

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

Agreed! The FDA should approve all PMTA applications so that people who want to quit smoking have access to the most effective smoking cessation method ever devised.

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.

Although 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.

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

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.

Research also continues to show that youth e-cigarette use increases the risk for trying regular cigarettes.

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. The World Health Organization reached the same conclusion in its July 2021 report.

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.

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

Not for long. As the authors well know, 300+ manufacturers of vapor products received marketing denial orders, leaving their business in legal limbo and their employees fearing for their livelihoods. Vape shops are closing around the country in droves due to the FDA's inaction and prohibitionist campaigns like these.

This would be a public health disaster. It would drive millions of adults who use vaping to quit back to cigarettes. The fact is that flavors are essential to adults who want to quit smoking, and the data bears this out. One study found that a flavor ban would cause 1 in 3 young adult vapers (18-34) to switch back to cigarettes while another survey found that 28% of vapers would find a way to access banned flavors, driving them to black markets.

Pure fantasy. Teen vaping has declined by 60% over the past two years according to the CDC's own National Youth Tobacco Survey (NYTS) findings. This year's NYTS found that only 3% of high schoolers vape daily. Compare that to other activities it's illegal for teens to partake in: 6.9% of 12th graders reported using marijuana daily and 16.8% of 12th graders reported recent binge drinking. Perhaps CTFK should turn its attention elsewhere.

Wait a second. Let's use the CDC data to estimate how many high schoolers use these products daily:

- Puff Bar: 0.81%
Vuse Alto: 0.33%
SMOK: 0.29%
JUUL: 0.18%
Suorin: 0.07%

Notice the sleight of hand. After paragraphs peddling the "youth vaping epidemic" canard, the authors pivot back to total sales. But of course, an increase in the sale of vapor products is perfectly compatible with a decline in youth vaping, and with the growing importance of vapor products as a way for adults to quit smoking combustible tobacco. In fact, that's exactly what's happening.

Only 5.4% of 12th graders vape daily.

"Little Evidence"? There is a national — and a global — community of millions who used vaping products to stop smoking. They're paying attention. And they vote.

Gee, I wonder if that has anything to do with the fact that Bloomberg Philanthropies has funded the WHO's global tobacco control efforts?

It's hard to imagine a more malicious inversion of reality. The truth—available to anyone with a functioning search engine—is that youth vaping is down, youth smoking is up, and the evidence continues to grow that vapor products have helped millions of adults quit smoking tobacco. Don't take our word for it, see the evidence for yourself!

Notice the authors never make an attempt to seriously argue that vaping flavors have a special or targeted appeal to youth, they simply ask FDA to take it as an article of faith.

What CTFK omits: All of the largest shipping services—USPS, UPS, DHL, and FedEx—have banned the shipment of vape products, making this a red herring.

Misguided regulators and misinformation campaigns like CTFK's have already led to thousands of small business closures across the country. This specious letter is trying to finish the job.

Each of the websites CTFK analyzed state in their Shipping Policies that they require adult (21+) signature confirmation on all orders. They're also forced to use small, local carriers instead of major shippers. There is simply no evidence that the highly controlled availability of flavored products on the internet in any way fuels youth vaping.

Let's be clear: the authors are lying. Vaping is not "surging" in popularity among youth. The opposite is true.

Synthetic nicotine is one of many innovations adopted by the vapor industry in the name of harm reduction. What does it say that a group called the "Campaign for Tobacco Free Kids" is openly arguing that "tobacco free" is a transparent marketing ploy?

What about the latest research that shows how flavor bans have driven teens back to cigarettes? Or how cigarette sales increased for the first time in 2020 thanks to reckless federal, state, and local regulations and taxes on vaping products?

The so-called "gateway" effect of nicotine has been discredited by a seminal, peer-reviewed study called "Most smokeless tobacco use is not a causal gateway to cigarettes."

What about the UK, which has rightly embraced e-cigarettes as a smoking cessation tool?

It's hard to think of another "public health" campaign with means and ends that are so badly mismatched and potentially disastrous. The FDA should absolutely complete a thorough and fair review, but a blanket denial of flavored vaping products would have the horrible effect of driving current vapers back to cigarettes, the exact opposite of CTFK's purported aim.

1. NEJM: Vaping is more effective than nicotine replacement therapy at helping smokers quit: https://www.nejm.org/doi/full/10.1056/NEJMoa1808779; JAMA: Vaping helps people quit who weren't trying to quit: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787453; Cochrane Library Database of Systematic Reviews: 50 studies found that "quit rates were higher in people randomized to nicotine [e-cigarettes] than in those randomized to nicotine replacement therapy." https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full
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