

FDA needs to do better at policing online tobacco retailers, new report says

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E-cigs market to teens using big tobacco tactics

CNN —

The US Food and Drug Administration is falling down on the job of policing online tobacco retailers, according to a [highly critical new report](#) from the US Department of Health and Human Services' [Office of Inspector General](#).

The report criticizes the FDA for its lack of oversight, saying that children's use of tobacco remains of "high concern" and that online sales are a potentially easy way for kids to buy tobacco products without having to verify their ages.

In 2022, nearly 17% high school students – or more than 2.14 million high schoolers – reported that they currently used e-cigarettes, according to the [US Centers for Disease Control and Prevention](#).

And [research shows](#) that almost all kids have easy access to the internet. About 95% of those ages 13 to 17 report having, or having access to, a smartphone. Close to half of those polled report using the internet on a "near-constant basis."

The new report is based on summary data from 2010 through 2020 as well as interviews with officials, written responses from the agency and information available on its public website.

In a [memo](#) to the Inspector General's Office in response to the report, Beethika Khan, the FDA associate commissioner for economics and analysis, wrote that her agency's online tobacco surveillance program is "flexible" and has played "a major role in supporting FDA's highest tobacco enforcement priorities."

Of the 16,511 online tobacco websites that the FDA flagged for review between 2010 and 2020, the agency sent warning letters to 899 of them, yet the Inspector General's report says that the agency took not a single enforcement action against those retailers. The FDA has the legal authority to fine retailers, among other punishments like criminal prosecution and seizing tobacco products.

The warning letters it sent most often cited retailers for advertising and labeling violations, the report says.

"It is unclear to what extent FDA conducted additional oversight of these online tobacco retailers at later dates and found subsequent violations that could result in FDA taking enforcement actions," the report says.

In some cases, the FDA didn't send warning letters when they may have been appropriate, the report says. For example, the FDA surveillance program took note of 400 online domestic retailers selling Ends products. There were 30 high-volume retailers that sold flavored cartridges, which are illegal, yet the FDA sent letters to only 19.

The report also notes that the FDA has failed to complete the rule-making process for online tobacco sales despite a deadline of 2011, more than a decade ago.

The Bureau of Alcohol, Tobacco, Firearms and Explosives, commonly known as ATF, [requires](#) tobacco product retailers to register with the agency, but the FDA has failed to work with ATF to get access to that information, according to the report. The FDA [does share](#) information on investigations, however.

While it can be difficult to police online retailers due to the sheer volume and the internet's "wild West" nature, as one FDA official described it in the report, it says the FDA could do better by collaborating more closely with ATF on the oversight of these online retailers.

The report recommends that the FDA finish making rules about online sales, as it was supposed to do years ago, and collect data about its oversight of online retailers.

When the Inspector General asked, the FDA was not able to determine how many investigations of online retailers it's done, saying that its investigations are just one tool that it uses to control kids' access to tobacco.

The Inspector General's report says the FDA should increase transparency of its investigations so parents and other interested parties can better understand what it's doing to keep kids safe online.

In response to the report, the FDA agreed that there may be additional opportunities to collaborate with ATF and promised to explore them.

The FDA also agreed about the need for transparency and promised that by March, it will create a dedicated website to offer more information about its efforts.

The agency did not make any promises to develop rules about online tobacco sales but said that other laws and requirements may achieve the same ends.

The FDA also did not make any promises about data collection but said it would explore ways to "maximize transparency without jeopardizing investigations."

Erika Sward, assistant vice president of national advocacy for the American Lung Association, said it is important to keep in mind that this report was done under a former director of the FDA's tobacco program and that she has started to see positive changes in terms of enforcement under the program's new leadership. Dr. Brian King was appointed director of the Center for Tobacco Products [in July](#).

Also [in July](#), FDA Commissioner Dr. Robert Califf [announced](#) that he had commissioned a review of the agency's tobacco program, as well as its work regulating food. The [independent review](#) of the tobacco

program is due to Califf by December 19.

What stood out to Sward in the report was the FDA's lack of follow-up beyond warning letters to online retailers.

"The IG report underscores the significant and serious challenges that the Center for Tobacco Products has had with enforcement," Sward said.

The tobacco industry is unlike any other in the FDA's purview, Sward said. Although drug companies and other regulated industries may adhere to any sort of letter from the agency, it will probably take more aggressive action to move the tobacco industry.

"It's not enough to send a letter. They have to be willing to follow up," Sward said. "Unless FDA is willing to put some teeth behind it – and that could involve ATF or other parts of [the US Department of Justice] – we really need the law enforcement component to come in and pursue these manufacturers or retailers when they continue their illegal behaviors and actions."