

## *The Loophole That's Fueling a Return to Teenage Vaping*

Sales are rising of flavored e-cigarettes using synthetic nicotine that evades regulatory oversight, a gap that lawmakers are now trying to close.

By Christina Jewett

March 8, 2022

The Food and Drug Administration's crackdown on flavored e-cigarettes in 2020 was meant to be a comprehensive, aggressive strategy to curtail the epidemic of teenage vaping.

But two years later, sales of disposable, flavored e-cigarettes have soared. Some companies have moved just beyond the reach of the F.D.A. by swapping out one key ingredient. They have circumvented federal oversight of tobacco plant-derived nicotine by using an unregulated synthetic version.

The agency had nearly wiped out the use of flavors in devices like Juul, once the teenage favorite, that could be refilled with pods in flavors like crème brûlée and mango. Jumping into the breach, though, companies like the teen favorite Puff Bar are selling disposable devices filled with candy flavors and tobacco-free or synthetic nicotine.

Scientists are just beginning to study the unknown health effects of synthetic nicotine, even as research is expanding into the harm caused by vaping and flavor ingredients alongside continuing cases of devastating vaping-related lung injury. To many public health advocates, new trends in the vaping industry are thwarting the F.D.A.'s efforts to protect a new generation from nicotine addiction.

"These companies like Puff Bar and others are deliberately driving their trucks of poison through this huge loophole," said Meredith Berkman, a founder of Parents Against Vaping E-Cigs. She recently hosted a webinar about synthetic nicotine attended by 700 people. "We think we need to regulate these products."

Lawmakers on Tuesday proposed language that they want inserted in the Congressional omnibus budget bill that would give the F.D.A. authority to regulate synthetic nicotine, although it is unclear if the issue will be included in the final bill.

Representative Frank Pallone Jr., Democrat of New Jersey and chairman of the House Energy and Commerce Committee, said the provision would be a public health victory over "bad actors" who circumvented the F.D.A.'s authority.

"That ends with passage of this bill, which will close this loophole and clarify F.D.A.'s authority to regulate all tobacco products, including those containing synthetic nicotine," Mr. Pallone said in a statement on Tuesday.

Sales of synthetic or tobacco-free nicotine went from virtually nonexistent in 2020 to taking up shelf space in two-thirds of U.S. vape shops in 2021, according to market research. Those stores said such products accounted for nearly 20 percent of sales, according to ECigIntelligence, which surveys hundreds of the shops each year. The company projected that the U.S. vape market, web sales included, would be nearly \$6 billion this year.



F.D.A. enforcement actions have had little effect on Lizzie Burgess's ability to get vapes over the last four years. "I think the F.D.A. should take it all off the market now," she said. Lee Klafczynski for The New York Times

Federal officials have been in a cat-and-mouse game with some e-cigarette makers. Spurred by a court order, the F.D.A. forced thousands of e-cigarette companies, including Juul, to apply in 2020 for authorization to remain on the market. With the agency focused on the most popular devices, like Juul's, that used insertable cartridges, makers of disposable vape pens in flavors like gummy bear and candy cane flooded the market. The agency then responded with a stern warning and even product seizures aimed at some of those companies, including Puff Bar.

By late last year, more than a million tobacco-sales applications had been denied. Applications to remain on the market by Juul and myriad other companies are pending.

By early 2021, Puff Bar returned to the market with "tobacco-free" or synthetic nicotine that didn't fall under F.D.A. oversight, loaded with the fruity flavors prohibited in vapes with tobacco-based nicotine. Other companies imported similar devices containing synthetic or tobacco-free nicotine from factories in Shenzhen, China, according to industry experts.

Patrick Beltran, who has identified himself in news reports as one of two executives of Puff Bar, did not respond to requests for comment.

Sales data released by the C.D.C. Foundation shows that since the F.D.A. stepped up e-cigarette enforcement in February 2020, sales of disposable fruit- and candy-flavored devices have grown by 290 percent, to 6.46 million devices a month by November 2021. Sales of the F.D.A.-targeted flavored pod and cartridge devices have nearly vanished.

Since early 2020, overall e-cigarette sales are up nearly 50 percent to about 22 million units per month, according to Information Resources, a data tracking consultant. The National Youth Tobacco Survey conducted in early 2021, when many students were learning via Zoom, reported that, overall, about 11 percent of high school students used e-cigarettes.

New e-cigarette suppliers can go into business easily: They contract with a manufacturer in China, set up a website and get space in a warehouse to store and ship devices, said Samantha Shusterman, a senior counsel supervising e-cigarette enforcement for the Massachusetts attorney general's office. They use shell companies and can quickly withdraw the profits if they face scrutiny.

“It’s a whack-a-mole situation,” said Ms. Shusterman, whose state banned all flavored e-cigarettes, except in licensed smoking bars. “They’re not following any of the laws.”

Mitch Zeller, director of the F.D.A.’s Center for Tobacco Products, said the agency recognized the problem.

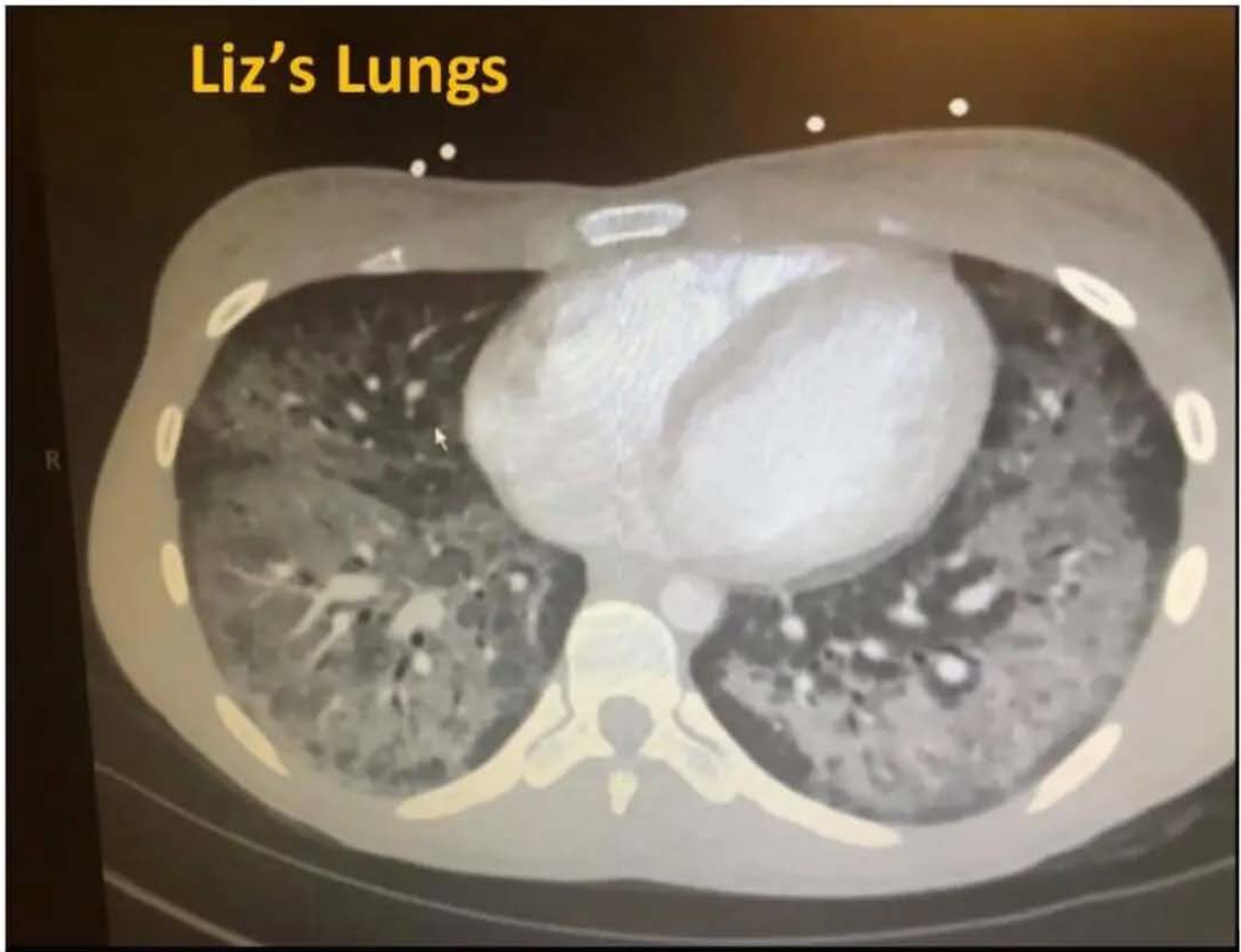
“Disposable e-cigarettes made only with synthetic nicotine pose a particular challenge for the F.D.A. when it comes to our tobacco authorities,” Mr. Zeller said in an email. “The F.D.A. is actively investigating this issue and considering how to best address such products.”

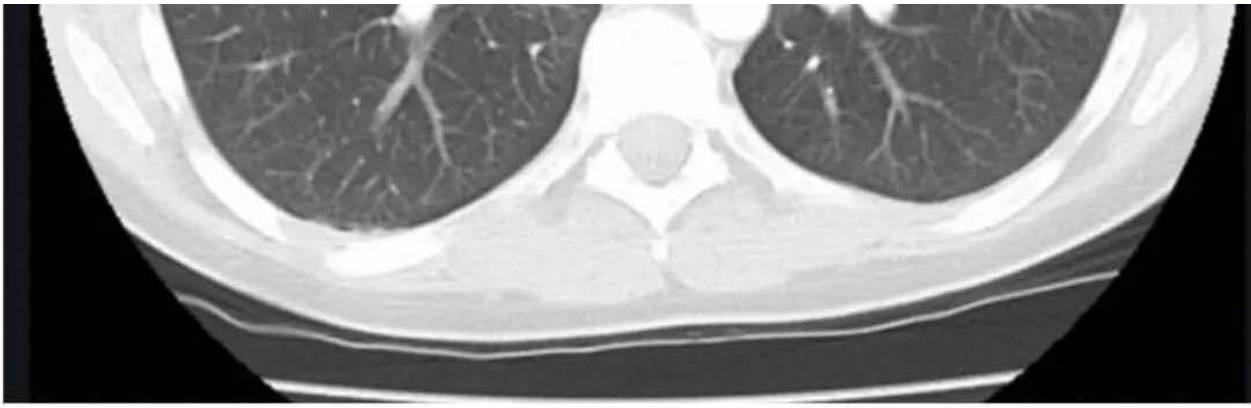






Ms. Burgess in the I.C.U. last year. When she arrived at the hospital, her oxygen saturation was 67, far below the normal range of 95 or higher. Lizzie Burgess





A scan of Ms. Burgess's lungs, top, compared with healthy lungs. Lizzie Burgess

Vaping is still popular among teenagers. Rani Dhiman, 16, said it is highly visible in the bathrooms and stairwells of her high school in the Detroit suburbs.

She said the stress and loneliness of the pandemic might have been a trigger for some teenagers to start. It's also portrayed glamorously, she pointed out, in "Euphoria," a popular HBO series about a teenager kicking drug addiction.

"Sometimes so many people are vaping in the bathrooms, it's hard to do anything about it," Ms. Dhiman said, adding that she doesn't vape.

The F.D.A.'s efforts to limit teenagers' access to flavored vapes had little effect on Lizzie Burgess's ability to get them over the last four years in the Indianapolis suburbs. Within weeks of starting to vape at 16, she said, she was addicted. There was always a gas station, older friend or website selling e-cigarettes in flavors like banana ice cream or sour apple, she said.

At 19, she said, she was vaping THC and using a device — now advertising tobacco-free nicotine — that has as much nicotine as two packs of cigarettes, every two to three days. She said she fell ill with what started like a cold, which progressed to rapid breathing, almost-gray lips and feeling depleted. By the time she went to the emergency room, her oxygen saturation was 67, far below the normal range of 95 or higher. Ms. Burgess said she was soon in the I.C.U. with vaping-related lung injury.

She's struggled to end her nicotine addiction and is down to two cigarettes a day.

"I think the F.D.A. should take it all off the market now," Ms. Burgess said of the flavored vapes. "I think it will be very very hard for them to reel it all in. It's so big and there are so many companies now."

Synthetic nicotine remains far more expensive than the tobacco-derived product, leading some industry experts to question whether a device label of "synthetic" is accurate.

The unregulated vaping market at this point is a problem of the F.D.A.'s making, said Gregory Conley, president of the American Vaping Association, an industry trade group. He said the agency fueled the problem by overregulating a product used by millions of adults who find vaping a safer alternative to smoking.

"This country should learn some lessons from past prohibitions that failed miserably," Mr. Conley said. "If you don't fairly regulate a market where there is a great deal of demand from legal adults, you will fuel gray and black markets where the operators are not concerned with checking IDs before selling."



Dr. Robert Jackler of Stanford University created a “synthetic teenager” named Joe, who used gift cards to buy flavored synthetic nicotine products online and have them shipped. Ian C. Bates for The New York Times

Dr. Robert Jackler, who studies tobacco company advertising at Stanford University, has also noted major tobacco retailers entering the synthetic nicotine market with flavored gums called “pouches.” He said his tobacco research group could pose as a teenager and use gift cards to easily buy the flavored synthetic nicotine gums from major retailers and have them shipped to a home in California.

“When we buy them, there’s no age gating,” Dr. Jackler said.

The loopholes are many with synthetic nicotine, he said, allowing the products to avoid hefty tobacco taxes and remain affordable and to evade the algorithms that online retailers use to weed out underage sales of tobacco products. The ease of purchasing was also concerning, Dr. Jackler said, given how little is known about the health effects of flavored, synthetic nicotine.

Recent research has focused in on the chemicals used to simulate butter, which is linked to lung damage, and vanilla, which is associated with birth defects in zebrafish.

Dr. Sven-Eric Jordt, an associate professor at Duke University who has studied synthetic nicotine, said it posed many unknowns.

About 99 percent of tobacco-derived nicotine is a psychoactive molecule called S-nicotine, he said. But a mirror-image molecule, known as R-nicotine, makes up 50 percent of most types of synthetic nicotine. He said the R-nicotine molecule appears to be less addictive, but very little research has been done on it in animals or humans.

“It could alter nerve transmission in the brain in different ways from classic nicotine,” Dr. Jordt said, “but we don’t understand that at this time.”

A version of this article appears in print on , Section A, Page 15 of the New York edition with the headline: A Loophole Has Fueled a Resurgence in Teenage Vaping