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FDA Vows to Battle Teen E-Cig Use

— Gottlieb announces "largest tobacco compliance effort" ever

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FDA Commissioner Scott Gottlieb, MD, declared teen use of electronic cigarettes an "epidemic" and said the agency would be addressing the issue with "the largest coordinated tobacco compliance effort in FDA's history."

Actions being considered -- but not yet undertaken -- include the immediate removal of certain flavored e-cigarettes from the market and shortening the time to market review for most cigarettes now being sold.

Last summer, Gottlieb unveiled a comprehensive tobacco policy aimed at reducing cigarette addiction, which recognized e-cigarettes as a potential smoking cessation tool to help adults give up combustible cigarettes.

But at a Wednesday morning press conference and in a statement posted on the agency's website, the FDA commissioner acknowledged that federal health officials failed to recognize "the extent of what's now become one of our biggest challenges."

"We didn't predict what I now believe is an epidemic of e-cigarette use among teenagers," Gottlieb said. "Today we can see that this epidemic of addiction was emerging when we first announced our plan last summer. Hindsight, and the data now available to us, reveal these trends. And the impact is clearly apparent to the FDA."

In his remarks, Gottlieb criticized e-cigarette manufacturers for failing to address teen use of their products.

"I've been warning the e-cigarette industry for more than a year that they needed to do much more to stem the youth trends," he said. "In my view, they treated these issues like a public relations challenge rather than seriously considering their legal obligations, the public health mandate, and the existential threat to these products. And the risks mounted."

The FDA has been widely criticized by anti-smoking groups for extending the product review application period for e-cigarettes introduced to the market before August of 2016 to the summer of 2022.

Gottlieb said the FDA is rethinking the extension given the explosive growth of e-cigarette use among adolescents.

"We're seriously reconsidering our compliance dates for the submission of product applications when it is apparent that there's widespread youth use of the product," he said. "We're especially focused on the flavored e-cigarettes. And we're seriously considering a policy change that would lead to the immediate removal of these flavored

considering a policy change that would lead to the immediate removal of these flavored products from the market."

On Wednesday, FDA also sent letters to the five leading e-cigarette manufacturers -- JUUL, Vuse, MarkTen, blu, and Logic -- requesting plans within 60 days to address sales to minors.

In the absence of such plans, Gottlieb vowed "to revisit the FDA's exercise of enforcement discretion for products currently on the market."

"Let's be clear. This may require these brands to revise their sales and marketing practices, including online sales; to stop distributing their products to retailers who sell to kids; and to remove some or all of their flavored e-cig products from the market until they receive premarket authorization and otherwise meet applicable requirements," Gottlieb said.

The five e-cigarette brands account for more than 97% of e-cigarette sales, according to the FDA. JUUL alone has more than 70% of e-cigarette sales in the U.S. according to recent Nielsen data.

JUUL Labs, which manufactures JUUL, did not immediately respond to request for comment by *MedPage Today*.

Among the other actions announced Wednesday:

- More than 1,100 letters to convenience stores and other commercial establishments warning of illegal sales to minors, and they sent another 131 civil money penalties to stores that continued to violate restrictions on sales to minors
- Stepped up enforcement aimed at monitoring, penalizing, and preventing e-cigarette sales to minors in convenience stores and other retail sites
- National public campaign aimed at warning teenagers of the dangers of nicotine and e-cigarette use

Gottlieb's announcement was met with some skepticism by the American Lung Association's (ALA) national president and CEO, Harold Wimmer.

Last spring, the ALA, the American Academy of Pediatrics, Campaign for Tobacco Free Kids and four other public health groups filed a federal lawsuit against the FDA challenging the decision to delay federal review of e-cigarettes, including "candy flavored products that appeal to kids."

In a press release Wednesday, Wimmer charged that the FDA's lack of action has resulted in the epidemic use of e-cigarettes among teens and he urged the agency to act immediately.

"The action FDA threatened to 'consider' using against the manufacturers of five e-cigarette brands — removing certain products that are clearly aimed at youth from the market — is the very authority the American Lung Association has urged the FDA to actively use, broadly. With our nation's youth at risk for a lifetime of addiction to tobacco products, now is not the time to 'consider' but to meaningfully act," Wimmer said.

The press released called on the FDA to immediately begin "requiring all e-cigarettes and other newly deemed tobacco products to go through the premarket review process required in the Tobacco Control Act, and removing all flavored tobacco products from the marketplace."

Campaign for Tobacco Free Kids President Matthew Myers offered cautious praise for Gottlieb and the FDA, calling Wednesday's announcement "potentially the most important step FDA has taken to curtail youth use of e-cigarettes."

But he, too, said this can only happen if e-cigarette manufacturers are forced to remove flavored products from the market until the FDA specifically approves them, and if federal officials require manufacturers to alter current marketing practices, eliminate

federal officials require manufacturers to alter current marketing practices, eliminate online sales, and take other steps to curtail illegal sales to youth.

"Today's announcement will represent a fundamental turning point, if but only if, FDA formally requires all manufacturers to comply with these requirements and FDA reverses its policy and requires that all of these products undergo premarket review now, not four years from now," he said.

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