



July 18, 2018

Scott Gottlieb, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: FDA-2017-N-6565, Regulation of Flavors in Tobacco Products

Dear Commissioner Gottlieb:

The American College of Physicians appreciates the opportunity to comment on the Regulation of Flavors in Tobacco Products advance notice of proposed rulemaking (ANPRM). ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 152,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP policy recommends that characterizing flavors should be banned from all tobacco products, including electronic nicotine delivery systems (ENDS), such as electronic cigarettes (i). The College has also recommended that the Food and Drug Administration (FDA) implement a ban on menthol as a flavoring in all tobacco products, as it has done with other flavors in cigarettes.

We respectfully offer the following responses to the agency's questions presented in the ANPRM:

1. *The role of flavors (other than tobacco) in tobacco products*: Tobacco use usually begins in adolescence, and tobacco companies have targeted this vulnerable and impressionable age group by offering flavored products that appeal to young palates. A 1972 Brown and Williamson company document discussing a potential "youth cigarette" states that "[a]pples connote goodness and freshness and we see many possibilities for our youth-oriented cigarette with this flavor" (ii). Tobacco industry documents show health concerns prompt regular

cigarette smokers to switch to mentholated cigarettes (iii). Menthol flavor may also weaken the perception of harshness from ENDS with high nicotine concentrations (iv).

2. *Flavors and initiation of combusted tobacco use:* Evidence suggests that new smokers are more likely to use menthol cigarettes than established smokers. Menthol cigarettes are most popular among younger populations and are associated with increased smoking initiation by youth and young adults (v). According to the FDA’s report “newer smokers prefer menthol at levels substantially above that of the general population” and that menthol in cigarettes is likely associated with increased initiation and progression to regular cigarette smoking (v). Youth gravitate to other flavored combustible products, like cigars and hookah (vi). An analysis of the 2014 National Youth Tobacco Survey found that “the popularity of flavors across the range of tobacco products suggests that flavoring might have broad appeal to young tobacco users. Therefore, it is important that comprehensive tobacco prevention and control strategies for youths address all forms of flavored tobacco products and not just cigarettes” (vii).

3. *Flavors and initiation of noncombusted tobacco use:* Likewise, youths and young people often initiate use of ENDS because of flavors. According to the United States Surgeon General’s 2016 report, ENDS use among youth and young adults is a major public health concern. The report found that “[f]lavored e-cigarette use among young adult current users (18–24 years of age) exceeds that of older adult current users (25 years of age and older). Moreover, among youth who have ever tried an e-cigarette, a majority used a flavored product the first time they tried an e-cigarette” (viii). According to one systematic review of the literature, “Adolescents could consider flavor the most important factor in their decision to try e-cigarettes and were more likely to initiate vaping through flavored e-cigarettes (especially fruit and sweet ones for non-smokers)” (ix). Nearly 42% of middle and high school students cite availability of “good flavors” as a reason for trying ENDS for the first time (x).

Additional Public Health Considerations

11. Studies show that youths and young adults have positive perceptions of flavored tobacco products like hookah, little cigars, and ENDS compared to cigarettes (xi,xii,xiii). Fruit flavorings used in tobacco are often the same as artificial fruit flavorings used in candy. For example, the chemical flavorings used in “cherry” Jolly Rancher, Zotz, and Life Savers candies were also prevalent in cherry-flavored tobacco products, leading study authors to conclude that “[t]he same, familiar, chemical-specific flavor sensory cues that are associated with fruit flavors in popular candy and drink products are being exploited in the engineered designs of flavored tobacco products. What we are seeing is truly candy-flavored tobacco” (xiv).

Conclusion

ACP policy recommends that flavors, including menthol, be eliminated from all tobacco products. The FDA’s own Tobacco Products Scientific Advisory Committee has concluded that

“removal of menthol cigarettes from the marketplace would benefit public health in the United States” (v). Flavors have been used by tobacco companies to attract young people to tobacco products. Many young people, including nonusers, mistakenly believe that flavored tobacco products are less harmful (xv). Selective regulation or prohibition of some flavored products may cause people to use other unregulated flavored tobacco products; for example, many users of flavored cigarettes switched to flavored cigars, menthol cigarettes, and other tobacco products following the ban on flavored cigarettes (xvi). Removing flavors from tobacco products may not completely eliminate tobacco use, but it could substantially lower it and prevent young people from starting altogether (xvii).

Further, ACP strongly supports efforts to regulate ENDS. The U.S. Preventive Services Task Force concludes that the current evidence is insufficient to recommend ENDS for smoking cessation (xviii). ENDS use among youths and young adults is a major public health concern and the massive variety of flavors, including cherry, mint, and chocolate, among thousands more, are designed to appeal to young people.

The Family Smoking Prevention and Tobacco Control Act prohibited the use of some characterizing flavors in cigarettes. This was a promising first step but more needs to be done. We urge the FDA to take action to prohibit characterizing flavors, including menthol, in combustible and noncombustible tobacco products.

Sincerely,



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President
American College of Physicians

ⁱ Crowley RA. Electronic Nicotine Delivery Systems: Executive Summary of a Policy Position Paper from the American College of Physicians. *Ann Intern Med.* 2015;162(8):583-584. Accessed at <http://annals.org/aim/fullarticle/2275390/electronic-nicotine-delivery-systems-executive-summary-policy-position-paper-from>

ⁱⁱ Marketing Innovations, Inc. Letter to Brown and Williamson Corporation. Youth cigarette – new concepts. September 1972. University of California, San Francisco. Legacy Tobacco Documents Library.

ⁱⁱⁱ RJ Reynolds. Project “Y” Secret. September 1, 1977. University of California, San Francisco. Legacy Tobacco Documents Library. Accessed at <https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=krcx0099>

^{iv} Rosbrook K and Green BG. Sensory Effects of Menthol and Nicotine in an E-Cigarette. *Nicotine Tob Res.* 2016;18(7):1588-1595 Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4902888/>

^v Food and Drug Administration. Preliminary Scientific Evaluation of the Possible Health Effects of Menthol Versus Nonmenthol Cigarettes. Accessed at <https://www.fda.gov/downloads/ucm361598.pdf>

^{vi} Campaign for Tobacco-Free Kids. Flavored Tobacco Products Attract Kids. Accessed at <https://www.tobaccofreekids.org/assets/factsheets/0383.pdf>

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- viii U.S. Department of Health and Human Services. E-cigarette Use Among Youth and Young Adults. 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, 2016. Accessed at https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf
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- xiii American Lung Association. An Emerging Deadly Trend: Waterpipe Tobacco Use. February 2007. Accessed at http://www.lungusa2.org/embargo/slati/Trendalert_Waterpipes.pdf
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