TESTIMONY

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Introduction

Chair Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, thank you for the opportunity to testify before you to discuss the Food and Drug Administration's (FDA or the Agency) important work to regulate tobacco products. Tobacco product use is the single most preventable cause of disease, disability, and death in the United States. Each year, an estimated 480,000 Americans die prematurely from smoking or from exposure to second-hand smoke. More than 16 million people in the United States live with a serious illness caused by smoking. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FDCA) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products and to protect the public from the harmful effects of tobacco product use. The Tobacco Control Act directed FDA to establish the Center for Tobacco Products (CTP) to implement this law. CTP's comprehensive approach to reducing the negative health effects of tobacco product use is guided by our strategic plan and executed in partnership with our colleagues across the federal government. We appreciate Congress's support and interest in these efforts and look forward to further engagement as we seek to advance our important mission.

Progress to Date

In the last 15 years, CTP has built and stood up a fully functioning Center with almost 1,200 dedicated public servants working to improve public health by regulating tobacco products to reduce tobacco-related disease and death. During this time, we have published 14 final rules and over 100 final guidances to help industry understand and comply with all regulations and the law. We have funded important research projects and studies, such as the National Youth Tobacco Survey (NYTS) and the Population Assessment of Tobacco and Health (PATH) Study. We have conducted over 1.5 million tobacco retailer inspections, taken action to address sales of tobacco products to underage purchasers, resulting in more than 140,000 warning letters, 34,000 civil money penalties, and 230 No-Tobacco-Sale Orders. We have educated youth, young adults, and adults through several public education campaigns, including one that has prevented more than half a million youth from starting to smoke cigarettes and will save an estimated $53 billion in future costs.[1] Throughout the rapidly changing marketplace, we have developed and implemented the processes for the three different statutory pathways to market new tobacco products and have resolved applications for more than 26 million products.

We continue to build on this foundation. In just the last two years, we have taken many first-of-their-kind actions, including: filing the first civil money penalty complaints against e-cigarette manufacturers – which now number more than 60; filing the first civil money penalty complaints against retailers for sales of unauthorized e-cigarettes – which now number more than a hundred; and participating in a joint operation with U.S. Customs and Border Protection (CBP) resulting in the seizure of more than $18 million worth of imported, unauthorized e-cigarettes. In addition, FDA and the U.S. Department of Justice (DOJ) seized more than $700,000 of unauthorized e-cigarette products in coordination with the U.S. Marshals Service. Moreover, DOJ, on behalf of FDA, has filed eight complaints for permanent injunctions in federal district courts against e-cigarette manufacturers.

[1] https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-cost-effective-approach

Our work has contributed to results that have improved public health. Among adults, cigarette smoking has declined from 20.6 percent in 2009 to 11.5 percent in 2023. Over the past six years, we have seen a more than 70 percent decline in the number of middle and high school students using e-cigarettes, including 500,000 fewer in 2024 alone. These are not just numbers. These are people who will live healthier lives.

Our work during this short period has been impactful. However, despite this progress, more work is needed, and we are employing a strategic, science-based, forward-thinking plan, using a comprehensive, all-of-government approach.

Five-Year Strategic Plan

In December 2023, CTP issued a new comprehensive five-year strategic plan, which outlines the Center's programmatic and workforce initiatives through 2028. CTP's Strategic Plan represents a new chapter that builds upon the strong foundation that was established and has been cultivated since the Center's inception in 2009. Guided by this plan, CTP aims to ensure a well-regulated marketplace, prevent people from starting to use tobacco products, encourage people who use tobacco products to quit, and reduce the harm caused by tobacco product use.

CTP is committed to using robust science to inform application reviews, pursuing timely and impactful compliance and enforcement strategies, and educating the public about the risks of tobacco products.

Woven throughout this programmatic work is an unwavering commitment to advance four key overarching themes that are common to all five of the goals of the strategic plan: science, stakeholder engagement, health equity, and transparency. Each of the goals is discussed in more detail below.

Goal 1: Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance

CTP has developed and issued a significant suite of regulations to implement authorities in the Tobacco Control Act, as well as guidance documents to inform industry and the public about FDA's current thinking on a wide range of tobacco-related issues. This work has provided comprehensive parameters for tobacco regulation and has created a strong foundation on which to build future work. A significant focus of CTP's work is to fully implement these regulations and advance its regulatory agenda. In conjunction with its strategic plan, and informed by feedback from stakeholders, CTP has developed and published its regulation and guidance agenda, which FDA plans to update annually. CTP will continue to develop and issue additional guidance documents and regulations that address premarket requirements, registration and listing, tobacco product testing, and compliance, among other things. Additionally, in order to promote understanding of tobacco regulation and ensure that tobacco regulation and policies are clear and accessible, the Center will also seek other ways to communicate with stakeholders, for example, through listening sessions and public meetings.

FDA has issued foundational rules on premarket applications and recordkeeping requirements and another on the content and format of substantial equivalence reports. Most recently, FDA issued a proposed rule to establish tobacco product manufacturing practice requirements for manufacturers and on August 30, issued the Tobacco 21 final rule. Other actions that continue to be worked on include the Tobacco Product Standard for Menthol in Cigarettes, the Tobacco Product Standard for Characterizing Flavors in Cigars, and the Tobacco Product Standard for Nicotine Level of Certain Tobacco Products.

The Center issues guidance documents that explain FDA's approach for implementing statutory or regulatory provisions and to describe the Agency's current thinking on various topics. These guidances are for the benefit of all stakeholders and help foster transparency. Recently, we have issued revised guidance documents to clarify how to demonstrate that a new tobacco product is substantially equivalent to a predicate product and regarding civil money penalties and no-tobacco-sale orders for retail violations.[2] Upcoming priorities include providing guidance on tobacco product test methods and additional guidance on civil money penalties.

Goal 2: Ensure Timely, Clear, and Consistent Product Application Review

Ensuring new tobacco products undergo premarket evaluation by FDA is a critical part of our mission to protect the public health, particularly for youth, and to reduce tobacco-related disease and death. To date, FDA has received premarket tobacco applications (PMTAs) for nearly 27 million e-cigarette products. The PMTAs that FDA has received included applications for nearly one million non-tobacco nicotine products from more than 200 applicants. This overall total also includes applications for more than 6.5 million products received by September 9, 2020.[3] 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 34 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, among other things, 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 applicants 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.

Goal 3: Strengthen Compliance of Regulated Industry Utilizing All Available Tools, Including Robust Enforcement Actions

[2] https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/guidance

[3] 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).

FDA takes compliance and enforcement actions on a case-by-case basis according to our enforcement priorities, including by increasing consequences across the supply chain for manufacturers, distributors, retailers, and importers. 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. 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 attempt 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 fails to do so, the Agency may collect evidence of continued violations and take escalated actions such as seeking civil money penalties or working with federal partners on judicial actions such as injunctions and seizures.

To date, FDA has conducted over 6,600 inspections of tobacco manufacturers and distributors, including vape shops, which, combined with online surveillance and import investigations have resulted in more than 880 warning letters, 67 civil money penalty complaints, eight injunctions, and joint operations resulting in multiple seizures. 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 addition to the aforementioned actions related to manufacturers and distributors, the Agency also takes actions among retailers. Specifically, FDA contracts with states, territories, and third parties to conduct retailer compliance check inspections, including undercover buy inspections. To date, FDA has conducted more than 1.5 million inspections of tobacco retailer establishments. FDA has issued over 140,000 warning letters, and filed 34,000 civil money penalty complaints and 230 No-Tobacco-Sale Orders for underage sales violations. The Agency has also issued more than 690 warning letters to retailers for selling unauthorized products and taken escalating action by seeking civil money penalties against more than 140 retailers for continuing to sell unauthorized products. The total amount of civil money penalties that has been sought in these actions is more than $2.6 million.

FDA also 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. 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 unauthorized 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, one of the most used products among youth, with an estimated retail value of more than $18 million. Many of these products were intentionally mis-declared as various items such as toys or shoes and listed with incorrect values.

As a result of the above efforts, tens of millions of unauthorized e-cigarettes have been kept off the market and, importantly, out of the hands of youth.

In an effort to further expand and enhance enforcement efforts, in June 2024, FDA and DOJ announced the creation of a federal multi-agency task force[4] to combat the illegal distribution and sale of e-cigarettes. The task force brings together agencies across government, including multiple law enforcement partners to coordinate and streamline efforts to bring all available criminal and civil tools to bear against the illegal distribution and sale of e-cigarettes responsible for nicotine addiction among American youth.

The task force is focusing on several topics and goals, including enhanced coordination, investigating and prosecuting new criminal, civil, seizure and forfeiture actions under the Prevent All Cigarette Trafficking (PACT) Act of 2009; the FDCA, as amended by the Tobacco Control Act; and other authorities. Violations of these statutes can result in felony convictions and significant criminal fines and civil monetary penalties. They can also result in seizures of unauthorized products, which can help to make unauthorized e-cigarettes less accessible, including to young people.

The task force has a shared commitment to use all the enforcement tools at its disposal and leverage partnerships across the federal government to ensure additional progress. We look forward to continued collaboration and to providing updates on the task force's efforts, as appropriate.

Goal 4: Enhance Knowledge and Understanding of the Risks Associated with Tobacco Product Use

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 prioritizes 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.[5] 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. FDA will continue to expand its successful youth campaigns and will build scientific knowledge to inform further development of adult educational strategies as they related to cessation and relative risk.

Goal 5: Advance Operational Excellence

[4] https://www.fda.gov/news-events/press-announcements/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and-sale
[5] https://www.fda.gov/tobacco-products/real-cost-campaign/real-cost-cost-effective-approach

CTP's staff are the core of the Center, and a strong, supported workforce is what makes the work to effectively achieve our mission possible. As such, CTP champions meaningful initiatives to enhance employee retention and engagement and to grow the Center's workforce while building and maintaining a positive workplace culture and focusing on the key organizational values. The Center will also continue to invest in staff—our greatest resource.

CTP also recognizes the importance of accountability and responsible stewardship of financial resources through strategic and effective resource management. The Center will continue to carefully align resources to our highest priorities and work toward a fair and equitable way to collect user fees for all regulated products. As discussed more below, however, there is a resource inequity as the current user fee framework does not reflect the realities of the tobacco product marketplace.

Preventing Youth Use of Tobacco Products

Youth prevention is central to our work. Almost 90 percent of adult daily smokers started smoking by the age of 18, and about 1,500 youth under 18 smoke their first cigarette every day in the United States. Use of tobacco products, no matter what type, is almost always started and established during adolescence when the developing brain is most vulnerable to nicotine addiction. Protecting youth from the dangers of tobacco products is among the Agency's most important responsibilities.

CTP has taken a series of actions to stop youth use of tobacco products with a special focus on three key areas:

- Preventing youth access to tobacco products;
- Curbing marketing of tobacco products aimed at youth; and
- Educating teens about the dangers of using any tobacco product, including e-cigarettes, as well as educating retailers about their key role in protecting youth.

Our priorities evolve as the market changes. When data showed an increase in youth use of disposable e-cigarettes, for example, we implemented targeted enforcement actions across the supply chain to address these products.

FDA runs a Vaping Prevention and Education Resource Center to provide e-cigarette prevention information in English and Spanish, including lesson plans, activity sheets, and videos, to middle and high school educators. We have expanded the award-winning youth tobacco prevention campaign, "The Real Cost," to help ensure teens understand the risks of e-cigarettes, and launched a voluntary retailer education effort, "This is Our Watch," to help retailers comply with age restrictions.

Providing Cessation and Relative Risk Resources for Adults Who Smoke

Significant progress has been made in reducing cigarette smoking in the United States through comprehensive, population-level strategies. However, more than 30 million U.S. adults still

smoke cigarettes, and smoking remains the leading cause of premature disease and death nationwide. Most people who smoke want to quit.

FDA's Center for Drug Evaluation and Research has approved several smoking cessation products, including Nicotine Replacement Therapy products such as over-the-counter skin patches, chewing gum, and lozenges; and prescription products such as nicotine spray and nicotine inhaler, and two tablets that do not contain nicotine, varenicline tartrate and bupropion hydrochloride.

FDA also collaborates with our federal partners to develop and promote cessation resources, including quit lines, websites, posters, connecting those who want to quit to counselors, and smokefree apps.

In addition to preventing youth initiation and promoting cessation among people who use tobacco products, CTP is working to educate adults who smoke about the relative risks of tobacco products. The concept of relative risk is complex, and it is important to ensure efforts to educate adults who smoke on this topic are evidence-based and likely to achieve desired outcomes, while also minimizing impact on unintended audiences, including youth.

CTP is continuing to build scientific knowledge through research to inform the development of educational strategies and approaches, including potential messaging. Studies are being conducted on messages related to the relative risks of tobacco products that include participation by adults who smoke, as well as research among health care providers in primary care settings who may play a key role in the delivery of potential messaging.

Current Challenges and Opportunities

While CTP has made considerable progress since its inception in 2009, the accomplishments and goals described above are just a part of the important work FDA is doing to protect the public from the dangers of tobacco use. We also face several challenges that threaten our ability to effectively carry out our mission. For one, the size and complexity of the tobacco product landscape continues to grow while CTP resources 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.

Although CTP receives no funding from e-cigarette manufacturers and importers, a substantial proportion of CTP resources have had to be expended to regulate e-cigarettes, both product application reviews and compliance and enforcement efforts. The additional resources and authority proposed in the Agency's fiscal year (FY) 2025 budget request will support CTP's work in a number of areas.

First, the FY 2025 budget includes a legislative proposal which seeks to authorize FDA to collect user fees from e-cigarette manufacturers and importers. 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 FY 2019, this amount has been capped at $712 million. Under current law, this amount is not indexed to inflation. 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 $114.2 million to account for the workload associated with the additional product categories and annual inflation; and index all future collections to inflation to ensure resources keep up with all tobacco products into the future.

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 progress in addressing the adverse health impacts from tobacco product use is made possible through the work of 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 prevent people, particularly youth, from starting to use tobacco products, encourage people who use tobacco to quit, and to reduce the harm caused by tobacco use.

Thank you again for the opportunity to testify about FDA's comprehensive efforts to regulate tobacco products. We are committed to working 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.