supra* note 16, at 74; FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 15, 2022.

<sup>20</sup> U.S. Department of Health and Human Services (HHS), *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012.

<sup>21</sup> Niksic, M, “Flavored Smokes: Mmmmm . . . More Profits?” *Tobacco Retailer*, April 2007.

<sup>22</sup> Swedish Match, *No. 2 worldwide in cigars*, March 7, 2007, <http://www.swedishmatch.com/en/Media/Articles/No-2-worldwide-in-cigars/>.

<sup>23</sup> Savona, D, *Cigars of a Different Flavor*, CIGAR AFICIONADO, July/August 2005.

<sup>24</sup> Campaign for Tobacco-Free Kids et al. to Director Zeller, CTP, Aug. 9, 2021, “Continued introduction of new menthol cigarettes and flavored cigars without FDA marketing authorization,” at 4-5, [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/2021\\_08\\_10\\_FDA\\_Letter\\_Newport.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/2021_08_10_FDA_Letter_Newport.pdf).

<sup>25</sup> Convenience Store News, *ITG Brands Backwoods Banana*, CONVENIENCE STORE NEWS, at 29, February 2022, <https://issuu.com/ensembleiq/docs/csn-0222?fr=sM2NjMjgwODQ2MQ>.

<sup>26</sup> Convenience Store News, *Swisher Sweets Purple Swish*, Oct. 8, 2019, <https://www.csnews.com/swisher-sweets-purple-swish>.

### C. Youth Usage of Flavored Cigars is Significant.

Large numbers of youth are using cigars. In the United States, while cigarette smoking has declined rapidly, particularly in the last five years, cigar smoking has declined much more slowly. Currently, 380,000 middle and high school students use cigars. In 2021, 2.1% of high school students reported smoking cigars in the past 30 days. More high school boys smoke cigars (2.6%) than smoke cigarettes (2.0%).<sup>27</sup> Each day, more than 1,400 kids under 18 years old try cigar smoking for the first time.<sup>28</sup> Of particular concern, in 2021, 20.7% of current middle and high school students who smoked cigars smoked them on at least 20 of the preceding 30 days, which is considered frequent use and a sign that these youth users may be addicted.<sup>29</sup>

Data from the 2018-2019 Population Assessment of Tobacco and Health (PATH) study found that 60.4% of youth (12-17 years old) who have ever used cigars reported their first cigar was flavored.<sup>30</sup> 87 Fed. Reg. at 26,404. The 2016-2017 wave of the PATH study found that 56.8% of 12-17 year olds who had ever smoked cigarillos started with a flavored product.<sup>31</sup> Data from the 2013-2014 PATH study found that 73.8% of youth who smoked cigars reported that they did so “because they come in flavors I like.”<sup>32</sup> A higher proportion of youth and younger adults start using cigars with flavored versions compared to older adults. 87 Fed. Reg. at 26,404.<sup>33</sup>

Data from the 2021 National Youth Tobacco Survey (NYTS) show that 41.1% of high school students who smoke cigars and nearly 60% of middle school students who smoke cigars use flavored cigars, amounting to 160,000 youth. Flavored cigar use is high across the various cigar products: More than one-third (33.9%) of youth who smoke traditional cigars, 46.0% of youth who smoke cigarillos, and more than half (50.2%) of youth who smoke filtered cigars

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<sup>27</sup> Gentzke, A, et al., “Tobacco Product Use and Associated Factors Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021,” *MMWR* 71(5):1-29, 2022.

<sup>28</sup> Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, “Table 4.9A – Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, Prior to Age 21, and at Age 21 or Older: Numbers in Thousands, 2018 and 2019,” *Results from the 2019 National Survey on Drug Use and Health: Detailed Tables*, September 11, 2020. Cigars are defined as cigars, cigarillos or little cigars.

<sup>29</sup> Gentzke, A, *supra* note 27.

<sup>30</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 6, 2022.

<sup>31</sup> FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, March 13, 2019, <https://www.federalregister.gov/documents/2019/03/14/2019-04765/modifications-to-compliance-policy-for-certain-deemed-tobacco-products-draft-guidance-for-industry>.

<sup>32</sup> Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association, JAMA* 314(17):1871-1873, 2015.

<sup>33</sup> See also FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 6, 2022.



reported using flavored versions.<sup>34</sup> Among current youth users of flavored cigars, the most popular flavor is fruit (65%).<sup>35</sup>

Preference for sweet flavors is also inversely correlated with age. A national study found that 95% of 12-17 year-olds who smoked cigars reported a usual brand that makes flavored cigars, compared with 63% of cigar smokers aged 35 and older.<sup>36</sup> Data from the 2013-2014 National Adult Tobacco Survey indicate that use of flavored cigars decreases with age. The rates of flavored cigar use among people who smoked cigars were 48.3% among 18-24 year-olds, 41.0% among 25-29 year-olds, 37.1% among 30-44 year-olds, 28.8% among 45-64 year-olds, and 17.8% among those ages 65 and older.<sup>37</sup>

The top five most popular cigar brands among 12-17 year-olds who have used cigars—Swisher Sweets, Black & Mild, Backwoods, White Owl, and Dutch Masters—all come in flavor varieties.<sup>38</sup> For example, Black & Mild cigars come in flavors such as apple and cherry; Swisher Sweets' wide flavor varieties include tropical fusion, sweet cream, chocolate, cherry dynamite, and banana smash, and White Owl has flavors such as mango, tropical twist, chocolate & vanilla swirl, and blue raspberry.

Cigars are disproportionately used by Black youth. Black high school students smoke cigars at higher rates compared to other races or ethnicities (4.4% for Black vs. 2.1% for white, non-Hispanic or 1.2% for Hispanic high school students).<sup>39</sup> A previous study using PATH data also showed that non-Hispanic Black youth were more likely to initiate cigarillo or little cigar use and transition to regular use at earlier ages compared to non-Hispanic white youth.<sup>40</sup> Another study of youth and young adults found that non-Hispanic African Americans had a higher likelihood of progressing from experimentation to current and more frequent cigar use in a short period (within six months) compared to their white counterparts. This study also generally showed that among those who continued to use cigars, younger cigar smokers had a higher risk of becoming more frequent users within a short period.<sup>41</sup> 87 Fed. Reg. at 26,406.

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<sup>34</sup> National Institute of Health & Food and Drug Administration, Population Assessment of Tobacco and Health, "Past 30-Day Use of Any Flavored Cigars Among Youth (aged 12-17), by Sociodemographics," 2021, <https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/Youth-30Day-Flavored-AnyCigar.pdf>.

<sup>35</sup> Gentzke, A, *supra* note 27.

<sup>36</sup> Delnevo, C, et al., "Preference for flavoured cigar brands among youth, young adults and adults in the USA," *Tobacco Control* 24(4):389-94, 2015.

<sup>37</sup> Bonhomme, MG, et al., "Flavoured non-cigarette tobacco product use among US adults: 2013-2014," *Tobacco Control* 25:ii4-ii13, 2016.

<sup>38</sup> U.S. Dept. of Health and Human Services, SAMHSA's public online data analysis system (PDAS), *National Survey on Drug Use and Health*, 2019, <https://www.datafiles.samhsa.gov/dataset/national-survey-drug-use-and-health-2019-nsduh-2019-ds0001>.

<sup>39</sup> Gentzke, A, *supra* note 27.

<sup>40</sup> Chen, B, et al., "Age of initiation of cigarillos, filtered cigars and/or traditional cigars among youth: Findings from the Population Assessment of Tobacco and Health (PATH) study, 2013–2017," *PLoS ONE* 15(12):e0243372, 2020.

<sup>41</sup> Cantrell, J, et al., "Cigar Use Progression Among New Cigar Initiators: A Two-Part Growth Curve Analysis Among a Youth and Young Adult Cohort," *Nicotine & Tobacco Research* 24(1):28-36, 2022.

There are also youth cigar use disparities by sexual identity and disability status. Data from the 2020 NYTS showed that nearly twice as many middle and high school youth who identify as lesbian, gay, or bisexual (6%) used cigars compared to heterosexual youth (3.1%).<sup>42</sup> Youth who identified as transgender used cigars at higher rates than those who did not. In particular, more than twice as many girls who identified in a sexual minority reported ever using or currently using (past 30 days) cigars compared to heterosexual girls.<sup>43</sup> Research also indicates higher cigar use among youth reporting a disability, as well as an association between poor mental health status and greater odds of ever using cigars.<sup>44</sup>

Given the data on brand preference, market sales, and the growth of flavored cigars with “concept” names that do not provide obvious descriptions of flavors, it is possible that survey data underestimate the prevalence of flavored cigar use. Youth may not recognize or report that they are using flavored cigars if the names are ambiguous and the flavor type is not easily identifiable. Between 2009 and 2020, the proportion of all flavored cigar sales comprised of “concept flavors” increased nearly 10-fold, making up 21.4% of all flavored cigars sold in convenience stores in 2020.<sup>45</sup> Data from 2012 to 2016 show that the increase in these flavored products was greatest among cigarillos, among which the number of unique concept flavors more than doubled, from 17 to 46.<sup>46</sup>

Adding to the concern is that many youth and young adults perceive cigars to be less harmful than other tobacco products. At least one national survey found that nearly one-third of youth (31.5%) believe cigars are less addictive than cigarettes, and youth who used these products were even more likely to report that they believed them to be less addictive than cigarettes.<sup>47</sup> FDA previously raised this concern in the Deeming Rule extending FDA jurisdiction over cigars. In the proposed rule, the agency stated, “[R]esearch reflects that many people inaccurately think cigars . . . are safe alternatives to cigarettes. Indeed, research suggests that youth perceive cigars in a more positive light than cigarettes and believe cigars are more natural and less harmful, and some do not realize that cigars contain nicotine.”<sup>48</sup> And in the final Deeming Rule FDA also found that, “Many consumers believe that noncigarette tobacco products, including cigars, are less harmful than cigarettes.”<sup>49</sup> Flavors can factor into this misperception, with studies showing that younger people generally perceive flavored tobacco

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<sup>42</sup> Gentzke, A, et al., “Tobacco Product Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2020,” *MMWR* 69(50):1881-88, 2020.

<sup>43</sup> Johnson SE, et al., “Sexual and Gender Minority U.S. Youth Tobacco Use: Population Assessment of Tobacco and Health (PATH) Study Wave 3, 2015-2016,” *American Journal of Preventive Medicine* 57(2):256-261, 2019.

<sup>44</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 7-8, 2022.

<sup>45</sup> Delnevo, CD, *supra* note 11, at 2432; *see* Viola, AS, et al., “A cigar by any other name would taste as sweet,” *Tobacco Control* 25(5):605-6, 2016.

<sup>46</sup> Gammon, DG, *supra* note 15, at 400.

<sup>47</sup> Amrock, SM, et al., “Perceptions of e-cigarettes and noncigarette tobacco products among US youth,” *Pediatrics* 138(5), 2016.

<sup>48</sup> 79 Fed. Reg. 23,142, 23,158 (April 25, 2014).

<sup>49</sup> 81 Fed. Reg. 28,974, 29,024 (May 10, 2016).

products as less harmful,<sup>50</sup> and specifically believe that flavored cigars are less harmful and less addictive.<sup>51</sup> Perceiving lower risk from flavors in cigars has been found to be associated with higher likelihood of using flavored cigars.<sup>52</sup>

#### **IV. CIGAR SMOKING IS A SIGNIFICANT PUBLIC HEALTH CONCERN, PARTICULARLY FOR YOUNG PEOPLE.**

We agree with the proposed rule and FDA’s Scientific Assessment, which comprehensively reviewed and summarized the evidence demonstrating the link between regular cigar use and increased health risks, including respiratory disease, cancer, heart disease, and addiction.<sup>53</sup> 87 Fed. Reg. at 26,418-23. As FDA has previously stated, “Cigars are associated with significant risk and provide no public health benefit.”<sup>54</sup>

##### **A. All Cigars Increase Health Risks.**

All people who smoke cigars are exposed to dangerous levels of toxins and are at risk of addiction. Cigar smoke is composed of the same toxic and carcinogenic constituents found in cigarette smoke, including nicotine, carbon monoxide, NNAL (a tobacco-specific lung carcinogen), and heavy metals.<sup>55</sup> Cigar smoking causes cancer of the oral cavity, larynx, esophagus, and lungs, and people who smoke cigars daily have an increased risk of heart disease, chronic obstructive pulmonary disease (COPD), and aortic aneurysm.<sup>56</sup> While health risks may vary based on usage patterns, the level of risk is likely related to the level of exposure to the toxic constituents in the smoke, such as the frequency of use and whether or how much smoke is

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<sup>50</sup> Huang, LL, et al., “Impact of non-menthol flavours in tobacco products on perceptions and use among youth, young adults and adults: a systematic review,” *Tobacco Control* 26(6):709-719, 2017.

<sup>51</sup> Sterling, KL, Fryer, CS, & Fagan, P, “The Most Natural Tobacco Used: A Qualitative Investigation of Young Adult Smokers’ Risk Perceptions of Flavored Little Cigars and Cigarillos,” *Nicotine & Tobacco Research* 18(5):827-33, 2016.

<sup>52</sup> Nyman, AL, et al., “Flavors and Risk: Perceptions of Flavors in Little Cigars and Cigarillos Among U.S. Adults, 2015,” *Nicotine & Tobacco Research* 20(9):1055-1061, 2018.

<sup>53</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 74-81, 2022.

<sup>54</sup> FDA, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance*, March 13, 2019, <https://www.federalregister.gov/documents/2019/03/14/2019-04765/modifications-to-compliance-policy-for-certain-deemed-tobacco-products-draft-guidance-for-industry>.

<sup>55</sup> Pickworth, WB, et al., “Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure,” *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, 2017; Chen, J, et al., “Biomarkers of Exposure among U.S. Cigar Smokers: An Analysis of 1999-2012 National Health and Nutrition Examination Survey (NHANES) Data,” *Cancer Epidemiology, Biomarkers & Prevention* 23(12):2906-15, 2014; Hac, PJ, Cieslik, BM, & Konieczka, P, “Review of cigars and cigar-type products as potential sources of consumer exposure to heavy metals,” *Journal of Environmental Science and Health*, published online, April 25, 2022, DOI: 10.1080/26896583.2022.2052708..

<sup>56</sup> See National Cancer Institute (NCI), *Cigars: Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9*, 1998, [http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9\\_complete.pdf](http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9_complete.pdf).

inhaled. However, any cigar use increases health risks compared to those who do not use tobacco at all.<sup>57</sup>

All cigars contain nicotine and can facilitate nicotine addiction.<sup>58</sup> 87 Fed. Reg. at 26,407. Nicotine exposure during adolescence can affect brain development in various ways, including by priming the brain to addiction.<sup>59</sup> Studies show that many exclusive cigar users report strong tobacco cravings or show signs of dependence.<sup>60</sup> 87 Fed. Reg. at 26,407. FDA's Scientific Assessment cites additional studies linking cigar use with nicotine dependence, including the 2010 Surgeon General's report indicating that people who smoked cigars showed symptoms of nicotine dependence after limited exposure to nicotine during adolescence.<sup>61</sup> This is particularly concerning given that one in five youth who smoke cigars report frequent cigar use.<sup>62</sup>

Cigars, like cigarettes, also produce secondhand smoke with similar toxic constituents. The links between secondhand smoke exposure and health problems are well documented. The 2014 Surgeon General's report concluded, "Exposure to secondhand tobacco smoke has been causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children" and that secondhand smoke exposure increases the risk of stroke in people who do not smoke.<sup>63</sup> FDA stated that the "evidence supports the conclusion that these data apply to secondhand cigar smoke, as well, and there is no basis to conclude that secondhand smoke from cigars is any less hazardous than secondhand smoke from cigarettes." 87 Fed. Reg. at 26,421. A further concern is the disparate levels of exposure to secondhand smoke among more disproportionately affected or underserved populations: children, Black Americans, those living in poverty, those with less education, and those who live in rental housing have relatively higher exposure to secondhand smoke.<sup>64</sup>

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<sup>57</sup> NCI, *Cigars: Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9*, 1998; National Academies of Sciences – Engineering, and Medicine (NASEM), "Premium Cigars: Patterns of Use, Marketing, and Health Effects," *Washington, DC: The National Academies Press*, 2022.

<sup>58</sup> NCI, *Cigars: Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9*, 1998.

<sup>59</sup> HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*, 2012, <https://www.ncbi.nlm.nih.gov/books/NBK99237>; England LJ, et al., "Developmental toxicity of nicotine: A transdisciplinary synthesis and implications for emerging tobacco products," *Neuroscience and Biobehavioral Reviews* 72:176-189, 2017.

<sup>60</sup> Rostron BL, Schroeder MJ, Ambrose BK, "Dependence symptoms and cessation intentions among US adult daily cigarette, cigar, and e-cigarette users, 2012-2013," *BMC Public Health* 16(1):814, 2016; Blank MD, et al., "Acute Effects of 'Hyping' a Black & Mild Cigarillo," *Nicotine & Tobacco Research* 18(4):460-9, 2016.

<sup>61</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 26-27, 2022.

<sup>62</sup> Gentzke, A, *supra* note 27.

<sup>63</sup> U.S. Department of Health and Human Services, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, 2014, [https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf\\_NBK179276.pdf](https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf).

<sup>64</sup> Homa, DM., et al "Vital Signs: Disparities in Nonsmokers' Exposure to Secondhand Smoke—United States, 1999–2012," *MMWR* 64(4), 103-08, 2015.

In the proposed rule, FDA recognized the importance of addressing the serious health risks from cigar use:

Given th[e] causal relationship between cigar smoking and all-cause mortality, it is critical that FDA propose action to decrease the appeal and ease of cigar use, making it less likely that youth and young adults will experiment with cigars or progress to regular use. FDA also expects that the proposed product standard, if finalized, will cause a large number of existing cigar smokers to cease combusted tobacco product use . . . and, therefore, be less likely to suffer the negative health consequences of cigar smoking.

87 Fed. Reg. at 26,419.

### **B. Characterizing Flavors in Cigars Create Added Risks.**

As the proposed rule aptly summarized, characterizing flavors increase the harms of cigars. Research consistently shows that characterizing flavors raise the harms of cigars to non-users in three distinct ways: (1) enticing them to use the products, (2) masking the harshness of the tobacco, and (3) enhancing the addictiveness of nicotine. As detailed earlier in these comments and as thoroughly summarized in the proposed rule, survey data show that youth are drawn to and prefer flavored cigars. Previously confidential tobacco industry documents show that companies intentionally added flavors to make cigars more palatable to inexperienced young people.<sup>65</sup>

Flavors in cigars enhance the addictiveness of nicotine, not only by inducing experimentation and transitions to regular use of cigars, but also by activating the brain’s reward circuit and reinforcing nicotine’s effects. FDA’s analysis of the 2019-2020 NYTS data found an association between past 30-day use of flavored tobacco and increased odds of reporting strong cravings and desire to use tobacco within 30 minutes of waking—an indicator of addiction—compared to use of non-flavored tobacco products.<sup>66</sup>

Research demonstrates that those who initiate with flavored cigars are more likely to continue use and become regular, frequent users. An analysis of PATH study data found an association between the initial use of a flavored cigar product and daily or non-daily use of these products a year later among young adults and older adults (the sample was not large enough to evaluate the trend among youth).<sup>67</sup> 87 Fed. Reg. at 26,406.

Further, research indicates that the flavor chemicals themselves come with certain potential health risks. Beyond the 4,000 compounds found in tobacco smoke, 50 of which are

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<sup>65</sup> Kostygina, G, *supra* note 16, at 74.

<sup>66</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 26, 2022.

<sup>67</sup> Villanti, AC, et al., “Association of Flavored Tobacco Use With Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013-2015,” *JAMA Network Open* 2(10):e1913804, 2019.

carcinogens,<sup>68</sup> the added flavor chemicals increase the number of toxicants in the smoke. The proposed rule lists some toxicants found in cigar smoke due to flavor chemicals, along with potential health risks to users. *See* 87 Fed. Reg. at 26,417. In addition, one study found “measurable levels” of benzaldehyde in wild cherry-flavored cigar filler.<sup>69</sup>

There can be no public health justification for leaving flavored cigars on the market when there is ample evidence that the products increase harm. As the proposed rule stated, “[F]lavored cigar use exposes users to more toxicants than are present in non-flavored cigars and there is no evidence that flavored cigars present any countervailing benefits to public health.” 87 Fed. Reg. at 26,424.

## **V. FLAVORED CIGARS DISPROPORTIONATELY HARM THE HEALTH OF BLACK AMERICANS AND OTHER UNDERSERVED POPULATIONS.**

The disparate rates of cigar use among youth and adults from certain subgroups reflect decades of targeted industry marketing.

### **A. The Tobacco Industry Targets Black Youth with Cheap, Flavored Cigars.**

The tobacco industry has a history, which continues to this day, of targeting Black communities with marketing for cheap, flavored cigars, with devastating health consequences for this community.<sup>70</sup> FDA’s proposed rule and Scientific Assessment includes multiple sources indicating “flavored tobacco products in particular, have been disproportionately marketed to youth and young adults, racial and ethnic minority populations, and women,” a practice that FDA recognizes continues today.<sup>71</sup> 87 Fed. Reg. at 26,412-13. FDA also noted, “The differences found in exposure to flavored cigar marketing contribute to observed disparities in tobacco use and associated tobacco-related health disparities and health outcomes among vulnerable populations.” 87 Fed. Reg. at 26,413.

Cigar companies market their products using young and attractive Black models, social media influencers, and themes popular among Black youth. Studies show that music has been an important strategy used by cigar companies—a strategy also used by cigarette companies to market menthol cigarettes. Popular Black performers like Snoop Dogg and Jadakiss have been

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<sup>68</sup> NCI, *Cigars: Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9*, 1998.

<sup>69</sup> Lisko, JG, Stanfill, SB, & Watson, CH, “Quantitation of Ten Flavor Compounds in Unburned Tobacco Products,” *Analytical Methods* 6(13):4698-4704, 2014.

<sup>70</sup> *See* Campaign for Tobacco-Free Kids, et al., *Stopping Menthol, Saving Lives: Ending Big Tobacco’s Predatory Marketing to Black Communities*, 2021, [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/industry\\_watch/menthol-report/2021\\_02\\_tfk-menthol-report.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/menthol-report/2021_02_tfk-menthol-report.pdf).

<sup>71</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 19-20, 2022.

spokespeople for cigar brands,<sup>72</sup> and several cigar companies sponsor music events and programs to promote upcoming hip-hop artists.<sup>73</sup>

Even an informal scan of the social media pages and websites of popular cigar brands show the close relationship between Black music artists and cigars. Cigar companies highlight their sponsored events on their social media accounts, and in some cases, the artists post about their performances on their own social media accounts, amplifying the exposure to followers who may not normally be exposed to cigar marketing. Most of the influencers used in some major cigar brands' Instagram accounts are people of color, connected to the hip-hop music industry, and have a large following.<sup>74</sup> Similarly, Tik Tok videos featuring Swisher Sweets were more likely to show younger, female, Black, and Asian individuals compared to videos of large cigars generally. These Tik Tok videos also serve to highlight celebrities' promotion of cigar brands to a wider audience: one in ten Tik Tok videos with Swisher Sweets cigars played Cardi B's "Swisher Sweets" audio.<sup>75</sup> Cardi B has been associated with Swisher Sweets for many years, including receiving the brand's "Spark Award" in 2019 and a pair of UGGs designed with the Swisher Sweets logo.<sup>76</sup>

As with menthol cigarettes, years of research have documented greater cigar availability and more cigar marketing, including flavored cigars and price promotions, in Black neighborhoods.<sup>77</sup> This easy and cheap access to flavored cigars only increases the opportunities to buy and use these products, while normalizing the pervasive presence of pro-cigar imagery.

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<sup>72</sup> Sterling, KL, "Exposure to Celebrity-Endorsed Small Cigar Promotions and Susceptibility to Use among Young Adult Cigarette Smokers," *Journal of Environmental and Public Health* 2013:520286, 2013; Richardson, A, Ganz, O, & Vallone, D, "The cigar ambassador: how Snoop Dogg uses Instagram to promote tobacco use," *Tobacco Control* 3:79-80, 2013; Kostygina, G, Huang, J, & Emery, S, "TrendBlendz: how Splitarillos use marijuana flavours to promote cigarillo use," *Tobacco Control* 26(2):235-236, 2017.

<sup>73</sup> Ganz, O, Rose, SW, & Cantrell, J, "Swisher Sweets 'Artist Project': using musical events to promote cigars," *Tobacco Control* 27:e93-e95, 2018; Navarro, MA, et al., "Influencer prevalence and role on cigar brand Instagram pages," *Tobacco Control*, 0(e1):e33-e36, 2021.

<sup>74</sup> Navarro, MA, *supra* note 73.

<sup>75</sup> Wu, J, et al., "The Impact of Influencers on Cigar Promotions: A Content Analysis of Large Cigar and Swisher Sweets Videos on TikTok," *International Journal of Environmental Research and Public Health* 19(12):7064, 2022.

<sup>76</sup> Lawrence, K, "Cardi B Shined at the Swisher Sweets Spark Awards," *Complex*, May 20, 2019, <https://www.complex.com/pop-culture/2019/05/cardi-b-shined-at-the-spark-awards>; Spill The Tea YouTube channel, Cardi b gets SWISHER SWEETS UGGS, December 30, 2017, <https://www.youtube.com/watch?v=VffRc7YQs5Q>.

<sup>77</sup> Cantrell, J, et al., "Marketing Little Cigars and Cigarillos: Advertising, Price, and Associations With Neighborhood Demographics," *American Journal of Public Health* 103:1902-1909, 2013; Ribisl, KM, et al., "Disparities in Tobacco Marketing and Product Availability at the Point of Sale: Results of a National Study," *Preventive Medicine* 105:381-388, 2017; Smiley, SL, et al., "Disparities in retail marketing for little cigars and cigarillos in Los Angeles, California," *Addictive Behaviors Reports* 9:100149, 2019; Giovenco, DP, Spillane, TE, & Merizier, JM, "Neighborhood Differences in Alternative Tobacco Product Availability and Advertising in New York City: Implications for Health Disparities," *Nicotine & Tobacco Research* 21(7):896-902, 2019; Kong, Amanda, et al., "Neighborhood Disparities in the Availability, Advertising, Promotion, and Youth Appeal of Little Cigars and Cigarillos, United States, 2015," *Nicotine & Tobacco Research* 22(12): 2170-2177, December 2020.

As mentioned earlier, Black youth use cigars at disproportionately higher rates compared to other races or ethnicities<sup>78</sup> and were found to be more likely to initiate cigarillo or little cigar use, and to transition to regular use at earlier ages compared to non-Hispanic white youth.<sup>79</sup> This disparity in use among youth is not surprising, as Black youth are often surrounded by cigar imagery. Black non-tobacco users are more than two times more likely to recall seeing ads for cigarillos and/or little cigars compared to non-Hispanic white persons.<sup>80</sup>

Higher exposure to tobacco marketing and products at retail increase susceptibility to use among youth. Studies show that recall of cigar marketing at the point of sale, as well as more visits to corner stores, by youth are associated with greater susceptibility to use of cigars.<sup>81</sup>

### **B. Cigars Have a Disproportionate Impact on Underserved Populations.**

The proposed rule effectively describes how the disparities in cigar use, cessation success, and environment (through exposure to secondhand smoke) translate to unequal health outcomes. *See* 87 Fed. Reg. at 26,422-23

Research showing earlier age of cigar initiation,<sup>82</sup> higher likelihood of using cigars (particularly cigarillos),<sup>83</sup> poly-tobacco use,<sup>84</sup> unchanged cigar smoking trends over time,<sup>85</sup> and lower rates of discontinuing cigar use<sup>86</sup> among non-Hispanic Black Americans compared to the non-Hispanic white population mean longer tobacco use and longer exposure to harmful tobacco constituents that increase the likelihood of developing tobacco-caused morbidity and mortality. Disproportionately higher exposure to secondhand smoke adds to these higher health risks.

Data from the 2018-2019 PATH study found the highest rates of flavored cigar use among non-Hispanic Black adult cigar smokers (47.9%), followed by Hispanic adults (40.6%) and non-Hispanic other or multi-race adults (33.9%). The rate for non-Hispanic white adult cigar

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<sup>78</sup> Gentzke, A, *supra* note 27.

<sup>79</sup> Chen, B, *supra* note 40.

<sup>80</sup> Moran, MB, et al., “Ethnic and socioeconomic disparities in recalled exposure to and self-reported impact of tobacco marketing and promotions,” *Health Communications* 34(3):280–289, 2019.

<sup>81</sup> Pasch, KE, et al., “Recall of Point-of-Sale Marketing Predicts Cigar and E-Cigarette Use Among Texas Youth,” *Nicotine & Tobacco Research* 20(8):962-969, 2018; Trapl, ES, et al. “Individual, Parental, and Environmental Correlates of Cigar, Cigarillo, and Little Cigar Use Among Middle School Adolescents,” *Nicotine & Tobacco Research* 18(5):834-41, 2016.

<sup>82</sup> Chen, B, *supra* note 40.

<sup>83</sup> Chen-Sankey, JC, “Cigar-Smoking Patterns by Race/Ethnicity and Cigar Type: A Nationally Representative Survey Among U.S. Adults,” *American Journal of Preventive Medicine* 60(1):87-94, 2021.

<sup>84</sup> Hirschtick, JL, et al., “Short communication: Racial/ethnic disparities in cigar and cigarette exclusive, dual, and polyuse among adults,” *Addictive Behaviors* 15:100412, 2022, doi: 10.1016/j.abrep.2022.100412.

<sup>85</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.

<sup>86</sup> Kasza, KA, 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.



smokers was 30.3%.<sup>87</sup> Another recent analysis of 2018-2019 PATH data among a larger range of young adults (18-34 years old) found the highest rates of flavored cigar and blunt use among those who smoked cigars in the past 30-days and identified as Hispanic and multiracial/other race compared to those who identified as other races and ethnicities.<sup>88</sup>

Other underserved populations, including lower income and homeless populations, show similar patterns of higher cigar use and disproportionately higher burdens from tobacco-related diseases and exposure to secondhand smoke. Data from the 2013-2014 PATH study found that adults living below the federal poverty line had significantly higher rates of using large (non-premium) cigars, cigarillos, and filtered cigars compared to higher income populations.<sup>89</sup> A study of people experiencing homelessness in San Francisco, CA found that 74% of respondents who used alternative nicotine products also used cigars in the past 30 days, with more than half (55%) reporting using flavored cigars in the past 30 days.<sup>90</sup>

As stated in the Regulatory Impact Analysis for the proposed rule, “Because cigar smoking exposes users to many of the same harmful constituents as cigarette smoking and is associated with many of the same health risks as cigarette smoking, disparities in cigar use contribute to tobacco-related health disparities observed in morbidity and mortality . . . for vulnerable populations.”<sup>91</sup> These differential health impacts include higher death rates among Black Americans from tobacco-related cancers, heart disease, and strokes compared to other races and ethnicities.<sup>92</sup> 87 Fed. Reg. at 26,422-23. Similarly, counties with the lowest

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<sup>87</sup> National Institute of Health & Food and Drug Administration – Population Assessment of Tobacco and Health, *Past 30-Day Use of Any Flavored Cigars Among Adults (Aged 25+), by Sociodemographics*, 2021, <https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/OlderAdult-30Day-Flavored-AnyCigar.pdf>.

<sup>88</sup> Watkins, SL, et al., “Flavored Tobacco Product Use Among Young Adults by Race and Ethnicity: Evidence From the Population Assessment of Tobacco and Health Study,” *Journal of Adolescent Health*, 9:S1054-139X(22)00334-2, 2022.

<sup>89</sup> Corey, CG, et al., “US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014,” *Nicotine & Tobacco Research* 20(12):1457-1466, 2018.

<sup>90</sup> Alizaga, NM, et al., “Alternative flavored and unflavored tobacco product use and cigarette quit attempts among current smokers experiencing homelessness,” *Addictive Behaviors Reports* 12:100280, 2020.

<sup>91</sup> FDA, *Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Characterizing Flavors in Cigars*, Docket No. FDA-2021-N-1309, at 14-15, <https://www.fda.gov/media/158013/download>. (“RIA”).

<sup>92</sup> American Cancer Society, *Cancer Facts & Figures for African American/Black People 2022-2024*, 2022, <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/2022-2024-cff-aa.pdf>; American Cancer Society, *Cancer Facts & Figures for African Americans, 2019-2021*, 2019, <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/cancer-facts-and-figures-for-african-americans-2019-2021.pdf>; National Center for Health Statistics, “Racial and Ethnic Disparities in Heart Disease.” *Health, United States Spotlight*, 2019, [https://www.cdc.gov/nchs/hsu/spotlight/HeartDiseaseSpotlight\\_2019\\_0404.pdf](https://www.cdc.gov/nchs/hsu/spotlight/HeartDiseaseSpotlight_2019_0404.pdf).

educational attainment or highest poverty have the highest tobacco-related cancer incidence and death rates as well as the slowest decline in incidence rates.<sup>93</sup>

Like cigarettes, cigars produce secondhand smoke, with larger cigars producing more smoke. Black Americans are disproportionately affected by exposure to secondhand smoke. Nearly half (48.0%) of Black individuals are still exposed to this preventable health hazard.<sup>94</sup> Rates are even higher among youth. Among Black kids aged three to 11 years, two-thirds (66.2%) are exposed to secondhand smoke, compared to 38.1% of white kids of the same age.<sup>95</sup> In 2017-2018, 44.6% of people living below the poverty level were exposed to secondhand smoke, compared to 21.3% of people living at or above the poverty level.<sup>96</sup> The prevalence of secondhand smoke exposure in the home is also highest among lower-income adults and children.<sup>97</sup>

## **VI. PROHIBITING FLAVORED CIGARS WILL PRODUCE SUBSTANTIAL PUBLIC HEALTH BENEFITS, INCLUDING REDUCING HEALTH DISPARITIES.**

In the proposed rule, FDA recognized the impact that cigars, including flavored cigars, have on health, and consequently, the health benefits that would accrue by implementing the proposed product standard:

Given th[e] causal relationship between cigar smoking and all-cause mortality, it is critical that FDA propose action to decrease the appeal and ease of cigar use, making it less likely that youth and young adults will experiment with cigars or progress to regular use. FDA also expects that the proposed product standard, if finalized, will cause a large number of existing cigar smokers to cease combusted tobacco product use . . . and, therefore, be less likely to suffer the negative health consequences of cigar smoking.

87 Fed. Reg. at 26,419.

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<sup>93</sup> Center for Disease Control (“CDC”), “Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004-2013,” *MMWR*, 65(44): 1212-1218, 2016, <http://www.cdc.gov/mmwr/volumes/65/wr/mm6544a3.htm>.

<sup>94</sup> Shastri, SS, Talluri, R, Shete, S, “Disparities in Secondhand Smoke Exposure in the United States: National Health and Nutrition Examination Survey 2011-2018,” *JAMA Internal Medicine* 181(1):134–137, 2021.

<sup>95</sup> Brody, DJ, Lu, Z, Tsai, J. “Secondhand smoke exposure among nonsmoking youth: United States, 2013–2016,” *NCHS Data Brief*, no 348. HYATTSVILLE, MD: NATIONAL CENTER FOR HEALTH STATISTICS, 2019, <https://www.cdc.gov/nchs/products/databriefs/db348.htm>.

<sup>96</sup> Shastri, SS, *supra* note 94, at 137.

<sup>97</sup> See CDC, “Disparities in Secondhand Smoke Exposure—United States, 1998-1994 and 1999-2004,” *MMWR*, 57(27):744-747, 2008; HRSA, Maternal and Child Health Bureau, “Smoking in the Household,” 2010; King, K., et al., “Family Composition and Children’s Exposure to Adult Smokers in Their Homes,” *Pediatrics* 123(4):559-564, 2009.

**A. Prohibiting Flavored Cigars Will Likely Reduce Cigar Initiation, Particularly Among Young People.**

Data presented above and in the proposed rule clearly demonstrate that adding flavors to cigars entices youth, promotes experimentation and transition to regular use, and heightens risk of addiction. Thus, as detailed in the proposed rule, removing characterizing flavors from cigars would reduce the appeal of the products and consequently diminish the likelihood of experimentation and progression to regular use by non-users, particularly youth. 87 Fed. Reg. at 26,424-26.

In the proposed rule and its Scientific Assessment, FDA also summarized the evidence from localities that implemented sales restrictions on flavored tobacco products.<sup>98</sup> 87 Fed. Reg. at 26,425-26. As FDA noted, studies from Providence, RI, New York City, localities in Massachusetts, San Francisco, and Canada provide evidence that sales restrictions on flavored tobacco products reduce youth use of tobacco products, including flavored cigars. 87 Fed. Reg. at 26,426. The demonstrated impact from these local policies indicates that a national product standard prohibiting flavored cigars would have a far greater impact on youth, particularly since it would avoid many of the implementation issues that localities have experienced, including the ability for youth to continue to access flavored products in neighboring localities that have not implemented flavored tobacco sales restrictions. For instance, the proposed rule stated, “[A] nationwide product standard would eliminate the manufacture of these products as well as the opportunity for youth to easily travel to neighboring jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.” 87 Fed. Reg. at 26,426.

As FDA stated in the proposed rule:

Overall, FDA finds that evidence regarding the role of flavors in increasing appeal of cigars to youth and young adults, promoting progression to regular use, and increasing the addiction potential indicates that *removing flavors from cigars would reduce initiation and use of such products, especially among youth and young adults*. As a majority of adult regular tobacco users become dependent on or addicted to nicotine as youth and young adults, reducing initiation and use of cigar products in youth would reduce the likelihood that youth progress to nicotine dependence and regular use, as well as subsequent tobacco-related illness and death. Therefore, *FDA anticipates that removing flavors from cigars would substantially reduce tobacco-related disease and death as a result of averted youth initiation*.

87 Fed. Reg. at 26,406 (emphasis added).

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<sup>98</sup> FDA, *Scientific Assessment of the Impact of Flavors in Cigar Products*, at 30-31, 2022.

**B. Prohibiting Flavored Cigars Will Likely Cause Significant Numbers of People Who Currently Smoke Cigars to Stop Smoking.**

As indicated above and in the proposed rule, a significant number of people who smoke cigars identify flavors as a contributing factor for their cigar use. Removing flavors from cigars would make them less attractive, leading to less transition from experimenting with cigars to becoming regular users, and incentivizing those who prefer flavors to quit. Sales data from localities with sales restrictions on flavored tobacco products show declines not only in flavored cigar sales, but also in overall cigar sales following implementation. This data implies that not only were there reductions in flavored cigar use, but there was also minimal transition from flavored cigars to non-flavored cigars.<sup>99</sup>

In the proposed rule, FDA recognized that prohibiting flavored cigars would likely lead many people who currently smoke cigars to stop smoking:

FDA anticipates that the proposed standard would increase the likelihood that some existing flavored cigar smokers would find tobacco-flavored cigars unappealing and consequently stop smoking cigars altogether, yielding health benefits from smoking cessation. . . . Given the substantial proportion of existing cigar users using flavored cigars, the consistently high endorsement of characterizing flavors as a reason for use, empirical evidence of lower tobacco sales (as a proxy for consumption) following a flavored tobacco product restriction in multiple localities, and evidence suggesting decreased cigar use among adult consumers following implementation of flavor restrictions in two studied localities, FDA expects that the proposed standard would lead many flavored cigar smokers to reduce or stop using cigars.

87 Fed. Reg. at 26,426.

Though some people who smoke flavored cigars may switch to non-flavored cigars or other tobacco products, experience from localities indicate that the switching rate is low. In fact, in reviewing the experiences with local policies restricting sales of flavored tobacco products in its Regulatory Impact Analysis, FDA stated, “these decreases in overall cigar sales indicate that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction.”<sup>100</sup>

In addition, because this is a national regulation, consumers cannot simply cross borders to try to circumvent the policy—a fact noted by FDA in its Regulatory Impact Analysis. “FDA anticipates that this nationwide product standard would eliminate the opportunity for consumers

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<sup>99</sup> Farley, SM & Johns, M, “New York City flavoured tobacco product sales ban evaluation,” *Tobacco Control* 26(1):78-84, 2017; Rogers, T, et al., “Changes in cigar sales following implementation of a local policy restricting sales of flavoured non-cigarette tobacco products,” *Tobacco Control* 29(4):412-419, 2020.

<sup>100</sup> RIA at 28.

to travel to local neighboring U.S.-based jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.”<sup>101</sup>

FDA estimates that 780 premature tobacco-related deaths will be avoided annually due to this product standard, with more than 25,000 deaths avoided over the next 40 years.<sup>102</sup> In order to maximize these life-saving benefits, we support taking steps to enhance the cessation support available to people who smoke cigars, as set out in detail in the comments of various public health, medical, education, civil rights, and community organizations in response to the Proposed Rule for a Tobacco Product Standard for Menthol in Cigarettes, 87 Fed. Reg. 26,454, May 4, 2022, incorporated by reference herein.

FDA has proposed to adopt the statutory one-year implementation period, but has requested comment on whether a shorter period would be necessary for the protection of the public health. 87 Fed. Reg. at 26,438. The one-year implementation period gives the agency ample time to work with other federal agencies and non-governmental organizations to plan how to assist people who smoke but would like to quit. In no event should FDA consider an implementation period of more than one year to accommodate industry concerns. Given that industry compliance is simply a matter of taking flavored cigars off the market, or no longer using flavoring additives in the manufacture of cigars, the statutory one-year period is more than sufficient to permit the industry to comply with the rule in an orderly fashion.

FDA also has asked for comment on whether it should provide for a “sell-off” period—for example, 30 days after the effective date of a final rule—for retailers to sell through their current inventory of flavored cigars. 87 Fed. Reg. at 26,438. Given FDA’s proposed implementation period of one year prior to the effective date, retailers will be given sufficient time to plan for removal of flavored cigars from their inventory and to minimize any adverse financial impact of such removal. Therefore, there is no justification for an additional 30 days to continue to sell products that cause such substantial public health harm.

### **C. Prohibiting Flavored Cigars Will Promote Health Equity.**

The disproportionate use of cigars among Black adults and youth, as well as the unequal health burden due to that cigar use makes this proposed rule even more urgent. As detailed above and in the proposed rule, cigar use among Black youth is much higher than cigar use among other race/ethnicities. Removing the flavors from cigars will make them less attractive to youth and reduce initiation.

FDA carefully evaluated the research in this area in recognition of the disparities in use and impact. It stated, “Considerations related to health equity helped inform FDA’s decision to

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<sup>101</sup> *Id.* at 29.

<sup>102</sup> *Id.* at 36, 39.

prioritize this proposed product standard. In particular, FDA took into account the disproportionate toll flavored cigars have taken on certain population subgroups. We note that the expected health benefits of this proposed standard are expected to be greater in these subgroups than in the population more generally.” 87 Fed. Reg. at 26,403.

Given the evidence showing persistent unequal distribution and availability of flavored cigars in various neighborhoods, this product standard will remove these products across the board, even in places where the industry has tried to circumvent existing local laws. A recent study demonstrating noncompliance with New York City’s sales restriction on flavored tobacco products, including flavored cigars, specifically found higher noncompliance in neighborhoods with greater proportions of Black and Hispanic residents.<sup>103</sup> Thus, the proposed product standard will advance health equity by eliminating the greater presence of these products in underserved communities.

Not only would removing flavored cigars from commerce reduce access, but it would also lead to reduced marketing for these products in neighborhoods targeted by the industry. A recent study comparing the availability of flavored tobacco products in California localities with sales restrictions to those without, found significant reductions in store availability of flavored little cigars, as well as significant reductions in the presence of exterior marketing for those products.<sup>104</sup> Combining these findings with the industry’s targeted marketing of flavored cigars in underserved neighborhoods indicates that this proposed product standard would reduce not only the availability, but also the marketing of those products for populations most impacted by flavored cigars.

We agree with FDA’s assessment that, “Reducing the appeal and use of cigars by eliminating characterizing flavors (other than tobacco) also is expected to substantially decrease tobacco-related health disparities and to equitably promote health across population groups.” 87 Fed. Reg. at 26,400.

## **VII. THERE IS NO PUBLIC HEALTH RATIONALE FOR CONTINUING TO PERMIT CHARACTERIZING FLAVORS IN ANY CIGAR, WATERPIPE, OR PIPE TOBACCO PRODUCT.**

Given the role flavors play in attracting young people to use tobacco products, there is no public health rationale for continuing to permit any characterizing flavors in any cigar,

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<sup>103</sup> Farley, SM, et al., “Flavored Tobacco Sales Prohibition (2009) and Noncigarette Tobacco Products in Retail Stores (2017), New York City,” *American Journal of Public Health* 110:725-730, 2020..

<sup>104</sup> Holmes, LM, Lempert, LK & Ling, PM, “Flavored Tobacco Sales Restrictions Reduce Tobacco Product Availability and Retailer Advertising,” *International Journal of Environmental Research and Public Health* 19(6):3455, 2022.

waterpipe, or pipe tobacco product. Thus it is important that this proposed rule be implemented with the same effective date as the rule prohibiting menthol cigarettes.

After the TCA prohibited non-menthol characterizing flavors in cigarettes, tobacco product manufacturers responded by introducing a host of kid-friendly flavors in other tobacco products. Youth usage of these products boomed even while the prevalence of cigarette smoking by young people fell. With respect to flavors in cigar, waterpipe, or pipe tobacco products, there is no reason for FDA to spend resources deciding which of the flavors or which category of tobacco products are the most egregious; none of them can possibly provide a net benefit to the public health. No such distinctions can justify the continued marketing of any flavored cigar, waterpipe, or pipe tobacco product because no such product can play a role in reducing smoking initiation or encouraging cessation.

**A. The Public Health Impact of the Flavored Cigar Product Standard Would Be Enhanced if Implemented Alongside the Product Standard on Menthol Cigarettes.**

Removing flavored cigars, including menthol cigars, from the market will have a significant public health impact. This impact will be enhanced if menthol cigarettes are removed from the market concurrently to minimize the risk that some people who formerly smoked flavored cigars will switch to those products. Studies show that consumers substitute<sup>105</sup> cigarettes and cigars, particularly little or filtered cigars, and in some cases confuse products<sup>106</sup> for each other. In addition, experience has shown that category-specific regulations create loopholes that manufacturers exploit to circumvent regulations.

Implementing both of these proposed rules will have a compound benefit for the most at-risk populations. Past actions by tobacco companies have shown that they are willing to cast a wide net to attract youth users of any tobacco product. In the 1970s, Reynolds American and American Tobacco tried to grow sales of menthol little cigars with targeted ads to the Black community, building on the popularity of menthol cigarettes among this group.<sup>107</sup> In addition, survey data show racial disparities in connections between cigars and cigarettes among youth. A recent national longitudinal study found that between 2013 and 2018, “9.1% of cigarette initiation among non-Hispanic black youth was attributable to cigar products.” According to the study’s authors, “decreasing cigar use among youth could prevent up to 4.6% of cigarette initiation overall and 9.1% among black youth specifically.”<sup>108</sup> While this study was not specific

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<sup>105</sup> Gammon, DG, “Effect of price changes in little cigars and cigarettes on little cigar sales: USA, Q4 2011-Q4 2013,” *Tobacco Control* 25(5):538-44, 2016.

<sup>106</sup> Casseus, M, et al., “Cigarette smokers’ classification of tobacco products,” *Tobacco Control* 25:628-630, 2016.

<sup>107</sup> Kostygina, G, *supra* note 16, at 74.

<sup>108</sup> Stokes, A, et al., “Racial/Ethnic Differences in Associations of Noncigarette Tobacco Product Use with Subsequent Initiation of Cigarettes in US Youths,” *Nicotine & Tobacco Research* 23(6):900-908, 2021.

to flavored cigars, the most popular cigar brands among Black youth are those that offer a variety of flavors.<sup>109</sup>

The evidence shows that, when a specific type of flavored combustible product is prohibited, many younger consumers will switch to another combustible tobacco product that remains available in flavors. A 2017 study analyzed data from the 1999-2013 Youth Tobacco Surveys to look at the impact of the 2009 statutory prohibition of non-menthol characterizing flavors in cigarettes on youth tobacco use. It found that while cigarette use declined significantly after 2009, cigar and pipe tobacco use significantly increased.<sup>110</sup> Similarly, a study from Ontario, Canada found that after its prohibition on menthol cigarettes, people who smoked menthol cigarettes daily or occasionally were more likely to use flavored cigars compared to people who smoked non-menthol cigarettes.<sup>111</sup>

In the proposed rules, FDA has already described how menthol has been shown to independently increase the number of nicotinic receptors in the brain, which would allow for more nicotine to bind and, consequently, greater nicotine withdrawal symptoms and stronger signs of nicotine dependence. 87 Fed. Reg. at 26,418. These findings only reinforce the need to ensure that people who smoke menthol cigars will not switch to menthol cigarettes in the absence of menthol cigars.

Manufacturers will manipulate their products to fit any loophole. As mentioned previously, we have already seen cigarettes become so-called little or filtered “large” cigars, and roll-your-own (RYO) tobacco become pipe tobacco in order to skirt more restrictive regulations.

## **B. Flavored Waterpipe Tobacco Products Attract Young Users.**

Waterpipe tobacco products, also known as hookah, originated in Middle Eastern countries, but their use has rapidly increased in the U.S. Traditionally, raw tobacco was used in waterpipes, but in the 1990s, flavored waterpipe tobacco, or shisha, was introduced, leading to increased popularity among young people around the world.<sup>112</sup> Now, the tobacco mixture used in waterpipes often has flavorings or sweeteners added to enhance the taste and aroma. In the U.S., many kid-friendly flavors are available, such as watermelon, tropical fruit, orange cream,

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<sup>109</sup>U.S. Dept. of Health and Human Services, SAMHSA’s public online data analysis system (PDAS). *National Survey on Drug Use and Health*, 2019, <https://www.datafiles.samhsa.gov/dataset/national-survey-drug-use-and-health-2019-nsduh-2019-ds0001>.

<sup>110</sup> Courtemanche, CJ, et al., “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use,” *American Journal of Preventive Medicine* 52(5):e139-e146, 2017.

<sup>111</sup> Chaiton M, et al., “Product Substitution After A Real-World Menthol Ban: A Cohort Study,” *Tobacco Regulatory Science* 6(3):205-212, 2020.

<sup>112</sup> World Health Organization, *Fact Sheet: Waterpipe Tobacco Smoking & Health*, 2015, [https://apps.who.int/iris/bitstream/handle/10665/179523/WHO\\_NMH\\_PND\\_15.4\\_eng.pdf;jsessionid=CD4B4EF29B1513226BF554DF1700F5F7?sequence=1](https://apps.who.int/iris/bitstream/handle/10665/179523/WHO_NMH_PND_15.4_eng.pdf;jsessionid=CD4B4EF29B1513226BF554DF1700F5F7?sequence=1).



caramel, chocolate, tutti frutti, vanilla, and strawberry.<sup>113</sup> The online retailer, Zahrah, lists the “Top 25 Shisha Flavors,” including:

- Al Fakher: Orange Mint, Two Apples, Blueberry with Mint;
- Trifecta: Peppermint Shake;
- Fumari: White Gummi Bear, Tropical Punch, Watermelon, Blueberry Muffin; and
- Starbuzz: Passion Fruit, Blue Mist.<sup>114</sup>

In 2021, 1.2% of high school students used waterpipe tobacco in the past 30 days. However, Black high schoolers reported a higher rate of waterpipe tobacco use (3.2%) compared to non-Hispanic white (0.8%) and Hispanic (1.3%) high school students. Among middle and high school students who currently used waterpipe tobacco, nearly 1 in 5 (19.9%) reported using it on 20 of the previous 30 days, which is considered frequent use and could be an indication of addiction.<sup>115</sup>

The appeal of flavored waterpipe tobacco contributes to its popularity among youth and young adults. The 2021 NYTS found that 46.6% of current high school waterpipe tobacco users reported using a flavored product in the last month. Fruit is the most popular flavor among youth who currently use flavored waterpipe tobacco.<sup>116</sup> The 2013-2014 PATH study found that 88.7% of 12-17 year-olds who had ever smoked waterpipe tobacco used flavored waterpipe tobacco the first time they tried the product.<sup>117</sup> According to the PATH study, use of flavored tobacco is higher for users of waterpipe tobacco than for any other tobacco product, and more than three-quarters (78.9%) of youth hookah users reported that they use waterpipe tobacco “because they come in flavors I like.”<sup>118</sup>

Youth and young adults also consistently underestimate the health risks of waterpipe tobacco. The 2013-2014 PATH study found that 60.6% of current youth waterpipe tobacco users use hookah because they think it might be less harmful than cigarettes.<sup>119</sup> Studies also find that college students believe waterpipe tobacco use to be less harmful, less addictive, and more socially acceptable than cigarette smoking.<sup>120</sup> However, according to the CDC, using a waterpipe

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<sup>113</sup> American Lung Association, *An Emerging Deadly Trend: Waterpipe Tobacco Use*, 2007,

<https://www.lung.org/getmedia/ec1a184f-0fc9-4a08-a83b-5f56b5f35eaf/2007-tobacco-policy-trend.pdf.pdf>.

<sup>114</sup> Zahrah, “Top 25 Shisha Flavors,” ZAHRAH, accessed May 12, 2022, <https://www.zahrahusa.com/pages/top-25-shisha-flavors>.

<sup>115</sup> Gentzke, A, *supra* note 27.

<sup>116</sup> *Id.*

<sup>117</sup> Ambrose, BK, *supra* note 32.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> Wackowski, OA and Delnevo, CD, “Young Adults’ Risk Perceptions of Various Tobacco Products Relative to Cigarettes: Results from the National Young Adult Health Survey,” *Health Education & Behavior* 43(3): 328-336, 2016; *see* Primack, AB, et al., “Prevalence of and Associations with Waterpipe Tobacco Smoking among U.S. University Students,” *Annals of Behavioral Medicine*, 36(1):81-86, 2008; Grekin, ER and Ayna, D., “Waterpipe

to smoke tobacco poses serious health risks to people who smoke and others exposed to the smoke from the waterpipe tobacco.<sup>121</sup> Because the flavors and the smoking technique create a more soothing (“smooth”) experience, people who smoke waterpipe tobacco can inhale more deeply and spend more time in a “waterpipe tobacco session,” which typically lasts for 40 to 45 minutes (three to four times longer than it takes to smoke a cigarette). While a typical cigarette requires about 20 puffs, an hour-long waterpipe tobacco session may involve 100 to 200 puffs,<sup>122</sup> potentially exposing the user to more smoke over a greater period of time than what occurs when smoking a regular cigarette.<sup>123</sup> The World Health Organization (WHO) determined that “waterpipe smoking results in significant exposure to all these compounds, and waterpipe smokers have much greater exposure to CO [carbon monoxide], significantly greater exposure to PAH, similar exposure to nicotine and significantly lower exposure to tobacco-specific nitrosamines than cigarette smokers.”<sup>124</sup> A review of the evidence indicates that waterpipe tobacco smoking is associated with nicotine dependence, including experiences of withdrawal and difficulty quitting, at least among some users.<sup>125</sup> The WHO indicated “[strong] support [for] the possibility that waterpipe smoking serves as a gateway to cigarette smoking and suggest the plausibility of the concept that more frequent (dependent) smokers are more likely to turn to cigarettes.”<sup>126</sup> As mentioned earlier, many youth are already using waterpipe tobacco frequently.<sup>127</sup>

FDA should include waterpipe tobacco with characterizing flavors in the final rule to discourage youth from using these products.

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Smoking Among College Students: A Review of the Literature,” *Journal of American College Health*, 60(3):244-249, 2012; Smith-Simone, SY, et al., “Differing psychosocial risk profiles of college freshman waterpipe, cigar and cigarette smokers,” *Addictive Behaviors*, 33(12):1619-1624, 2008; Smith, SY, et al., “Harm perception of nicotine products in college freshman,” *Nicotine & Tobacco Research*, 9:977-982, 2007; Eissenberg, T, et al., “Waterpipe tobacco smoking on a U.S. college campus: prevalence and correlates,” *Journal of Adolescent Health*, 42:526-529, 2008.

<sup>121</sup> CDC, *Hookahs*, April 22, 2021,

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

<sup>122</sup> *Id.*

<sup>123</sup> World Health Organization (WHO). *Advisory Note: Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators*, 2015; HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012; American Lung Association, *An Emerging Deadly Trend: Waterpipe Tobacco Use*, 2007; American Lung Association, *Hookah Smoking: A Growing Threat to Public Health*, 2011.

<sup>124</sup> WHO, *supra* note 123, at 31.

<sup>125</sup> Aboaziza, E and Eissenberg, T., “Waterpipe tobacco smoking: what is the evidence that it supports nicotine/tobacco dependence?” *Tobacco Control* 24 Suppl 1(Suppl 1):i44-i53, 2015.

<sup>126</sup> WHO, *supra* note 123, at 40.

<sup>127</sup> Gentzke, A, *supra* note 27.

### C. Exempting Flavored Pipe Tobacco Could Create a Loophole for Manufacturers to Circumvent the Product Standard.

Pipe tobacco is available in flavors, also known as aromatics, such as crème brulee and vanilla custard.<sup>128</sup> Though youth use of pipe tobacco is currently low, trends in product preference can change, oftentimes due to manufacturers' actions to avoid regulations. The increase in flavored cigars after the TCA's prohibition on non-menthol characterizing flavors in cigarettes is a prime example. The tobacco industry has already demonstrated its willingness and ability to manipulate products to circumvent regulations by narrow product categories.

If FDA excludes pipe tobacco from the rules prohibiting all characterizing flavors, including menthol, in all combustible tobacco products, manufacturers could easily circumvent the prohibition by re-labeling RYO tobacco used for cigarettes and cigars as "pipe tobacco," because a standard definition for pipe tobacco does not exist. In fact, many manufacturers have already re-labeled their products to avoid the higher federal excise tax rates on RYO tobacco compared to pipe tobacco.<sup>129</sup> The Alcohol and Tobacco Tax and Trade Bureau has tried to delineate between the two products for over 10 years, but it still has not issued any final rules to do so.<sup>130</sup> Instead of trying to distinguish the products, the most efficient solution is to apply the prohibition on characterizing flavors broadly to close all loopholes, particularly ones we know have already been exploited, as demonstrated by warning letters to manufacturers selling RYO tobacco as "pipe tobacco" that FDA has issued. *See* 87 Fed. Reg. at 26,435.

Youth do not draw strong distinctions between products and are willing to switch to or use multiple products. As mentioned earlier, a study looking at youth tobacco use after the TCA's 2009 prohibition on non-menthol characterizing flavors in cigarettes found a significant increase in youth pipe tobacco and cigar use while cigarette use declined significantly.<sup>131</sup> Furthermore, data from the 2021 NYTS show that 4.4% of high school students currently use any combustible tobacco product and 3.8% of high school students use two or more tobacco products. In addition, non-Hispanic Black students had the highest prevalence of any current combustible use compared to other race/ethnicities.<sup>132</sup>

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<sup>128</sup> Smith, T, "Top 11 Best-Selling Aromatic Tobaccos," SMOKING PIPES, February 8, 2022, <https://www.smokingpipes.com/smokingpipesblog/single.cfm/post/top-best-selling-aromatic-tobaccos>.

<sup>129</sup> U.S. Government Accountability Office (GAO), *Tobacco Taxes: Large Disparities in Rates for Smoking Products Trigger Significant Market Shifts to Avoid Higher Taxes*, April 18, 2012, GAO-12-475, <https://www.gao.gov/products/gao-12-475>.

<sup>130</sup> *See* Extension of Package Use-Up Rule for Roll-Your-Own Tobacco and Pipe Tobacco, 74 Fed. Reg. 48,687 (Sept. 24, 2009); Standards for Pipe Tobacco and Roll-Your-Own Tobacco; Request for Public Comment, 75 Fed. Reg. 42,659 (July 22, 2010); Standards for Pipe Tobacco and Roll-Your-Own Tobacco; Request for Public Comment, 76 Fed. Reg. 52,913 (Aug. 24, 2011).

<sup>131</sup> Courtemanche, CJ, *supra* note 110.

<sup>132</sup> Gentzke, A, *supra* note 27.

If FDA does not include pipe tobacco in the final product standard, manufacturers will exploit the loophole. Loose tobacco products of any variety will be sold in flavors and improperly labeled as pipe tobacco. As the only remaining flavored combustible product on the market—provided that flavored waterpipe tobacco is included in the rule—youth would be incentivized to switch to flavored pipe tobacco products.

**D. As FDA Proposes, the Final Rule Should Apply to All Cigars.**

We support FDA’s proposal to apply this rule to all cigars. 87 Fed. Reg. at 26,434. To the extent that products labeled as premium cigars do not have characterizing flavors, this rule will not apply to them. However, we caution FDA to continue to monitor the cigar market, as some companies may try to use the “premium” label to claim that they are not subject to this product standard.

It is critical that FDA apply this rule to all cigars. As the National Academies of Sciences, Engineering, and Medicine committee on premium cigars concluded:

Based on the extensive literature on the effects of flavors on cigars and other tobacco products, there is **moderately suggestive evidence** that **adding characterizing flavors** (that is, flavors added to the product that are not inherent to the tobacco itself) **to premium cigars** could result in a greater appeal to non-users and lead to more frequent use with potentially increased nicotine intake, increased addiction potential, and increased exposure to harmful and potentially harmful constituents present in premium cigar smoke” (emphasis in original).<sup>133</sup>

PATH data from 2018-2019 show that more than one-third of past 30-day youth users of “premium” cigar products reported using flavored traditional cigars. That includes 46.4% of non-Hispanic Black/other/multi-race youth and 62.3% of Hispanic youth (higher than non-Hispanic white youth, at 22.1%), and 43.0% of girls (a higher rate than boys, at 31.2%), who use traditional cigars.<sup>134</sup> To achieve the maximum public health benefit from the flavored cigar product standard, it must apply to all cigars.

**E. The Substantial Equivalence Exemption Pathway May Be Appropriate for Certain Unflavored Cigars that Come Into Compliance with the Rule.**

FDA has also requested comments regarding how manufacturers who change their flavored cigars to comply with the rule may satisfy the premarket review requirements of the TCA. 87 Fed. Reg. at 26,434. If a manufacturer *only* removes flavor additive(s) from a flavored

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<sup>133</sup> NASEM, *Premium Cigars: Patterns of Use, Marketing, and Health Effects*, Washington, DC: The National Academies Press, 2022.

<sup>134</sup> National Institute of Health & Food and Drug Administration, *Population Assessment of Tobacco and Health, Past 30-Day Use of Any Flavored Cigars Among Youth (aged 12-17), by Sociodemographics*, 2021, <https://www.icpsr.umich.edu/files/NAHDAP/pathstudy/Youth-30Day-Flavored-AnyCigar.pdf>.

cigar that, prior to the effective date of the rule, was a legally marketed tobacco product, then the substantial equivalence (SE) exemption pathway may be appropriate for the new unflavored cigar, provided that all other requirements of the SE exemption pathway are satisfied. It is imperative that FDA protect the public health by rigorously applying the statutory and regulatory requirements of the SE exemption pathway, including requiring manufacturers to provide detailed descriptions and explanations of the proposed modification, why such modification is minor, and why an SE report under section 905(j)(1) of the TCA is not necessary to ensure that marketing of the new tobacco product is appropriate for the protection of the public health.<sup>135</sup> A “responsible official of the manufacturer” must also include a certification “summarizing the supporting evidence and providing the rationale for the official’s determination that the modification does not increase the tobacco product’s appeal to or use by minors, toxicity, addictiveness, or abuse liability,” which would necessarily include a certification that *no other modifications were made to the predicate tobacco product*.<sup>136</sup> Of course, in accordance with the statute, FDA must then make its own determination that any modification is, in fact, a minor modification to an additive,<sup>137</sup> an SE report under section 905(j)(1) is not necessary to ensure that the marketing of the product is appropriate for the protection of the public health,<sup>138</sup> and that an exemption is otherwise appropriate.<sup>139</sup> However, if any of these conditions are not met, a manufacturer should be required to seek marketing authorization through a different pathway, such as the SE or premarket tobacco product application pathways, as mandated by the TCA.

## **VIII. ANY RISKS OF UNINTENDED AND ADVERSE CONSEQUENCES FROM PROHIBITING FLAVORED CIGARS CAN BE AMELIORATED AND WILL NOT OUTWEIGH THE PUBLIC HEALTH BENEFITS.**

### **A. Prohibiting Flavored Cigars Will Not Cause the Emergence of an Illicit Market that Will Nullify the Public Health Gains From Such a Policy.**

FDA has requested comment on “whether and to what extent this proposed rule would result in an increase in illicit trade in flavored cigars and how any such increase could impact the marketplace or public health.” 87 Fed. Reg. at 26,432. While much of the discussion on the illicit tobacco market has been focused on cigarettes, these experiences are pertinent to the issues raised for the flavored cigars proposal, given the similar distribution channels. The tobacco industry historically has both contributed to the global illicit market in cigarettes<sup>140</sup> and then argued that the possibility of an uncontrolled illicit market justifies opposing tobacco control strategies proven to reduce smoking prevalence and save lives—including higher cigarette taxes,

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<sup>135</sup> 21 C.F.R. § 1107.1(b).

<sup>136</sup> *Id.* § 1107.1(b)(7).

<sup>137</sup> 21 U.S.C. § 387e(j)(3)(A).

<sup>138</sup> 21 C.F.R. § 1107.1(a)(2).

<sup>139</sup> 21 U.S.C. § 387e(j)(3)(A)(iii).

<sup>140</sup> National Research Council and Institute of Medicine, *Understanding the U.S. Illicit Market: Characteristics, Policy Context, and Lessons from International Experiences*, National Academies Press, at 62-63, 2015.

stronger health warnings and stronger regulation. The industry invariably exaggerates the risk of an illegal market,<sup>141</sup> including the fear of the unlikely scenario that the illicit market in the affected products would be so large as to completely undermine the public health benefits of the proposed tobacco control policy. For the reasons given below, the evidence does not support the conclusion that an illicit market would arise from the proposed rule that would come close to nullifying the public health gains from that rule. As the National Research Council and the Institute of Medicine found, “[T]he limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest.”<sup>142</sup>

The hypocritical argument that product standards should not be imposed at all because they will lead to illegal sales to buyers too young to purchase them legally ignores the reality that the tobacco industry has long marketed directly—and relied on illegal sales—to buyers too young to purchase its products legally. Yet no one could credibly argue that the prohibition on sales to youth should be repealed because it has led to illegal sales. One of the central purposes of the proposed rule prohibiting characterizing flavors in cigars is to curtail use by and sales to youth, and thus reduce this illicit market. In this context, it is ironic that product standards are opposed with the argument that they would “create” illicit markets. In reality, given that most use starts in adolescence, today’s tobacco use rates are, in large measure, the product of an existing illicit market that makes tobacco products available to consumers too young to buy them legally. Prohibiting characterizing flavors in cigars would sharply reduce this illicit market by making tobacco products less appealing to young people. Moreover, historically, those who have argued most vociferously against product standards because of concerns about illicit markets are the very companies whose conduct has been found to have created and sustained the illicit marketing of tobacco products to youth and who continue to derive their customer base from that market.<sup>143</sup>

The industry’s arguments focus largely on the current illicit market consisting of the diversion of cigarettes from the legal to the illegal market, in the form of smuggling finished packs of legal cigarettes from low-tax states to high-tax states.<sup>144</sup> The industry fails to account for the substantial, unique barriers to sustaining a robust underground market for flavored cigars that do not affect the current illegal market for cigarettes. For the reasons given below, there is a sound basis for FDA’s view that “while there may be potential countervailing effects that could

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<sup>141</sup> *Id.* at 9-10.

<sup>142</sup> *Id.* at 9.

<sup>143</sup> *U.S. v. Philip Morris USA Inc.*, 449 F.Supp.2d 1, 561-691 (D.D.C. 2006), *aff’d in relevant part*, 595 F.3d 1095 (D.C. Cir. 2009).

<sup>144</sup> See e.g., Altria Client Services, Comments in Docket No. FDA-2018-N-0529 (83 Fed. Reg. 11,754, March 16, 2018), “Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard” (July 16, 2018), <https://www.altria.com/-/media/Project/Altria/Altria/about-altria/federal-regulation-of-tobacco/regulatory-filings/documents/ALCS-Comments-to-Dkt-No-FDA-2018-N-0529-Draft-Concept-Paper-Illicit-Trad.pdf> (Cigarette black markets in United States “due primarily to price differentials driven by state and municipal taxation.”).

diminish the expected population health benefits of the proposed standard, such effects would be minimal . . . and would not outweigh the potential benefits of the proposed product standard.” 87 Fed. Reg. at 26,432.

First, whereas interstate smuggling involves the diversion of finished products into the illegal market, a substantial illicit market in flavored cigars must involve the large-scale manufacturing of illegal products. The establishment of a clandestine manufacturing facility, involving multiple individuals and capable of producing and shipping a substantial number of flavored cigars—in violation of a host of federal laws—is highly implausible.

Second, in order for widespread marketing of flavored cigars to occur, the cigars must be readily identifiable as flavored from their packaging and promotion for consumers to know what they are buying. Put differently, the illegality of the cigars will be clear from the packaging and promotion of the cigars themselves. This is in stark contrast to current illicit cigarette markets, in which the illicit market functions to conceal the illegality of the product. Thus, cigarettes smuggled from low-tax to high-tax jurisdictions often have counterfeit tax stamps and thus are not immediately apparent as illegal; even counterfeit cigarettes are disguised as legitimate. Moreover, even if it were not clear from the packaging or promotion that cigars were flavored, the presence of characterizing flavors would be readily apparent to anyone inspecting or sampling them. Thus, the manufacture and sale of illicit flavored cigars is inherently difficult to conceal from the authorities.

Third, given the difficulties in conducting the clandestine manufacture, promotion and sale of significant numbers of illicit flavored cigars, there is every likelihood that federal enforcement will be sufficient to minimize the illegal market. Particularly relevant here is the conclusion of 23 state and territorial Attorneys General, the leading law enforcement officials in their jurisdictions, in comments filed in support of the Citizen Petition to Prohibit Menthol as a Characterizing Flavor in Cigarettes:

Federal enforcement ranges from U.S. Customs and Border Protection actions to prevent the importation of prohibited products, to Alcohol and Tobacco Tax and Trade Bureau inspections of cigarette manufacturers and to the FDA’s own requirements that manufacturers report ingredients. Also, the FDA’s Office of Enforcement and Compliance operates a nationwide tobacco retailer inspection and enforcement program, inspecting tens of thousands of stores every year. Thus, at all levels—manufacturing, importing and selling—there are nationwide programs that make it unlikely that an illicit trade in menthol cigarettes will emerge.<sup>145</sup>

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<sup>145</sup> Attorney General of Connecticut, et. al., Comment in Docket No. FDA-2013-P-0435 “Comments on Tobacco Control Legal Consortium, et al., Citizen Petition to the Federal Food and Drug Administration Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes” (January 22, 2021), at 11-12, <https://www.regulations.gov/comment/FDA-2013-P-0435-0101>.

These same enforcement capabilities would also minimize the emergence of an illicit market in flavored cigars.

Moreover, the experience of states and cities in increasing cigarette taxes itself undermines the industry's assertion that a burgeoning illicit market in flavored cigarettes would undermine any public health gains from the proposed rule. Despite interstate smuggling of cigarettes, the general consensus of economic studies is that every 10% increase in the real price of cigarettes reduces overall cigarette consumption by approximately 3-5%, reduces the number of young adults who smoke by 3.5%, and reduces the number of kids who smoke by 6-7%.<sup>146</sup> This is not to deny the existence of illicit markets that function to reduce the effectiveness of tax increases in reducing smoking. Rather, it is to establish that illicit markets do not come close to nullifying the effects of tax increases in reducing cigarette consumption. As CDC found, "Significant increases in state and local tobacco taxes generate reductions in tobacco use and raise tobacco tax revenues for the jurisdiction, despite the tax avoidance and evasion that results from significant tax and price differentials in the United States."<sup>147</sup> Ironically, the tobacco industry itself repeatedly has acknowledged that tax increases lead to reduced consumption of cigarettes. In the words of a Philip Morris executive, "A high cigarette price, more than any other cigarette attribute, has the most dramatic impact on the share of the quitting population . . . price, not tar level, is the main driving force for quitting."<sup>148</sup> In short, nothing in the history and economics of cigarette tax and price increases suggests that an illicit market in flavored cigars would be so substantial as to nullify the public health gains from the proposed rule.

The national experience with cigarette flavor prohibitions in the U.S. and Canada provides no support for the likelihood that the proposed rule would lead to a burgeoning illicit market in flavored cigars. In the U.S., there is no evidence that the Special Rule for Cigarettes in the Tobacco Control Act, prohibiting all flavors in cigarettes other than menthol, has led to an illicit market in flavored cigarettes. Indeed, in the Preamble to the proposed rule to prohibit menthol as a characterizing flavor in cigarettes, FDA cites studies showing that the Special Rule for Cigarettes was associated with a significant reduction in cigarette smoking for youth, *See* 87 Fed. Reg. at 26,470, which would not be expected if youth were able to access illicit flavored cigarettes as substitutes for the legally prohibited products.

The Canadian experience with a national prohibition of menthol cigarettes further indicates the low likelihood that the rise of an illicit market in the U.S. will nullify the public health benefits of the proposed flavored cigar rule. Between May 2015 and July 2017, seven out

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<sup>146</sup> *See generally*, Chaloupka, FJ, et al., "Macro-Social Influences: The Effects of Prices and Tobacco Control Policies on the Demand for Tobacco Products," *Nicotine and Tobacco Research* 1(Supp. 1):S105-09, 1999; Campaign for Tobacco-Free Kids, *Raising Cigarette Taxes Reduces Smoking, Especially Among Kids (and the Cigarette Companies Know It)*, 2021 and sources cited therein.

<sup>147</sup> Chaloupka, FJ et al., "Preventing and Reducing Illicit Tobacco Trade in the United States," *CDC*, at 6, 2015.

<sup>148</sup> Philip Morris Executive Claude Schwab, "Cigarette Attributes and Quitting," March 4, 1993, Bates No. 2045447810; *see* Campaign for Tobacco-Free Kids, *supra* note 146.



of 10 Canadian provinces implemented menthol cigarette prohibitions, with a federal law disallowing menthol in cigarettes effective in October 2017. A study of illicit cigarette seizures in Nova Scotia (noted by FDA, *see* 87 Fed. Reg. at 26,432), which in 2015 became the first jurisdiction in the world to prohibit menthol cigarettes, found that the number of illegal cigarettes seized did not increase after the menthol prohibition was implemented, despite an intensification of enforcement efforts. Thus, the study found that “illicit cigarette sales in the province are similarly unlikely to be increasing.”<sup>149</sup> A subsequent analysis of the pre- and post-prohibition behavior of Canadians who smoke (also noted by FDA in the Preamble to the proposed rule on menthol cigarettes, 87 Fed. Reg. at 26,484), showed that 19.5% of people who smoked menthol cigarettes reported still smoking menthol cigarettes after the prohibition.<sup>150</sup> However, after removing incorrect reporting of post-prohibition menthol cigarettes, less than 10% of people who smoked menthol cigarettes (13 of 138) were smoking illicit menthol cigarettes and there was no statistically significant difference between the percentage of pre-prohibition menthol and non-menthol smokers who purchased cigarettes from illegal sources after the prohibition.<sup>151</sup> Thus, the data suggest that the Canadian menthol cigarette prohibition has had a negligible effect on the illicit market, an experience that suggests a similar effect from a U.S. prohibition of characterizing flavors in cigars.

Of primary importance, as discussed previously, the data indicates that the Canadian menthol prohibition is having a significant positive impact on public health by causing people who smoke to stop smoking. After the prohibition, people who smoked menthol cigarettes were significantly more likely than people who smoked non-menthol cigarettes to have quit smoking for at least six months (12.1% vs. 5.9%).<sup>152</sup> People who smoked menthol cigarettes daily (the group most likely to turn to illicit sources of menthol cigarettes) were significantly more likely than people who smoked non-menthol cigarettes daily to have quit for at least six months (12.7% vs. 5.2%).<sup>153</sup> Thus, whatever illicit market has developed in Canada, the menthol prohibition is having its intended effect of causing people who smoke to stop smoking. Again, the Canadian menthol experience is instructive on the prospect of illicit trade arising from a U.S. prohibition of flavored cigars.

Furthermore, to the extent that greater enforcement tools are needed to prevent any increase in illicit trade, FDA should supply those tools by implementing the mandate in Section 920(b) of the TCA to adopt a “track and trace” system that should include a unique, counterfeit-

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<sup>149</sup> Michael Stoklosa, “No surge in illicit cigarettes after implementation of menthol ban in Nova Scotia,” *Tobacco Control* 28:702-794, 2018.

<sup>150</sup> Chung-Hall J, et al., “Evaluating the impact of menthol cigarette bans on cessation and smoking behaviors in Canada: Longitudinal findings from the Canadian arm of the 2016-18 ITC Four Country Smoking and Vaping Surveys. *Tobacco Control*,” *Tobacco Control* 31:556-563, 2022.

<sup>151</sup> Fong, GT, *The Canada-Wide Menthol Cigarette Ban did NOT Increase Illicit Purchases*, April 5, 2021, [https://itcproject.s3.amazonaws.com/uploads/documents/ITC-Menthol\\_Ban-No\\_Increase\\_in\\_Illicit\\_Purchases-Apr52021.pdf](https://itcproject.s3.amazonaws.com/uploads/documents/ITC-Menthol_Ban-No_Increase_in_Illicit_Purchases-Apr52021.pdf).

<sup>152</sup> Chung-Hall, *supra* note 150, at 5.

<sup>153</sup> *Id.*

proof identifier on every tobacco product and further require companies to maintain records that would make firms at every level of the supply chain accountable to ensure that each product gets to its lawful buyer. As noted above, illegal flavored cigar products will be inherently difficult to conceal from law enforcement. However, to the extent that their packaging, promotion and product characteristics do not themselves evidence their illegality, the absence of the legally-required identifier would do so.

It is noteworthy that the inclusion of Section 920(b) shows that Congress did not regard the threat of illegal markets as a justification for the failure to establish strict product standards. Rather, the statute explicitly requires FDA to protect against such a threat—whether real or posited by the tobacco industry as a pretext for opposing strong regulation. Several of the groups joining these Comments long ago filed a Citizen Petition calling on FDA to establish the required “track and trace” system.<sup>154</sup> It is revealing that Altria, which has opposed a prohibition of menthol cigarettes in part because of the risk of an illicit market, filed an opposition to the Citizen Petition.<sup>155</sup>

In summary, we fully support the conclusion of the Attorneys General in their comments filed in support of the menthol Citizen Petition and believe it is equally applicable to a product standard prohibiting characterizing flavors in cigars: “There is little reason to suggest that prohibiting menthol cigarettes will cause the emergence of an illicit market that will threaten the public health gains from prohibiting menthol cigarettes . . . . The FDA should not be swayed by the tobacco industry’s doomsday predictions of an increase in illegal trade.”

#### **B. Prohibiting Flavored Cigars Will Not Increase the Likelihood of Police Abuse in Black and Other Underserved Communities.**

FDA recognizes that concerns have been expressed that, given the disproportionate use of flavored cigars in the Black community, a prohibition of such products will exacerbate the problem of police abuse in that community by criminalizing the conduct of Black people who smoke. Thus, the agency has requested comments on “policy considerations related to potential racial or social justice implications of this rule,” including comments on “any potential for this proposed rule to result, directly or indirectly, in disparate impacts within particular underserved communities of vulnerable populations” and on “the existence, nature and degree of any change in police activity or community encounters with State or local law enforcement . . . following implementation of a prohibition of flavored cigars.” 87 Fed. Reg. at 26,435.

There is no question that police abuse of Black people and other communities of color is a matter of urgent national concern. However, the need for police reform is not a sound basis to

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<sup>154</sup> New York City Department of Health & Mental Hygiene, et. al., Comment in Docket #FDA-2013-P-0285, “Citizen Petition”, (March 6, 2013), <https://www.regulations.gov/document/FDA-2013-P-0285-0001>.

<sup>155</sup> Altria Client Services, Comment in Docket #FDA-2013-P-0285, (Sept. 6, 2013), <https://www.regulations.gov/comment/FDA-2013-P-0285-0018>.

oppose a product standard that will save many thousands of Black lives by preventing Black youth from beginning to smoke and helping Black adults to quit. We need not choose between protecting the health of Black people against the purveyors of deadly and addictive tobacco products and protecting their safety against police violence. Though made in reference to menthol cigarettes, the addictiveness and disproportionate marketing of flavored cigars makes this quote from Carol McGruder of the African American Tobacco Control Leadership Council equally relevant to this proposed rule: “. . . we’re not going to wait and let the biggest predator and profiler of our Black men and boys roam in our neighborhoods and addict another generation of our children while we get . . . police reform under control. We’re going to do both of those things simultaneously.”<sup>156</sup>

Three states,<sup>157</sup> and over 150 localities nationwide, have prohibited or restricted sales of most flavored cigars,<sup>158</sup> and there are no indications that these laws have been enforced through abusive police tactics directed at Black Americans and other people of color. Moreover, nothing in the proposed rule itself will function to increase the risk of such police abuse. First, the rule does not criminalize the conduct of Black people who smoke. As FDA has made clear, “this regulation does not include a prohibition on individual consumer possession or use” and thus “FDA cannot and will not enforce against individual consumer possession or use of flavored cigars.” 87 Fed. Reg. at 26,435. Instead, the rule provides that “No person may manufacture, distribute, sell, or offer for distribution or sale” cigars with characterizing flavors or their components or parts. 87 Fed. Reg. at 26,450 (proposed 21 CFR 1166.1(b)). Thus, “FDA’s enforcement . . . will only address manufacturers, distributors, wholesalers, importers, and retailers.” 87 Feb. Reg. at 26435. In addition, FDA has stated unequivocally that, “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.” *Id.*

The proposed rules on menthol cigarettes and flavored cigars, therefore, will protect the health of Black Americans without increasing the risk of police harassment and abuse in the Black community. For this reason, organizations and individual leaders in the Black community, all intensely committed to ending police violence and other misconduct in that community, strongly support ending the manufacture, promotion and sale of menthol cigarettes and flavored cigars. For example, an overwhelming majority of the Congressional Black Caucus (CBC) voted for H.R. 2339, the “Protecting American Lungs and Reversing the Youth Epidemic Act of 2020,” legislation that would prohibit both menthol cigarettes and flavored cigars.<sup>159</sup> Moreover, in April of last year, 34 CBC members sent a letter to HHS Secretary Becerra urging the

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<sup>156</sup> AshOrgUSA, *Post FDA Lawsuit Decision - Plaintiffs & Partners Discussion*, YouTube (Apr. 20, 2021), [https://www.youtube.com/watch?v=oBvNShBZU-w&t=93s&ab\\_channel=AshOrgUSA](https://www.youtube.com/watch?v=oBvNShBZU-w&t=93s&ab_channel=AshOrgUSA).

<sup>157</sup> The implementation of California’s law is pending a November 2022 referendum vote.

<sup>158</sup> Campaign for Tobacco-Free Kids, *State & Localities That Have Restricted The Sale of Flavored Tobacco Products*, April 19, 2022, <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

<sup>159</sup> <https://www.congress.gov/116/bills/hr2339/BILLS-116hr2339rfs.pdf>

Administration to “remove menthol cigarettes from the marketplace.”<sup>160</sup> On April 20 of this year, in a letter to the FDA, NAACP President and CEO Derrick Johnson called on the agency to move forward with this rulemaking, rejecting the message that prohibiting menthol cigarettes “would be discriminatory.” Instead, “The failure to prohibit the sale of menthol cigarettes and products would be discriminatory and counter the goal and function of the FDA to protect and promote public health for all, including the African American community.”<sup>161</sup> In April of last year, ten Black civil rights, medical, and public health organizations, including the NAACP, wrote to HHS Secretary Becerra urging him to support commencement of this rulemaking because “further delays will cost Black/African American lives.” The letter directly addresses the argument that the enforcement burden of the rule will fall disproportionately on the Black community:

The tobacco industry’s spokespeople have attempted to stoke fears that prohibiting menthol cigarettes is discriminatory, but this could not be further from the truth. The industry has mischaracterized a prohibition on menthol cigarettes as criminalizing Black/African American smokers when the tobacco industry is directly responsible for this disparity in menthol use. Therein lies the true injustice. There are undoubtedly racial injustices in our criminal justice system, but FDA’s rulemaking process should clarify that just as it enforces other tobacco regulations, a prohibition of menthol cigarettes will focus enforcement efforts on manufacturers and retailers, not individual consumers.<sup>162</sup>

Again, while more directly referencing menthol cigarettes, given the similar health risks and marketing tactics used by the industry to target Black Americans, these actions and statements are applicable to the proposed rule on flavored cigars as well. As noted above, the proposed rule makes it clear that, as with other tobacco regulations, enforcement will necessarily be directed at commercial entities, not individuals.

U.S. Rep. Karen Bass (D-CA) has made the case against allowing the tobacco companies to exploit legitimate concerns about police abuse to oppose life-saving action to end the suffering, disease, and death inflicted by menthol cigarettes on the Black community in words equally applicable to flavored cigars:

Recent incidents of police brutality against Black Americans have forced our nation to confront racism and injustice in its many forms . . . As we continue to protect Black lives, we must put an end to one of the most pernicious destroyers

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<sup>160</sup> [https://www.tobaccofreekids.org/assets/content/press\\_office/2021/CBCletter.pdf](https://www.tobaccofreekids.org/assets/content/press_office/2021/CBCletter.pdf)

<sup>161</sup> <https://naacp.org/articles/naacp-writes-letter-urging-fda-ban-menthol-flavored-cigarettes-and-flavored-cigar-products>

<sup>162</sup> [https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204\\_14\\_21.pdf](https://www.nbna.org/files/2021/AA%20group%20letter%20to%20Becerra%20re%20Menthol%20Cigarettes%204_14_21.pdf)

of Black health and lives: deadly menthol cigarettes and the tobacco industry's decades-long targeted marketing to our kids and communities.<sup>163</sup>

We urge FDA to heed the wisdom of these words. It is difficult to imagine an action FDA could take that would more directly and substantially advance the goals of decreasing existing tobacco-related health disparities than the adoption of the proposed rules on menthol cigarettes and flavored cigars. The agency must not allow this historic opportunity to advance health equity to pass without final action to issue and implement this rule.

## **IX. OTHER IMPACTS OF THE PROPOSED RULE**

### **A. Impact on Small Business Entities**

Although the Regulatory Flexibility Act requires FDA to analyze regulatory options that would minimize any significant impact of a rule on small entities, there is no requirement that the impact on small entities be reduced at a cost to public health. FDA's analysis of the impact of the proposed rule on small entities includes several observations of particular importance.

At the manufacturing level, FDA determined that 31 of 57 domestic cigar companies manufacture flavored cigars, with five of those companies only making flavored cigars, and therefore would be impacted by this rule. Twenty-seven companies are considered small manufacturers under the Small Business Administration's definition.<sup>164</sup> However, only four companies account for the vast majority—91.8%—of flavored cigar sold in the U.S. and almost all of the revenue (88.3%) generated by those sales.<sup>165</sup>

FDA suggests extending the effective date of the rule from one to two years in order to reduce the impact of the rule on small manufacturers, because a longer date could slightly reduce costs by allowing entities more time to change their production methods to conform with the product standard.<sup>166</sup> However, that option should be rejected as undermining the public health goals of the rule. As to extending the effective date, as FDA states, "Additional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with and become regular smokers after experimenting with flavored cigars, would delay cessation by current smokers, and would exacerbate tobacco-related health disparities." 87 Fed. Reg. at 26,438.

### **B. Impact on Retailers**

Tobacco retailers will argue that prohibiting flavored cigars will hurt their business

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<sup>163</sup> Karen Bass, *California must ban menthol cigarettes to protect Black lives from Big Tobacco's greed*, THE SACRAMENTO BEE, July, 16, 2020, <https://www.sacbee.com/opinion/op-ed/article244221177.html>.

<sup>164</sup> RIA at 19.

<sup>165</sup> RIA at 53.

<sup>166</sup> RIA at 112.

because these products are a significant part of their sales. However, when looking at actual sales data and the larger context of consumer behavior, this product standard will have limited impact on their sales.

First, though the vast majority of cigars affected by this product standard are sold in convenience stores<sup>167</sup> and flavored cigars make up a majority of the cigars sold in convenience stores,<sup>168</sup> cigars as a whole make up only about 5% of their overall tobacco sales,<sup>169</sup> and tobacco sales are only about a third of total product sales.<sup>170</sup> Taken together, this means that flavored cigar sales make up less than 1% of convenience stores' dollar sales.

Second, FDA reasonably recognizes that the money that consumers have been spending on flavored cigars will not be entirely lost by retailers. The Regulatory Impact Analysis notes that "lost revenue could in part be offset with revenue from whatever the consumer purchases with money previously spent on flavored cigars."<sup>171</sup> It also states, "[a]s consumers use money they were previously spending on flavored cigars on other products, including non-tobacco products, some retailers may see a reduction in sales while others experience an increase in sales."<sup>172</sup>

### **C. Impact on Tobacco Farming and Manufacturing**

As summarized in the Regulatory Impact Analysis, by any measure the role of tobacco farming in the nation's economy has been shrinking steadily and significantly. In the meantime, tobacco growers have been able to shift to growing other crops in response to these trends. FDA concludes, "Given that cigar type tobacco is a small portion of overall leaf tobacco production, we do not predict that the proposed rule will have a substantial impact on tobacco farmers."<sup>173</sup>

Over the past five years, tobacco leaf production in the United States has decreased 40%, from 630 million pounds in 2016 to about 390 million pounds in 2020.<sup>174</sup> FDA reported that in 2020, tobacco grown for use in cigars is less than 1% of overall tobacco production in the U.S.<sup>175</sup>

Farmers have turned to other crops to replace tobacco. FDA's Regulatory Impact Analysis of the proposed product standard for menthol in cigarettes noted that some tobacco

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<sup>167</sup> CSP, "Where the gains are: Tobacco," CSP MAGAZINE, at 49, April 2022, <https://www.qgdigitalpublishing.com/publication/?m=20858&i=743243&p=50&ver=html5>.

<sup>168</sup> Delnevo, CD, *supra* note 11.

<sup>169</sup> CSP, *supra* note 167, at 49.

<sup>170</sup> Counter Tobacco, *Highlights from the Convenience Store News 2020 Tobacco Report*, COUNTER TOBACCO, 2020.

<sup>171</sup> RIA at 112

<sup>172</sup> RIA at 73.

<sup>173</sup> RIA at 73.

<sup>174</sup> RIA at 72.

<sup>175</sup> RIA at 72.

farmers are growing hemp.<sup>176</sup> In 2013, tobacco farmers in Virginia turned to chickpeas in response to reduced tobacco consumption and increased interest in hummus.<sup>177</sup> A series of news articles on tobacco farming in North Carolina described growers' transitions away from tobacco due to various reasons including higher costs and trade issues resulting from the Trump Administration's tariffs on imported products from China. One featured long-time grower said that he was switching to soybeans, corn, and wheat,<sup>178</sup> and another said this may be his last year growing tobacco.<sup>179</sup>

The decline in tobacco farming has been matched by a decline in tobacco manufacturing jobs. Those declines are entirely due to tobacco companies shutting down or moving factories, or otherwise restructuring. For instance, the *Winston-Salem Journal* reported that Reynolds American cut more than 10% of its employees, or more than 500 jobs, from 2020 to 2021,<sup>180</sup> though not all of those jobs are in manufacturing. Between 1997 and 2020, overall tobacco manufacturing jobs declined by 68.2%; in 2020 those jobs made up less than 0.1% of all manufacturing jobs in the United States, and even in the two states with the most tobacco manufacturing (North Carolina & Virginia), related employment makes up less than 2% of all state manufacturing jobs, and even smaller fractions of total employment.<sup>181</sup>

Thus, the proposed rule will make a small contribution to the continued decline in the importance of tobacco to the economy, but with significant public health benefits.

## **X. EFFECT OF THE RULE ON STATE AND LOCAL LAWS**

As FDA observed, Section 916 of the TCA “broadly preserves the authority of states and localities to protect the public against the harms of tobacco use.” 87 Fed. Reg. at 26,440. Federal courts consistently have upheld local prohibitions on the sale of flavored tobacco products against industry lawsuits alleging that they are preempted by federal law.<sup>182</sup> Thus, although Section 916(a) of the FD&C Act gives the FDA exclusive authority to issue product standards limiting the additives and other constituents that manufacturers may use in producing tobacco

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<sup>176</sup> FDA, *Preliminary Regulatory Impact Analysis of Tobacco Product Standard for Menthol in Cigarettes*, Docket No. FDA-2021-N-1349, at 200-01, 2022, <https://www.fda.gov/media/158012/download>.

<sup>177</sup> Kesmodel, D & Fletcher, O, “Hummus Is Conquering America,” *THE WALL STREET JOURNAL*, April 30, 2013, [Hummus Is Conquering America - WSJ](https://www.wsj.com/articles/hummus-is-conquering-america-2013-04-30).

<sup>178</sup> Quillin, M, “‘The point where there’s no money there’: Some have moved on to soybeans, corn and wheat,” *THE NEWS & OBSERVER*, February 27, 2022, <https://www.newsobserver.com/news/local/article257977483.html>.

<sup>179</sup> *Id.*

<sup>180</sup> Craver, R, “Reynolds has 10% workforce reduction during 2021; BAT chief executive's total compensation jumps 51%,” *WINSTON-SALEM JOURNAL*, March 18, 2022, [https://journalnow.com/business/local/reynolds-has-10-workforce-reduction-during-2021-bat-chief-executives-total-compensation-jumps-51/article\\_855797ae-a5e4-11ec-bcab-4f8877278bd9.html](https://journalnow.com/business/local/reynolds-has-10-workforce-reduction-during-2021-bat-chief-executives-total-compensation-jumps-51/article_855797ae-a5e4-11ec-bcab-4f8877278bd9.html).

<sup>181</sup> U.S. Census Bureau, *Annual Survey of Manufactures*, <https://www.census.gov/programs-surveys/asm.html>.

<sup>182</sup> See *R.J. Reynolds Tobacco Co. v. County of Los Angeles*, 29 F.4th 542 (9th Cir. 2022); *National Association of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71 (1st Cir. 2013); *U.S. Smokeless Tobacco Mfg. Co. v. City of New York*, 708 F.3d 428 (2d Cir. 2013); *R.J. Reynolds Tobacco Co. v. City of Edina*, 482 F.Supp.3d 875 (D. Minn. 2020).

products, it preserves to states and localities the authority to restrict, or prohibit, the sale of those products within their jurisdictions. It thereby gives states and localities authority to protect the health of their residents against tobacco products, even though FDA has permitted their introduction into the stream of commerce. FDA concluded that “[s]tate and local prohibitions on the sale and distribution of flavored tobacco products, including flavored cigars, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by section 916(a)(1) of the FD&C Act or, as applicable, excepted from express preemption by section 916(a)(2)(B) of the FD&C Act.” 87 Fed. Reg. at 26,440. This conclusion is entirely consistent with the applicable case law.

**XI. CONCLUSION: A PRODUCT STANDARD PROHIBITING CHARACTERIZING FLAVORS IN CIGARS MEETS THE STATUTORY PUBLIC HEALTH STANDARD.**

The proposed flavored cigar product standard meets the statutory standard of being “appropriate for the protection of the public health,” considering the risks and benefits to the population as a whole, including users and non-users of tobacco products.

As to non-users of tobacco products, the proposed standard will significantly reduce youth smoking initiation and progression to regular use. For users of tobacco products, the proposed standard will substantially increase smoking cessation because people who smoke flavored cigars are likely to find unflavored cigars unappealing. The proposed rule will yield especially significant benefits for the Black community, which has borne a disproportionate burden of disease and mortality from flavored cigars, due to the industry’s targeted marketing and promotion of flavored cigars directed at Black youth and Black people who smoke. The rule also will produce particularly significant benefits for other vulnerable groups that now experience a disproportionate burden of cigar use. The proposed rule would therefore reduce long-entrenched health disparities and lead to greater equity in health outcomes. Extending the rule to all combustible tobacco products will enhance these important public health benefits.

FDA’s public health mission requires it to finalize the proposed rule to permit its life-saving benefits to be realized as quickly as possible.

Respectfully submitted,

Academic Pediatric Association  
Academy of General Dentistry  
Action on Smoking & Health  
African American Tobacco Control Leadership Council  
Allergy & Asthma Network  
Alpha-1 Foundation



American Academy of Family Physicians  
American Academy of Nursing  
American Academy of Oral and Maxillofacial Pathology  
American Academy of Oral and Maxillofacial Radiology  
American Academy of Pediatrics  
American Association for Cancer Research  
American Association for Dental, Oral, and Craniofacial Research  
American Association for Respiratory Care  
American Cancer Society Cancer Action Network  
American College Health Association  
American College of Cardiology  
American College of Physicians  
American College of Preventive Medicine  
American Dental Association  
American Heart Association  
American Lung Association  
American Medical Association  
American Pediatric Society  
American Public Health Association  
American Society of Addiction Medicine  
American Thoracic Society  
Americans for Nonsmokers' Rights  
Asian Pacific Partners for Empowerment, Advocacy and Leadership (APPEAL)  
Association for Clinical Oncology  
Association for the Treatment of Tobacco Use and Dependence  
Association of Black Cardiologists  
Association of Black Women Physicians  
Association of Medical School Pediatric Department Chairs  
Association of Schools and Programs of Public Health  
Association of Women's Health, Obstetric and Neonatal Nurses  
Asthma and Allergy Foundation of America  
ASTHO  
Big Cities Health Coalition  
Black Men's Health Initiative  
Black Women's Health Imperative  
Breathe Southern California

Campaign for Tobacco-Free Kids  
CATCH Global Foundation  
Catholic Health Association of the United States  
Center for Black Equity  
CenterLink: The Community of LGBT Centers  
CHEST  
Commissioned Officers Association of the USPHS  
Common Sense Media  
Community Anti-Drug Coalitions of America (CADCA)  
COPD Foundation  
Emphysema Foundation of America  
First Focus on Children  
GLMA: Health Professionals Advancing LGBTQ Equality  
GO2 Foundation for Lung Cancer  
HealthHIV  
International Association for the Study of Lung Cancer  
Islamic Society of North America (ISNA)  
League of United Latin American Citizens (LULAC)  
Mesothelioma Applied Research Foundation  
National Alliance for Hispanic Health  
National Association of County and City Health Officials  
National Association of Hispanic Nurses  
National Association of Pasifika Organizations (NAOPO)  
National Association of Pediatric Nurse Practitioners  
National Association of School Nurses  
National Association of Secondary School Principals  
National Black Church Initiative  
National Black Nurses Association  
National Center for Health Research  
National Council of Asian Pacific Islander Physicians  
National Education Association  
National Eta Sigma Gamma  
National Forum for Heart Disease & Stroke Prevention  
National Hispanic Council on Aging  
National Hispanic Medical Association  
National LGBT Cancer Network

National Medical Association  
National Network of Public Health Institutes  
National Partnership for Women & Families  
National Tongan American Society  
North American Quitline Consortium  
Oncology Nursing Society  
Parents Against Vaping e-Cigarettes (PAVe)  
Pediatric Policy Council  
PHS Commissioned Officers Foundation for the Advancement of Public Health  
Prevent Cancer Foundation  
Preventing Tobacco Addiction Foundation/Tobacco 21  
Preventive Cardiovascular Nurses Association  
Respiratory Health Association  
Save A Girl, Save A World  
Society for Cardiovascular Angiography and Interventions  
Society for Pediatric Research  
Society for Research on Nicotine & Tobacco  
Southern Black Policy & Advocacy Network  
Students Against Destructive Decisions  
The Center for Black Health and Equity  
The National Alliance to Advance Adolescent Health  
The Society of State Leaders of Health and Physical Education  
The Society of Thoracic Surgeons  
Truth Initiative  
US PIRG