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### Scott Gottlieb's last word as FDA chief: Juul drove a youth addiction crisis

Youth vaping is surging. Trump's FDA chief says the Silicon Valley startup sparked the teen epidemic.

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By 2018, the number of high school seniors who say they vaped nicotine in the past 30 days doubled over the previous year — from 11 percent to nearly 21 percent. | Zach Gibson/Getty Images

It's not that often that you hear a top Trump official unabashedly blaming a US company for a health crisis. But that's exactly what FDA chief Scott Gottlieb did Tuesday in an interview during his final week in office.

"The dramatic spike of youth [vaping] — that was driven in part at the very least if not largely by Juul," the maker of hugely popular vape products, Gottlieb told Vox by phone. "I hope they recognize the problem that's been created has been created largely by their product."

Gottlieb joined the Trump administration in 2017, hoping to use policy to further reduce cigarette smoking, still the leading cause of preventable death in the US.

But then the teen vaping epidemic — what he calls an "**addiction crisis**" — exploded under his watch. By 2018, the number of high school seniors who say they vaped nicotine in the past 30 days doubled over the previous year — from 11 percent to nearly 21 percent, according to the **National Institutes of Health survey**. That was the largest increase ever recorded in any substance of the survey's 43-year history.

In the same period, **Juul Labs took over three-quarters of the US e-cigarette market.**

Gottlieb, who **resigned** on March 5 to spend more time with his family, acknowledged there's no definitive data showing the teens now experimenting with vaping are using Juul. He also said the 2019 national survey will fill in that blank with questions about which brands kids are using. But that didn't stop him from pointing the finger at the company he believes enflamed a public health crisis.

"There's no question the Juul product drove a lot of the youth use," he continued. "I'm not willing to concede the point that the Juul product was responsible — at least in part — for the sharp uptick in youth use."

## **A pro-regulation leader in an anti-regulation administration**

As a member of the pro-industry Trump administration, Gottlieb has often defied expectations. A doctor and former venture capitalist, he arrived at FDA **with strong ties to the industries** he was supposed to steer and a history of writing **anti-regulatory screeds in conservative journals**. Critics wondered if he was right for the job.

The 46-year-old quickly proved himself to be an outspoken advocate of public health. He's put forward policies on everything from reducing the nicotine levels in cigarettes to lowering drug prices by getting more generic options on the market.

"I never felt my public health agenda was at odds with the administration or broader philosophy," he said. "I have had really good support from the White House and from the department [of Health and Human Services] for what we've done."

Now, even in his last week in office, he's calling for more regulation of the vaping industry — and especially companies that've marketed to young people, like Juul.

## **A crackdown on Juul-like products may be necessary to curb the "addiction crisis," Gottlieb says**

Juul is a discreet **device** that looks like a USB drive and vaporizes a liquid that contains nicotine salts through e-liquid "pods." Each pod contains as much nicotine as at least one pack of cigarettes, and its nicotine salts are absorbed into the body at almost the same speed as nicotine in regular cigarettes, which is why officials worry Juul may be more addictive than other e-cigarettes.

Though the company has repeatedly stated that it's in the business of helping adult smokers to quit, Juul's early marketing campaign — **blasted out through social media, often featuring youth influencers and young people partying** — tells a different story.

"If you go back and look at their marketing campaigns from 2015 and 16," Gottlieb said, "it's hard not to look at that marketing and conclude that it's not going to be appealing to a youth, to a teenager. It certainly in my view had some impact on creating the problem we have now."

But Gottlieb's early record at FDA on e-cigarettes was somewhat mixed. **In 2017**, he delayed the compliance deadline for the **regulation of e-cigarette products** to 2022. This gave the industry five more years to file public health applications that show that their products are safe alternatives to conventional cigarettes and that they weren't unduly targeting minors. Gottlieb positioned the delay as a way to give manufacturers time to get in step with the new laws while ensuring smokers had access to cigarette alternatives that could save their lives.

Some public health advocates viewed the move as a giveaway for the vaping industry, and a chance for e-cigarette makers to further expand their market share among kids at a time when e-cigarette in teens has far **eclipsed conventional cigarette use**. For these reasons, health groups **sued the FDA** over the delay **and sent a letter to Gottlieb** asking the FDA to begin to regulate e-cigarette products like other cigarettes immediately.

Since then, as data about rising teen vaping levels piled up, Gottlieb moved to restrict the sale of flavored e-cigarette products to young people, and asked companies to take voluntary steps to withdraw them. Vaping advocates have criticized these moves, saying the FDA might make it harder for smokers to access e-cigarettes for smoking cessation.

Looking ahead, Gottlieb said concerns about youth vaping should take priority over concerns about smokers if adolescent vaping rates continue to rise. "This is now an addiction crisis, and it's going to take time to reverse. I don't anticipate we're going to see a decline in youth use of e-cigarettes this year."

“Does e-cigarette use among adolescents go up 10 percent or 40 percent? If it goes up 40 percent, we’re going to step in with additional regulatory steps and take more dramatic action to address the access of these products to kids,” Gottlieb said.

When asked what that might look like, Gottlieb suggested the broad category of e-cigarette products Juul is part of — known as “pod mods” — could be the focus of regulatory action.

“If [e-cigarette companies] can’t keep these [products] out of the hands of kids to a better degree than they’re doing now, these products are no longer going to be marketed.”

## Life after FDA

There’s one other blemish on Gottlieb’s otherwise respectable track record. The opioid epidemic has continued to worsen during the last two years. While Gottlieb’s actions were generally lauded by opioid experts, as **Vox’s German Lopez explained**, he was also criticized for failing to approve the opioid overdose treatment **naloxone** for over-the-counter use, and for bringing to market yet another **opioid painkiller** despite concerns about its potential for abuse.

Despite those concerns, however, his resignation was still generally viewed as a loss for public health.

Gottlieb plans to return to the American Enterprise Institute, a conservative think tank, to focus on the **problem of drug pricing**. He’s repeatedly denied his reasons for resigning are anything more than the **personal desire to spend more time with family**. For now, we know that Ned Sharpless, the current director of the National Cancer Institute, will be replacing him as interim FDA chief.

Gottlieb hopes the next commissioner will build on his legacy — and believes the Trump administration will help that person do so.

“Secretary Azar [at HHS] has been extremely supportive of our efforts to reduce death and disease from tobacco [and] my recent efforts to keep these products out of the hands of kids. I expect [Azar] to continue to be a strong champion.”