



U.S. PIRG’s comment in response to the Food and Drug Administration’s Draft Guidance: “Modifications to Compliance Policy for Certain Deemed Tobacco Products”

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Efforts laid out in the draft guidance are not bold enough and not quick enough. The FDA should prohibit all flavored e-cigarettes, and other flavored tobacco products, and remove e-cigarettes without premarket approval from the market until they undergo the legally required public health review.

Addictive and damaging to kids

Tobacco use is the leading cause of preventable death and disease in the United States.¹ Nearly 90 percent of cigarette smokers start smoking by their eighteenth birthday.² Restricting youth access and appeal to tobacco products is critical to reducing the strain that tobacco use puts on Americans’ health.

E-cigarettes entered the U.S. marketplace around 2007 and since 2014 have been the most commonly used tobacco product among youth in the U.S.³ As the FDA notes in its proposed guidance, the National Youth Tobacco Survey showed a drastic rise in e-cigarette use among young people from 2017-2018, with use surging by nearly 80 percent among high schoolers in one year.⁴ The U.S. Surgeon General considers e-cigarette use among young people an epidemic.⁵

¹ Gentzke AS, et al. “Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018,” MMWR Morbidity and Mortality Weekly Report (MMWR) Rep 2019; 68:157–164. DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>.

² Centers for Disease Control and Prevention, *Youth and Tobacco Use*, accessed 28 April 2019 at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/youth_data/tobacco_use/index.htm.

³ Giovenco, D. P. et al, “E-Cigarette Market Trends in Traditional U.S. Retail Channels, 2012-2013” *Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco*, 17(10), 1279–1283. doi:10.1093/ntr/ntu282, 26 December 2014; See note 1.

⁴ Food and Drug Administration, *Guidance for Industry: Modifications to Compliance Policy for Certain Deemed Tobacco Products*, 14 March 2019.

⁵ Office of the Surgeon General, *Surgeon General’s Advisory on E-cigarette Use Among Youth*, 18 December 2018.

E-cigarettes almost always contain nicotine, an addictive drug that can impact learning, memory and attention among adolescents.⁶ It can also contribute to mood disorders and increased risk of future addiction to other dangerous substances.⁷ Research also suggests that young people using e-cigarettes are more likely than non-users to start smoking combustible cigarettes. A meta-analysis of recent studies shows that young adults who vape are 3 times more likely than non-users to start smoking cigarettes.⁸

The immediate health risks posed by e-cigarette use among America's youth warrant actions beyond what the FDA has proposed in its draft guidance.

The Food and Drug Administration should pull e-cigarettes without premarket approval off the market until they undergo the required public health review.

E-cigarettes are on the market right now without having gone through the FDA's legally required public health review.

Pursuant to the Family Smoking Prevention and Tobacco Control Act (FSPTCA), the FDA has regulated cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products since 2009.⁹ In 2016, the FDA extended this authority to include e-cigarettes.¹⁰

The FSPTCA requires FDA to review a tobacco product before authorizing its marketing based on the ingredients and design of the product, its health risks, and the potential appeal to youth and people who don't currently use tobacco products.¹¹ The agency allowed e-cigarettes to bypass this review by exercising "enforcement discretion," and as a result opened Pandora's box.¹² E-cigarette companies are marketing and selling their products with little to no oversight.

The FDA extended the deadline for e-cigarette makers to submit applications for review until 2022, but recently proposed moving the date up to August 8th, 2021 given concerns about the rise in use among young people.¹³ Leaving e-cigarettes on the market without proper review and regulation could result in millions more young people getting hooked on nicotine. The products

⁶ Ibid.

⁷ Office of the Surgeon General, "Know the Risks: E-cigarettes and Young People," accessed 22 April 2019 at <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html>

⁸ Soneji, S et al, "Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults: A Systematic Review and Meta-analysis," *JAMA pediatrics*, 171(8), 788–797 doi:10.1001/jamapediatrics.2017.1488 26 June 2017; Soneji, S "Errors in Data Input in Meta-analysis on Association Between Initial Use of e-Cigarettes and Subsequent Cigarette Smoking Among Adolescents and Young Adults," *JAMA Pediatrics*, January 2018.

⁹ FDA, *Family Smoking Prevention and Tobacco Control Act - An Overview*, updated 31 October 2018, accessed at: <https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm246129.htm>

¹⁰ FDA, *The Facts on the FDA's New Tobacco Rule*, 16 June 2016, accessed at: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm506676.htm>

¹¹ Ibid.

¹² Scott Gottlieb and Alex M. Azar, "The future of e-cigarettes depends on the industry's willingness to protect teens," *Washington Post*, 20 March 2019.

¹³ FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars*, 13 March 2019.

will remain on the market even after e-cigarette companies submit their applications for review, and that review process could take years.¹⁴

The FDA should take e-cigarettes without premarket approval off the market until they are properly reviewed and regulated.

The Food and Drug Administration should prohibit all flavored e-cigarettes and other flavored tobacco products because they attract kids

As the FDA notes in the draft guidance, there is significant evidence that flavored e-cigarettes attract and hook kids on the products. According to the agency's own analysis of the 2016-2017 (Wave 4) Population Assessment of Tobacco and Health (PATH) Study, 96.1 percent of users aged 12-17 reported that they used a flavored e-cigarette the first time they tried the product, and 70.3 percent of current youth users said that they used e-cigarettes "because they come in flavors I like."¹⁵

Although the agency is proposing to limit the sales of many fruit and candy flavored e-cigarettes, the proposal still leaves appealing flavors available for sale, and many avenues, like online sales, open. For example, the FDA will not include mint and menthol flavored products in its proposed restrictions. Studies show that mint and menthol are popular flavors among young people using e-cigarettes. According to the agency's analysis, mint and menthol ranked fourth most popular in a combined response option among e-cigarette users aged 12-17.¹⁶ A Truth Initiative survey also found that mint was a popular flavor among Juul users who used the device in the past 30 days, a finding that was consistent among users aged 12-24.¹⁷ According to the survey, mint ranked third as the most recent flavor used by Juul users aged 12-17 and 22-24 who used the device in the past 30 days.¹⁸

Excusing mint and menthol flavored e-cigarettes from restrictions leaves open a significant source of appeal for young people. It's also likely that young users will simply switch to using mint and menthol flavored e-cigarettes if the other flavors are less accessible.

The FDA's proposal to restrict many of the flavors to online sales also falls short of what's needed to prevent young people from using the products. Half of the minors involved in a Truth Initiative case study successfully purchased a Juul product online.¹⁹ As part of its Framework on

¹⁴ Lauren Kass Lempert, JD, MPH et al, *FDA's proposed modifications to its compliance policy for e-cigarettes leaves millions of youth at risk for starting to use e-cigarettes; FDA needs to remove these products from the market now and clamp down on illegal therapeutic and modified risk claims in Juul and other e-cigarette advertising*, 21 March 2019.

¹⁵ See note 4.

¹⁶ Ibid.

¹⁷ The Truth Initiative, *Juul fails to remove all of youth's favorite flavors from stores*, 15 November 2018.

¹⁸ Ibid.

¹⁹ The Truth Initiative, *6 key takeaways from the new FDA plan on e-cigarettes and other flavored tobacco products*, 21 November 2018.

Tobacco Control, The World Health Organization recommended a complete ban on all internet sales of tobacco products.²⁰

The benefit, if any, to the smokers who claim to be using these flavored e-cigarettes as part of a cessation program simply doesn't outweigh the public health risk these products pose to America's young people. Moreover, these cessation claims are unsubstantiated, and no e-cigarette company has received FDA authorization to market their e-cigarette products for cessation. The FDA should prohibit all flavored e-cigarettes and other flavored tobacco products that attract kids.

It's time to end the nicotine trap

Given the rampant rise in vaping in one year, it's critical that the FDA pull e-cigarettes that haven't been properly reviewed off the market quickly. Otherwise, potentially millions more kids will get caught in the nicotine trap, and derail their health and futures.

²⁰ World Health Organization, WHO Framework Convention on Tobacco Control, *Conference of the Parties to the WHO Framework Convention on Tobacco Control: Third session Durban, South Africa, 17-22 November 2008*, published 16 February 2009.