

July 25, 2022

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

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

Capital District Tobacco-Free Communities (CDTFC), serving the New York State counties of Albany, Rensselaer and Schenectady, appreciates the opportunity to express our strong support for the Food and Drug Administration's proposed rule to prohibit all characterizing flavors in cigars. The FDA's proposed rule systematically lays out the evidence showing that prohibiting flavored cigars will protect young people, reduce health disparities and save lives.

CDTFC, a program of St. Peter's Health Partners and funded by the New York State Department of Health, has been in operation for more than two decades with the primary goals of preventing youth tobacco use, reducing tobacco use overall, and protecting people from harms caused by exposure to toxic secondhand smoke. Our current staff have a combined total of more than sixty years' experience in local tobacco control efforts, and structure all our workplan goals to address the pervasive, persistent and disproportionate impact of tobacco-related death and disease on African Americans, people living with mental illness, people living with disabilities, and the LGBTQ+ community.

Our success over the years has been dramatic; New York State 2020 data boasts a 12% adult smoking rate¹ and two of the three counties we serve boast even lower rates based on 2018 data (11.6% in Albany and 11.3% in Schenectady). This success has been the result of a concerted and coordinated effort to increase the identification and treatment of tobacco dependence in these disproportionately impacted populations and to promote community changes that advance health equity goals, including ending the sale of tobacco in pharmacies, raising the legal age for the sale of tobacco to 21, increasing the availability of smoke-free multi-unit housing and smoke-free outdoor shared spaces, and local laws reducing the impact of tobacco marketing by regulating tobacco retailer density and location.

Reducing youth tobacco use has been more challenging. The record low rates in 2020 of New York high school student use of cigarettes (2.4%) and other tobacco products (OTP) including cigars, smokeless tobacco, pipe tobacco and hookah, (6.1%)3 is tempered by the concurrent precipitous increase in high school student use of e-cigarettes. The rate of New York State high school student use of any tobacco product increased from 19.5% in 2014 to 30.6% in 2018, ⁴ a period of only four years. One of the primary contributors to the epidemic use of e-cigarettes by youth was the industry's aggressive marketing of fruit, candy and menthol-flavored products that appeal to kids.⁵

The preference that young people have for flavored tobacco products is demonstrated by the data; nearly 81% of youth ages 12 to 17 who ever used a tobacco product reported that the first product they used was flavored. In fact, the younger a smoker is, the more likely they are to smoke flavored tobacco products, including menthol-flavored products. In New York, the average age of a new smoker is only 13.8

The most recent New York State data indicates that youth tobacco use decreased between 2018-2020, although how much of that decrease was COVID-related and potentially unsustainable remains unknown. Since New York State data was last compiled, a state law was passed to end the sale of all flavored ecigarettes, including menthol. While the strain placed on local health departments to respond to COVID-19 has interfered with robust local enforcement of this new law, we do expect to experience a significant decrease in high school student use of e-cigarettes in the longer term.

We worry, though, that other flavored tobacco products will replace flavored e-cigarettes as an appealing alternative for youth experimentation and a pathway to nicotine addiction. Although the use of OTP among NY high school students declined by 34% over 14 years from 2000 to 2014, in the following six years from 2014-2020 when e-cigarette use was at its peak, OTP use decreased by nearly 50%. ¹⁰ In addition, the continued legal sale of flavored cigars provides an easy pathway for young people who became addicted to nicotine through the use of e-cigs to switch to exclusive use of little cigars or to engage in dual use.

Of additional concern is the fact that New York high school student use of OTP is two and a half times the rate of high school student cigarette use;¹¹ the rate of smoking cigars by male high school students in the U.S. exceeds their rate of cigarette use;¹² and African American high school students in the U.S. smoke cigars at more than twice the rate of cigarettes.¹³

Prohibiting flavored cigars will reduce initiation and use of cigars, especially among young people. Flavors play a key role in attracting youth to start using tobacco products, including cigars. ¹⁴ Flavors increase the appeal of cigars and make them easier to use by improving their taste and masking the harshness of tobacco products. ¹⁵ Flavors in cigars promote initiation in young people and increase the likelihood that they will become regular cigar smokers. ¹⁶

CDTFC recently conducted local tobacco retailer visits as part of an evaluation project which included data collection regarding what flavored tobacco products are currently being sold and advertised. We visited a 10% random sample of licensed tobacco retailers throughout our three-county catchment area. Flavored cigars was the only flavored tobacco product category (including menthol cigarettes as a category) being sold in 100% of tobacco retailers visited in all three counties. ¹⁷ Moreover, more tobacco retailers had interior and exterior advertising for cigars than any other tobacco category. ¹⁸

Photos taken at tobacco retailer locations show that exterior ads for popular cigars/little cigars such as Swisher Sweets, Backwoods, Black & Mild, and Show are extremely common, which is of particular concern because they are typically sold in small package sizes, available in fruit and candy flavors including watermelon, wild berry, grape and tropical fusion, and can be priced as low as \$1, all of which make them particularly appealing to youth.¹⁹

Prohibiting flavored cigars will reduce tobacco-caused disease and death. Cigars are addictive and harmful.²⁰ As is well documented in the proposed rule, flavored cigar smokers, like all cigar smokers, are at increased risk for developing cancers of the mouth and throat, lung cancer, heart and lung diseases, and many other negative health consequences.²¹ The FDA has previously concluded that "all cigars pose serious negative health risks" and that "all cigar use is harmful and potentially addictive."²² Indeed, each year about 9,000 Americans die prematurely from regular cigar use.²³ Removing flavors from cigars will substantially reduce initiation and use and subsequently tobacco-related disease and death.²⁴

Prohibiting flavored cigars will decrease tobacco-related health disparities and advance health equity, especially among Black Americans. The tobacco industry has targeted Black communities with marketing for cheap, flavored cigars for decades. ²⁵ As a result, Black high school students smoke cigars at higher rates compared to other races or ethnicities. ²⁶ In the adult population, cigars, cigarillos and little cigars are most popular among African Americans. ²⁷

In addition to youth and Black smokers, the FDA's proposed rule recognizes the disproportionate burden that cigar use – including flavored cigar use – has on members of many underserved communities, stating, "Such disparities in cigar use contribute to higher rates of observed tobacco-related morbidity and mortality among underserved communities and vulnerable populations, such as youth and young adults, some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+)." ²⁸ Given the disproportionate health burden experienced in some communities, the FDA expects that eliminating flavored cigars will substantially decrease tobacco-related health disparities and will promote health equity across population groups. ²⁹

We urge the FDA to move quickly to finalize this lifesaving rule to prohibit all flavored cigars without exceptions as well as extend it to cover other combustible tobacco products, including hookah and pipe tobacco. Implementing this rule will protect and improve health, and will promote health equity nationally, in New York and for the residents of our three-county catchment area.

Respectfully submitted,

Theresa Zubretsky, Community Engagement Coordinator On behalf of Capital District Tobacco-Free Communities

¹ New York State Behavioral Risk Factor Surveillance Survey 2020. Department of Health, Bureau of Chronic Disease Evaluation, Research Bureau of Tobacco Control. Available at https://www.health.ny.gov/statistics/brfss/reports/docs/2022-12 brfss cigarette smoking.pdf

² New York State Behavioral Risk Factor Surveillance System 2018. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.2/Aug 2021. Available at https://www.health.ny.gov/prevention/tobacco control/reports/statshots/volume14/n2 prevalence of current sm oking.pdf

³ New York State Youth Tobacco Survey 2000-2020. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.3/Sept 2021. Available at https://www.health.ny.gov/prevention/tobacco control/reports/statshots/volume14/n3 milestones in tobacco control.pdf

⁴ New York State Youth Tobacco Survey 2000-2020. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.3/Sept 2021. Available at https://www.health.ny.gov/prevention/tobacco control/reports/statshots/volume14/n3 milestones in tobacco control.pdf

⁵ Vasiljevic M, Petrescu DC, Marteau TM. Impact of advertisements promoting candy-like flavoured e-cigarettes on appeal of tobacco smoking among children: An experimental study. *Tob Control*. 2016;25(e2):e107-e112.

⁶ Villanti AC, Johnson AL, Ambrose BK, Cummings KM, Stanton CA, Rose SW, Feirman SP, Tworek C, Glasser AM, Pearson JL, Cohn AM, Conway KP, Niaura RS, Bansal-Travers M, Hyland A. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). Am J Prev Med. 2017 Aug;53(2):139-151. doi: 10.1016/j.amepre.2017.01.026. Epub 2017 Mar 16. PMID: 28318902; PMCID: PMC5522636.

⁷ Villanti AC, Johnson AL, Ambrose BK, Cummings KM, Stanton CA, Rose SW, Feirman SP, Tworek C, Glasser AM, Pearson JL, Cohn AM, Conway KP, Niaura RS, Bansal-Travers M, Hyland A. Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014). Am J Prev Med. 2017 Aug;53(2):139-151. doi: 10.1016/j.amepre.2017.01.026. Epub 2017 Mar 16. PMID: 28318902; PMCID: PMC5522636.

- ⁹ New York State Youth Tobacco Survey 2000-2020. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.3/Sept 2021. Available at https://www.health.ny.gov/prevention/tobacco control/reports/statshots/volume14/n3 milestones in tobacco control.pdf
- ¹⁰ New York State Youth Tobacco Survey 2000-2020. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.3/Sept 2021. Available at https://www.health.ny.gov/prevention/tobacco_control/reports/statshots/volume14/n3_milestones_in_tobacco_control.pdf
- ¹¹New York State Youth Tobacco Survey 2000-2020. Bureau of Chronic Disease Evaluation and Research, New York State Department of Health, Bureau of Tobacco Control StatShot Vol. 14, No.3/Sept 2021. Available at https://www.health.ny.gov/prevention/tobacco control/reports/statshots/volume14/n3 milestones in tobacco control.pdf
- ¹² CDC, "Tobacco Use Among Middle and High School Students United States, 2011–2017," MMWR 67(22), June 8, 2018.
- ¹³ CDC, "Tobacco Use Among Middle and High School Students United States, 2011–2017," MMWR 67(22), June 8, 2018.
- ¹⁴ 87 Fed. Reg. 26396, 26405 (May 4, 2022).
- ¹⁵ 87 Fed. Reg. 26396, 26405 (May 4, 2022)
- ¹⁶ 87 Fed. Reg. 26396, 26405 (May 4, 2022)
- ¹⁷ Capital District Tobacco-Free Communities, Local Level Evaluation Project Report 2021-2022, *Licensed Tobacco Retailer Observation Data*, June 2022. Available at https://smokefreecapital.org/wp-content/uploads/2022/07/Final_report_2021-22.pdf
- ¹⁸ Capital District Tobacco-Free Communities, Local Level Evaluation Project Report 2021-2022, *Licensed Tobacco Retailer Observation Data*, June 2022. Available at https://smokefreecapital.org/wp-content/uploads/2022/07/Final report 2021-22.pdf
- ¹⁹ Capital District Tobacco-Free Communities, Local Level Evaluation Project Report 2021-2022, *Licensed Tobacco Retailer Observation Data*, June 2022. Available at https://smokefreecapital.org/wp-content/uploads/2022/07/Final_report_2021-22.pdf
- ²⁰ 87 Fed. Reg. 26396, 26413 (May 4, 2022).
- ²¹ 87 Fed. Reg. 26396, 26418 (May 4, 2022)
- ²² 81 Fed Reg 29020, 29022 (May 10, 2016).
- ²³ 87 Fed. Reg. 26397, 26399 (May 4, 2022).
- ²⁴ 87 Fed. Reg. 26396, 26406 (May 4, 2022).

⁸ New York State Department of Health. Health Data NY. <u>Youth Tobacco Survey: Beginning 2000</u>. Updated November 4, 2021.

²⁵ 87 Fed. Reg. 26396, 26412 (May 4, 2022).

²⁶ CDC, "Tobacco Product Use Among Middle and High School Students—United States, 2021," MMWR 71(5), March 11, 2022, https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7105a1-H.pdf

²⁷ Wang TW, Asman K, Gentzke AS, et al. Tobacco Product Use Among Adults - United States, 2017. MMWR Morb Mortal Wkly Rep. 2018;67(44):1225-1232.

²⁸ 87 Fed. Reg. 26396, 26401 (May 4, 2022).

²⁹ 87 Fed. Reg. 26396, 26397 (May 4, 2022).