

JOSH STEIN
ATTORNEY GENERAL



June 28, 2021

Via E-Mail and U.S. Mail

The Honorable Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Woodcock:

I write to urge the FDA to act swiftly to take strong action to protect young people from harmful e-cigarette products. As the chief law enforcement officer in North Carolina, I have fought for consumers and taken legal action against JUUL and a number of other e-cigarette companies that have marketed these dangerous products to kids in our state. During the course of our investigations and litigation, we have learned in detail just how harmful these products are, how they were designed, marketed and sold to appeal to young people, and how damaging they have been to families all across the country.

The FDA should act to the full extent of its authority and (1) prohibit all non-tobacco flavors—including menthol—in e-cigarettes, (2) limit the amount of nicotine in e-cigarette products, and (3) impose marketing restrictions to prevent youth appeal.

The country is in the middle of an e-cigarette crisis. The explosion of e-cigarette products on the market over the last decade has given rise to an epidemic of youth nicotine use.¹ E-cigarette use among high school students increased dramatically, from 1.5% in 2011 to 11.7% in 2017, and then to 27.5% in 2019.² 2020 data show that 19.6% of high school students have used an e-cigarette in the past 30 days, with 38.9% of those reporting e-cigarette use on 20 or more days of the past 30 days, and 22.5% reporting daily use. That's 1.3 million high schoolers regularly using e-cigarettes.

¹ See 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>.

² Cullen KA, Gentzke AS, Sawdey MD, Chang JT, Anic GM, Wang TW, et al. e-Cigarette Use Among Youth in the United States, 2019. JAMA. 2019 Dec 3;322(21):2095-2103.

The rapid growth in underage e-cigarette use has been facilitated by, among other things, flavor additives that make these products more appealing to youth; the rise of high-nicotine formulas that addict people more quickly; and relentless marketing, including on social media.

Nicotine has particularly harmful effects on the developing brain, with adolescents being significantly more likely to become addicted to nicotine than adults.³ Adolescent nicotine consumption is also associated with numerous adverse physical outcomes such as nicotine poisoning and toxicity, as well as mental health and behavioral problems like major depressive disorder, academic problems, antisocial personality disorder, and addiction to other substances.⁴ Moreover, use of e-cigarettes is associated with higher susceptibility to later use of combustible cigarettes.⁵

Now is the time for the FDA to take decisive action to stem the tide of youth nicotine addiction. The FDA should use its authority to address and significantly reduce the youth epidemic of nicotine use in America in a comprehensive way, starting with the following actions:

1. Ban Non-Tobacco Flavors, Including Menthol

The FDA should ban all non-tobacco flavors—including menthol—from e-cigarettes.

We know that the use of non-tobacco flavors in e-cigarettes is a big draw for kids. Young people are more likely to report interest in trying an e-cigarette if it is flavored, with e-cigarette “taste” being one of the top reasons why teens start using e-cigarettes.⁶ More than 80% of adolescents using e-cigarettes use non-tobacco-flavored e-cigarettes, and the most often used flavors are fruit, mint, and menthol.⁷

Critically, after a number of non-tobacco-flavored e-cigarette products were pulled from the market in recent years—including after the FDA issued enforcement priorities for e-cigarettes in January 2020—we witnessed a surge in popularity among youth of menthol and other mint-based flavors,⁸ demonstrating that menthol flavor carries a danger of underage use similar to that of more obviously youth-oriented flavors.

³ Yuan M, Cross SJ, Loughlin SE, Leslie FM. Nicotine and the adolescent brain. *J Physiol (Lond)*. 2015;593(16):3397-3412.

⁴ Douglass B, Solecki S, Fay-Hillier T. The Harmful Consequences of Vaping: A Public Health Threat. *J Addict Nurs*. 2020;31(2):79-84; Gaiha SM, Halpern-Felsher B. Escalating Safety Concerns Are Not Changing Adolescent E-Cigarette Use Patterns: The Possible Role of Adolescent Mental Health. *Journal of Adolescent Health*. 2020;66(1):3-5; Gaiha SM, Halpern-Felsher B. Public Health Considerations for Adolescent Initiation of Electronic Cigarettes. *Pediatrics*. 2020;145(Suppl 2):S175-S180; Obisesan OH, Mirbolouk M, Osei AD, et al. Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System, 2016-2017. *JAMA Netw Open*. 2019;2(12):e1916800.

⁵ Berry KM, Fetterman JL, Benjamin EJ, Bhatnagar A, Barrington-Trimis JL, Leventhal AM, et al. Association of electronic cigarette use with subsequent initiation of tobacco cigarettes in US youths. *JAMA Network Open*. 2019;2(2):e187794-e.

⁶ King BA. Flavors Are a Major Driver of the Youth E-Cigarette Epidemic. *Am J Public Health*. 2020;110(6):773-774.

⁷ Ambrose BK, Day HR, Rostron B, Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014, *JAMA Research Letter*, 2015;314(17):1871-1873; King BA. Flavors Are a Major Driver of the Youth E-Cigarette Epidemic. *Am J Public Health*. 2020;110(6):773-774.

⁸ Diaz MC, Donovan EM, Schillo BA, Vallone D. Menthol e-cigarette sales rise following 2020 FDA guidance. *Tobacco Control*. Published online September 23, 2020; Ali FRM, Diaz MC, Vallone D, et al. E-cigarette Unit Sales, by Product and Flavor Type — United States, 2014–2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1313–1318.

In addition, at a recent June 23, 2021, hearing on youth vaping before the House Oversight Committee, you noted that: “Menthol has additional properties . . . that I believe potentiate the effects of nicotine addiction and make it harder to stop either vaping or smoking. And so it’s, to my mind, like actually having a higher concentration of nicotine in whatever delivery system.”⁹

The FDA should act upon the large body of research that shows adding flavors other than tobacco to e-cigarettes poses a grave risk to health of children. The FDA should use its authority to protect our youth by banning e-cigarettes offered in menthol or any other non-tobacco flavor.

2. Limit Nicotine Amounts

In addition to prohibiting flavored e-cigarette products, the FDA should limit the amount of nicotine in e-cigarettes.

Research shows that higher amounts of nicotine are related to greater likelihood of becoming addicted and dependent.¹⁰ And with the advent of Juul’s 5% nicotine salt formula, we saw a “nicotine arms race” that resulted in extremely powerful and addictive e-cigarette products flooding the market and quickly addicting young people who had never used a tobacco product before.¹¹

Other countries have tackled this problem by imposing limits on the amount of nicotine in cigarettes, and the FDA should follow suit. For instance, the United Kingdom allows only 20mg/mL nicotine; by contrast, in the United States, Juul’s 5% product delivers a staggering 59mg/mL nicotine.¹²

In addition to limiting the amount of nicotine in e-cigarettes, the FDA should also ensure that companies do not game or circumvent nicotine percentage limits by manipulating the e-cigarette device or formula in a way that delivers more nicotine per puff, as some contend JUUL considered doing with a “turbo” product designed to evade nicotine limits in the European market.¹³

3. Restrict Marketing that Attracts Youth

The FDA should also use its authority to ensure e-cigarette companies and retailers do not market in ways that entice youth.

⁹ <https://www.c-span.org/video/?512820-1/hearing-underage-vaping-legislation>

¹⁰ Goldenson, NI, Leventhal, AM, Stone, MD, McConnell, RS, Barrington-Trimis, J Associations of E-Cigarette Nicotine Concentration and Subsequent Cigarette Smoking and Vaping Levels in Adolescents JAMA Pediatrics, 2017 December 01, 171(12), 1192-1199.

¹¹ See Jackler RK, Ramamurthi D. “Nicotine Arms Race:” JUUL and the high nicotine product market. Tob Control. 2019; 28; 623-628.

¹² *Id.*

¹³ See Sairam V. Jabba, Sven-Eric Jordt, Turbocharged Juul device challenges European tobacco regulators, European Respiratory Journal Aug 2020, 56 (2) 2002430.

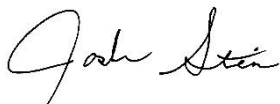
Research shows that marketing influences decision making by young people and is a significant reason young people use e-cigarettes.¹⁴ Adolescents are particularly susceptible to marketing and advertising, and exposure to e-cigarette marketing is associated with lower perceptions of e-cigarette-related risks, including risk of addiction.¹⁵

The use of the Internet and social media to market e-cigarettes heightens the problem as it greatly increases the reach and opportunity of e-cigarette manufacturers to interact with young consumers.¹⁶ And the use of social media and “influencers” can be especially pernicious for youth given that tobacco marketing messages are more effective when they appear to come from peers rather than the manufacturer.¹⁷

Accordingly, the FDA should impose restrictions on e-cigarette companies that ensure marketing materials are not attractive to youth and that youth are not bombarded with messages encouraging them to use these products. In addition to more traditional marketing restrictions, the FDA should also closely examine the digital marketing landscape, including website advertising and the use of social media platforms like Facebook, Instagram, Snapchat, and TikTok, which deliver nicotine product messaging literally into the hands of America’s youth.

North Carolina will continue to exercise its jurisdiction under state law to do everything possible to keep our kids safe. But the FDA has the authority to effect broader systemic change in response to the youth nicotine epidemic. An entire generation of youth is—right now—being introduced to nicotine through e-cigarettes, and we must protect them. Now is the time for the FDA to take decisive action to rein in these harmful practices before more irreversible damage to public health is done.

Sincerely,



Josh Stein

¹⁴ Marynak K, Gentzke A, Wang TW, Neff L, King BA. Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014–2016. *MMWR Morb Mortal Wkly Rep.* 2018;67(10):294-299.

¹⁵ Collins L, Glasser AM, Abudayyeh H, Pearson JL, Villanti AC. E-Cigarette Marketing and Communication: How E-Cigarette Companies Market E-Cigarettes and the Public Engages with E-cigarette Information. *Nicotine Tob Res.* 2019;21(1):14-24; Pokhrel P, Fagan P, Kehl L, Herzog TA. Receptivity to e-cigarette marketing, harm perceptions, and e-cigarette use. *Am J Health Behav.* 2015;39(1):121-131; McKelvey, K., Baiocchi, M., Ramamurthi, D., McLaughlin, S., Halpern-Felsher, B. Youth say ads for flavored e-liquids are for them. *Addictive Behaviors.* 2019 Apr;91:164-170; Vogel EA, Ramo DE, Rubinstein ML, et al. Effects of Social Media on Adolescents’ Willingness and Intention to Use E-Cigarettes: An Experimental Investigation. *Nicotine Tob Res.* Published online January 8, 2020.

¹⁶ Jackler, Robert K., Vanessa Y. Li, Ryan A. L. Cardiff, and Divya Ramamurthi. “Promotion of Tobacco Products on Facebook: Policy versus Practice.” *Tobacco Control* 28, no. 1 (2019): 67–73.

¹⁷ Sepe E, Ling PM, Glantz SA. Smooth moves: bar and nightclub tobacco promotions that target young adults. *Am J Public Health.* 2002;92(3):414-9.

CC: The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Mitch Zeller
Director
Center for Tobacco Products
Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002