

FDA Commissioner Gottlieb Resigns

Food and Drug Administration (FDA) Commissioner, Scott Gottlieb, has resigned after about 2 years (1). Gottlieb was a controversial appointee by the Trump administration due to his ties to the pharmaceutical industry. However, he stood out in the anti-regulatory Trump administration, where some officials such as Scott Pruitt, the former head of the Environmental Protection Agency, appeared intent on reducing the clout of the departments and agencies they headed. For nearly two years, Gottlieb has avidly promoted the FDA, inserting the agency into important health issues and sometimes taking on industries regulated by the agency.

Under Gottlieb's leadership the FDA has made sweeping moves to lower smoking and vaping amongst minors. Gottlieb's departure could throw into question other controversial tobacco initiatives he championed that have not yet emerged from the FDA, including proposals to ban menthol cigarettes and to reduce nicotine levels in cigarettes. In his resignation letter to Health and Human Services Secretary, Alex Azar, Gottlieb listed his accomplishments, including accelerating the approval of generic drugs and modernizing the process for handling novel gene and precision therapies to treat those with cancer.

The resignation took some senior FDA officials by surprise, and came as Gottlieb's signature issue – youth vaping – is being reviewed by the White House Office of Management and Budget. The plan, detailed by Gottlieb last fall, would sharply restrict the sale of flavored e-cigarettes to curb a surge in underage vaping, which he argues could lead to a whole new generation addicted to nicotine.

Gottlieb, who has been commuting weekly to Washington from his home in Connecticut, said he wants to spend more time with his family. The resignation was apparently not sought by the White House. A senior White House official said Gottlieb had spoken to President Trump, and that the president liked the FDA chief and did not want him to leave. While Gottlieb had some policy disagreements with the White House, he is well respected, and could even be asked to take another post, said two officials. Gottlieb declined to comment on that possibility.

Most praised Gottlieb including his predecessor, Robert Califf, and Friends of Cancer Research and Tobacco Free Kids (1). However, he was not without his critics. Pieter Cohen, an associate professor at Harvard Medical School who conducts research into the safety of dietary supplements, faulted Gottlieb for not taking significant action on major safety problems involving dietary supplements. Raeford Brown, a professor of anesthesiology and pediatrics at the University of Kentucky, criticized Gottlieb's opioid policy. "I am concerned, because he seems to have a tendency to spend most of his time talking and very little of his time implementing policy." The advocacy group Public Citizen said that Gottlieb's time as the agency's head "was marked by regulatory decision making regarding medications and medical devices that tilted further in favor of industry's financial interests rather than the interests of public health (2)." The group

cited the controversial approval in April of an opioid called Dsuvia, which is 10 times more powerful than fentanyl.

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References

1. Laurie McGinley L, Bernstein L, Dawsey J. FDA Commissioner Gottlieb, who raised alarms about teen vaping, resigns. Washington Post. March 5, 2019. Available at: https://www.washingtonpost.com/health/2019/03/05/fda-commissioner-gottlieb-who-raised-alarms-about-teen-vaping-resigns/?utm_term=.b50dd0bbb2ae (accessed 3-6-19).
2. Scutti S, Diamond J, Goldschmidt D. FDA Commissioner Dr. Scott Gottlieb to resign next month. CNN Politics. March 5, 2019. Available at: <https://www.cnn.com/2019/03/05/politics/gottlieb-resigning-fda-health-bn/index.html> (accessed 3-6-19).