United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

August 29, 2024

The Honorable Gene Dodaro
Comptroller General of the United States
Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

Since 2014, e-cigarettes have become the most common form of tobacco product among youth. Today, more than two million children report vaping—approximately 10 percent of middle and high school students. The Centers for Disease Control and Prevention and the U.S. Surgeon General have stated that e-cigarettes are not safe, especially for children, teens, and young adults. E-cigarettes contain nicotine, which is highly addictive and can harm adolescent brain development relating to attention, learning, mood, and impulse control. E-cigarettes also can contain cancer-causing chemicals, heavy metals, tiny particles that can be inhaled deep into the lungs, and chemical flavorings linked to lung disease.

Despite the known harms of e-cigarettes, more than six thousand distinct types of e-cigarette products are available in retail settings nationwide—nearly all of which are sold in violation of federal law.

Under the 2009 *Family Smoking Prevention and Tobacco Control Act* (TCA), no tobacco product is permitted to enter the market unless its manufacturer first proves to FDA that it is "appropriate for the protection of public health." In 2016, the Food and Drug Administration (FDA) finalized the "Deeming Rule" to exercise jurisdiction over e-cigarettes as tobacco products, subjecting them to FDA's pre-market authorization requirement. Despite this action, FDA did not enforce the pre-market authorization requirement until the U.S. District Court for the District of Maryland ruled in 2019 that FDA's inaction violated the TCA. The Court ordered e-cigarette manufacturers to submit premarket tobacco product applications (PMTAs) by September 9, 2020, and directed FDA to complete PMTA reviews within one year—*i.e.,* by September 9, 2021.

Following that date, all unauthorized e-cigarettes on the market should have been subject to enforcement action under the TCA. In fact, FDA stated on December 13, 2023, "It is illegal to sell, import, distribute, or offer for sale or distribution to U.S. consumers any e-cigarette that has not been authorized by FDA … For unauthorized tobacco products, the pendency of an application does not create any sort of a safe harbor to sell that product."

To date, FDA has authorized only 34 e-cigarettes for sale in the United States, manufactured by Logic, NJOY, and RJ Reynolds. All other e-cigarettes being sold—including all fruit, candy, or sweet flavored e-cigarettes—are unauthorized and illegal as adulterated and misbranded products under the TCA. Notably, 90 percent of teens who use e-cigarettes consume unauthorized, flavored products.

As part of the district court's 2019 ruling, FDA was ordered to provide quarterly status reports on the agency's progress in adjudicating applications for the class of e-cigarettes with the largest market shares. Currently, FDA has acted on 185 of 186 of those applications. However, the agency still has thousands of pending PMTAs, including for e-cigarettes using synthetic or "non-tobacco" nicotine (nicotine that is not derived from a tobacco leaf, but synthesized chemically), which came under the FDA's jurisdiction in March 2022 and which became subject to enforcement action starting on July 14, 2022, even for timely filed applications. Some of the most popular e-cigarettes used by children today use synthetic nicotine and are on the market illegally.

FDA shares responsibility with the Department of Justice (DOJ) for removing unauthorized e-cigarettes from the market. FDA is empowered to pursue certain administrative actions, including issuing warning letters, civil monetary penalty (CMP) complaints, and fines. The agency has utilized these tools to some degree, including by issuing more than 1,000 warning letters to manufacturers, distributors, and retailers regarding unauthorized tobacco products; 200 CMP complaints (primarily to brick and mortar retailers); and fines for the sale of unauthorized tobacco products in amounts of approximately $20,000 (a fraction of the $1.2 million maximum fine FDA may issue in a single proceeding for multiple violations). DOJ, in contrast, has sole authority to institute judicial enforcement actions, such as injunction proceedings, on behalf of FDA in federal court. To date, FDA and DOJ have pursued injunctions against only eight manufacturers.

In December 2022, the independent Reagan-Udall Foundation issued a report evaluating the regulatory, application review, enforcement, and public communication activities of FDA's Center for Tobacco Products, which oversees implementation of the TCA. In that review, the Reagan-Udall Foundation identified several challenges with respect to FDA-DOJ coordination on enforcement actions, characterizing the process as "cumbersome" and subject to competing demands with limited resources, and finding that DOJ "may be reluctant to bring cases" that risk adversely affecting FDA's authorities if the actions fail a legal challenge.

On June 10, 2024, DOJ and FDA announced the establishment of a federal task force to enhance enforcement against these illegal and dangerous products through collaboration among FDA; DOJ; Bureau of Alcohol, Tobacco, Firearms and Explosives; U.S. Marshals Service; U.S. Postal Inspection Service; and the Federal Trade Commission. Two days later, the Senate Judiciary Committee held a hearing featuring witnesses from DOJ and FDA to examine their roles in taking enforcement action against unauthorized e-cigarettes that pose a threat to children.

To inform the Senate Judiciary Committee's efforts to address the public health harm to children from the widespread market availability of unauthorized e-cigarettes, I request that the Government Accountability Office examine interagency enforcement activities. Specifically:

1. Who FDA uses to conduct inspections of retailers, distributors, and manufacturers to examine potential illegal distribution or sale of unauthorized e-cigarettes, including the number of personnel and resources allocated between FDA employees, third-party contractors, and state partnerships.

2. The process by which FDA issues warning letters and CMPs, including the timeline for re-inspections to verify compliance, the compliance rate of warned firms, and the specific steps undertaken by FDA before issuing a CMP.

3. The resources FDA allocates to process and review submitted PMTAs, including the allocation of resources for products that the agency refuses to file or refuses to accept, or for which FDA issues a marketing denial order.

4. FDA's approach to CMPs, including any obstacles that would explain FDA's failure to thus far assess multiple violations in a single proceeding, despite the ability to bring an action involving multiple violations up to $1.2 million.

5. The evaluation process and prioritization strategy for enforcement against retailers, distributors, and manufacturers of unauthorized e-cigarettes, including for products with pending PMTAs. In particular, a determination of whether FDA or DOJ have taken any enforcement action against a manufacturer for its unauthorized e-cigarette product if the manufacturer filed a PMTA on time or after the relevant deadline (i.e. Sept 9, 2020 for a tobacco-derived nicotine product, and May 14, 2022, for a synthetic nicotine product) and that PMTA was pending at the time of FDA enforcement.

6. DOJ's process upon receiving a referral from FDA regarding an unauthorized e-cigarette, including the number of cases FDA has referred to DOJ, the resources assigned to such cases, and what guidance DOJ may have provided to FDA regarding the types of cases that are appropriate for referral to DOJ.

7. The particular focus of the interagency task force announced on June 10, 2024, its established goals and strategies, and how this interagency task force will augment existing enforcement activities by each member agency.

8. An assessment of what additional resources FDA and DOJ may require to adequately monitor and enforce the law against unauthorized e-cigarettes on the market.

Thank you for your attention to this request. If you have any questions please contact in Chair Durbin's office ( ).

Sincerely,

Richard J. Durbin
Chair