

United States Senate

WASHINGTON, DC 20510

July 12, 2022

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

In March, Congress gave the Food and Drug Administration (FDA) the clear authority to regulate synthetic nicotine as it does tobacco-derived nicotine, ensuring that all e-cigarettes on the market would be subject to the agency's public health oversight (Sec. 111 of P.L. 117-103). This bipartisan Congressional action came after FDA sounded the alarm that certain e-cigarette manufacturers were abusing an ambiguity in the law that threatened to upend the agency's longstanding efforts to regulate vaping products. Despite the agency drawing attention to the need to close this loophole, we are concerned that FDA is failing to implement the law, which has grave consequences for the health of children across America.

The most popular e-cigarette used by children, PuffBar, is a synthetic nicotine product that was reformulated to evade FDA regulation after it was subject to a warning letter from the agency. Additionally, several e-cigarette manufacturers whose applications were subject to marketing denial orders attempted to circumvent the agency's oversight by switching to synthetic nicotine. In Congressional testimony at the time, you stated, "we've got to close this loophole."

We led the bipartisan effort to close this loophole and establish clear timelines for FDA's review, which FDA celebrated in public statements and publications.

Recent reporting from *STAT News* suggests that FDA has failed to take enforcement action against e-cigarette manufacturers that are on the market illegally and failed to submit a timely premarket tobacco product application (PMTA) by May 14, 2022, as required by the new law. Senators also have requested information from FDA on the number of submissions filed, and those inquiries have gone unanswered. This delay and neglect of enforcement is unacceptable—especially considering the youth appeal of many of these e-cigarette products.

This apparent lack of enforcement is particularly shocking given FDA's previous failure to maintain a list of products that were on the market at the time of the August 8, 2016, deeming rule effective date—a system which would have enabled the agency to understand which products were entering the market without proper authorization. We fear FDA is stumbling down the same path that ignited the youth vaping epidemic in the first place.

Fortunately, there is an opportunity for FDA to rectify these mistakes. The agency has another deadline—July 13, 2022—to clear the market of all unauthorized e-cigarettes that use synthetic nicotine. The law gives FDA the clear authority and duty to remove all unauthorized synthetic nicotine e-cigarettes from the market.

This enforcement delay is not happening in a vacuum. Right now, the agency is 10 months past a court ordered-deadline to finish reviewing PMTAs for all other e-cigarettes that submitted applications by September 9, 2020. To better understand FDA's plans for implementing the new synthetic nicotine law requirements, we request answers to the following questions by July 20, 2022:

1. How many timely filed applications did FDA receive for synthetic nicotine e-cigarettes?
2. How many synthetic nicotine e-cigarettes that were on the market by the effective date set forth in subsection (c) of the new law failed to submit timely applications?
3. Did the FDA keep a list of synthetic nicotine e-cigarettes that were on the market by the effective date set forth in subsection (c) of the new law?
4. What lessons did FDA learn from its failure to keep a list of e-cigarettes that were on the market by August 8, 2016, and are these being employed to implement the synthetic nicotine regulation?
5. How many warning letters, and to which companies, has FDA sent to synthetic nicotine e-cigarette manufacturers that failed to submit a timely filed application?
 - a. As set forth in the law, has FDA taken further enforcement action, including injunctions or product seizures, of any such violative synthetic nicotine e-cigarettes?
6. Will FDA comply with the law and remove from the market any synthetic nicotine e-cigarettes without a marketing authorization by July 13, 2022?
 - a. Will FDA make public the list of such products?
7. Would additional resources enable FDA to improve its e-cigarette enforcement activities?

We find it deeply disappointing and unacceptable that FDA appears to be on the brink of failing yet again at protecting our nation's children from the dangers of nicotine addiction. When presented with an emerging public health challenge identified by FDA, Congress took swift bipartisan action to provide FDA with the tools needed to properly regulate synthetic nicotine. We encourage FDA to immediately use these tools and follow the law.

Sincerely,



Richard J. Durbin
United States Senator



Susan M. Collins
United States Senator