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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-1349 for "Tobacco Product Standard for Menthol in Cigarettes"

Capital District Tobacco-Free Communities (CDTFC), serving the New York State counties of Albany, Rensselaer and Schenectady, appreciates the opportunity to submit comments in strong support of the proposed product standard prohibiting menthol as a characterizing flavor in cigarettes, which will reduce youth smoking, save lives, and advance health equity. The proposed rule will have an enormous public health impact both in the short and long term.

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 rate<sup>1</sup> 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).<sup>2</sup> 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,<sup>4</sup> 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.<sup>5</sup>

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.<sup>6</sup> In fact, the younger a smoker is, the more likely they are to smoke flavored tobacco products, including menthol-flavored products.<sup>7</sup> In New York, the average age of a new smoker is only 13.<sup>8</sup>

The most recent New York State data indicates that youth tobacco use decreased between 2018-2020,<sup>9</sup> 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 e-cigarettes, 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 flavored tobacco products, including menthol cigarettes, will replace flavored ecigarettes as an appealing alternative for youth experimentation and a pathway to nicotine addiction. Indeed, the most dramatic decline in youth cigarette use coincided with the most dramatic increase in ecigarette use during the four-year period of 2014 to 2018.<sup>10</sup> In addition, the continued legal sale of flavored, combustible tobacco products provides an easy pathway for young people who became addicted to nicotine through the use of e-cigs to switch to combustible products or to engage in dual use.

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. Menthol-flavored cigarettes were being sold in 98% of all stores visited, exceeded only by the percentage of stores selling flavored cigars (100%).<sup>11</sup> Moreover, more stores had interior and exterior advertising for menthol cigarettes than any other tobacco category excepting cigars.<sup>12</sup>

**Prohibiting menthol cigarettes will reduce youth smoking.** Menthol cools and numbs the throat, reduces the harshness of tobacco smoke, and makes cigarettes more appealing to new smokers, particularly young people. As is well-documented in the proposed rule, menthol facilitates experimentation, progression to regular smoking of menthol cigarettes and contributes to greater nicotine dependence.<sup>13</sup> Half of youth who have ever tried smoking started with menthol cigarettes<sup>14</sup> and menthol cigarettes were responsible for 10.1 million additional new smokers between 1980 and 2018.<sup>15</sup>

**Prohibiting menthol cigarettes will increase smoking cessation and save lives.** Smoking remains the leading cause of preventable disease and death in the United States.<sup>16</sup> Studies show significantly reduced rates of quitting among African-American and Hispanic menthol smokers compared to non-menthol smokers.<sup>17</sup> Prohibiting menthol cigarettes, which are more difficult to quit than non-menthol cigarettes, will reduce this burden by increasing smoking cessation.<sup>18</sup> As described in the rule, modeling studies have estimated that 324,000 to 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States.<sup>19</sup>

**Prohibiting menthol cigarettes would decrease tobacco-related health disparities and advance health equity, especially among Black Americans.** Menthol cigarettes have caused substantial harm to public health, and particularly to Black Americans. For more than 60 years, the tobacco industry has targeted Black Americans with marketing and price promotions for menthol cigarettes,<sup>20</sup> and as a result, 85% of Black smokers in the U.S. smoke menthol cigarettes compared to 29% of white smokers.<sup>21</sup> In New York State, Black and Hispanic adults smoke menthols almost exclusively (86% of Black and 72% of Hispanic smokers) as compared to only 36% of White smokers.<sup>22</sup>

The industry's aggressive promotion of menthol cigarettes to the Black community is evident in all three of our local catchment counties and is documented in CDTFC's 2017 report *Addressing Tobacco Use Health Inequities in the City of Albany* and 2020 report *Addressing Tobacco Use Health Inequities in the County of Schenectady*. (The onset of the COVID-19 pandemic prevented us from completing data collection in Rensselaer County, but preliminary data analysis reflected similar findings to those in Albany and Schenectady.) Our findings across all three counties show increased density of tobacco retailers and, on average, more interior and exterior ads for menthol cigarettes, in low-income, predominantly Black communities as compared to higher-income, predominantly white communities.<sup>23</sup>

The afore-mentioned Health Inequities reports also describe the series of conversations that we hosted with residents of the Cities of Albany and Schenectady and the reactions of participants to data related to the disproportionate use of tobacco by people living below the poverty level, the disproportionate rates of tobacco-related death and disease among African Americans, and the local store observations. Of 90 total participants, 88% were non-white (including 62% Black) and 72% had incomes of \$25,000 or less.<sup>24</sup> Fully 70% of the participants identified as former or current smokers and, without exception, they had started smoking before age 18.<sup>25</sup>

Specific participant comments included:

"Older smokers aren't attracted to fruit and candy flavors."<sup>26</sup>

"It's almost like it's a conspiracy to kill poor people."27

"I go between very sad and angry about the whole issue. That's messed up. Beyond terrible that tobacco industry purposely pushed menthol in black communities."<sup>28</sup>

"Companies are earning money off of us." 29

"I can barely walk up the street without my chest hurting. I feel the effects. At this point, I am trying to stop, I want to stop, it's real though, I don't want to die from it. It was brought up around me. I was brought up in poverty. A lot of things need to change. I'm a smoker but I'm not a proud smoker."<sup>30</sup>

Another City of Albany resident, Tammy Miller, widely shared her personal story to help educate the community and local decision-makers. She remembers when the tobacco industry began heavily marketing menthol cigarettes in her neighborhood. Vans drove through the streets selling and passing out menthol cigarettes for free. As a result, she, like her mother, began using menthol cigarettes regularly. Two years after losing her mother to lung cancer, she found out she also had lung cancer. Her story, like so many others we heard from participants of the neighborhood conversations, illustrated the devastating impact of menthol cigarettes on the lives of Black community residents. The version of Tammy's story that was published locally is attached in its entirety and is also available for viewing on our website here: It's Not Just Campaign | Capital District Tobacco-Free Communities (smokefreecapital.org)

In addition to youth and Black smokers, use of menthol in the U.S. is also disproportionately high among Asian smokers, lesbian, gay, and bisexual smokers, smokers with mental health problems, socioeconomically disadvantaged populations, and pregnant women.<sup>31</sup> The proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across all these population groups.

We urge the FDA to move quickly to finalize this lifesaving rule to prohibit menthol in cigarettes without exceptions as well as extend it to cover other combustible tobacco products, including cigars, 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

<sup>1</sup> New York State Behavioral Risk Factor Surveillance Survey 2020. Department of Health, Bureau of Chronic Disease Evaluation, Research Bureau of Tobacco Control. Available at <u>https://www.health.ny.gov/statistics/brfss/reports/docs/2022-12\_brfss\_cigarette\_smoking.pdf</u>

<sup>2</sup> 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 <u>https://www.health.ny.gov/prevention/tobacco\_control/reports/statshots/volume14/n2\_prevalence\_of\_current\_smoking.pdf</u>

<sup>3</sup> 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 <a href="https://www.health.ny.gov/prevention/tobacco\_control/reports/statshots/volume14/n3\_milestones\_in\_tobacco\_control\_lpdf">https://www.health.ny.gov/prevention/tobacco\_control/reports/statshots/volume14/n3\_milestones\_in\_tobacco\_control\_lpdf</a>

<sup>4</sup> 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 <a href="https://www.health.ny.gov/prevention/tobacco">https://www.health.ny.gov/prevention/tobacco</a> control/reports/statshots/volume14/n3 milestones in tobacco control/reports/statshots/volume14/n3 milestones in tobacco</a> control

<sup>5</sup> 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.

<sup>6</sup> 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.

<sup>7</sup> 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.

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

<sup>9</sup> 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 <a href="https://www.health.ny.gov/prevention/tobacco">https://www.health.ny.gov/prevention/tobacco</a> control/reports/statshots/volume14/n3 milestones in tobacco control/reports/statshots/volume14/n3 milestones in tobacco</a> control

<sup>10</sup> 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 <u>https://www.health.ny.gov/prevention/tobacco\_control/reports/statshots/volume14/n3\_milestones\_in\_tobacco\_control\_lpdf</u>

<sup>11</sup> Capital District Tobacco-Free Communities, Local Level Evaluation Project Report 2021-2022, *Licensed Tobacco Retailer Observation Data*, June 2022. Available at <u>https://smokefreecapital.org/wp-</u> <u>content/uploads/2022/07/Final\_report\_2021-22.pdf</u>

<sup>12</sup> Capital District Tobacco-Free Communities, Local Level Evaluation Project Report 2021-2022, *Licensed Tobacco Retailer Observation Data*, June 2022. Available at <u>https://smokefreecapital.org/wp-</u> <u>content/uploads/2022/07/Final\_report\_2021-22.pdf</u>

<sup>13</sup> Tobacco Product Standard for Characterizing Flavors in Cigars, 87 Fed. Reg. 26396, 26463-26466 and 26469-26470 (proposed May 4, 2022) (to be codified at 21 C.F.R. pt. 1166).

<sup>14</sup> Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," Journal of the American Medical Association, published online October 26, 2015.

<sup>15</sup> Le, TT, "An Estimation of the Harm of Menthol Cigarettes in the United States from 1980 to 2018," Tobacco Control, published online on February 25, 2021.

<sup>16</sup> U.S. Department of Health and Human Services (HHS). The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

<sup>17</sup> Tobacco Products Scientific Advisory Committee's Report and Recommendations on the Impact of the Use of Menthol in Cigarettes on the Public Health. 2011.

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<sup>18</sup> Levy DT, Meza R, Yuan Z, *et al.* Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study. *Tobacco Control* Published Online First: 02 September 2021. doi: 10.1136/tobaccocontrol-2021-056604

<sup>19</sup> Levy, D.T., J. Pearson, A. Villanti, et al. "Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and SmokingAttributable Deaths in the United States." American Journal of Public Health, 101:1236-1240, 2011. Available at https://doi.org/10.2105/AJPH.2011.300179. Levy, D.T., R. Meza, Z. Yuan, et al. "Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study." Tobacco Control, 2021. Available at https://doi.org/10.1136/tobaccocontrol-2021-056604.

<sup>20</sup> Gardiner, PS, "The African Americanization of menthol cigarette use in the United States," Nicotine & Tobacco Research, 6(S1): S55-S65, 2004. Yerger, VB, et al., "Racialized geography, corporate activity, and health disparities: Tobacco industry targeting of inner cities," Journal of Health Care for the Poor and Underserved, 18: 10-38, 2007. Hafez, N. & Ling, P.M. "Finding the Kool Mixx: how Brown & Williamson used music marketing to sell cigarettes," Tobacco Control 15: 359-366, 2006.

<sup>21</sup> Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," Nicotine & Tobacco Research, 22(10): 1673-1675, 2020.

<sup>22</sup> 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. 1 /Jan 2021. Available at <a href="https://www.health.ny.gov/prevention/tobacco">https://www.health.ny.gov/prevention/tobacco</a> control/reports/statshots/volume14/n1 menthol cigarette use.pdf

<sup>23</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco\_Use\_Inequities\_Albany\_FINAL.pdf (smokefreecapital.org)</u>

Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the County of Schenectady*, July 2020. Available at <a href="https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf">https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf</a>

<sup>24</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco\_Use\_Inequities\_Albany\_FINAL.pdf (smokefreecapital.org)</u>

Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the County of Schenectady*, July 2020. Available at <a href="https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport FINAL-072020.pdf">https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport FINAL-072020.pdf</a>

<sup>25</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco Use Inequities Albany FINAL.pdf (smokefreecapital.org)</u>

Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the County of Schenectady*, July 2020. Available at <a href="https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport FINAL-072020.pdf">https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport FINAL-072020.pdf</a>

<sup>26</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco Use Inequities Albany FINAL.pdf (smokefreecapital.org)</u>

<sup>27</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco Use Inequities Albany FINAL.pdf (smokefreecapital.org)</u>

<sup>28</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the County of Schenectady*, July 2020. Available at <a href="https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf">https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf</a>

<sup>29</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the City of Albany*, February 2017. Available at <u>Tobacco Use Inequities Albany FINAL.pdf (smokefreecapital.org)</u>

<sup>30</sup> Capital District Tobacco-Free Communities. *Addressing tobacco use health inequities in the County of Schenectady*, July 2020. Available at <a href="https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf">https://smokefreecapital.org/wp-content/uploads/2022/07/SchenectadyNCReport\_FINAL-072020.pdf</a>

<sup>31</sup> Delnevo, CD, et al., "Banning Menthol Cigarettes: A Social Justice Issue Long Overdue," Nicotine & Tobacco Research, 22(10): 1673-1675, 2020.