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Gottlieb Leaves Vocal Legacy At FDA

By **Emily Field**

Law360 (March 6, 2019, 11:06 PM EST) -- Scott Gottlieb didn't shy away from publicly calling on e-cigarette companies to address youth vaping or from telling drug companies to quit anti-competitive practices during his tenure as head of the U.S. Food and Drug Administration, shining a light on key issues.

Gottlieb, who is leaving in a month, brought an energetic, pragmatic approach to tackling problems such as the opioid crisis, and his public presence — from media appearances to speeches to his frequent use of Twitter — spotlighted the FDA's activities and limitations, attorneys said.

In a tumultuous administration marked by sudden ousters, Gottlieb also managed to stay in President Donald Trump's good graces and garnered the support of Republicans and many Democrats.

"He has navigated the political situation with the administration in a pretty amazing way," said Christopher Mikson, Mayer Brown's FDA regulatory practice leader. "We haven't seen a lot of that. We've seen a lot of distractions with other folks in the administration and other areas, and we haven't seen that at all with him."

Gottlieb's announcement Tuesday of his departure, however, raises questions about what will happen to the policy issues he advanced during his tenure, said Scott Liebman, head of the FDA practice at Loeb & Loeb LLP, especially as only two months ago, Gottlieb adamantly denied rumors he was leaving the agency.

"Now we are left wondering who will take over, and do we start from square one with new passion projects and a new list of priorities for a new commissioner?" Liebman said. "Gottlieb raised attention to some important issues: opioid crisis, youth vaping, tobacco use."

Here, attorneys look back at Gottlieb's two years at the FDA and consider what might come next.

Focus on Drug Pricing

Gottlieb, a medical doctor, broke with tradition in taking on the issue of drug pricing as historically the FDA had taken the position that it plays no role in setting the cost of drugs, according to Chad Landmon of Axinn Veltrop & Harkrider LLP.

Unlike government programs such as Medicare and Medicaid, the FDA has no direct impact in purchasing drugs or on what prices are charged, FDA practice group chair Landmon said. But Gottlieb took the position that the FDA could play a role in drug pricing by encouraging competition, according to Landmon.

That has taken the form of speeding up the approval process and reducing the regulatory burdens to approve innovator drugs, which then compete with each other on the market, potentially lowering drug prices, Landmon said.

“More importantly, the agency has been very aggressive at trying to increase generic competition,” Landmon said.

The FDA in September laid out guidance aimed at cutting down the time it takes for new and generic drugs to reach the market by clarifying what the agency wants to see in a drug application, so companies can make a higher quality submission that doesn’t have to go through multiple review cycles because of missing information.

During Gottlieb’s tenure, the agency has also set records for approvals of generic drugs. In fiscal year 2018, the agency approved 971 generics, surpassing the previous year’s approval of 937 generic drugs.

Gottlieb has also openly criticized practices used by innovator drug manufacturers to hurt generic competition, attorneys noted.

At a 2017 Federal Trade Commission conference, Gottlieb blasted innovator drug companies for abusing risk evaluation and mitigation strategies, or REMS, often required by regulators to restrict the distribution of potentially dangerous medicines. Innovators sometimes prevent generic drug companies from having access to samples of brand-name drugs, stifling research needed to get a generic drug approved.

“My message is this: End the shenanigans,” Gottlieb said.

That concern led to the CREATES Act, a proposed bill that would give generic-drug companies a new cause of action to sue if they’re not getting the samples they should, Mikson said

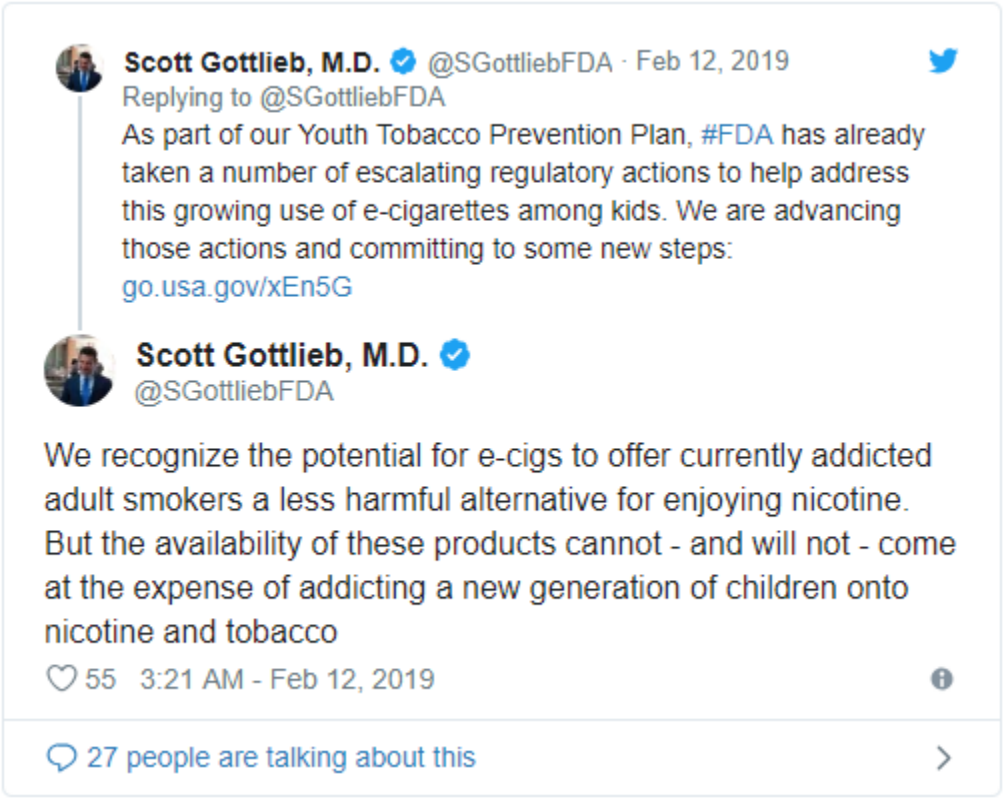
Trump has frequently voiced a desire to see drug prices cut, and U.S. Department of Health and Human Services Secretary Alex Azar has also focused on the issue, Landmon said.

“I would expect the successor to be continued to be focused on in it," Landmon said. “It will be interesting to see who ends up in that spot and if they have the same inclinations.”

Future of E-Cigarettes

Youth use of e-cigarettes was one of Gottlieb’s top priorities, and he called out vaping companies whose

marketing practices he believed were aimed at minors, indicating that a ban on e-cigarettes was possible if youth vaping rates didn't go down.



Last fall**,** the FDA proposed restricting sales of flavored e-cigarettes to locations that bar minors, along with a ban on menthol cigarettes and flavored cigars.

In announcing the proposal, Gottlieb pointed to a 78 percent increase in e-cigarette use from 2017 among youth of high school age and a nearly 50 percent increase among those of middle school age.

Gottlieb has also called on e-cigarette makers to take voluntary steps to address teen use, and last month he requested meetings with the heads of JUUL and tobacco giant Altria to address questions about their commitment to lowering teen use of their products.

"The fact that he has been relatively aggressive on the vaping issues isn't necessarily what you'd expect from an administration that generally has touted reducing regulations, but I think the FDA and Gottlieb has been a little different on that front," Landmon said.

The nonprofit Campaign for Tobacco-Free Kids said Tuesday that Gottlieb deserves credit for calling attention to youth vaping and for aggressive enforcement actions.

In one enforcement blitz, the FDA in September sent more than 1,300 warning letters and fines to retailers who sold e-cigarettes to youths and gave five manufacturers 60 days to come up with plans to keep their products out of children's hands.
But the nonprofit pointed out that none of Gottlieb's proposals, such as banning menthol cigarettes and flavored cigars, have yet been adopted.

“Commissioner Gottlieb’s legacy will depend on whether his many proposals are implemented and, in the case of the youth e-cigarette epidemic, strengthened going forward,” the campaign said in a statement.

Tackling the Opioid Crisis

Gottlieb made the opioid crisis a priority early in his tenure, and has acknowledged that the FDA took too long to detect the rise in opioid addiction and counter it.

“The FDA is also not immune from responsibility,” Gottlieb said in a November speech**.** “We were too slow to act at some key moments.”

On average, 115 Americans die each day from an opioid overdose. The number of overdose deaths involving opioids, including prescriptions and illegal opioids like heroin, was five times higher in 2016 than in 1999, according to the Centers for Disease Control.

“He was very active and outspoken on the opioid crisis, and it’s interesting because generally I don’t think the agency has a lot of different tools it can use to combat the opioid crisis,” Landmon said.

The FDA has explored whether naloxone, an overdose treatment, should be prescribed along with opioid medications. Late last year, an FDA advisory committee voted in favor of adding changes to labeling that would recommend adding a prescription for naloxone for some or all patients.

Gottlieb also said that his agency is looking to develop evidence-based guidelines for the safe prescribing of opioids, even though focusing on how doctors prescribe drugs isn’t typically part of its purview.

“For too many years, we as doctors were too cavalier about the prescribing of these powerful and addictive drugs,” Gottlieb said in November. “An entire generation of physicians was trained — inappropriately we now know — on opioid prescribing practices that were far too loose.”

CBD Regulations

Gottlieb’s sudden departure also means it’s likely that regulations regarding nonpsychoactive cannabidiol derived from hemp will be delayed, according to Jonathan Havens of Saul Ewing Arnstein & Lehr.

The production of hemp was legalized late last year with the passage of the farm bill. Hemp, a relative of the marijuana plant that has low concentrations of the psychoactive compound tetrahydrocannabinol, or THC, has a number of industrial uses. But while the market for CBD foods has grown sharply in recent years, the FDA has said that CBD is not legally allowed in food.

Just last week**,** Gottlieb said that the agency would hold a public meeting in April on CBD about how to address it.

“My concern is now that he’s leaving, what happens at the public meeting?” Havens said.
The FDA is unlikely to make CBD a priority, and it remains to be seen if senior officials at the agency have the appetite to take on the issue in Gottlieb's absence, Havens said.

Gottlieb put forth a framework under which high or pure concentrations of CBD would be considered a drug product, and lower concentrations of CBD could used in foods.

While the food and dietary supplement industry would welcome that approach, the FDA could also be worried about setting a precedent of allowing lesser concentrations of drugs in foods, Havens said.

And while lawmakers might be motivated to act, that might mean revising the Food, Drug, and Cosmetic Act, which would be a tall order, Havens said.

“That would be a Christmas tree of a bill [with everyone adding what they want],” Havens said.

--Additional reporting by Jeff Overley. Editing by Jill Coffey and Emily Kokoll.