Flavored vapes draw FDA ire, with some exceptions

Today, the Food and Drug Administration took another step towards limiting the sale of sweet-flavored e-cigarettes in places where kids can buy them. But public health experts wonder if the move will be enough to make a dent in the massive increase of youth vaping.

After announcing plans in November to restrict the sale of e-cigarettes that come in kid-friendly flavors, the FDA today issued what's called a "draft guidance" that starts to spell out how the agency intends to do so. For one thing, if the FDA catches companies marketing sweet-flavored e-cigarette products to kids or selling them in places minors can shop, the FDA may force these companies to pull the products from the market. FDA's soon-to-be-ex-commissioner Scott Gottlieb said in a statement today: "We're putting all manufacturers and retailers on notice."

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That means changing the way the FDA has been treating e-cigarette products that were introduced before August, 2016. In a backwards approval process, these essentially unregulated products are allowed to be sold while e-cigarette companies apply for FDA authorization to sell them. That application deadline has bounced around from 2018 to 2022. Today, the FDA proposed moving up the deadline to 2021 for flavored vapes, not including mint, menthol or tobacco flavors.

Excluding mint and menthol from this new push against flavored vapes worries public health experts like Kathleen Hoke, a law professor at the University of Maryland. "Those are flavors that are also quite popular among people," she says. "They're

trying to draw a line, I see that, but I don't think the line is in the best place for public health."

In the meantime, the FDA plans to crack down especially on vapes marketed to kids. The new guidance emphasizes the restrictions the FDA already proposed in November, including limiting the sale of sweet-flavored vapes in places kids can freely access or in stores that have been caught selling to minors. Those restrictions include plans to take action against online stores that don't independently check ages and IDs, and ones that fail to limit the number of products you can buy at any one time.

The guidance isn't limited to e-cigarettes: the FDA also plans to make manufacturers stop selling flavored cigars — including mint and menthol — that hit the market between 2007 and 2016 while the FDA considers whether to authorize their sale. Ultimately, flavored cigars might be banned altogether — although plans for that are still in their infancy. In today's statement, the FDA said it's "moving forward with a proposed rule to ban all characterizing flavors in cigars."

Everything here is in draft form, so it could take a few months to go into effect. But the moves are all aimed at making sweet-flavored e-cigarettes less available, since study after study says they're appealing to teens. Last year, the number of high school and middle school students who'd vaped in the past 30 days climbed to 3.6 million. The worry is that some of these kids who start vaping will transition to traditional cigarettes, which is backed up by a recent study and a massive report from the National Academy of Sciences, Engineering, and Medicine in January 2018.

The FDA's announcement follows on the heels of yet another study showing the appeal of fruity- and candy-flavored vapes to young people. Researchers led by Samir Soneji, an associate professor of health policy at Dartmouth College, found that nearly 78 percent of teens said they vaped because they liked

the flavors. The study, published Tuesday in *Public Health Reports*, finds that teens between the ages of 12 and 17 are about three times more likely to use fruit-flavored vapes than adults, and almost four times more likely to use candy-flavors.

The findings mean that the FDA's plans for restricting flavors are on the right track. But Soneji worries they're not harsh enough. "The strongest protection against the harms of e-cigarette use for youth would be an immediate and outright ban of non-tobacco flavored e-cigarettes," he says in an email to *The Verge.* And while the FDA works to stop the sale of *some* e-cigarette products, kids will keep trying them, Soneji says — adding "to a growing number of nicotine-addicted adolescents and young adults."

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The guidance comes at a time of turmoil for the federal agency. News broke last week that FDA commissioner Scott Gottlieb plans to step down "in about a month," according to *The Washington Post*. Public health experts worried that his resignation meant progress on curbing youth vaping would stall, or stop. The report in *Bloomberg* yesterday that the director of the National Cancer Institute, Ned Sharpless, will step in as acting FDA head, combined with today's announcement, shows that the FDA won't be letting up its pressure on the tobacco or e-cigarette industries. "This is definitely a more concrete step than what they have been doing, which is a lot of announcements that they intend to do things," says Natalie Hemmerich, an attorney at the Public Health Law Center of the Mitchell Hamline School of Law.

But public health experts like Hemmerich worry that by leaving mint- and menthol-flavored vapes on convenience-store shelves, the FDA still isn't doing as much as it could. "Not addressing menthol in e-cigarettes was a huge missed opportunity," she says. "This action would have begun to address the disparities

that exist in menthol product use." Menthol cigarettes, for example, are known to appeal especially to young people, and black communities have been especially targeted by menthol marketing efforts.

"There's a lot more that the FDA could do, and I think the exception for menthol is problematic," agrees Micah Berman, an associate professor of public health and law at The Ohio State University. And in an emailed statement, Harold Wimmer, President and CEO of the American Lung Association, said: "Until FDA is willing to take meaningful action by removing all flavored tobacco products, including mint and menthol, from the marketplace, America's youth remain at high risk for a lifetime of addiction to tobacco products."

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Gottlieb explained the agency's rationale for keeping mint- and menthol-flavors readily available in a statement, saying, "recent evidence indicates that mint- and menthol-flavored ENDS products are preferred more by adults than minors." He added that the agency is "aware" that adults may be using those vape flavors "with the goal of ceasing combusted tobacco use." (The problem is that e-cigarettes are *not* FDA approved for helping smokers quit, Hoke says. So this dynamic of talking about them that way, she says, "gets a little frustrating.") But Gottlieb promised that the agency would keep a close watch on youth use of mint and menthol flavored vapes, and reconsider the plan if it needs to.

"I'm not sure this will have a huge impact," Berman says. "It's positive that the FDA is stepping in and starting to take action, but this alone is not going to be enough."

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