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July 19, 2018

Scott Gottlieb, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2017-N-6565-0001 for "Regulation of Flavors in Tobacco Products."

Dear Dr. Gottlieb,

On behalf of the Prevent Cancer Foundation®, the only nonprofit organization in the U.S. dedicated solely to cancer prevention and early detection, we appreciate the opportunity to submit comments in support of the proposed rule FDA-2017-N-6565-0001. This rule, seeking to review the role of flavored tobacco and its impact on smoking behaviors, is a move in the right direction for addressing addiction, and we thank the FDA for taking this first step. We support any attempt aimed at reducing the use of tobacco products and stemming addiction, and we appreciate the focus on protecting children and other vulnerable populations.

Through the Tobacco Control Act, the FDA has been given the authority to regulate tobacco products, including flavors of these products. As the FDA moves to create new standards for flavors, the agency must continue to focus on the overall impact on public health. As the agency weighs the data and evidence, we ask you to consider a few key points:

I. Flavors Encourage More Tobacco Use

The adverse effects of tobacco are well-documented, and the nicotine in these products is both harmful and addictive, making it hard for smokers to quit. This addiction is compounded by the use of flavors, which increase the appeal of smoking. It is estimated that regular smokers may try 30 or more times to quit smoking before they are ultimately successful.¹ Tobacco flavors create a more pleasant taste and a more stimulating product through associations to other foods consumers are familiar with, which reinforces reward responses in the brain. Adding sugars to create an array of flavors like cherry, vanilla, piña-colada and berry can help mask the unpleasant taste of many tobacco products and

Diemert, J.E. Cohen, et al., "Estimating the Number of Quit Attempts It Takes to Quit Smoking Longitudinal Cohort of Smokers," *BMJ Open*,6(6):e011045, 2016.

make them more enjoyable.² Combined with nicotine, it becomes harder for smokers to stop. Limiting or restricting the use of flavors can go a long way in reducing the use of tobacco.

II. Flavored Tobacco Targets Youth

Children and adolescents are among the most vulnerable to picking up smoking habits. Kids and teenagers are especially drawn to sweet flavors that imitate the taste of candy or other sweet products, and young people are often targeted through marketing campaigns that promote these flavors. In 2014, the National Youth Tobacco Survey (NYST) found that 70 percent of middle and high school students who participated in the survey reported using flavored tobacco within the past 30 days.³ Adding flavors also gives kids the perception that these types of tobacco are a safer alternative to traditional tobacco products, which is not the case.

The Prevent Cancer Foundation® recommends the FDA restrict the use of flavors in tobacco to decrease the risk of children and adolescents developing an addiction to these dangerous products.

III. Menthol Cigarettes Target African-Americans

Menthol cigarettes have been heavily marketed in the African-American population as a “smoother” and “safer” alternative to traditional cigarettes. According to the FDA’s own analysis, the availability of menthol flavors hinders cessation efforts within the African-American community and poses an increased risk for addiction.⁴ The Tobacco Product Scientific Advisory Committee (TPSAC) reports this concern is disproportionately felt in the African-American Population, with 420,000 new smokers projected to start smoking due to menthol products by 2020.⁵ Without swift action from the FDA to curtail the use of menthol and other flavorings in tobacco products, countless individuals will fall victim to false claims, aggressive marketing and addiction.

² Real Parents Real Answers, “What you need to know about e-cigarettes – Infographic,” April 23, 2014, accessed November 7, 2014, <http://www.realparentsrealanswers.com/what-you-need-to-know-about-e-cigarettes-infographic/>. See also

https://tobacco.ucsf.edu/sites/tobacco.ucsf.edu/files/u9/What%20you%20need%20to%20know%20about%20e-cigarettes%20%E2%80%93%20Infographic%20_%20Real%20Parents%20Real%20Answers_may31-2014.pdf.

³ Corey, C.G., B.K. Ambrose, B.J. Apelberg, et al., “Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014,” *Morbidity and Mortality Weekly Report*, 64(38):1066-1070, 2015.

⁴ Tobacco Products Scientific Advisory Committee (TPSAC), *Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations*, July 21, 2011

⁵ TPSAC Report, 2011.

Conclusion

In light of these recent efforts, we support the proposed rule, FDA-2017-N-6565-0001, and encourage the FDA to continue its research on the impact of flavored tobacco and to continue to exercise oversight of these new products.

Thank you for the opportunity to comment.

Sincerely,

Carolyn Aldigé
Founder and CEO