

# United States Senate

WASHINGTON, DC 20510

January 15, 2025

Dr. Robert M. Califf, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

We remain concerned about the continued presence of unauthorized electronic nicotine delivery systems (ENDS) and illicit vaping products among vendors at large trade shows across the country. Vendors display and sell illicit products in the presence of Food and Drug Administration (FDA) personnel despite their lack of market authorization.<sup>1</sup> These concerns were brought to the FDA's attention on January 25, 2024 and again on June 6, 2024, but the FDA has not provided a satisfactory, substantive response. Meanwhile, manufacturers, mostly from China, continue to pour their illicit vapes into the United States with few, if any, consequences.<sup>2</sup> For this reason, we urge you to utilize enforcement actions against illicit products at 2025 trade shows, namely events hosted by the Total Products Expo (TPE) and the Alternative Products Expo (APE), across the country at locations in Florida, Nevada, Tennessee, and Texas.<sup>3</sup>

As mentioned in a letter dated June 6, FDA personnel were present at the 2024 TPE in Las Vegas, Nevada and were distributing educational materials—in the presence of unauthorized vendors—and yet did not utilize enforcement actions. Simply staffing a booth alongside illicit products is negligence. If illicit products are displayed in the presence of FDA personnel, they must enforce the law.

Many of the companies present at these trade shows have received warning letters from your agency and therefore should not be selling their products at all. On September 13, 2024, the FDA issued six new warning letters<sup>4</sup> to manufacturers of illicit products that were present at the 2024 TPE.

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<sup>1</sup> 21 U.S.C. § 387j(b)(1) (2018).

<sup>2</sup> CBS News. *Illegal Vaping Devices Mostly from China Are Target of FDA Crackdown*. CBS News (Sept. 12, 2023). Online at <https://www.cbsnews.com/news/illegal-vaping-devices-mostly-china-us-fda-crackdown/>.

<sup>3</sup> Alternative Products Expo (APE). *The Local Gateway to Growth! Miami 25': April 3-5*. Online at <https://altproexpo.com/miami/>;  
Total Products Expo (TPE). *TPE: January 29-31, 2025 at Las Vegas Convention Center*, Online at <https://www.totalproductexpo.com/attendee-schedule/>; APE. *Expand Your Business Throughout the Southeast! Nashville 25': June 19-21*. Online at <https://altproexpo.com/nashville/>; APE. *We Got a Tradeshow! Houston 25': August 7-9*. Online at <https://altproexpo.com/houston/#>.

<sup>4</sup> FDA. *FDA Takes Action Against Unauthorized E-Cigarettes Promoted at Industry Trade Show*. Press Release (Sept. 13, 2024). Online at <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-takes-action-against-unauthorized-e-cigarettes-promoted-industry-trade-show>.

Given that these products and distributors are likely to appear at the 2025 Total Products and Alternative Products Expos, please respond to the below questions.

- Aside from the initial formation of a federal, multi-agency task force, what concrete steps has FDA taken with federal partners, including the U.S. Department of Justice (DOJ) and U.S. Customs and Border Protection (CBP), to ensure illicit products exhibited at the 2024 expos are not present at the 2025 expos?
- What metrics are currently utilized across agencies to assess the efficiency of FDA's federal collaboration on illicit vaping products and ENDS?
- Has DOJ historically rejected FDA's requests for enforcement actions such as civil monetary penalties or product seizures? If yes, please provide specific details of each instance.
- Considering FDA's two recent import alerts announced this year,<sup>5</sup> please provide details about the implementation of 'detention without physical examination.' Will the FDA keep record of violators at the point of detention for the purpose of future federal joint operations? If yes, will this list be made public for law enforcement in all jurisdictions?
- How does FDA, with federal partners, implement admission refusal and/or product destruction in cases such as the 53,700 ENDS seized by Chicago CBP?<sup>6</sup>

Please respond to this letter no later than **January 24, 2025**.

Sincerely,



Ted Budd  
United States Senator



Thom Tillis  
United States Senator



Martin Heinrich  
United States Senator

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<sup>5</sup> FDA. *FDA Updates Import Alerts to Reinforce That All Unauthorized E-Cigarettes May Be Detained Without Physical Examination*. (January 3, 2025) Online at <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-updates-import-alerts-reinforce-all-unauthorized-e-cigarettes-may-be-detained-without-physical>.

<sup>6</sup> U.S. Customs and Border Protection. *53,700 Electronic Nicotine Delivery Systems Seized by Chicago CBP*. (June 25, 2024) Online at <https://www.cbp.gov/newsroom/local-media-release/53700-electronic-nicotine-delivery-systems-seized-chicago-cbp>.

CC:

Merrick Garland, Attorney General, U.S. Department of Justice  
Alejandro Mayorkas, Secretary of Homeland Security, U.S. Department of Homeland Security  
Steve Dettelbach, Director, Bureau of Alcohol, Tobacco, Firearms and Explosives  
Pete R. Flores, Commissioner, U.S. Customs and Border Protection