

The background of the top section is a photograph of the United States Capitol building in Washington, D.C., featuring its iconic dome and neoclassical architecture. The sky is a clear, pale blue.

VTA REPORT

FDA Enforcement Strategies and Priorities are Failing Smokers & Industry

Vapor Technology Association

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vaportechnology.org

There are more than 350,000 convenience stores, gas stations, grocers, tobacco shops, vape shops, and other retailers where tobacco products are sold in the U.S. The primary focus, and the majority of CTP’s investment in enforcement activity in the past four years has been on retail inspections – where FDA sends minors under 21 years of age into small businesses across the country to see if they can “catch” retailers in youth sales sting operations. In FY2021, CTP’s 290 person Office of Compliance & Enforcement budgeted \$140M to fund its 700 inspection contractors nationwide. This year, CTP is seeking an additional \$100M in new user fees to help fund its work focused on e-cigarettes.

Recently, VTA conducted a detailed analysis of FDA’s enforcement data and found some interesting facts that raise serious questions about the utility of FDA’s enforcement activities and, more importantly, about FDA’s willingness to be transparent with its own real-world experience.

FDA Retail Enforcement Data Proves Strong Retailer Compliance

First, of the more than 325,000 retail inspections conducted by the FDA in the last four years, 86% of them resulted in “no violations”¹ at all (See Table 1), demonstrating a high compliance rate amongst retailers.² Second, virtually all of FDA inspections were conducted “with minors” (96%) and yet the overwhelming majority of those also resulted in “no violations” at all (85%), once again demonstrating a high retail compliance rate. (Table 1)

Table 1: FDA Retail Inspections & Violation Rate (w/ and w/o minors) 2019–2022

Total No. of Inspections	Inspections w/ No Violations	% Inspections w/ No Violations	% Inspections w/ Minors	% Insp. w/ Minors & No Violations
325,031	278,445	85.6%	96.3%	85.1%

FDA Tobacco Retail Inspection and Violation Rates since 2018 (1/1/2019 - 12/31/22)
 Source: FDA Compliance Check Inspections of Tobacco Product Retailers database

¹ Violations include the issuance of either a warning letter, a civil monetary penalty, or a “no tobacco sales order” (NTSO).

² VTA Analysis of FDA data housed on FDA’s Compliance Check of Retailers Database available at https://www.accessdata.fda.gov/scripts/occe/inspections/occe_insp_searching.cfm.

FDA Data Reveals Low Violation Rate for Vaping Products, Much Higher Violation Rate of for Combustible Products

FDA’s public narrative regarding e-cigarettes has been exclusively focused on youth vaping, and particularly the sales of vaping products to youth. This narrative has shielded the public from FDA data that shows, at retail, youth are 2X more likely to be able to purchase cigarettes and other combustible products, as opposed to vaping products.

According to FDA data, in the last four years, only a small fraction (3.8%) of its hundreds of thousands of retail inspections resulted in a warning letter for youth sales violations involving vaping products. By comparison, the number of warning letters issued for youth sales violations for combustible products (e.g., packs of cigarettes, loose cigarettes, cigarette tobacco, cigars, and hookah tobacco) were more than two times higher than for ENDS sales violations. (Table 2) In fact, in 2022 alone, the rate of combustible violations was two and a half times (245%) that of vaping violations. (See Table 2)

Table 2: Retail Warning Letters Issued for Tobacco Products

Year Ending	Combustible Warnings	ENDS Warning Letters	Combustible vs. ENDS Violations	% Combustible Violations to Inspections	% of ENDS Violations to Inspections
2019	8,877	4,515	197%	6.1%	3.1%
2020	1,870	592	316%	5.3%	1.7%
2021	3,366	2,578	131%	7.2%	5.5%
2022	11,247	4,597	245%	11.5%	4.7%
Totals	25,360	12,282	206%	7.8%	3.8%

FDA Rate of Combustible to Vape Youth Violations since 2018 (1/1/2019 - 12/31/22)
 Source: FDA Compliance Check Inspections of Tobacco Product Retailers database

Moreover, FDA acknowledges that its warning letters are not a formal initiation of enforcement actions. But, since 2018, FDA has only issued its toughest enforcement penalty – a “no tobacco sales order” for repeat violators on only 60 occasions, and only 3 of those have been issued for repeat sales of vaping products to youth. In fact, FDA has not issued a no tobacco sales order to a single retailer for repeat sales of vaping products to minor in the last two years.

Table 3: FDA Issuance of No Tobacco Sales Orders (NTSOs) 2018–2022

	All Cigarette NTSO	Cigar NTSO	Combustible Combined	ENDS NTSO	% of Combustible to ENDS NTSO
Totals	37	20	57	3	1900%

FDA No Tobacco Sales Orders
 Source: FDA Compliance Check Inspections of Tobacco Product Retailers database

Similarly, the rate of civil monetary penalties issued for repeat youth sales violations of combustible tobacco products far exceeds (333% higher) that of vaping products. For all its focus on youth vaping, FDA’s entire inspection effort in the last four years has resulted in civil monetary penalties being imposed for youth vaping sales only one half of one percent of the time (0.55%).

FDA Data Reveals that Adult-Only Stores Have Best Compliance Rate

To date, FDA’s drive to stamp out vaping have had a detrimental effect on adult-only vape shops all around the country. Between 2018 and 2021, the number of independent vape mom and pop vape shops which cater to adult smokers have dropped 27%. See, [Vapor Industry Economic Impact Study 2021, John Dunham & Associates](#). While the overall rate of retailer compliance is exceptionally high, as FDA data above reveals, it is equally clear that adult-only retailers, and specifically vape shops, are best positioned to prevent sales to youth.

While the overall rate of retailer compliance is exceptionally high, as the data above reveals, it is equally clear from FDA data that adult-only retailers, and specifically vape shops, are the best at preventing sales to youth. VTA’s analysis of FDA data reveals that between January 2019 and December 2022, 78% of all youth vaping sales violations have occurred in non-age-restricted facilities such as convenience stores, gas stations, and grocers.

Importantly, adult-only tobacco store and vape shop channels preferred by experts account for only 21% of such violations.

Number and Percent of Violations by Store Type

1/1/2019 - 12/31/2022

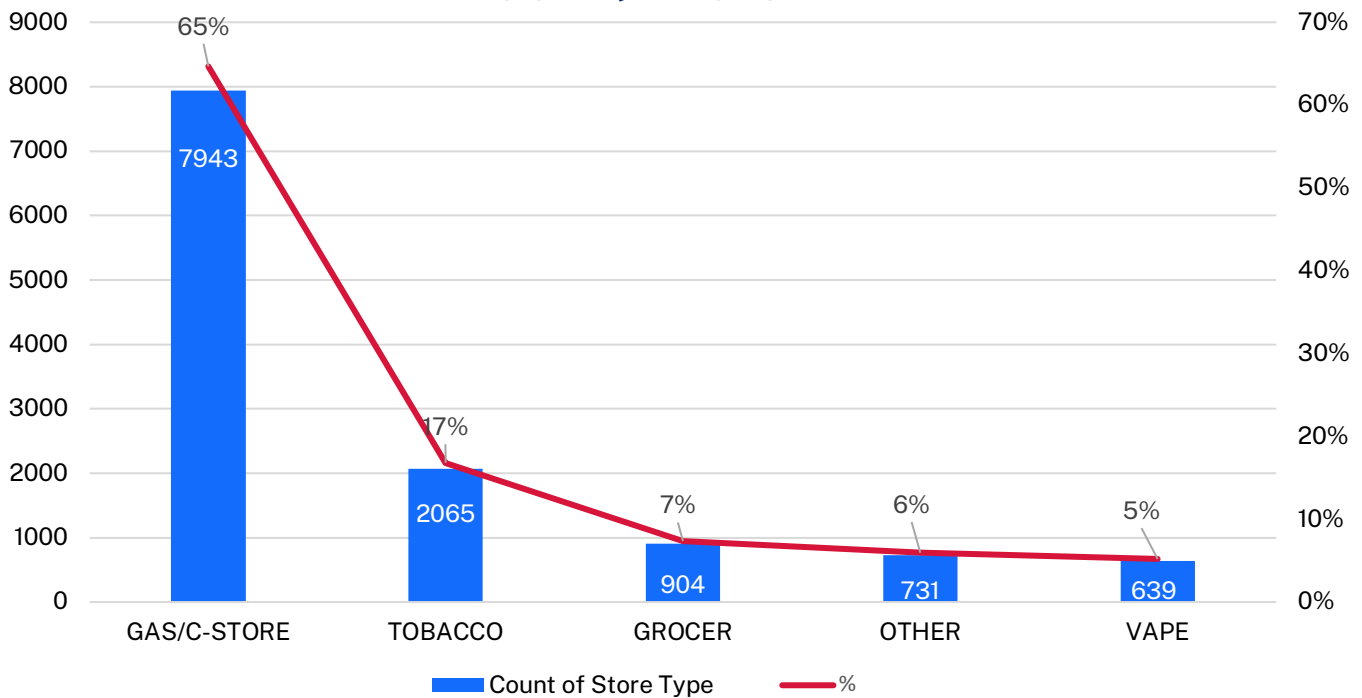


Figure 1: FDA Store Type Violations

About VTA

The Vapor Technology Association is the U.S. industry trade association whose members are dedicated to innovating and selling high-quality vapor products that provide adult smokers with a better alternative to combustible cigarettes. VTA represents the industry-leading manufacturers of vapor devices, e-liquids, and flavorings, as well as the distributors and retailers, including hardworking American mom-and-pop brick-and-mortar retail store owners.

Sign up for the monthly VTA Insider and stay informed of critical issues impacting the vaping industry and nicotine products.

