

Flavored vapes still in stores despite ban

December 28 2021, by Dennis Thompson



(HealthDay)—Kid-friendly flavored e-cigarettes are still widely available online and in stores, despite a federal judge's ruling that should have pulled the products off store shelves by early September, a new



report shows.

The judge's ruling follows on U.S. Food and Drug Administration action that is nearly two years old.

Citing risks to vulnerable children, the FDA first announced in January 2020 that "companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes [other than tobacco or menthol] within 30 days risk FDA enforcement actions."

That was then, this is now, critics say.

Today, more than 100 flavored vaping products with enticing <u>flavors</u> like Gummy Bear, Funnel Cake, Fruit Punch, Berry Crunch Cereal and Blueberry Lemonade are still sold through the five top online <u>e-cigarette</u> retailers, the Campaign for Tobacco-Free Kids report found.

Flavored vapes also were widely available in convenience stores and gas stations located in eight cities across the country, the <u>report</u> added.

"Flavored e-cigarettes of precisely the kind that youth are using are widely available both on the internet and in retail outlets," said Matthew Myers, president of the Campaign for Tobacco-Free Kids.

"Flavors attract them. Nicotine addicts them," Myers continued. "Without the flavors, many fewer kids would be attracted to these products—85% of the kids who use an e-cigarette use a flavored one."

A federal court had set a deadline of Sept. 9 for e-cigarette manufacturers to either get U.S. Food and Drug Administration approval for their products or face having them pulled from the market.

Unauthorized e-cigarette products remain on the market months past that



deadline, even though they are subject to FDA enforcement action, the report found.

In-store assessments conducted in eight cities found that:

- Juul was sold in all cities, and brands like Vuse, NJOY and blu were available in most.
- Flavored e-liquids were found in most cities, in flavors like Green Apple, Cola, Peachy Rings, Tropical Fruit, Strawberry Macaroon and Island Orange.
- Disposable e-cigarettes were available in every city in flavors like Coconut Pineapple Smoothie, Strawberry Ice Cream, Gummy Bear, Mango Slushee and Blue Razz Lemonade.

The cities included in the survey were Denver; Detroit; Los Angeles; Portland, Maine; Portland, Ore.; Seattle; Tempe, Ariz.; and Washington, DC.

The report helps explain why e-cigarette sales continue to skyrocket in the United States, Myers said.

Sales of disposable e-cigarettes increased by nearly 250% between February 2020 and September 2021, rising from 2.8 million unites to 9.6 million units, according to recent <u>sales tracking reported by the CDC</u> <u>Foundation</u>.

Four out of five disposable e-cigarettes sold come in flavors other than tobacco, mint and menthol, the CDC Foundation noted.

Total e-cigarette sales increased by more than 60% during the same period of time (from about 15 million to 24 million units), the CDC Foundation reports. That includes sales of non-tobacco flavored ecigarettes rising by 86%.



About 1 in every 5 <u>high school seniors</u> have used an e-cigarette within the last month, according to federal survey data cited by Myers.

FDA yet to act

"That's five times as many kids using e-cigarettes as are using cigarettes," Myers noted.

The FDA says it has acted on more than 98% of the e-cigarette applications it's received, and has issued denial orders for more than 1 million flavored vaping products, the report noted.

However, the agency has dragged its feet in reviewing applications from the e-cigarette manufacturers with the largest market shares, such as Juul, Vuse Alto, NJOY, blu, Smok and Suorin, the report noted.

Until decisions are made on those applications, the FDA has indicated that the products can still be sold. Attempts to reach the agency for comment were unsuccessful.

"It's clear that FDA really needs to quickly act and resolve the remaining applications that it has to go," said Erika Sward, assistant vice president of national advocacy for the American Lung Association. "They've claimed to go through millions of applications, but when you leave the products with the highest market share on the market, it's really only a drop in the bucket."

Sward and Myers suspect the FDA is being cautious and meticulous in reviewing applications from major manufacturers so that its final decisions will hold up in court.

The agency already faces more than 45 lawsuits from companies whose products have been denied, Myers said.



"Those applications are perhaps more complete and more substantive than a lot of the products from the smaller companies," Sward said of the major e-cigarette brands. "I would also assume FDA is trying to get all of its I's dotted and T's crossed, because while some of the smaller manufacturers are suing FDA over marketing denials, they're trying to avoid big lawsuits from the big companies."

The FDA also is grappling with a major loophole that some companies are using to keep selling flavored products.

Puff Bar and other manufacturers have started selling e-cigarettes containing synthetic nicotine. The companies assert that this "tobaccofree nicotine" doesn't fall under the jurisdiction of the FDA's Center for Tobacco Control.

The FDA issued a <u>warning letter</u> against Puff Bar in July 2020, ordering the company to remove its flavored disposable e-cigarettes from the market because they didn't have the required authorization.

In response, Puff Bar re-launched this February with a new synthetic nicotine formula that they claim doesn't fall under the FDA's current rules for vaping products.

Synthetic nicotine a new trick

The agency has said <u>in an online FAQ</u> that it's possible that synthetic nicotine "would not be regulated by the FDA as a tobacco product," adding that it will decide on a case-by-case basis.

However, Sward and Myers believe that the FDA still has approval power over these products. Even if it isn't derived from tobacco, synthetic nicotine remains a new drug that ought to be regulated, they argue.



"It is clear to us that even if the Center for Tobacco Products does not have jurisdiction over these products, the Center for Drug Evaluation can assert jurisdiction over these products as unapproved drugs—but hasn't," Myers said.

The way companies have been touting their synthetic nicotine products appears to justify treating the substance as a drug, said Linda Richter, Ph.D., vice president of prevention research and analysis for the Partnership to End Addiction.

"A lot of the companies that are selling these synthetic nicotine products are saying, 'Hey it's purer than nicotine that comes from tobacco, it's got these great ingredients and it's not going to harm you. They're kind of promoting it through health benefits, which puts it under the drug regulation authority of the FDA," Richter said.

Even better would be for Congress to intervene regarding <u>synthetic</u> <u>nicotine</u>, Myers said.

"The best possible solution would be for Congress to clarify the definition of a tobacco product to specifically include these products," Myers said. "Otherwise, FDA will be playing whack-a-mole from now to kingdom come."

Overall, the FDA has been timid in the face of continued opposition from the vaping industry, and needs to step up its efforts, Myers and Sward said.

"They've had more than three months past their deadline from the federal judge to deal with these products, and it's very disheartening that they have not so far," Sward said.

"The clear takeaway is that as long as flavored products are for sale, kids



will get them. The only way to protect kids from flavored products is to make it illegal to sell them," she concluded.

However, the FDA might simply be outgunned and overwhelmed, said Richter.

"I just don't know that it has the staff and the funding to keep up with this extremely well-funded industry, especially given that there's plenty of people within the government who don't think the regulations should be as strong as they are," Richter said.

"Even with something like cigarettes that clearly have no redeeming value, you still have very well-funded tobacco lobbyists who continue to restrict the regulations around <u>cigarettes</u> because of their economic interest," she added.

"Then you turn to a product like vaping that is presented as somewhat healthier, so you have a lot of people within Congress and regulators who say, hey, let's be careful how much restrict those because it might deter people from quitting smoking. That's the murkier landscape that allows a lot of this to go on," Richter concluded.

More information: The Partnership to End Addiction has more about <u>new nicotine products that target kids</u>.

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