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Health advocates worry about an FDA without Scott Gottlieb

His aggressive proposals on tobacco, opioids may not be priorities for a successor.

Health advocates worry FDA will be weakened without Scott Gottlieb. (Mark Wilson/Getty Images)

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Scott Gottlieb, one of the most activist Food and Drug Administration commissioners in recent years, pushed ideas such as banning menthol in cigarettes and packaging opioids in small blister packs to prevent overuse.

Those ideas seemed more startling because he was part of an anti-regulatory, pro-business administration. Now, with his surprise resignation, public health advocates are anxious about the fate of some of his more ambitious initiatives, whether his successor will embrace them — and whether the agency will get a permanent successor at all.

“I’m definitely concerned,” said Joshua Sharfstein, who served as principal deputy FDA commissioner during the Obama administration. He said Gottlieb, a physician, was respected by the agency’s career staff, which enabled him to push them "to do more and to do things differently. That combination is hard to find.”

The FDA regulates roughly 20 percent of the economy, and its policies have a major, direct impact on the American consumer. Not only does the agency approve drugs and oversee medical devices, but it

also is charged with policing the safety of dietary supplements and overseeing 80 percent of the nation's food supply.

Tobacco-control activists are among the most worried. While they sometimes pressed Gottlieb to go further on e-cigarette and tobacco issues, they are now anxious his successor will have neither the interest – nor the political or bureaucratic clout – to make the issue a top priority.

"We have real concerns that the tobacco industry will exploit the leadership vacuum at the FDA to aggressively press its profit-centered policy agenda," said American Heart Association chief executive Nancy Brown.

"We are at a fundamental crossroads and what happens in the next six to 12 months will have consequences for decades to come," said Matthew Myers, president of Campaign for Tobacco-Free Kids.

Gottlieb's draft guidelines restricting retail and online sales of many flavored e-cigarettes – policies outlined in November – are expected to be issued soon, perhaps in the next week or so.

E-cigarette enthusiasts, who say the FDA's anti-youth-vaping campaign harms adults wanting to use the products to quit regular cigarettes, took to Twitter to applaud his departure. But they conceded the next commissioner might carry on the vaping effort.

But his plans to ban menthol in cigarettes and reduce nicotine levels are not yet formal proposals and might not make it out of the administration, anti-tobacco groups fear.

The debate about the future of the FDA comes as the Trump administration considers a replacement. The expectation is it will name an acting commissioner before Gottlieb leaves in a month. Whether that person will be nominated for the post on a permanent basis is unknown.

Among those who have been mentioned as possible candidates for the top job are Norman "Ned" Sharpless, director of the National Cancer Institute, and Brett Giroir, assistant secretary for health at the Department of Health and Human Services. Amy Abernethy, Gottlieb's principal deputy commissioner, has been mentioned as a possible acting FDA chief, but her short tenure — she recently joined the agency — is thought to be a strike against her.

It's also possible that an acting commissioner ends up staying for the rest of the term. President Trump has said he's in no rush to name permanent members of his Cabinet after a series of departures, claiming that members of his administration serving in an acting capacity give him "more flexibility."

Serving in an "acting" status can hamstring a commissioner's ability to pursue an ambitious agenda, said Mark I. Schwartz, a former FDA official who now practices food and drug law. "Politically and pragmatically, there are limitations on how bold they can be because they are basically caretakers."

Among other initiatives that could get lost in the transition were Gottlieb's announcement that he would take a harder line on dietary supplements, an area where the agency has only limited authority. He recently warned several companies that some products were being illegally marketed with unproven claims to prevent or treat Alzheimer's disease and other serious conditions. Critics of the industry were hoping Gottlieb would take more aggressive steps in the future.

Gottlieb has also been outspoken on the opioid crisis. Gary Mendell, founder of the advocacy group Shatterproof, which is working to curb the epidemic, cited the commissioner's efforts to have small numbers of pills packaged in blister packs rather than dispensing large numbers in vials. Mendell said that's the kind of common-sense reform "that could save a lot of lives" that he hopes won't be overlooked by Gottlieb's successor.

Mendell also noted that Gottlieb wants opioid dose guidelines for caregivers broken out by type of injury, so prescribers have better prescribing instructions.

“We would be concerned that [with] anyone new, coming in with a new agenda, these two things could get lost.”

But Mendell and Ryan Hampton, a former heroin addict who founded the Wake Up FDA campaign, also said they hoped the next commissioner would do more to get opioid treatment medications on the market.

Hampton, who said he defeated a 10-year addiction with the use of suboxone, criticized the FDA for refusing to allow another treatment, Brixadi, on the market until November 2020. The FDA has ruled that Brixadi, an injectable form of buprenorphine is too similar to Sublocade, and would violate Sublocade’s exclusivity protections.

“He has a chance to correct this before he leaves, or the interim or new commissioner can take action,” Hampton said.

Paul Knoepfler, a cell biologist at the University of California at Davis, expressed concern about the future of the agency’s crackdown on the burgeoning for-profit stem cell industryusing the material in unapproved and unproven ways. Gottlieb called out “bad actors” and sued two companies, but the agency faces a long, difficult road in trying to assert control over the sprawling industry.

“I hope that the FDA’s momentum on stem cell clinics won’t evaporate after his departure,” Knoepfler wrote on his blog, The Niche. "My sense is that he personally made a major difference in how aggressively the agency moved forward,” he said. “The FDA under past commissioners failed on the stem cell clinic issue, and it’s still a mystery why. Too timid? Too political?”

Another issue that could be slowed down are decisions about how the FDA will regulate cannabidiol, or CBD, a non-psychoactive ingredient derived from hemp. Though the recent farm bill legalized hemp, “there’s a good deal of confusion” about how the FDA will handle CBD, said Bethany Hills, an attorney who specializes in food and drug law. Gottlieb recently said he would hold public meetings in April to discuss the issue.

While health advocates are uncertain about what lies ahead, some said Gottlieb did a good job preparing a guide for the agency for after his departure. “He’s leaving a very good map for success” said Robin Koval, chief executive officer of the anti-tobacco Truth Initiative. “And anyone who comes in needs not just to follow that but also to accelerate it.”