



AMERICAN
COLLEGE *of*
CARDIOLOGY

Heart House
2400 N Street, NW
Washington, DC 20037-1153
USA

202-375-6000
800-253-4636
Fax: 202-375-7000
www.ACC.org

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*The mission of the American College
of Cardiology and the American
College of Cardiology Foundation
is to transform cardiovascular care
and improve heart health.*

June 22, 2018

Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: **Regulation of Flavors in Tobacco Products [FDA-2017-N-6565]**

Dear Commissioner Gottlieb:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on the regulation of flavors in tobacco products. The American College of Cardiology is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

Cigarette smoking increases an individual's risk of cardiovascular disease by two to four times.¹ After one year, smoking cessation is associated with a 50 percent reduction in coronary heart disease compared to those still smoking.² While significant strides have been made to decrease the prevalence of smoking, tobacco use remains the chief cause of preventable death and disease in the United States. To further reduce the prevalence of cigarette smoking and associated health problems such as heart disease, the FDA must take all appropriate measures within its authority to steer current smokers toward cessation and prevent non-smokers from initiation.

Youth and adolescents represent a highly vulnerable portion of the population regarding smoking initiation and nicotine addiction. Youth tobacco use causes lasting cognitive and behavioral impairments and leads to greater risk of serious health problems in the future. Children consistently cite flavors as the primary reason for initiating tobacco product

¹ Warren GW, Alberg AJ, Kraft AS, Cummings KM. "The Health Consequences of Smoking: 50 Years of Progress". A Report of the Surgeon General; 2014. Accessed June 1, 2018. <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.

² Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention; 2010. Accessed June 1, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/21452462>.

use.³ While the Tobacco Control Act prohibited the presence of characterizing flavors other than menthol or tobacco in cigarettes, the product standard does not apply to other categories including cigars, e-cigarettes, or pipe tobacco.

E-cigarettes are the most commonly used tobacco product among youth and adolescents, which are now available in almost 8,000 different flavors. Flavor preferences tend to vary by age group, with younger users gravitating toward sweeter tastes. While the Tobacco Control Act takes a strong stance in opposition to the sale of characterizing flavors, popular flavors such as gummy bear, cotton candy, and chocolate are clearly designed to appeal to minors. Flavored cigar variety and popularity have also increased, accounting for over half of the U.S. cigar market in 2015.⁴ Most tobacco users initiate use before age 18, and fruit or candy-flavored products are manufactured and marketed to target vulnerable youth. **The College believes that the plethora of flavored tobacco products flooding the market are a serious public health threat to the nation's vulnerable youth.**

Despite the overall decline in youth cigarette smoking, youth rates of menthol smoking have remained stable in recent years. Youth and adolescents are more likely to smoke menthol cigarettes than nonmenthol compared to older smokers, and African Americans are disproportionately affected by the harmful consequences of menthol cigarettes. Eighty-five percent of all African-American smokers use menthol cigarettes compared to 28 percent of Caucasians, largely because of increased access to them and targeted marketing from the tobacco industry.⁵ The FDA previously concluded that menthol cigarettes increase initiation among youth and young adults, and according to its Tobacco Product Scientific Advisory Committee (TPSAC), public health in the U.S. would greatly benefit if they were removed from the marketplace.⁶ No new evidence has emerged to indicate this has changed. **Based on this, the ACC urges FDA to ban the sale of menthol cigarettes without further delay.**

Perceptions of tobacco harm influences tobacco use behavior, and evidence shows youth, young adult, and adult age groups all perceive flavored products as less harmful than non-flavored products.⁷ This association is especially troubling, as data from the PATH Study, a national longitudinal study of tobacco use and how it affects the health of Americans, indicate youth who first experiment with a flavored tobacco product are 13 percent more likely to sustain tobacco use compared to those whose first tobacco product is not flavored. Not only do flavored tobacco products contain the same harmful, addictive components as the non-flavored variety, but flavors may also contain compounds that become toxic when heated or burned.

As presented by the FDA, an abundance of scientific research shows that flavors increase the appeal of tobacco products to youth and promote initiation of new users, increasing the probability of lifelong use. **The FDA must prohibit the sale of all flavored tobacco products, including menthol, to cease the mass initiation of youth smokers and lessen the toll of tobacco-related death and disease for future generations.**

The ACC stands in strong support of regulating flavors in tobacco products and urges the FDA to use the fullest extent of its authority to restrict their availability to youth and young adults. The College

³ Villanti, A.C., A.L. Johnson, B.K. Ambrose, et al., "Flavored Tobacco Product Use in Youth and Adults: Findings From the First Wave of the PATH Study (2013-2014)," *American Journal of Preventive Medicine*, 53(2):139-151, 2017.

⁴ The Campaign for Tobacco Free Kids, The American Lung Association, The American Heart Association, The American Cancer Society, the American Academy of Pediatrics, The Flavor Trap, 2017. Accessed June 1, 2018. https://www.tobaccofreekids.org/microsites/flavortrap/full_report.pdf.

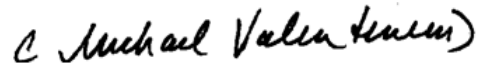
⁵ The Campaign for Tobacco Free Kids, *Impact of Menthol Cigarettes on Youth Smoking Initiation and Health Disparities*, 2017. Accessed June 1, 2018. <https://www.tobaccofreekids.org/assets/factsheets/0390.pdf>.

⁶ FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes, 2013.

⁷ Song, A.V., H.E. Morrell, J.L. Cornell, et al., "Perceptions of Smoking-Related Risks and Benefits as Predictors of Adolescent Smoking Initiation," *American Journal of Public Health*, 99(3):487-492, 2009.

appreciates the FDA's openness to stakeholder input throughout its ongoing initiative to lessen tobacco-related harm and welcomes the opportunity to provide further input as needed. Please direct any questions or concerns to Kelsey Creehan, Associate, Advocacy at (202) 375-6625 or kcreehan@acc.org.

Sincerely,



C. Michael Valentine, MD, FACC
President