



July 18, 2022

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

Re: *Public Comment on "Tobacco Product Standard for Menthol in Cigarettes"; Docket No. FDA-2021-N-1349 and Public Comment on "Tobacco Product Standard for Characterizing Flavors in Cigars"; Docket No. FDA-2021-N-1309*

On behalf of Children's Wisconsin, I am writing in support of the Food and Drug Administration's proposed product standards to prohibit menthol as a characterizing flavor in cigarettes and all characterizing flavors (other than tobacco) in cigars.

Children's Wisconsin (Children's) is the state's only independent health system dedicated solely to the health and well-being of kids. We serve children and families in every county across the state, with two inpatient hospitals and more than 30 primary, specialty and urgent care clinics. We care for every part of a child's health, from critical care at one of our hospitals, to routine check-ups in our primary care clinics.

At Children's, we strongly believe that tobacco use is never appropriate, healthy or safe for kids and teens. Our Children's primary care doctors see firsthand the prevalence of tobacco and e-cigarette use and are very concerned about the severe risks these products pose to kids' health. We strongly support policies, such as the product standards proposed in this rule, to reduce experimentation and potential for addiction to these harmful products.

Tobacco use remains the leading preventable cause of death and disease in the United States. We are all familiar with the harmful risks associated with tobacco use including various cancers, lung disease, heart disease, stroke and more. In Wisconsin, approximately 7,900 people die each year from smoking-related causes with a direct health care cost of \$3 billion¹. And each year, teens begin the habit and risk becoming life-long tobacco users.

We know that tobacco and nicotine habits start young: 90 percent of adults who use tobacco started in their teen years and 99 percent started before age 26.² According to the most recent Wisconsin Youth Risk Behavior Survey, almost 1 in 5 high school students in the state have tried a cigarette.³ The younger a person starts using tobacco, the faster they become addicted and the harder it is for them to stop. As detailed in the proposed regulation, traditional tobacco and e-cigarette products contain nicotine, the addictive drug which has a uniquely negative impact on adolescent brain development and can cause problems with learning and memory, as well as long-term behavioral impairments including depression, anxiety and mood disorders. In addition,

¹ Centers for Disease Control & Prevention [CDC]. (2021). *Extinguishing the Tobacco Epidemic in Wisconsin*. Office on Smoking & Health, National Center for Chronic Disease Prevention & Health Promotion.

<https://www.cdc.gov/tobacco/stateandcommunity/state-fact-sheets/wisconsin/index.html>

² CDC. (2022). *Youth and Tobacco Use*. Office on Smoking & Health, National Center for Chronic Disease Prevention & Health Promotion. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/

³ Wisconsin Department of Health Services (WI DHS). (2019). *Youth Risk Behavior Survey – Wisconsin High School Tobacco Use*. Division of Public Health, Tobacco Prevention and Control Program.

<https://www.dhs.wisconsin.gov/publications/p02862.pdf>

studies have shown that high exposure to nicotine in children makes them more susceptible to nicotine addiction and puts them at risk for lifelong addiction to tobacco products and other drug use.

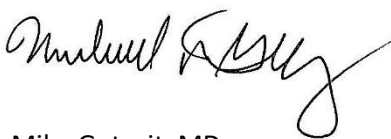
Research has shown that flavored products entice youth use; in fact, according to the 2018 Youth Tobacco Survey, 89 percent of Wisconsin high school students say they would not use unflavored tobacco products and more than half of current Wisconsin youth smokers usually smoke menthol-flavored cigarettes.⁴ Menthol makes tobacco products less harsh, easier to start smoking and harder to quit. Flavored cigars, which often come in fruit and candy flavors and bright-colored packaging, are more appealing to youth and lead to experimentation.⁵

Of great concern, is that menthol cigarettes and flavored cigars contribute to significant health disparities in this country. Targeted marketing of these products to young people, Black communities, LGBTQ+ populations, and in neighborhoods with families with lower incomes has resulted in disproportionate rates of use and tobacco-related morbidity and mortality among these users.⁶ Nationally, of the African American middle and high school students who report smoking, 70.5 percent use menthol cigarettes, compared to 51.4 percent of white students who report smoking.⁷ In particular, as detailed in the proposed regulation, 85 percent of Black smokers use menthol cigarettes and Black smokers bear the greatest burden of tobacco-related death in the United States. Among middle and high school students who reported smoking cigars, nearly half reported using flavored products. Further emphasizing the disparities, cigar use was especially prevalent among Black students. The proposed product standard for menthol cigarettes and flavored cigars is essential to reducing the use of tobacco amongst our youth and improving the health and well-being of marginalized Americans.

Children's Wisconsin strongly supports the proposed rule's clarity that only those that manufacture, distribute or sell these products are subject to enforcement under this rule and making it clear that the regulation does not include a prohibition on or penalty for individual consumer possession or use. We strongly support the FDA making clear this approach to the public and relevant state and local agencies.

As with most public health issues, prevention is critical. Limiting menthol cigarettes and flavored cigars as outlined in this proposed rule will save lives and advance health equity. Children's Wisconsin encourages you to finalize the proposed product standard.

Sincerely,



Mike Gutzeit, MD
Chief Medical Officer
Children's Wisconsin

⁴ WI DHS. (2019). *Youth Tobacco Survey 2018 - High School Snapshot*. Division of Public Health. Tobacco Prevention and Control Program. <https://www.dhs.wisconsin.gov/publications/p01624.pdf>

⁵ Rostron BL, Cheng YC, Gardner LD, Ambrose BK *Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-17*. *Am J Health Behav*. 2020, Jan. 1. 1;44 (1): 76-81. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6918456/>

⁶ WI DHS. (2020). *Tobacco is Changing: See How Menthol is Damaging Vulnerable Communities*. Division of Public Health. Tobacco Prevention and Control Program. <https://www.dhs.wisconsin.gov/publications/p02040c.pdf>

⁷ WI DHS. (2021). *Tobacco is Changing: Menthol*. Division of Public Health. Tobacco Prevention and Control Program. <https://www.dhs.wisconsin.gov/tobaccochanging/menthol.htm>