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July 11, 2018

Submitted electronically via the Federal eRulemaking Portal

**Re: Docket No. FDA-2017-N-6565
Regulation of flavors, including menthol, in tobacco products**

The mission of the Oregon Health Authority-Public Health Division (OHA-PHD) is to promote health by addressing the leading causes of death, disease and injury in Oregon. Tobacco use is the leading preventable cause of death in Oregon, killing nearly 8,000 people each year.¹ Tobacco use and exposure to secondhand smoke are expensive. In Oregon alone, tobacco-related diseases lead to \$1.4 billion in direct medical spending every year.²

OHA-PHD recommends all flavors (including menthol), flavor compounds, flavor additives and ingredients be prohibited from all tobacco products.

Flavored Tobacco Product Use and Youth Initiation

Youth use and initiation of tobacco products is a significant public health concern in Oregon. Oregon data show that the availability of flavored tobacco products is a key component of youth initiation. Flavored tobacco products are more popular among Oregon youth (65%) and young adults (64%) compared to older adults (21%).³ According to an October 2013 Centers for Disease Control and Prevention study on youth use of flavored tobacco products, "Flavors can mask the natural harshness and taste of tobacco, making flavored tobacco products easier to use and increasing their appeal among youth. Advertising for flavored tobacco products has been targeted toward youth, and flavored product use may influence the establishment of lifelong tobacco-use patterns among younger individuals."⁴

The rise in use of other tobacco products that are predominantly flavored, such as little cigars, electronic cigarettes and hookah, illustrates why this issue is of significant concern to OHA-PHD. Sweet flavored tobacco products have fueled the popularity of e-cigarettes and cigars among youth and young adults. In Oregon, e-cigarette use among 11th graders increased three-fold from 2013 to 2015 from 5% to 17%. Though 2017 marked the first year there was a decline in e-cigarette use among Oregon youth, nearly 13% of 11th graders still reported using e-cigarettes³.

Increasingly, evidence suggests that e-cigarettes are introducing youth and young adults to nicotine addiction. Approximately two in five Oregon high school students who are current e-cigarette users report that they never smoked conventional cigarettes. An additional two out of five 11th grade e-cigarette users are dual users, meaning that they also currently smoke combustible cigarettes.³ Flavors appear to be a key component for youth to start using products containing nicotine, lowering the barrier for subsequent combustible tobacco use.

In Oregon, flavored other tobacco product use has increased even as youth combustible cigarette smoking has decreased. From 1996 to 2017, combustible cigarette smoking decreased by 72 percent among 11th graders and more than 86% among eighth-graders in Oregon.³ Despite these decreases in youth smoking, many young people still use combustible cigarettes and products containing nicotine. Many of them will continue to smoke into adulthood.

Given the role of flavored products in youth tobacco use initiation, OHA-PHD recommends removing flavor additives, compounds, constituents or any other flavoring ingredient from all tobacco products, including all tobacco product components.

Menthol, Tobacco Initiation, and Tobacco Use Disparities

The U.S. Food and Drug Administration's (FDA) Tobacco Products Scientific Advisory Committee (TPSAC) Report states (1) that "the availability of menthol cigarettes increases the likelihood of addiction and the degree of addiction in youth smokers," and (2) that "the availability of menthol cigarettes increases prevalence of smoking in the general population and particularly in African Americans, beyond the anticipated prevalence if such cigarettes were not available."⁵

In Oregon, many young people still use cigarettes and will continue to do so into adulthood. Eighty-eight percent of adults who smoke cigarettes daily report that they started smoking before turning 18, and 80 percent of high school students who smoke will continue to do so as adults. Given the role menthol plays in increasing tobacco addiction among youth smokers, OHA-PHD strongly supports the prohibition of menthol as an important step in reducing youth initiation.⁶

OHA-PHD is also concerned about the effect of menthol cigarettes on the African American population and other minority groups. The tobacco industry continues to develop and aggressively market products that appeal to youth and minority communities, including African-Americans, American Indian/Alaska Natives, and sexual minorities. Higher rates of some tobacco-related diseases in these populations may partly result from greater use of menthol cigarettes, which have been heavily marketed in minority communities. Among current cigarette smokers in Oregon, 57% of African American adults and 17% of American Indian or Alaska Native adults currently smoke menthol cigarettes.⁷ Prohibiting menthol as a flavoring in cigarettes would help ease the disproportionate burden of tobacco-related disease in these racial and ethnic groups.

Flavored Tobacco Product Marketing

Tobacco products are sweet, cheap, easy to get and heavily promoted in the retail setting. In 2015, the tobacco industry spent \$1 million an hour on marketing in the U.S. alone.⁸ An estimated \$108 million was spent in Oregon in 2015 to promote and advertise cigarettes and smokeless tobacco products.⁹

Flavored non-cigarette tobacco products are of special concern because their packaging facilitates low prices for products with kid-friendly flavors. Retailers can sell these products in single units, which further reduces the price. Nearly nine in 10 stores that sell little cigars and cigarillos sell them as singles, which makes them cheap and accessible to young people.¹⁰ In Oregon, nearly 80 percent of tobacco stores advertised single, flavored little cigars for under \$1.

Tobacco products marketed in other ways to appeal to kids as well. Flavored tobacco products have candy-like packaging, come in sweet flavors, and are advertised or placed in locations frequented by youth, for example near candy or at youth eye-level. Non-cigarette tobacco products are heavily promoted in convenience stores and other locations accessible to youth. Nearly 93% of stores in Oregon

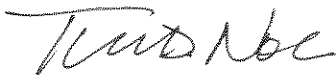
that sell tobacco sell flavored tobacco products. More than half of Oregon eighth-graders (59%) and 11th-graders (56%) shop in a convenience store at least once a week.²

The pervasiveness of flavored products, coupled with the documented aggressive marketing of these products by the tobacco industry makes their removal from the marketplace imperative. In the interest of the public's health and to prevent future tobacco-related harm, OHA-PHD urges the FDA to require that all flavored tobacco products, including menthol, be eliminated.

Conclusion

In keeping with our mission, OHA-PHD encourages the FDA to prohibit all flavors (including menthol), flavor compounds, flavor additives and ingredients from all tobacco products.

Sincerely,



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¹ Oregon Vital Statistics Annual Reports, Volume 2: Chapter 6. Mortality. Table 6-20. Available at <http://www.oregon.gov/oha/ph/BirthDeathCertificates/VitalStatistics/annualreports/Volume2/Pages/index.aspx>

² Oregon Tobacco Facts, 2017. Oregon Health Authority Public Health Division, Health Promotion and Chronic Disease Prevention Section. Available at <http://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/TOBACCPREVENTION/Pages/oregon-tobacco-facts.aspx>

³ Oregon Tobacco Facts, 2018. Oregon Health Authority Public Health Division, Health Promotion and Chronic Disease Prevention Section. Unpublished data.

⁴ King BA, Tynan MA, Dube SR, Arrazola R. Flavored-Little-Cigar and Flavored-Cigarette Use Among U.S. Middle and High School Students. *Journal of Adolescent Health* 2013;54(1):40-6

⁵ Tobacco Products Scientific Advisory Comm., U.S. Food & Drug Administration, Menthol Cigarettes and Public Health: review of the Scientific Evidence and Recommendations 220 (2011), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM247689.pdf>

⁶ Institute of Medicine, Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products, Washington, DC: The National Academies Press, 2015
<http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx>

⁷ Oregon Health Authority. Public Health Division. Oregon Health Promotion and Chronic Disease Prevention section. Behavioral Risk Factor Surveillance System. 2015-2016 Race oversample. Unpublished data.

⁸ Campaign for Tobacco-Free Kids. Broken Promises to Our Children: A State-by-State Look at the 1998 State Tobacco Settlement 18 Years Later. Available at: <http://www.tobaccofreekids.org/microsites/statereport2017/>. Accessed on January 26, 2018.

⁹ Centers for Disease Control and Prevention. Federal Trade Commission Cigarette Report for 2015. Available at: https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2015-federal-trade-commission-smokeless-tobacco-report/2015_cigarette_report.pdf. Accessed on January 26, 2018.

¹⁰ Oregon Health Authority. Public Health Division. Oregon Health Promotion and Chronic Disease Prevention section. Tobacco Retail Environment Assessment. 2016. Unpublished data