



**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.

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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. §387l(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 a

### **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.

### **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 –

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, C /P <</MCReferenceD 5 >>BDC (t/TT0 1 -c -0.003 w [(6)7.8-7 8

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):1881–1888, 2020. <https://doi.org/10.15585/mmwr.mm6950a1>

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

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>

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

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.

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, connpleonnnplbs. C2(nds)psr brcgr(i)-2 (rpl)7(bI4 by

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>

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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. 9.96006 14 9.9003.

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 SECONDHAND SMOKE EXPOSURE IN THE HOME.**

**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 *re*

**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-



prioritize this proposed product standard. In particular, FDA took into account the





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;
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to smoke tobacco poses serious health risks to people who smoke and others ex(s)-1 ( s)-11-1 ( s)-11-1 ( c)4 (c)4



If FDA does not include pipe tobacco

cigar that, prior to the effective date of the rule, was a legally marketed tobacco product, then the

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.

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

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, 42 U.S.C. § 502(a)(1)(A), would lead to a burgeoning illicit market in flavored cigars. In Canada, the experience with the ban on cigarette flavors shows that the market for flavored cigars did not surge after the ban took effect. Instead, the market for flavored cigars remained relatively stable, and the overall market for cigars continued to grow. This suggests that the proposed rule would not lead to a burgeoning illicit market in flavored cigars.



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

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>

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](https://www.foxnews.com/health/naacp-asks-fda-ban-menthol-cigarettes)

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



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,

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 health of the Nation.

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  
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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