EVALUATING THE IMPACT OF FEDERAL ENFORCEMENT ON THE ILLEGAL ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) MARKET

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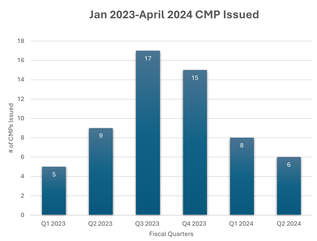
ABSTRACT

The illegal marketplace for electronic nicotine delivery systems (ENDS), poses substantial public health risks due to substandard manufacturing, evasion of federal regulatory requirements and the use of unknown ingredients. This abstract evaluates federal enforcement actions from January 2021 to June 2024, assessing the effectiveness of the actions taken by the Food and Drug Administration (FDA), the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), the Department of Justice (DOJ), and Customs and Border Protection (CBP) on the illegal ENDS products. The study approach analyzed the metrics through a lens of regulatory timelines and enforcement priority policies, comparing types of enforcement actions, entities issued actions and impact of the actions. Since January 2021, the FDA has issued over 700 warning letters and filed civil money penalties to manufacturers and retailers. The DOJ filed permanent injunctions against eight tobacco manufacturers. CBP and FDA have conducted seizures at ports and International Mail Facilities of shipments ranging from thousands to millions of dollars in illegal ENDS products. Despite the use of the range of enforcement tools, driven primarily by the FDA and DOJ, the illegal ENDS products such as the youth appealing Elf Bars and Esco Bars are still making it to the retail shelves and into consumers' hands. Enforcement actions by a single agency alone are insufficient to transform the illegal ENDS marketplace into a compliant and regulated one; a comprehensive, multipronged, whole-of-government approach is required. Leveraging the efforts and insights from all federal agencies that have developed strategies to combat illicit markets for other commodities can be highly beneficial. Enhanced inter-agency collaboration among federal and state partners is crucial to ensure comprehensive compliance with all tobacco-related laws which supports the broader goal of tobacco harm reduction.

CIVIL MONEY PENALTY (CMP)

Civil Money Penalty (CMP) is an administrative enforcement action imposes a fine for violations of the law. FDA has authority to assess CMPs for violations of the Federal Food, Drug and Cosmetic Act (FD&C Act) for unauthorized tobacco products and began issuing CMP to tobacco manufacturers for failure to have the required marketing authorization in February 2023. Currently, the maximum penalty amount for violating a requirement of the FD&C Act relating to tobacco products is $20,678 for a single violation. However, the FD&C Act also allows for an enhanced penalty amount for certain intentional violations relating to tobacco products. In the last year and half, FDA has filed 65 CMPs to ENDS manufacturers in 27 states for the single violation amount of $20,678.

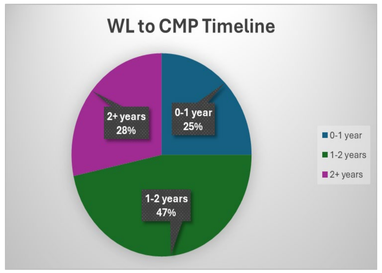
Figure 1 CMP Issued in Q1 2023- Q2 2024



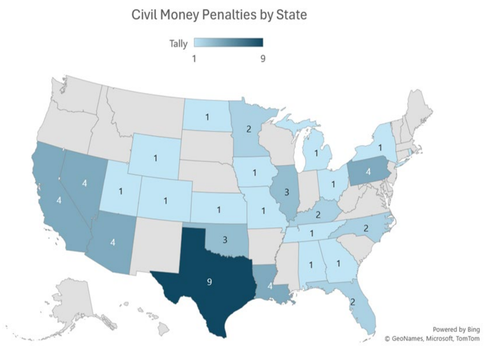
The figure signifies a peak of CMP issuance during Q3- July, August and September of 2023 and have since seen a steady decline.

*FDA has issued an additional CMP in Q3 of 2024 bringing the total to 66 to date.

Figure 2 Time between Warning Letter and CMP issuance



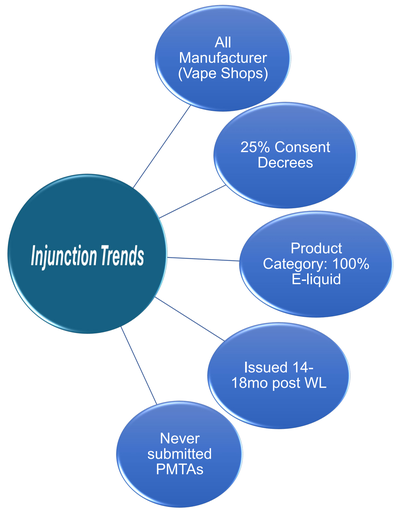
Approximately 47% of the CMPs issued were 1-2 years after receiving an FDA warning letter; 75% of the CMPs issued were over a year after receiving an FDA Warning Letter.



INJUNCTIONS

An injunction is a civil judicial process initiated to stop current violations of the law, halt the flow of violative products in interstate commerce, and correct the violations. DOJ and FDA initiated its first injunctions to tobacco manufacturers of unauthorized tobacco products in October 2022. To date, DOJ has initiated 8 injunctions with 25% resulting in consent decrees. A consent decree is a court-approved agreement where the defendant agrees to stop unlawful actions without admitting fault. It ensures the violative products are removed and future compliance is enforced under court supervision.

Figure 3: Injunction Trends October 2022- June 2024

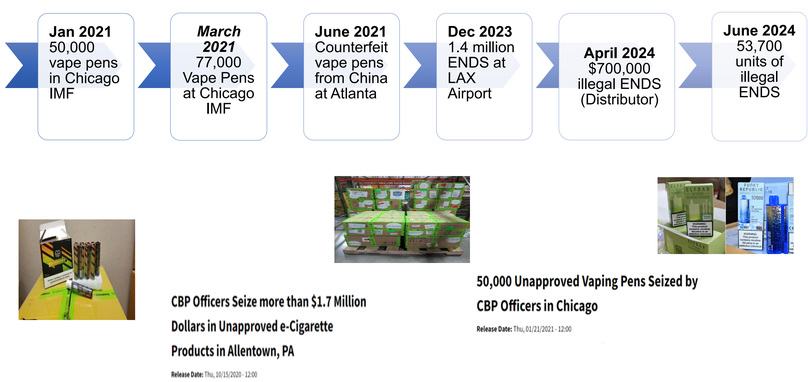


The figure above summarizes the key characteristics of the eight firms DOJ initiated for injunctions. All of these firms are small manufacturers, such as vape shops, that failed to submit PMTAs for their e-liquid products. Each injunction was initiated 14 to 18 months after the firms received an FDA Warning Letter. Outside of the initial six injunctions issued in October 2022, the DOJ has issued one injunction per year so far.

SEIZURES

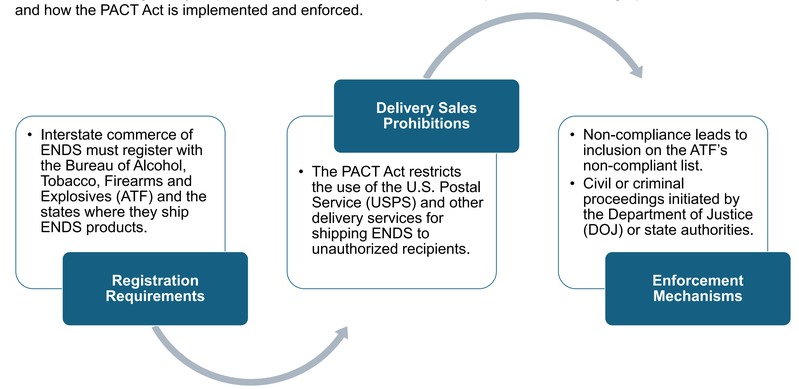
CBP and FDA collaborate to enforce the FD&C Act, targeting the entry of counterfeit and illegal ENDS into the U.S. These joint efforts, which often result in seizures at ports and International Mail Facilities, are crucial in combating illegal imports. Over the last three years, most seizures of illegal ENDS have occurred at the ports, with the first seizure directly from a tobacco distributor initiated during an inspection in 2024. The scale of this task is significant, as reflected in U.S. Department of Commerce data: in June 2024, the customs value of tobacco products imported for consumption exceeded $225.3 million, with electronic cigarette imports valued at nearly $163.6 million for the first half of 2024. Despite a decrease compared to 2023, these imports included approximately 144.4 million pieces, underscoring the challenge CBP and FDA face in intercepting illegal products amidst large volumes of legal imports. The seizure timeline below illustrates significant enforcement actions taken by CBP and FDA from January 2021 through June 2024, targeting illegal ENDS products entering the U.S. These seizures, although impactful, represent less than 0.03% of the total imported e-cigarette products according to U.S. Department of Commerce between January 2022 and March 2024.

Figure 4: CBP and FDA Seizure Timeline



PACT ACT ENFORCEMENT

The Prevent All Cigarette Trafficking (PACT) Act, as amended by the Preventing Online Sales of E-Cigarettes to Children Act, establishes regulatory requirements for the sale, transfer, and shipment ENDS. The graphic below describes who and how the PACT Act is implemented and enforced.



Recent Enforcement Trends: Since late 2022, ATF has increased surveillance and enforcement of the PACT Act provisions related to ENDS, in collaboration with the DOJ and FDA. This poster did not evaluate state enforcement actions on illegal ENDS products or the enforcement of any state bans.

In June 2024, a federal multi-agency task force to address the escalating issue of illegal distribution and sale of ENDS. Bringing **together FDA, FOJ, ATF, U.S. Postal Inspection Service (USPIS), the U.S. Marshals Service (USMS) ,and the Federal Trade Commission (FTC)** to enhance coordination and enforcement efforts across various government bodies.

CONCLUSION

Despite an increase in enforcement actions—over 700 warning letters, 65 CMPs, 8 injunctions, and fewer than 10 seizures—illegal ENDS products remain widely accessible, especially to youth. While the number of enforcement actions relative to the warning letters might suggest overall compliance, this is misleading. Many violative products continue to flood the market, and widespread non-compliance persists. To truly make an impact, a coordinated, multi-agency approach is essential, coupled with efforts to rebuild trust between the industry and regulatory agencies. By fostering inter-agency collaboration and streamlining enforcement actions, federal agencies can create a stronger defense against illegal ENDS products and establish an enforcement framework for regulating emerging illegal products like nicotine pouches. With estimates suggesting that up to 70% of the ENDS market is illegal, it's clear that the black market is thriving, while responsible, compliant manufacturers are at a disadvantage—reinforcing the need for a regulated, compliant marketplace.

The effectiveness of federal enforcement against illegal ENDS products hinges not only on these actions but also on creating an ecosystem of voluntary compliance and trust between the industry and regulatory agencies. Illegal ENDS products are a collective problem, not just a federal one. Demonstrating that product authorization through the regulatory review pathway is achievable can strengthen enforcement efforts and encourage voluntary compliance. Products that bypass this process pose significant risks to users, undermine public health protections, and compromise the integrity of a fair, regulated marketplace.

Recommendations:

- Accelerate enforcement actions following the issuance of Warning Letters.
- Utilize seizure and injunction authority across the entire supply chain
- Launch a communication campaign for the Multi-Agency Task Force.
- Authorize ENDS products through the PMTA pathway to create a fair and competitive marketplace.
- Rebuild trust with the industry by providing clear guidance and encouraging voluntary compliance.

REFERENCES

Birdsey J, Cornelius M, Jamal A, et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1173–1182. DOI: http://dx.doi.org/10.15585/mmwr.mm7244a1

Bureau of Alcohol, Tobacco, Firearms and Explosives. (n.d.). *Vapes and E-Cigarettes.* Retrieved August 10, 2024, from https://www.atf.gov/alcohol-tobacco/vapes-and-e-cigarettes

TMA Publications: US Tobacco Trade Barometer. Imports of Tobacco Products June 2024. US Trade Barometer: Imports of Tobacco Products - June 2024 | TMA

U.S. Customs and Border Protection. (n.d.). *Media Releases.* Retrieved August 10, 2024, from https://www.cbp.gov/newsroom/mediareleases/all?combine=&field_date_release_value=All&field_newsroom_type_target_id_1=54

U.S. Department of Justice. (2023, July 28). *Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb Distribution and Sale of Illegal ENDS Products.* Retrieved August 10, 2024, from https://www.justice.gov/opa/pr/justice-department-and-fda-announce-federal-multi-agency-task-force-curb-distribution-and

U.S. Food and Drug Administration. (n.d.). *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products.* Retrieved August 10, 2024, from https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products#4

U.S. Food and Drug Administration. (2024, August 15). *FDA Warns Online Retailers for Selling Unauthorized, Youth-Appealing E-Cigarettes.* FDA Newsroom. Retrieved from https://www.fda.gov/tobacco-products/ctp-newsroom/fda-warns-online-retailers-selling-unauthorized-youth-appealing-e-cigarettes