



January 14, 2022

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Sent by e-mail

Re: Need for FDA action on premarket applications for flavored e-cigarette products

Dear Director Zeller:

Four months have passed after the federal court-ordered deadline and FDA has not taken action on applications that are pending for flavored e-cigarette products with the largest youth market share. As a result, flavored e-cigarettes remain widely available and still dominate retail sales, youth use of flavored e-cigarettes remains at unacceptable levels, and the evidence of the impact of the availability of flavored e-cigarettes on youth continues to grow, while the evidence of the benefit of flavored e-cigarettes on adult smoking cessation remains inconclusive.

Therefore, we write to urge the U.S. Food and Drug Administration (FDA) to expedite decisions on the premarket tobacco product applications (PMTAs) still pending before the agency involving the flavored e-cigarette products, including those with menthol flavoring and, based on the best available scientific evidence, deny the pending applications for all non-tobacco flavored e-cigarettes in order to protect the nation's young people from the health harms of these products.

On December 17, 2021 the Campaign for Tobacco-Free Kids issued a [report](#) entitled an "E-cigarette Market Update," (TFK Report), demonstrating that an alarming variety of youth-appealing flavored e-cigarette products are still available online and in stores across the nation *four months after the September 9, 2021 court-ordered deadline*, after which products remaining on the market without the required marketing orders were to be subject to FDA enforcement.

In her September 9, 2021 statement on FDA's public health review of new tobacco products, Acting Commissioner Woodcock recognized the "public health threat posed by the well-documented, alarming levels of youth use" of flavored e-cigarette products.¹ Although

¹ Statement of Janet Woodcock, M.D., *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 million 'Deemed' New Tobacco Products Submitted*, at 1 (Sept. 9, 2021), <https://www.fda.gov/news-events/press-announcements/fda-makes-significant-progress-science-based-public-health-application-review-taking-action-over-90> (Woodcock Statement). FDA subsequently

FDA has issued marketing denial orders for over one million flavored products found not “appropriate for the protection of the public health,” the TFK Report documents the market reality that flavored products of the kind that have fueled the continuing epidemic of e-cigarette use among kids remain widely available and free of any FDA enforcement actions.

The report summarizes the results from a scan of five top online e-cigarette retailers and retail assessments conducted in 43 stores in eight cities across the country (Denver, CO; Detroit, MI; Los Angeles, CA; Portland, ME; Portland OR; Seattle, WA; Tempe, AZ; and Washington, D.C.). The brick-and-mortar stores included 28 gas stations or convenience stores and 15 vape/tobacco shops. The key findings include:

- **The most popular e-cigarette brands among youth are still available online and in stores**, including Puff Bar, Vuse Alto, SMOK, JUUL and Suorin.
- **The top-selling e-cigarette brands, including JUUL, Vuse Alto, NJOY and blu, remain widely available in youth-appealing menthol flavors, in stores across the country.** Other data shows that among high school users of flavored e-cigarettes, 30% report using menthol products. Sales of menthol products have increased significantly since FDA issued its 2020 Guidance prioritizing enforcement against flavored cartridge-based e-cigarettes, but exempted menthol cartridge products from that policy.
- **Dozens of kid-friendly flavored e-liquids remain widely available online and in stores.** Flavors sold online include fruit flavors like Banana Dragonberry, Watermelon Wave, Mango Tango and many more, as well as sweet and dessert flavors, like Blue Cotton Candy and Funnel Cake, and drink flavors like Fruit Punch and Orange soda. Flavored e-liquids were also available in brick-and-mortar stores in varieties like Green Apple, Cola, Peachy Rings and Tropical Fruit. These flavored e-liquids can be used with devices that are popular with youth, like SMOK and Suorin.
- **Flavored, disposable e-cigarettes, surging in popularity among youth, are available online and in stores.** An assortment of disposable e-cigarettes were found online in sweet/dessert flavors like Gummy Bear and Vanilla Strawberry Custard, and drink flavors like Cola Ice and Cherry Lemonade. Disposable e-cigarettes were also found in stores in every city surveyed, including flavors such as Coconut Pineapple Smoothie, Strawberry Ice Cream, Gummy Bear, Mango Slushee and Blue Razz Lemonade. Sales of disposable e-cigarettes have exploded in the last two years and over 55% of high school e-cigarette users report using disposable products, with Puff Bar, featured in a variety of flavors, now the most popular e-cigarette among youth. As we have discussed in previous [letters](#) to FDA, Puff Bar and other disposables are now

announced that it had issued additional MDOs and that MDOs had been issued for a total of over 1,167,000 flavored products.

being marketed with “tobacco-free” (synthetic) nicotine in a transparent effort to evade FDA regulation.

The court’s order in *American Academy of Pediatrics, et al. v. FDA*² was intended to end the years-long regulatory “holiday” (the court’s term) enjoyed by new tobacco products during which their products were allowed to stay on the market without the marketing authorization required by statute. Significantly, the court found a direct connection between this “holiday” and the e-cigarette epidemic among youth, concluding that the agency had allowed manufacturers to “continue to advertise and sell products that are addictive and that target a youth market”³ But the Tobacco-Free Kids Report shows that, despite the court’s order, the marketing of youth-appealing flavored products continues.

Consistent with the findings of the TFK Report, on December 10, 2021 the Centers for Disease Control Foundation issued its latest findings tracking the sales of e-cigarettes. This Report, documenting sales from 2017 through September 2021, shows that, since the FDA issued its enforcement policy, effective February 2020, prohibiting the sale of flavored prefilled cartridges, with the exception of tobacco and menthol flavored prefilled cartridges and single use disposable products, sales of non-tobacco flavored e-cigarettes rose by 86.1% from 9.7 million to 18.1 million units. The Report demonstrates that the increase was largely driven by the increase in the sale of menthol prefilled cartridges (an increase of 52.6%) and a 244.6% increase in the sale of flavored disposable products. Since 2019, menthol e-cigarette sales rose from 13% of the market to 40.4% in 2021. The Report also shows that the sales of menthol flavored e-cigarettes at an all-time high in July, August and September of 2021.

The continued widespread availability and sale of flavored products is occurring even as the latest research further demonstrates the threat of flavored products to young people, as well as the absence of evidence that such products confer any public health benefits by helping smokers to stop smoking.

In December, data was released from the 2021 Monitoring the Future survey. While the survey showed declines in youth e-cigarette use in 2021, one in five high school seniors (19.6%) are still current e-cigarette users—about the same level as in 2018 (20.9%) when the Surgeon General and FDA first declared youth e-cigarette use an epidemic.⁴ The survey also found that youth continue to report that e-cigarettes are easy to access, with over half (54.6%) of 10th graders reporting that it would be easy to get vaping devices if they wanted to.⁵

In addition to data from the National Youth Tobacco Survey showing a shift to youth use of disposable and menthol-flavored products, other research confirms that the e-cigarette products that remain on the market continue to be popular among youth. A national online survey of youth and young adults conducted in May 2020 found that among those under age 21

² 379 F. Supp. 3d 461 (D. Md. 2019); 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass’n of America*, 812 F. App’x 128 (4th Cir. 2020)

³ 379 F. Supp. at 492.

⁴ University of Michigan, 2021 Monitoring the Future Study, Nicotine Vaping: Trends in 12 Month Prevalence of Use in Grades 8, 10, and 12, http://monitoringthefuture.org/data/21data/VapNic/VapNic_jsFigures.htm.

⁵ University of Michigan, 2021 Monitoring the Future Study, *Table 16: Trends in Availability of Drugs as Perceived by 10th Graders*, <http://monitoringthefuture.org/data/21data/table16.pdf>.

who had ever used e-cigarettes, 54.4% of past-30 day users used disposable products and 45.3% used pod/cartridge-based products. Specifically, 85.9% had used JUUL, 66.8% had used Puff Bar, 30.1% had used Stig (a disposable), 27% had used Suorin, and 25.8% had used Smok. Among those who used pod/cartridge-based products, the most commonly used flavors in the past 30 days were mint/menthol (48.2%), fruit (27.4%) and sweet/dessert/candy (24.4%). Among disposable users, mint/menthol and fruit were tied as the most popular flavors (51.6%), followed by sweet/dessert/candy (24.7%).⁶

Research also continues to show that youth e-cigarette use increases the risk for trying regular cigarettes. A systematic review and meta-analysis of 25 studies, published in September, found that youth who had used e-cigarettes had three times the risk of ever trying cigarettes and more than two times the risk of current smoking.⁷ This study was cited in the World Health Organization (WHO) Global Tobacco Control Report released in July 2021 that warned “[a] non-smoker who uses ENDS may become addicted to nicotine and find it difficult to stop using ENDS and/ or become addicted to conventional tobacco products.”⁸

While there is overwhelming evidence of the serious risks e-cigarettes pose to young people, there is little evidence demonstrating that e-cigarettes are effective in helping smokers stop smoking. Leading public health authorities in the U.S. have found that there is not enough evidence to recommend e-cigarettes for cigarette smoking cessation.⁹ The World Health Organization reached the same conclusion in its July 2021 report.¹⁰

More recent research affirms these conclusions. A study published by Pierce and colleagues in October 2021 analyzed FDA’s Population Assessment of Tobacco and Health (PATH) survey data to evaluate the relationship between switching to e-cigarettes or another tobacco product and relapse to cigarette smoking. The study found that those who switched to e-cigarettes, or another tobacco product, had significantly higher relapse rates than those who quit without switching. Overall, findings from this study suggest that e-cigarettes are not associated with long-term successful cigarette smoking cessation.¹¹

⁶ Gaiha, SM, et al., “E-cigarette devices, brands, and flavors attract youth: Informing FDA’s policies and priorities to close critical gaps,” *Addictive Behaviors*, 126 (2022) 107179.

⁷ Yoong, SL, et al., “Association between electronic nicotine delivery systems and electronic non-nicotine delivery systems with initiation of tobacco use in individuals aged <20 years. A systematic review and meta-analysis,” *PLOS One*, 16(9): e0256044. Published online September 8, 2021.

⁸ WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021.

⁹ HHS, Office of the Surgeon General, “Smoking Cessation: A Report of the Surgeon General,” 2020 <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>; United States Preventive Services Task Force, “Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons, Final Recommendation Statement”, 2021 <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions>; National Academies of Sciences, Engineering, and Medicine (NASSEM), *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>.

¹⁰ WHO report, *supra* note 8.

¹¹ Pierce, John, et al., “Incidence of Cigarette Smoking Relapse Among Quitters Who Switched to E-Cigarettes or Other Tobacco Products: A Cohort Study,” *JAMA Network Open*. 2021;4(10).

Therefore, we urge FDA to take the following steps, in conducting the premarket review of new tobacco products, to protect young people from the continuing threat of highly-addictive, flavored e-cigarettes:

- (1) Complete public health review of all e-cigarette products without further delay;
- (2) Issue marketing denial orders for all non-tobacco flavored products, including menthol-flavored products, based on the continuing adverse impact of those products on public health, and particularly their impact on youth;
- (3) Immediately prioritize enforcement against e-cigarette products that continue to be sold without marketing authorization if they are (a) flavored products with the highest market shares or (b) products with the highest prevalence of youth usage; and
- (4) Identify, on an on-going basis, the products, and their flavors, that receive MDOs, including all menthol-flavored products.

Finally, as we have argued in prior [letters](#) to FDA, the agency must take action to prevent the continued evasion of FDA regulation through the marketing of synthetic nicotine products like Puff Bar. Action against such products is essential to protect the premarket review process from wholesale evasion by e-cigarette companies to the detriment of public health.

Thank you for your consideration of our views.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative