



April 5, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Becerra,

Our groups represent educators and administrators who, prior to the upending of the school year by COVID-19, were on the front lines of efforts to curb students' e-cigarette use. We write to urge you to support strong action by the Food & Drug Administration (FDA) to clear the market of flavored e-cigarettes. E-cigarettes are hooking a new generation of youth, thanks to thousands of kid-friendly flavors, slick marketing, and massive doses of nicotine. This dangerous epidemic has put millions of youth at risk and threatens decades of hard-fought progress in reducing youth tobacco use.

The education community has witnessed firsthand the devastating consequences of the e-cigarette epidemic, in terms of health and behavior changes among our students as well as disruptions in academic and extracurricular performance. In addition to the toll that the e-cigarette epidemic has taken on young people, school districts have been burdened with finding disciplinary, prevention and treatment solutions to mitigate the impact of the youth e-cigarette epidemic on the school environment. As a result, over 100 school districts across the country have taken legal action against JUUL and other e-cigarette manufacturers to recover the costs of prevention programs, counseling, and treatment programs for addicted students.¹ With the strain of limited resources and COVID-19 already weighing down upon school districts, the e-cigarette epidemic is not a crisis the education community can solve on its own—we need strong federal action to clear the market of these flavored, kid-friendly products.

We were disappointed in the weak enforcement policy implemented by the FDA last year that continues to allow all menthol-flavored e-cigarettes, flavored e-liquids and disposable e-cigarettes like Puff Bar to remain widely available. As a result, youth e-cigarette use remains at epidemic levels and youth have quickly migrated to the flavored products that remain on the market. According to the National Youth Tobacco Survey (NYTS), use of disposable e-cigarettes increased by 1,000% (from 2.4% to 26.5%) among high school e-cigarette users and 400% (from 3.0% to 15.2%) among middle school e-cigarette users from 2019 to 2020. The same survey also found that 37% of youth e-cigarette users reported using menthol-flavored products.² By not clearing the market of all flavored e-cigarettes, the FDA missed the opportunity to make far greater progress in reducing youth use.

¹ Walker, T, "Lawmakers Get Serious About Teen Vaping, But Politics May Derail Progress," *NEA News*, March 12, 2020, <https://www.nea.org/advocating-for-change/new-from-nea/lawmakers-get-serious-about-teen-vaping-politics-may-derail>.

² Wang, TW, et al., "E-cigarette Use Among Middle and High School Students – United States, 2020," *MMWR*, Volume 69, September 9, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

The FDA now has another opportunity to protect kids from flavored e-cigarettes. FDA is currently reviewing Premarket Tobacco Product Applications (PMTAs) for e-cigarettes and must determine whether these applications provide sufficient evidence that specific e-cigarette products are “appropriate for the protection of the public health.” The FDA has the authority to remove all flavored e-cigarettes from the market pending its review and to deny a marketing order for any e-cigarette that has increased or is likely to increase youth use of tobacco products, including flavored e-cigarettes. We urge the FDA to deny PMTAs for any flavored e-cigarette, including mint- or menthol-flavored products. The evidence is clear that the youth e-cigarette epidemic is driven largely by the appeal of flavored products, and therefore no flavored e-cigarette can meet the public health standard. Data from the 2020 NYTS found that eight out of ten (82.9%) middle and high school e-cigarette users are using flavored products.³ As long as any flavored e-cigarettes remain on the market, our students will find a way to get them and this public health crisis will not end.

FDA has indicated that products with the largest market share will receive expedited treatment in the review process. Because JUUL continues to have the largest share of the e-cigarette market, and therefore is undergoing expedited review, we write to express our strong opposition to authorization of any JUUL product. The skyrocketing rate of youth e-cigarette use that sparked national alarm was driven by JUUL, which became the most popular e-cigarette during the peak of the youth epidemic. JUUL delivers a flavored nicotine hit in a sleek, high-tech device that resembles a USB flash drive, which makes it easy to disguise the product from parents and teachers. According to the CDC, “The rise in e-cigarette use during 2017-2018 is likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavors that appeal to youths.”⁴ JUUL’s popularity among youth was also fueled by its egregious, youth-targeted marketing launch.⁵

JUUL is not only responsible for an epidemic of youth use, but an epidemic of youth addiction. JUUL delivers a powerful dose of nicotine using nicotine salt technology, which according to the Surgeon General, allows users to inhale high levels of nicotine more easily and with less irritation than other e-cigarettes. As a result, it is easier for young people to initiate the use of nicotine with products like JUUL.⁶ Research shows that an increasing proportion of youth are using JUUL and other e-cigarettes on a frequent or daily basis, a strong indicator of serious addiction.⁷ We are concerned about the long-term impact these products will have on our students’ health and education. According to the Surgeon General, nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development, particularly the parts of the brain responsible for attention, learning, mood and impulse control.⁸

³ Wang, TW, et al., “E-cigarette Use Among Middle and High School Students – United States, 2020,” *MMWR*, Volume 69, September 9, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

⁴ CDC, “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018,” *MMWR*, 67(45):1276-1277. https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w.

⁵ Jackler, RK, et al., “JUUL Advertising Over its First Three Years,”

http://tobacco.stanford.edu/tobacco_main/publications/JUUL_Marketing_Stanford.pdf.

⁶ 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>.

⁷ Wang, TW, et al., “E-cigarette Use Among Middle and High School Students – United States, 2020,” *MMWR*, Volume 69, September 9, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

⁸ HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>. See also: CDC Office on Smoking and Health, “Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults,” March 2019.

JUUL continues to be a widely popular e-cigarette brand among youth⁹ and is threatening decades of progress in reducing youth tobacco use. There is every reason to believe that as long as the FDA allows it to stay on the market, JUUL will continue to fuel the youth e-cigarette epidemic. We urge FDA to deny a PMTA for any JUUL product.

While it is essential for FDA to clear the market of flavored e-cigarettes, and to prevent their reemergence through the premarket review process, such actions should be part of a broader FDA policy to prohibit all flavored tobacco products, including menthol cigarettes. For decades, the tobacco industry has used menthol cigarettes to hook new smokers. Menthol cools and numbs the throat, reducing the harsh taste and irritation from tobacco, and making it easier to start smoking, particularly for youth.¹⁰ In 2011, the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) concluded that menthol cigarettes increase the number of children who experiment with cigarettes and the number of children who become regular smokers, increasing overall youth smoking. TPSAC also determined that young people who initiate using menthol cigarettes are more likely to become addicted and become long-term daily smokers.¹¹ Researchers recently estimated that between 1980 and 2018, menthol cigarettes were responsible for 10.1 million additional new smokers, or over 265,000 new smokers each year over the 38-year period.¹² While we have made tremendous progress in reducing overall youth smoking, menthol cigarettes continue to be used by half of all high school smokers.¹³ Thus, removal of flavored e-cigarettes from the market should be part of a broader agenda that prioritizes regulations to prohibit menthol cigarettes and flavors in all tobacco products.

The beneficial impact that removing flavored tobacco products from the market will have on our children's health and their education is immeasurable.

Respectfully submitted,

American Federation of School Administrators
American Federation of Teachers
American School Health Association
Association of School Business Officials International (ASBO)
Association of Schools and Programs of Public Health
Campaign for Tobacco-Free Kids
National Association of Elementary School Principals
National Association of School Nurses
National Association of Secondary School Principals
National Education Association
PTA
The School Superintendents Association

⁹ Miech, Richard, et al., "Trends in Use and Perceptions of Nicotine Vaping Among US Youth From 2017 to 2020," *JAMA Pediatrics*, published online December 15, 2020, <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2774132>.

¹⁰ Tobacco Products Scientific Advisory Committee (TPSAC), FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011. FDA. *Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes* (2013).

¹¹ TPSAC, FDA, "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations, 2011.

¹² Le, TT, "An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018," *Tobacco Control*, published online February 25, 2021.

¹³ Wang, TW, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019," *MMWR* 68(12), December 6, 2019, <https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf>.