

F.D.A. Targets Vaping, Alarmed by Teenage Use



The sleek Juul device, which looks like a flash drive, has become popular in high schools. CreditCredit Gabby Jones/Bloomberg, via Getty Images

By Sheila Kaplan and Jan Hoffman; for the New York Times
Sept. 12, 2018

WASHINGTON — The Food and Drug Administration on Wednesday declared that teenage use of electronic cigarettes has reached “an epidemic proportion,” and it put makers of the most popular devices on notice that they have just 60 days to prove they can keep their devices away from minors.

The order was part of a sweeping government action that targeted both makers and sellers of e-cigarettes. If Juul Labs and four other major manufacturers fail to halt sales to minors, the agency said, it could remove their flavored products from the market. It also raised the possibility of civil or criminal charges if companies are allowing bulk sales through their websites.

The agency said it was sending warning letters to 1,100 retailers — including 7-Eleven stores, Walgreens, Circle K convenience shops and Shell gas stations — and issued another 131 fines, ranging from \$279 to \$11,182, for selling e-cigarettes to minors.

Federal law prohibits selling e-cigarettes to anyone under 18. In a briefing with reporters, the F.D.A. commissioner, Dr. Scott Gottlieb, said that more than two million middle and high school students were regular users of e-cigarettes last year.

The government’s tactics underscore a dilemma in the public health community: In addressing one public health problem — cigarette smoking, which kills 480,000 people in the United States each year — e-cigarettes are creating another — hooking teenagers who have never smoked on nicotine.



Scott Gottlieb, commissioner of the Food and Drug Administration, in an appearance before a Senate committee last year.

Credit J. Scott Applewhite/Associated Press

E-cigarette users inhale far fewer toxic chemicals than do smokers of traditional cigarettes. But they can take in higher levels of nicotine, which is addictive.

“The developing adolescent brain is particularly vulnerable to addiction,” the F.D.A. said in its statement announcing the actions.

In particular, the agency has been watching the wildly popular Juul, which offers especially potent nicotine hits. Juul Labs launched the sleek device, which looks like a flash drive, in 2015. It comes with “pods” in eight flavors, among them mango, menthol and creme. In a short time, Juul has become the dominant seller of e-cigarettes and a fad among students. According to Nielsen data, Juul controls 72 percent of the market, and is valued by investors at \$16 billion.

In an emailed statement, a Juul spokeswoman said: “Juul Labs will work proactively with F.D.A. in response to its request. We are committed to preventing underage use of our product, and we want to be part of the solution in keeping e-cigarettes out of the hands of young people.”

Dr. Gottlieb said the F.D.A. would look closely at whether Juul and the other manufacturers were allowing bulk purchases of products through their own websites — a practice where the buyer could then sell to minors.

If such “straw sales” are happening, it should be readily apparent to the manufacturers, he said. “If the companies don’t know, or if they don’t want to know, we’ll now be helping to identify it for them.”

The other four products facing the 60-day deadline are RJR Vapor Co.’s Vuse, Imperial Brands’ blu and devices made by Logic. They said they were working with the F.D.A. as well. RJR, Imperial and Altria are all major tobacco companies. As smoking rates have declined, the industry sees e-cigarettes as an important piece of its survival, a fact that makes some in public health mistrustful.

“They say they’ve changed from the days of Joe Camel,” Dr. Gottlieb said. “But look at what’s happening right now, on our watch and on their watch. They must demonstrate that they’re truly committed to keeping these new products out of the hands of kids.”

Dr. Gottlieb has said many times he believes that e-cigarettes and similar products known as electronic nicotine delivery systems may be effective options for adults who want to stop smoking but still crave nicotine. But he said teenage vaping has become so concerning that regulators may have to curb the availability of the devices to keep them out of the hands of youths.

“Inevitably what we are going to have to contemplate are actions that may narrow the off-ramp for adults who see e-cigarettes as a viable alternative to combustible tobacco in order to close the on ramp for kids,” Dr. Gottlieb said. “It’s an unfortunate trade-off.”

Dr. Gottlieb’s aggressive approach against private industry is unusual for an official in the business-friendly Trump administration which has sought to roll back numerous environmental and health regulations. But critics said that his decision last summer to extend a deadline for e-cigarette manufacturers to demonstrate that their products comply with public health concerns helped perpetuate the current problem.

“It’s nice they want to do something but realistically, what are they going to accomplish this way when they could be so much more effective by following the regulatory plan that had been ready to put into place and that the commissioner postponed?” said Diana Zuckerman, president of the National Center for Health Research, a nonprofit health policy group.

She also pointed to the popularity of vaping among young adults. Researchers generally believe that the adolescent brain continues to develop through age 26. “It’s a big epidemic among people ages 18 to 30, too,” she said.

And while the F.D.A.’s announcement struck many as tough, legal experts said the agency could face a protracted legal fight if it follows through on its threats to ban flavors and curtail marketing.

Marc J. Scheineson, a health care lawyer and a former associate F.D.A. commissioner, said that the agency was relying on public opinion and its own bully pulpit to push the targeted manufacturers into “voluntary compliance.”

Some antismoking groups, while encouraged by the F.D.A.’s actions, expressed caution: “Asking the tobacco industry to come up with solutions is the proverbial case of asking the fox to guard the hen house,” said Robin Koval, the president and chief executive of Truth Initiative. “After decades, there is no evidence that the tobacco industry is able to regulate itself.”

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In April, the F.D.A. announced it was investigating Juul’s marketing practices to determine if the company deliberately targeted youths. The agency requested reams of documents from the company, including focus group reports and toxicology studies. Juul has submitted thousands of pages of records to the agency, but neither the F.D.A. nor Juul have made them public. Dr. Gottlieb said the agency’s tobacco division is still poring through them.

While the actions against the industry are alarming to the e-cigarette companies, they are also problematic for the F.D.A.

In July 2017, as part of a broad plan to reduce tobacco deaths in the United States, the F.D.A. extended the deadline for e-cigarette makers to comply with new tough federal guidelines, which, among other things, require companies to prove the e-cigarettes are beneficial to public health. In granting the five-year extension till 2022, Dr. Gottlieb said he would also

force manufacturers to cut nicotine levels in traditional cigarettes, to render them no addictive. For that to work, he said, smokers needed more and better cigarette substitutes.

But in an interview, Dr. Gottlieb said the immense popularity of vaping among teens and the growing addiction among young people was not something he foresaw last summer, and the agency must rethink its policy — perhaps moving the deadline closer and requiring companies to gain F.D.A. approval to stay on the shelves.

Risa Robinson, a professor of mechanical engineering at Rochester Institute of Technology, began studying e-cigarettes six years ago for the F.D.A. The early products did not have enough nicotine to cause concern, she said. But later products, like Juul, had more nicotine and, she said, can become even stronger depending on how deeply a user puffs.

“I’m highly concerned now,” Dr. Robinson said. Beyond nicotine, the addition of heat to the e-liquid flavors generates chemicals that have not yet been studied in depth, she added.

The attorney general of Massachusetts, Maura Healey, who recently began an investigation into the marketing and sale of e-cigarettes to minors, praised the F.D.A.’s action.
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“We’ve worked too hard over the past 50 years to reduce smoking rates among young people to let these companies profit off of getting them hooked on nicotine,” Ms. Healey said. “This move by the F.D.A. is a good first step to shut down companies targeting minors.” A Juul spokeswoman, Victoria Davis, said recently that the company had already stepped up its own patrol of retailers who advertise to youths or who don’t enforce age requirements, as well as social media posts. But it’s not always easy.

From Jan. 1 through July 28, Ms. Davis said, Juul asked Instagram to remove over 5,500 posts, and the social media company complied on 4,562. Facebook Marketplace was less agreeable. The company agreed to remove 45 of 144 posts. Amazon took down 13 of 33.

Dr. Gottlieb said he was not impressed by the measures Juul and the other companies have taken.

“It didn’t have the intended impact or I wouldn’t be viewing the statistics I’m now seeing,” he said.