

Trump administration announces plan to ban flavored e-cigarettes

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The Trump administration announced Wednesday that it is seeking to ban all flavored e-cigarettes. This comes in reaction to the developing epidemic that has seen more than 450 people develop severe lung illnesses attributable to the inhalation of vapor from e-cigs, or “vaping.” There are now six confirmed deaths reported.

The cause of these illnesses remains unknown. Medical officials speculate that a new toxin or adulterated vaping product may be the inciting factor. However, Juul, the most brand of e-cigs among children, has not been implicated in the epidemic.

Contributing to this furor over the developing lung illness epidemic is the acknowledgment of the epidemic of teenage nicotine addiction associated with the wide prevalence of e-cigarette use among middle- and high school-aged people.

According to the Centers for Disease Control and Prevention (CDC), the use of e-cigarettes among adolescents in the US climbed to 3.6 million in 2018, up from 2.1 million in 2017. The Federal Drug Administration (FDA) and US congressional members are under pressure from anti-vaping advocates to address these striking statistics. At the forefront has been the grassroots organization called Parents Against Vaping E-cigarettes.

The FDA has been working on a “guidance document” that would ban all e-cigarette flavors in the next few weeks. Health and Human Services Secretary Alex Azar told reporters, “Once the FDA would finalize this guidance, we would begin enforcement actions to remove all such products from the marketplace ...we will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth.”

The FDA explained that once the proposed ban on

flavored e-cigarettes takes effect, only tobacco-flavored products would be allowed on the markets and producers would have until May 2020 to submit their applications for their “new tobacco product.”

FDA’s regulations on e-cigarettes went into effect on August 8, 2016. According to their rules, companies that produced e-cigarettes had two years to file “new tobacco product” applications with the FDA. An additional year of manufacturing was granted while the FDA reviewed the application. According to NPR, “Without such applications on file, e-cigarette products currently on the market are technically illegal and subject to government action.”

In the face of such seemingly bold and decisive action by the FDA, the admission by former commissioner of the FDA, Scott Gottlieb, in an NPR interview earlier this year is astonishing. He said, “[T]hese products are on the market out of an exercise of enforcement discretion by the FDA. They [manufacturers] don’t have these applications in. They haven’t submitted them. No company has submitted an application for an e-cigarette.”

It is worth highlighting a section from the FDA’s 2016 section on Rules, Regulations and Guidance on e-cigarettes which stated, “Before this rule, there was no federal law to stop retailers from selling e-cigarettes, hookah, or cigars to youth under age 18.” They also noted then the alarming rise in e-cigarette use by high school students. These regulatory measures and concerns were merely rhetorical in nature.

On May 16, 2019, the American Lung Association posted an article on their web site titled, “Federal Judge Rules FDA Acted Illegally in Delaying Required Review of E-Cigarettes, Cigars.” Despite its own regulations, the FDA was allowing e-cigarettes to remain on the market until 2022 before producers had

to apply for “new tobacco product” authorization. Furthermore, they would permit products to remain on the market indefinitely during the FDA’s review.

On May 15, Judge Paul W. Grimm of the US District Court for the District of Maryland found that the FDA had exceeded its legal authority. According to his Memorandum Opinion, “FDA’s delay gave manufacturers responsible for the public harm a holiday from meeting the obligations of the law. Instead of addressing public health concerns associated with tobacco use by minors and others, the August 2017 Guidance [which delayed the product review requirement] exacerbated the situation by stating, in essence, that manufacturers can continue to advertise and sell products that are addictive and that target a youth market ... at a time when minors’ use of tobacco products like e-cigarettes is at an epidemic level and rising.”

This provides significant context to the current frenzy that has taken hold of congressional busybodies and FDA officials. They are furiously trying to cover for their criminal negligence and culpability in the present epidemic attributed to the vaping crisis as well as for the nicotine addiction that is placing these young people at risk of turning to combustible tobacco.

Juul Labs Inc., which has come to dominate more than 70 percent of the e-cigarette market in the US, has become the target of congressional and FDA investigations. On July 24 and 25, the House Oversight and Reform Subcommittee on Economic and Consumer Policy, spearheaded by Illinois representative Raja Krishnamoorthi, held a hearing to examine Juul Labs’ responsibility for the youth nicotine addiction epidemic, grilling Juul Labs Chief Products Officer and co-founder James Monsee during his testimony.

The hearing gathered evidence of the deceptive practices and false claims directed at high school students, including the safety of the products, despite no such data being available. Also cited were the fraudulent practice in their presentation to the Cheyenne River Sioux Tribe Health Committee on their “Make the Switch” campaign.

Additionally, Juul was involved in programs to pay schools \$10,000 or more for the right to speak to students after school and as well as providing various grants for summer programs on “healthy lifestyles.” Based on these revelations, the FDA has issued a

warning letter over unauthorized marketing and a letter of concern requesting Juul provide documents regarding their marketing, advertising and promotional campaigns.

Juul’s Monsee informed members of the House subcommittee that the company had voluntarily made fundamental changes in their practices before the hearing, such as pulling flavors that appeal to high-school-aged teenagers, suspending their social media accounts and toughening their online age verification protocol. Much of this amounts to political theater.

In December 2018, Altria Group, one of the world’s largest cigarette manufacturers, bought 35 percent of Juul for \$12.8 billion. Juul Labs Inc., with annual revenue of about \$2 billion, is valued at \$38 billion. Altria is the parent company of Philip Morris USA (producer of Marlboro cigarettes). The area served is worldwide, and the Juul brand is being marketed for global distribution as current trends demonstrate the astronomical rise in the e-cigarette market, while traditional tobacco is on the decline. The acquisition/merger places Altria in a unique situation to capture both markets.

Reuters reported that Altria Group has raised \$750 million in funding as it moves to bring the Juul product into China using online storefronts. China is the largest tobacco market with over 300 million smokers. India is second with close to 275 million users.

According to the World Health Organization, tobacco kills more than 8 million people worldwide annually. Around 80 percent of the world’s 1.1 billion smokers live in low- to middle-income countries. In the US, 480,000 people die each year due to cigarette smoking (1,300 deaths per day).

BIS research report estimates the global e-cigarette market will surpass \$86 billion by 2025 as consumers shift to alternatives to tobacco cigarettes due to rising health awareness regarding traditional tobacco. The present global combustible tobacco market (2017) is worth \$785 billion if China is excluded. Over 5,400 billion tobacco cigarettes are consumed each year.



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