

United States Senate

November 5, 2025

The Honorable Martin Makary, M.D., M.P.H.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Makary:

I write to express concern about illicit Chinese nicotine products sold in the United States. Communist China is waging a war on Americans by flooding our market with dangerous products, specifically targeting children.

The FDA has acknowledged that illicit e-cigarettes manufactured in Communist China contain harmful additives including formaldehyde, lead, and acrolein. Studies show some illicit disposable e-cigarettes release lead amounting to nearly 20 packs of cigarettes during a single day's use, with chromium and nickel increasing up to 1,000-fold over an e-cigarette's lifespan. The 2019 EVALI outbreak resulted in over 2,800 hospitalizations and 68 deaths, strongly linked to vitamin E acetate in illicit vapor products. The vitamin E acetate – used as the diluting agent for THC liquid – was a direct export from China. As the Attorney General has noted, unregulated illicit Chinese e-cigarettes are also at a risk for containing fentanyl, which killed over 48,000 Americans in 2024.

I commend recent Trump administration actions to curb distribution of illicit Chinese e-cigarettes. On September 25, 2025, FDA announced the seizure of more than 2.1 million Chinese e-cigarette products across seven states.¹ FDA also announced the seizure of 4.7 million units valued at \$86.5 million, the largest ever seizure of its kind.²

While FDA's actions show progress, more must be done. The work must continue until these products are no longer found in America. To combat Chinese influence, FDA should increase the number of regulated, legal, American products available to consumers. To date, FDA has authorized just 39 e-cigarette products, from only five companies, despite receiving over 26 million applications. Only when adult consumers have legal, regulated, and satisfactory alternatives available in the American marketplace will the market demand for illicit Chinese products disappear.

I respectfully request responses to the following questions by December 5, 2025:

1. What additional authorities does FDA need to further curb distribution of illicit Chinese e-cigarettes? When might Americans see their disappearance from store shelves?
2. What is FDA's plan to increase the number of regulated American products available in the U.S. market?

Sincerely,



Tom Cotton
United States Senator

¹<https://www.justice.gov/opa/pr/more-two-million-illicit-vaping-products-seized-nationwide-sweep>

²<https://www.fda.gov/news-events/press-announcements/hhs-cbp-seize-865-million-worth-illegal-e-cigarettes-largest-ever-operation>