



## THE ADMINISTRATION'S PLAN TO RESTRICT SOME FLAVORED E-CIGARETTES FAILS TO PROTECT KIDS FROM E-CIGARETTE INDUSTRY

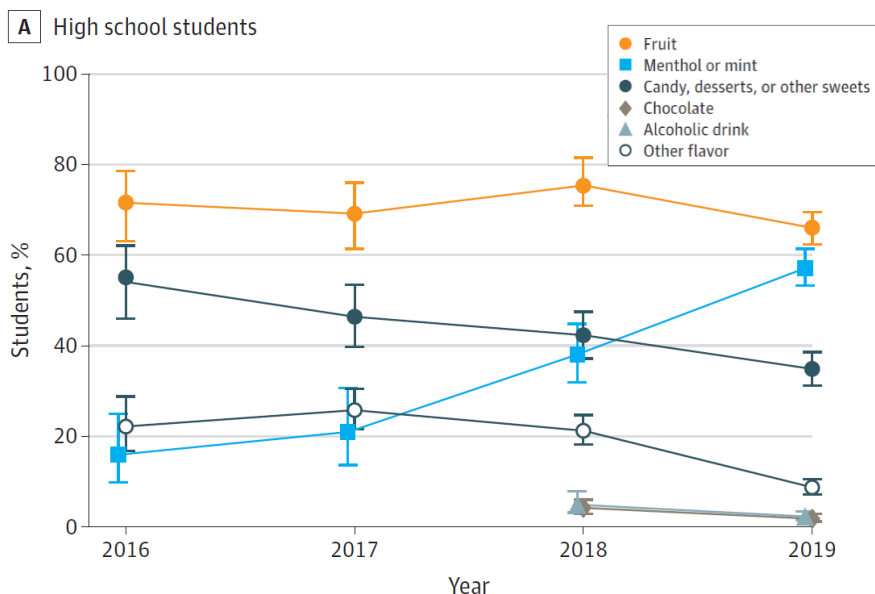
The Trump Administration's policy exempts all menthol and tobacco flavored e-cigarettes and only restricts flavors in some cartridge-based e-cigarettes, leaving flavored e-liquids in every imaginable flavor widely available. Only the elimination of all flavored e-cigarettes can end the worsening youth e-cigarette epidemic and stop e-cigarette companies from luring and addicting kids with flavored products.

This decision is a clear win for Juul, Altria and vape shops. Describing the policy to the media, President Trump said that while we have to protect families, "At the same time, it's a big industry. We want to protect the industry."<sup>1</sup> By failing to clear the market of all flavored e-cigarettes, this policy prioritizes the e-cigarette industry over the health of America's kids.

Youth e-cigarette use in the United States is a public health crisis. Rates have skyrocketed to what the U.S. Surgeon General and the FDA have called "epidemic" levels.<sup>2</sup> From 2017 to 2019, e-cigarette use among high school students more than doubled to 1 in 4 high schoolers (27.5%).<sup>3</sup> Altogether, over 5.3 million middle and high schoolers now use e-cigarettes.<sup>4</sup>

### Leaving menthol e-cigarettes on the market will not solve the youth e-cigarette epidemic. Menthol tobacco products are uniquely appealing to youth.

- Half (50.1%) of youth who have ever tried smoking initiated with menthol flavored cigarettes.<sup>5</sup> Over half (54%) of current youth smokers ages 12-17 smoke menthol cigarettes, compared to less than one-third of smokers ages 35 and older.<sup>6</sup> There is no reason to believe that menthol e-cigarettes are not equally appealing to kids—especially if they are the only available flavor for cartridge-based products.
- The tobacco industry has known for decades that menthol appeals to youth. Menthol cools and numbs the throat, reducing the harsh taste and irritation from nicotine, making it easier to start smoking, particularly for youth.<sup>7</sup> The FDA has concluded that menthol increases the number of teens who start smoking and who become regular smokers.<sup>8</sup>
- Data from the 2019 National Youth Tobacco Survey show that over half (57.3%) of high school e-cigarette users use mint or menthol flavored e-cigarettes. This is an increase from just 16% in 2016.<sup>9</sup>
- The evidence indicates that if any e-cigarette flavors are left on the market, kids will shift from one flavor to another. In November 2018, Juul removed other flavors – but not mint and menthol – from stores. In response, youth easily substituted mango and fruit with mint and menthol. From 2018 to 2019, youth use of fruit flavors fell, while youth use of mint and menthol flavors increased by 50%.<sup>10</sup>



**Exempting menthol will protect Juul, the company that created the youth e-cigarette epidemic.**

- Mint and menthol make up a large majority of Juul's sales, with estimates as high as 80%.<sup>11</sup> This plan will protect the profits and sales of Juul – the company that created the youth e-cigarette epidemic – rather than the health of America's kids.
- In Congressional testimony, Juul's co-founder James Monsees repeatedly described Juul's mint flavor as a "menthol-based flavor."<sup>12</sup> According to a *Wall Street Journal* report, Juul has considered renaming its mint flavored pods to a menthol variant.<sup>13</sup>
- Since Juul is already in compliance with this policy (it has stopped selling all of its flavors except tobacco and menthol), this plan can only benefit Juul. The policy will protect Juul's market share from its main competitors, like NJOY, Vuse and blu, which still sell pods in a variety of flavors.

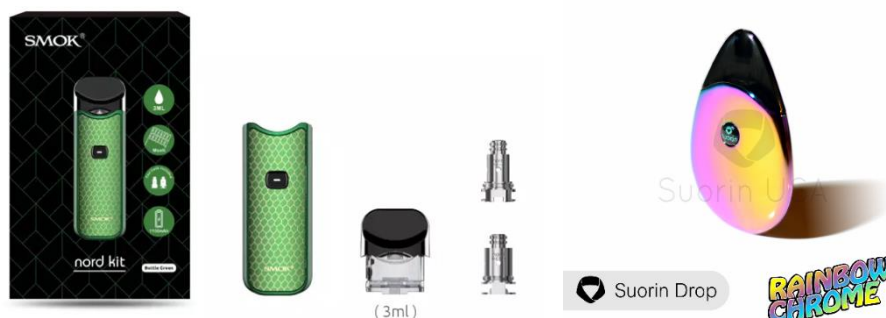
**The Administration's plan will leave thousands of kid-friendly e-liquids widely available.**

- There are over 15,000 available e-cigarette flavors,<sup>14</sup> but since the Administration's plan only addresses closed pod products, the vast majority of these flavors will still be available.
- Many of the most egregious kid-friendly flavors—like gummy bear, cotton candy, and s'mores—are primarily available as e-liquids, not pods, and will be exempt from this policy.



**The Administration's plan will exempt new refillable pod systems like Suorin and Smok that are becoming increasingly popular among kids.**

- Open systems are becoming much simpler and kid-friendly. Unlike Juul, which sells pre-filled, closed pods, newer devices like Suorin and Smok come with empty, refillable pods that can be filled with e-liquids of varying nicotine strengths and thousands of flavors that are exempt from the Trump Administration's policy.
- Data from the 2019 National Youth Tobacco Survey, published in *JAMA*, found that after Juul, Suorin and Smok are the most popular e-cigarette devices among high school students and are the preferred brands of more than one out of ten high school e-cigarette users (likely an underestimation\*).<sup>15</sup>



\* Suorin and Smok were not listed as response options on this question, so prevalence estimates only come from write-in response. Therefore, actual use rates are likely higher.

**The Administration's plan will exempt new disposable e-cigarettes—like Puff Bar, Mojo and Stig—which are becoming popular with youth.**

- FDA's guidance prioritizes enforcement of flavored, cartridge-based products, but explicitly states that this does not include disposable e-cigarettes ("An example of products that would not be captured by this definition include completely self-contained, disposable products").
- A 2019 study identified over 30 brands of disposable e-cigarettes. These products are similar in appearance to Juul, but are pre-charged, cheaper (some for less than \$5), available in a wide variety of flavors, and some have even higher nicotine concentrations.<sup>16</sup>



**The Administration's plan protects vape shops, which are a popular source for youth users.**

- Vape shops and online retailers are the most popular source for e-liquids, which are exempt from the Administration's new policy. These retailers should not be given special protection since there is clear evidence that they have inadequate protections to prevent sales to minors.
- New data from the 2019 Monitoring the Future Study shows that almost two-thirds (64.3%) of 10<sup>th</sup> graders report that it would be easy for them to get e-liquids.<sup>17</sup>
- According to the 2018 National Youth Tobacco Survey (NYTS), 16.5% of middle and high school e-cigarette users under 18 report obtaining e-cigarettes from a vape shop in the past month, compared to just 9.8% from a gas station or convenience store.<sup>18</sup>
- A study in *JAMA Pediatrics* found that in California, e-cigarette sales to minors violations are significantly higher in tobacco and vape shops than any other type of retailer, with 44.7% selling to underage buyers.<sup>19</sup>
- Studies have found that youth can successfully purchase e-cigarettes over the internet in 94 to 97 percent of their online purchase attempts.<sup>20</sup> Many online retailers do not have adequate age verification, with some retailers simply requiring purchasers to check a box affirming that they are over age 18 or 21 to enter the site.

**There is no credible evidence that flavored e-cigarettes help adults quit.**

- E-cigarettes have become increasingly popular among youth and young adults, while uptake has remained low among older adults. 27.5% of high school students are current e-cigarette users,<sup>21</sup> compared to just 3.2% of all adults.<sup>22</sup> 5.3 million middle and high school students are current e-cigarette users<sup>23</sup> and 8.1 million adults are current e-cigarette users (about 2.3 million of whom are young adults).<sup>24</sup> This means that about 40% of all e-cigarette users in the US are youth, and about 57% are under age 25.
- On the same day that news outlets reported the Administration's plan, the FDA filed a brief in the U.S. Court of Appeals for the Fourth Circuit stating that, "**the claim that vaping helps smokers quit in meaningful numbers remains unproven.**"<sup>25</sup> FDA is the federal agency charged with determining what products are effective at helping smokers quit.
- While the tobacco industry asserts that flavors play an important role in helping smokers to switch or quit, these assertions are unproven. No e-cigarette manufacturer has ever even applied to FDA with evidence that e-cigarettes are effective at helping smokers quit.
- Public health authorities in the U.S., including the CDC and the U.S. Preventive Services Task Force, have found that there is not enough evidence to recommend e-cigarettes for tobacco cessation.<sup>26</sup> A report from the highly respected National Academies of Science, Engineering and Medicine (NASEM) came to the same conclusion.<sup>27</sup>

- 
- <sup>1</sup> White House, Remarks by President Trump Before New Year's Eve Celebration, December 31, 2019, [https://www.whitehouse.gov/briefings-statements/remarks-president-trump-new-years-eve-celebration/?utm\\_source=link&utm\\_medium=header](https://www.whitehouse.gov/briefings-statements/remarks-president-trump-new-years-eve-celebration/?utm_source=link&utm_medium=header).
- <sup>2</sup> Office of the Surgeon General, "Surgeon General's Advisory on E-Cigarette Use Among Youth," December 18, 2018, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.
- <sup>3</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>4</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>5</sup> Ambrose, BK, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the American Medical Association*, published online October 26, 2015.
- <sup>6</sup> Villanti, A., et al., "Changes in the prevalence and correlates of menthol cigarette use in the USA, 2004-2014," *Tobacco Control*, published online October 20, 2016.
- <sup>7</sup> TPSAC, FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011, <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>. FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).
- <sup>8</sup> FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).
- <sup>9</sup> Leventhal, AM, et al., "Flavors of e-Cigarettes Used by Youths in the United States," *JAMA*, published online November 5, 2019.
- <sup>10</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>11</sup> Kaplan, S, et al., "Juul Replaces its CEO with a Tobacco executive," *New York Times*, September 25, 2019 <https://www.nytimes.com/2019/09/25/health/juul-vaping.html>
- <sup>12</sup> House Committee on Oversight and Reform, *Examining JUUL's Role in the Youth Nicotine Epidemic: Part II*, July 25, 2019, <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>.
- <sup>13</sup> Maloney J. "Juul Debates Pushing Back on E-Cigarette Ban," *Wall Street Journal*, September 12, 2019, <https://www.wsj.com/articles/juul-debates-pushing-back-on-e-cigarette-ban-11568327978?mod=djemwhatsnews>.
- <sup>14</sup> Zhu, S-H, et al., "Evolution of Electronic Cigarette Brands from 2013-2014 to 2016-2017: Analysis of Brand Websites," *Journal of Medical Internet Research*, 20(3), published online March 12, 2018.
- <sup>15</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>16</sup> Williams, R, "The rise of disposable JUUL-type e-cigarette devices," *Tobacco Control*, published online December 5, 2019.
- <sup>17</sup> Monitoring the Future, *Trends in Availability of Drugs as Perceived by 10<sup>th</sup> Graders*, <http://monitoringthefuture.org/data/19data/19drtbl16.pdf>.
- <sup>18</sup> Liu, ST, et al., "Youth Access to Tobacco Products in the United States, 2016-2018," *Tobacco Regulatory Science*, 5(6): 491-501, 2019.
- <sup>19</sup> Roeseler, A, et al., "Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops," *JAMA Pediatrics*, published online June 24, 2019.
- <sup>20</sup> Williams, RT, Derrick J, & Ribisl, KM, "Electronic cigarette sales to minors via the internet." *JAMA Pediatrics* 169(3):e1563, doi: 10.1001/jamapediatrics.2015.63, Epub March 2, 2015. Nikitin, D, Timberlake, DS, & Williams, RS, "Is the E-Liquid Industry Regulating Itself? A Look at E-Liquid Internet Vendors in the United States," *Nicotine & Tobacco Research* 18(10):1967-72, 2016.
- <sup>21</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>22</sup> Creamer, MR, et al., "Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018," *Morbidity and Mortality Weekly Report (MMWR)*, 68(45): 1013-1019, November 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6845a2-H.pdf>.
- <sup>23</sup> Cullen, KA, et al., "e-Cigarette Use Among Youth in the United States, 2019" *JAMA*, published online November 5, 2019.
- <sup>24</sup> Creamer, MR, et al., "Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018," *Morbidity and Mortality Weekly Report (MMWR)*, 68(45): 1013-1019, November 15, 2019, <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6845a2-H.pdf>. Number of adult e-cigarette users calculated using 2018 American Community Survey 1-Year Estimates, <https://www.census.gov/programs-surveys/acs>.
- <sup>25</sup> American Academy of Pediatrics et al., v. U.S. Food & Drug Administration, et al. Government's Opposition to the Motions for Stay Pending Appeal and Consent to the motion to Expedite Review, December 31, 2019.
- <sup>26</sup> King, BA, et al., "Awareness and Ever Use of Electronic Cigarettes Among U.S. Adults, 2010-2011," *Nicotine & Tobacco Research*, 15(9):1623-7, 2013. See also, King, BA, et al., "Trends in Awareness and Use of Electronic Cigarettes among U.S. Adults, 2010-2013," *Nicotine & Tobacco Research*, first published online September 19, 2014; U.S. Preventive Services Task Force, *Final Recommendation Statement: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*, May 2019, <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1;>
- <sup>27</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Public Health Consequences of E-Cigarettes*, Washington, DC: The National Academies Press, 2018, <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx> NASEM, *Public Health Consequences of E-Cigarettes*, 2018.