

**TESTIMONY
OF
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DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BEFORE THE
COMMITTEE ON THE JUDICIARY
UNITED STATES SENATE**

**“COMBATTING THE YOUTH VAPING EPIDEMIC BY ENHANCING
ENFORCEMENT AGAINST ILLEGAL E-CIGARETTES”**

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RELEASE ONLY UPON DELIVERY

Introduction

Chair Durbin, Ranking Member Graham, and Members of the Committee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA or the Agency) efforts, in collaboration with our federal partners, to address the sale of unauthorized e-cigarettes. FDA's Center for Tobacco Products (CTP)'s mission is to protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products, including through enforcement actions; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone. FDA shares the goals and the urgency of keeping all tobacco products out of the hands of our youth and preventing the sale of unauthorized e-cigarettes. An "all of government" approach is critical to achieving these goals. FDA has actively been working, including with our colleagues across the federal government, to meet those shared goals.

Background

Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to tobacco smoke alone. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which authorized FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products. Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. On August 8, 2016, pursuant to the Tobacco Control Act, FDA published the final "deeming" rule, which brought e-cigarettes and other products that meet the statutory definition of a tobacco product (except accessories of newly deemed tobacco products) under FDA's regulatory authority.

Regulatory Requirements for E-cigarette Products

Manufacturers are required to submit a premarket tobacco product application (PMTA) for "new tobacco products," which is reviewed by FDA to determine if authorization for marketing is granted. Pursuant to the Tobacco Control Act, a "new tobacco product" is one that was not commercially marketed as of February 15, 2007, or one that was modified after February 15, 2007. Since no e-cigarette product is known to have been commercially marketed in the United States as of February 15, 2007, all such products are understood to be new tobacco products. All "deemed" products, including e-cigarettes, became subject to FDA regulation, including the premarket authorization requirements in the Tobacco Control Act in August 2016. All "new tobacco products" are required to obtain authorization from FDA before they can be legally marketed. Following reports of e-cigarette manufacturers switching to nicotine not derived from tobacco in an attempt to evade FDA regulation, in 2022, Congress enacted legislation providing the Agency with authority to regulate tobacco products containing nicotine from any source, including "non-tobacco nicotine" (e.g., synthetic nicotine). To date, 23 e-cigarette products have been authorized to be marketed. FDA provides guidance and information to support industry's compliance with tobacco laws and regulations.

Data on Youth Use of E-Cigarettes

FDA collaborates with the Centers for Disease Control and Prevention (CDC) to administer the National Youth Tobacco Survey (NYTS), a school-based survey of U.S. middle school (grades 6 to 8) and high school (grades 9 to 12) students.

In 2019, NYTS data indicate that use of e-cigarettes peaked at 5.3 million youth. Since then, youth use of these products has declined substantially, overall. In 2023, an estimated 2.1 million kids were using e-cigarettes, which includes 580,000 fewer U.S. high school students using e-cigarettes since 2022.

For middle school students, the 2023 NYTS data show a slight increase (4.5 percent to 6.6 percent) in overall tobacco product use from 2022 to 2023. There was no specific product, including e-cigarettes, for which a significant increase occurred. However, this finding reinforces the importance of redoubling FDA's comprehensive efforts to address all tobacco product use among youth, including those of middle school age.

FDA will continue its surveillance of youth use of tobacco products, including through the most timely and scientifically rigorous methods available. This surveillance informs our compliance and enforcement work, which is an important component of our comprehensive efforts to address youth use of e-cigarettes. We remain committed to working alongside our federal government partners, to reduce the health burden of tobacco product use, especially among youth, in the United States.

Collaboration with Federal Partners

FDA is actively engaged with other government agencies and organizations to enhance enforcement and compliance activities. The Agency works closely with the Department of Justice (DOJ) to inform its compliance and enforcement actions. DOJ also files and litigates judicial enforcement actions, such as injunctions and seizures, on behalf of the Agency.

On June 10, 2024, FDA and DOJ announced the establishment of a Task Force to bring together and coordinate relevant expertise, operational abilities, and enforcement authority to strengthen our efforts related to unauthorized e-cigarettes. The Task Force will bring together multiple law enforcement partners, including the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), the Federal Trade Commission (FTC), the U.S. Marshals Service, and the U.S. Postal Inspection Service (USPIS).

Actions to Address the Sale of Unauthorized E-cigarette Products

FDA has a comprehensive tobacco compliance and enforcement program, which monitors for violations of federal tobacco laws and regulations and takes enforcement action across the supply chain—including manufacturers, distributors, retailers, and importers.

FDA prioritizes compliance and enforcement actions against products that appeal to youth. According to the 2023 NYTS, disposable e-cigarettes were the most common type of e-cigarette used by youth. Elf Bar, a disposable product, was the most commonly used brand and has been the focus of targeted FDA compliance and enforcement actions for the past several months.

Compliance and enforcement actions the Agency has taken, including against Elf Bar, are summarized below. In general, the Agency's comprehensive approach to enforcement focuses on three areas: 1) providing education and training to promote voluntary compliance; 2) conducting surveillance, inspections, and investigations to monitor the marketplace online and in brick-and-mortar establishments; and 3) taking action when violations are found.

Education and Training to Promote Voluntary Compliance

FDA provides educational materials and webinars, training videos, and guidance documents to help industry, including retailers, comply with the law. CTP's Office of Small Business Assistance provides technical and other nonfinancial assistance to small tobacco product manufacturers and other small businesses to help them comply. FDA also publicizes its actions on its website, which includes, among other things, information about advisory and enforcement actions and a searchable retailer inspection database. Earlier this year FDA launched the Searchable Tobacco Products Database, which is a list of tobacco products, including e-cigarettes, that may be legally marketed in the United States.

Conducting Surveillance, Inspections, and Investigations

FDA conducts inspections of distributors and manufacturing establishments, including vape shops. During these inspections, FDA seeks to determine the type of activities that are performed at the establishment (i.e., manufacturing, packaging, distributing) and whether they are in compliance with federal law. In addition, FDA contracts with states to conduct compliance check inspections, including undercover buy inspections, of tobacco product retailers. In Fiscal Year (FY) 2023, FDA conducted 108,000 inspections of tobacco retailer establishments and over 800 inspections of tobacco product manufacturers, including vape shops.

Taking Action When Violations are Found

FDA takes compliance and enforcement actions on a case-by-case basis, including increasing consequences, across the supply chain, to manufacturers, distributors, retailers, and importers, according to our enforcement priorities. When potential violations are found, FDA collects and reviews evidence to build a case. Typically, upon finding a violation and gathering the necessary evidence, FDA first issues a warning letter to achieve voluntary compliance. The warning letters describe the violation(s) and give firms the opportunity to take corrective action. FDA follows up on warning letters, prioritizing follow-up inspections, investigations, and surveillance activities for firms that are most likely to continue to violate the law, such as firms that fail to respond to a warning letter or provide an inadequate response. Many recipients of warning letters correct the violative conduct; however, if the company's response is not adequate, the Agency may collect evidence and take escalated actions such as seeking civil money penalties or working with federal partners on judicial actions such as injunctions and seizures.

Manufacturers & Distributors

To date, FDA has conducted over 6,600 inspections of tobacco manufacturers and distributors, including e-cigarette manufacturers and vape shops, resulting in more than 880 warning letters, 57 civil money penalties, six injunctions obtained (with a seventh currently in litigation and an eighth complaint filed), and one seizure. These actions were taken for various violations of the law, but the vast majority were for the manufacture, distribution, and/or sale of unauthorized e-

cigarette products.

In April 2024, FDA and DOJ seized tobacco products in coordination with the U.S. Marshals Service for the first time. More than 45,000 unauthorized e-cigarettes valued at more than \$700,000 were seized at a warehouse in California. The seized products were mostly flavored, disposable youth-appealing e-cigarettes.

Retailers

To date, FDA has issued over 550 warning letters to retailers for selling unauthorized products and taken escalating action by seeking civil money penalties against 140 retailers for continuing to sell unauthorized products. The total collective amount of CMPs sought is more than \$2,600,000.

Moreover, FDA has taken action to address sales of tobacco products to underage purchasers, including conducting nearly 1.5 million inspections of tobacco retailers working with its partners in the states and territories that resulted in FDA issuing more than 138,000 warning letters, 33,000 civil money penalties, and 228 No-Tobacco-Sale Orders.

Importers

FDA works with CBP, and the U.S. Postal Service at the International Mail Facilities, to screen FDA-regulated products at entry for compliance with applicable requirements. Challenges in the import compliance space include manufacturers changing product names to avoid identification at the border as well as fraudulent import declarations.

FDA has two Import Alerts to inform FDA field staff, CBP, and the public about unauthorized tobacco products that can be detained without physical examination. Currently, these Import Alerts address over 40 firms importing e-cigarettes, each of which covers multiple products (e.g., Elf Bar, Esco Bar, and other disposable products from China). FDA regularly updates the Import Alerts, including to account for changes in brand name (e.g., Elf Bar to EB Design). FDA has generally been refusing admission to products listed on these Import Alerts.

Many e-cigarette products offered for import are not properly declared. CBP has authority to administratively seize products that are smuggled or clandestinely imported. The agencies are collaborating to stop the flow of illegal e-cigarettes into the United States. For example, FDA participated in a joint operation with CBP at Los Angeles International Airport that resulted in the administrative seizure of approximately 1.4 million units of unauthorized e-cigarette products, including Elf Bar, with an estimated retail value of more than \$18 million. Most of these products were intentionally mis-declared as various items such as toys or shoes and listed with incorrect values.

Future Actions

In addition to more joint operations and continued escalating actions, FDA is currently working on, and expects to publish later this year, a draft guidance on civil money penalties for violations of the FD&C Act requirements that relate to tobacco products. This guidance intends to describe the Agency's approach to issuing Enhanced Civil Money Penalties (intentional violations), Continuous Enhanced Civil Money Penalties (intentional and other violations that continue after

written notice), and multiple violations in a single complaint (either as a retailer, a manufacturer, or as both). We will continue to engage with our federal government partners to take strong compliance and enforcement actions and with Congress to explore additional strategies for effective enforcement.

FDA's Comprehensive Actions to Prevent Youth Use of E-cigarette Products

Protecting youth from the dangers of tobacco products is among the Agency's most important responsibilities. In addition to our work to protect youth from tobacco products with compliance and enforcement actions as described above, we also conduct premarket review of new products before they may be legally marketed, develop regulations and related guidance documents that protect the public health, and educate the public about the harms of youth tobacco product use.

Premarket Review

Ensuring new tobacco products undergo premarket evaluation by FDA is a critical part of our mission to protect the public health, particularly youth, and to reduce tobacco-related disease and death. To date, FDA has received PMTAs for nearly 27 million e-cigarette products. The PMTAs that FDA has received have included applications for nearly one million non-tobacco nicotine products from more than 200 applicants. This also includes more than 6.5 million products received by September 9, 2020.¹ The volume of tobacco applications received is exponentially greater than submission volume for other regulated products; for example, FDA medical product Centers receive thousands of applications a year.

To date, FDA has resolved more than 26 million of these applications. The Agency has authorized 23 tobacco-flavored e-cigarette products and devices. These products were authorized because the applicant submitted data that demonstrated that the marketing of the products met the applicable public health standard required by law. As part of FDA's evaluation of these products, the Agency determined that the potential for these products to benefit adults who smoke outweighed the risk to youth. In addition, the Agency has resolved marketing applications for millions of products, including through marketing denial orders, because the applicant failed to show that the products meet the public health standard required by the law. FDA is working to complete review of the pending applications as efficiently as possible, consistent with science and the law.

Regulations and Guidances

FDA issues regulations to implement the Tobacco Control Act and guidance documents that explain FDA's approach for implementing statutory or regulatory provisions. This includes a number of rules that outline requirements for e-cigarettes. For example, the Deeming regulation expanded retailer restrictions to include restrictions on sales of e-cigarettes and required a nicotine warning statement for e-cigarettes. More recently, FDA has issued a proposed rule to establish tobacco product manufacturing practice requirements for manufacturers.

¹ Applications for deemed new tobacco products on the market as of August 8, 2016, were required to be submitted to FDA by September 9, 2020, per a federal court order. *American Academy of Pediatrics, et al. v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019).

Public Education

Mass market public education campaigns are a proven strategy to reduce and prevent use of tobacco products, especially among youth, and are another important tool in FDA’s efforts to prevent youth tobacco product use. For example, FDA prioritized public education prevention efforts to address youth tobacco product use. From its launch in February 2014 to November 2016, “The Real Cost” campaign, FDA’s first public education cigarette prevention effort, prevented up to 587,000 youth ages 11 to 19 from initiating smoking, and over time those prevention efforts will save more than \$53 billion in smoking-related costs for youth, their families, and society at large—a cost savings of \$180 for every dollar of the nearly \$250 million invested.² In 2018, FDA launched “The Real Cost” Youth E-Cigarette Prevention Campaign, targeting over 10 million teens who have used e-cigarettes or are susceptible to use, which has successfully reached and engaged teens, generating over 26 billion ad views.

Challenges and Opportunities

The progress described here is just a part of the important work FDA is doing to protect the public health by regulating the manufacture, distribution, marketing, and sale of tobacco products, including e-cigarettes. In addition to the progress we have made, we also face several challenges such as the size and complexity of the tobacco product landscape and resources that have been flat for the last five years.

The sheer volume of premarket applications, receiving applications for millions of products nearly simultaneously, and the rapidly evolving tobacco product landscape have been unprecedented. It is a challenge that no other FDA Center has undergone. FDA is diligently working to complete review of the pending applications as efficiently as possible, consistent with science and the law. Specifically, a substantial proportion of CTP resources have had to be allocated to e-cigarettes—both product reviews and enforcement actions—without receiving any funding from e-cigarette manufacturers, in contrast to most other types of tobacco products.

The additional resources and authorities included in the Agency’s FY 2025 budget request will support CTP’s work in a number of areas, including enforcement and our plans to do more with all of our federal enforcement partners.

First, the FY 2025 budget includes a legislative proposal which seeks to authorize FDA to collect user fees from e-cigarette manufacturers. The statute currently authorizes FDA to assess and collect tobacco user fees from domestic manufacturers and importers of six classes of products: cigars, pipe tobacco, cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, and specifies the total amount of tobacco user fees FDA must assess and collect each year. Since FY2019, this amount has been capped at \$712 million. Because e-cigarettes were a new product category when the Tobacco Control Act was enacted in 2009, the authorized funding did not take into account the resources required for the regulation of e-cigarettes. The FY 2025 proposal seeks to promote a fair distribution of tobacco user fee assessments to all regulated tobacco products, including e-cigarettes; increase the current tobacco user fee collections by \$114 million to account for the workload associated with the additional product categories; and index all future collections to inflation.

² <https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-cost-effective-approach>

Second, FDA seeks to extend the agile hiring authorities of the 21st Century Cures Act (Cures Act) for CTP to improve its ability to recruit, hire, and retain personnel with the needed skills to effectively meet its public health mandate. CTP is the only FDA Center to which Congress has not granted such Cures Act hiring authority.

Conclusion

FDA’s accomplishments in protecting the public from the adverse health impacts of tobacco product use are made possible through our dedicated civil servant staff. Their critical efforts tirelessly support CTP’s mission. Guided by our five-year strategic plan, we will continue to collectively take strong actions to protect youth and monitor the effectiveness of our actions.

Thank you again for the opportunity to testify about FDA’s comprehensive efforts to regulate e-cigarettes, especially those popular among youth. We stand ready to work with our federal government partners and Congress to meet the shared goal of removing unauthorized e-cigarette products off the market and keeping all tobacco products out of the hands of youth.