

United States Senate

WASHINGTON, DC 20510

June 18, 2024

Commissioner Robert M. Califf, M.D.
U.S. Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Attorney General Merrick Garland
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, D.C. 20530

Dear Commissioner Califf and Attorney General Garland:

I continue to be concerned by the pervasive and exponential growth of the illegal e-cigarette market in the United States. Last year, more than 98 percent of e-cigarettes marketed and sold in the U.S. were illegal.¹ The Food and Drug Administration (FDA), and Department of Justice (DOJ), together with other agency partners, must ensure that these dangerous and illegal products are not marketed to the American people, particularly to our children and teenagers. As the heads of the newly-announced multi-agency task force to combat the illegal distribution and sale of e-cigarettes, you need to act swiftly to regain control of the e-cigarette marketplace, protect American consumers, and help reverse the alarming trend of youth vaping that threatens to create a new generation of nicotine addiction.

Despite decades of anti-smoking campaigns, young people are becoming addicted to nicotine as a result of an illegal e-cigarette market that is saturated with products designed to appeal to youth. In 2023, 10 percent of middle and high school students, approximately 2.1 million youth, reported using e-cigarettes.² Current FDA guidance states that the agency will prioritize enforcement against any unauthorized flavored e-cigarettes and e-cigarettes that are accessible by, or marketed towards, minors.³ All flavored e-cigarettes—which are the most popular with youth—are currently illegal, yet they remain easily accessible in gas stations, convenience stores, and other retail outlets across America.⁴

The majority of illegal e-cigarettes are manufactured in and imported from China, largely from under-the-radar manufacturers which have altered their practices to skirt existing enforcement mechanisms such as agency review and marketing authorization.⁵ Effective enforcement strategy

¹ AP News, [*US seizes more illegal e-cigarettes, but thousands of new ones are launching*](#)

² CDC, [*E-cigarette Use Down Among U.S. High School Students in 2023*](#)

³ FDA, [*Enforcement Priorities for Electronic Nicotine Delivery Systems \(ENDS\) and Other Deemed Products on the Market Without Premarket Authorization \(Revised\)*](#)

⁴ CNBC, [*Flavored e-cigarette sales are booming despite federal crackdown*](#)

⁵ CBS News, [*Thousands of types of illegal vaping devices, mostly from China, flooding U.S. despite FDA crackdown, report says*](#)

should make broad use of all federal enforcement authorities—including injunctions, import restrictions, no-tobacco-sale orders, civil monetary penalties, and product seizures—with a goal of regaining control over the runaway illegal market and protecting consumers.

It is imperative that the FDA, DOJ, and partner agencies assert consistent, uncompromising enforcement over the e-cigarette marketplace. I request answers to the following questions and a briefing by the task force on its plans to ensure illegal e-cigarettes are not available in the United States, and to prevent e-cigarettes from being marketed or sold to minors, by July 12, 2024:

1. Given all flavored e-cigarettes are illegal, why are flavored e-cigarettes available for sale in the United States?
 - a. What consequences do manufacturers, distributors, and retailers of illegal flavored e-cigarettes currently face, and what more is the task force doing to ensure businesses take these illegal products off their shelves?
2. What is the criteria for determining when e-cigarettes are accessible by, or marketed towards, minors and therefore become a priority for enforcement?
3. The DOJ has only sought injunctions against seven manufacturers of illicit e-cigarettes— a far cry from the number of retailers the FDA has identified as selling unauthorized products.
 - a. How many cases does the FDA have cases pending with the DOJ?
 - b. What criteria does a case have to meet in order for the DOJ to move forward with an injunction or other enforcement measures?
4. The Tobacco Control Act gives the FDA the authority to charge companies civil monetary penalties for multiple violations of the statute, up to \$1.2 million in a single proceeding.
 - a. Is the FDA currently pursuing statutory maximum penalties, including issuing multiple penalties for individual product and manufacturer violations?
 - b. Is the current statutory maximum penalty sufficient to be an effective enforcement mechanism, particularly with respect to deterring the importation of illicit products from foreign manufacturers?
5. The majority of illicit e-cigarettes in the U.S. are imported from China, and the CBP is responsible for inspecting imported products.
 - a. Why does the multi-agency taskforce, announced on June 10th, not include the CBP?
 - b. How is the task force going to address the problem of illegally imported e-cigarettes?

6. Are additional authorities needed to ensure illegal e-cigarettes are not available in the United States and prevent e-cigarettes from being sold to minors?

Sincerely,

A handwritten signature in blue ink that reads "Mitt Romney". The signature is written in a cursive style with a large, stylized "M" and "R".

Mitt Romney
United States Senator