



April 15, 2019

**Re: Modifications to Compliance Policy for Certain Deemed
Tobacco Products: Draft Guidance for Industry
Docket #: FDA-2019-D-0661-0001**

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 \$1.5 billion in direct medical spending every year.²

To most effectively protect youth from the harms of tobacco and nicotine products, OHA-PHD makes the following recommendations to the Food and Drug Administration (FDA):

1. *Prohibit all flavors (including mint and menthol), flavor compounds, flavor additives and ingredients from all tobacco products, including ENDS and cigars;*
2. *Reinstate the original August 2018 deadline for electronic nicotine delivery systems (ENDS) manufacturers to submit premarket review applications;*
3. *Establish and enforce legal restrictions on advertising, marketing and online sales of ENDS and cigars; and,*
4. *Exercise full authority to regulate availability of products on the market to truly make an impact and reverse the growing youth ENDS epidemic.*

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. More than 60% of Oregon youth and young adults use flavored tobacco products, compared to only 21% of older adults.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. The U.S. Surgeon General and FDA have declared that youth e-cigarette use is an epidemic and urged immediate action.⁵ The Surgeon General urged parents, teachers, health professionals, and states, tribes and communities to protect youth from e-cigarettes. Sweet flavored tobacco products have fueled the popularity of ENDS and cigars among youth and young adults. In Oregon, ENDS use among 11th graders nearly tripled from 2013 to 2017 from 5% to 13%.⁶

Increasingly, evidence suggests that ENDS are introducing youth and young adults to nicotine addiction. Approximately one in two Oregon high school students who are current ENDS users report that they never smoked conventional cigarettes. Nearly two out of five 11th grade ENDS users are dual users, meaning that they also currently smoke combustible cigarettes.⁷ Flavors appear to be a key component for youth to start using products containing nicotine, lowering the barrier for subsequent combustible tobacco use.

The rise in flavored other tobacco product use, such as ENDS, little cigars and hookah, could potentially undo decades of public health progress in decreasing youth smoking. In Oregon, flavored other tobacco product use has increased even as youth combustible cigarette smoking has decreased. From 1997 to 2017, combustible cigarette smoking decreased by nearly 75 percent among 11th graders and more than 86% among eighth-graders in Oregon.⁸ 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.

Menthol, Tobacco Initiation, and Tobacco Use Disparities

The FDA's 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."⁹ Among adults who smoke in Oregon, 58% of African Americans smoke menthol cigarettes compared to 15% of non-Latino whites.¹⁰

Nearly 9 in 10 cigarette smokers first try cigarette smoking before turning 18,¹¹ and the vast majority of youth who smoke will continue to do so as adults.¹² Given the role menthol plays in increasing tobacco addiction among youth smokers nationally, OHA-PHD strongly supports prohibiting menthol as an important step in reducing youth initiation.¹³

Tobacco Product Marketing to Youth

Tobacco products are sweet, cheap, easy to get and heavily promoted in the retail setting. In 2018, the tobacco industry spent \$1 million an hour on marketing in the U.S. alone.¹⁴ An estimated \$116 million was spent in Oregon in 2018 to promote and advertise cigarettes and smokeless tobacco products.¹⁵

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.¹⁶ In Oregon, nearly 60 percent of tobacco stores advertised single, flavored little cigars for under \$1.¹⁷

Tobacco products are 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. About 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 and 70% of youth have been exposed to tobacco advertising.¹⁸ Additionally, in Oregon, retailers still sell tobacco products illegally to youth, and the retailer violation rate for e-cigarettes is higher than for cigarettes. OHA-PHD inspections

in 2018 found that 22% of inspected retailers illegally sold e-cigarettes to underage persons. For cigarettes, the violation rate was 18%.¹⁹

In addition, it is clear that youth in Oregon have access to ENDS through the internet. Despite Oregon's law prohibiting the sales and distribution of tobacco products to those under 21, 7% of high school youth in Oregon obtain tobacco products through internet sales.²⁰ OHA-PHD expects 2019 data to show a higher percentage given that national data show a significant increase in youth use of these products over the last year. In addition, over the last year OHA-PHD received a notable increase in communications from concerned parents about youth purchases of ENDS through the internet along with questions as to how OHA-PHD plans to address the issue.

The pervasiveness of flavored products coupled with the documented aggressive marketing of these products by the tobacco industry makes their removal from the online and brick and mortar marketplaces 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.

In addition, the FDA should immediately remove from the market any ENDS that have not submitted an application for premarket review demonstrating public health benefits as required by law. Allowing these unregulated products to remain on the market dismisses the serious health and developmental impacts these products have on Oregon youth.

Experience has shown that voluntary compliance is not effective in meaningfully reducing youth access to and use of tobacco products. OHA-PHD urges FDA to create legally enforceable regulations in order to truly make an impact and reverse the growing youth ENDS epidemic.

Conclusion

In keeping with our mission, OHA-PHD urges the FDA to:

1. *Prohibit all flavors (including mint and menthol), flavor compounds, flavor additives and ingredients from all tobacco products, including ENDS and cigars;*
2. *Reinstate the original August 2018 deadline for electronic nicotine delivery systems (ENDS) manufacturers to submit premarket review applications;*
3. *Establish and enforce legal restrictions on advertising, marketing and online sales of ENDS and cigars; and,*
4. *Exercise full authority to regulate availability of products on the market to truly make an impact and reverse the growing youth ENDS epidemic.*

Sincerely,



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- ² Oregon Tobacco Facts, 2018. 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. Available at <http://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/TOBACCPREVENTION/Pages/oregon-tobacco-facts.aspx>
- 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 U.S. Surgeon General’s Advisory on E-cigarette Use Among Youth. Available at: <https://ecigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-one-cigarette-use-among-youth-2018.pdf>.
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- ⁷ Oregon Health Authority. Oregon Healthy Teens, 2017. Unpublished data.
- ⁸ Oregon Health Authority. Oregon Healthy Teens, 2017. Unpublished data.
- ⁹ 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>
- ¹⁰ Oregon Health Authority. Oregon Behavioral Risk Factor Surveillance System (BRFSS) race over-sample, 2015-2017.
- ¹¹ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta: 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.
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<http://www.iom.edu/Reports/2015/TobaccoMinimumAgeReport.aspx>
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- ¹⁹ 2017-2018 Oregon Tobacco Retail Enforcement Inspection Results, Oregon Health Authority.
- ²⁰ Oregon Health Authority. Oregon Healthy Teens, 2017.