



Illicit Markets and State Policy

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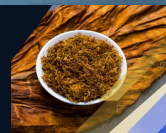
Altria

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Tobacco and Nicotine Products
Regulation and Policy Conference

October 24–25, 2024 | Washington, DC & Virtual
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Restoring Order to the Market



Authorization

Shift course on PMTAs
to establish a legal
market of smoke-free
alternatives



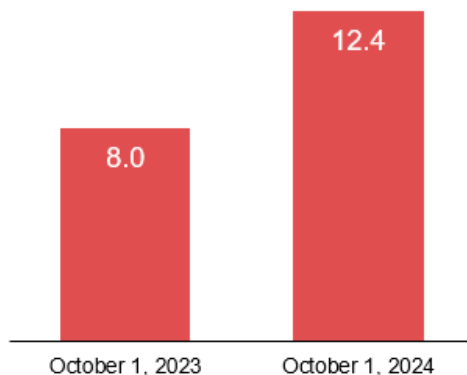
Enforcement

Use all available tools
to hold rule-breakers
accountable



Since Last Year, the Illicit Market Has...

1 | Grown by 55%



Number (MM) of Adult Consumers of Illicit Vapor Products in the U.S.*

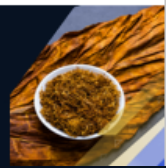
2 | Moved to More Egregious Varieties



"[T]hese devices gamify the vaping experience and encourage users to take more puffs to earn points and compete with their peers."*

*ATCT a monthly, nationally representative survey designed to measure tobacco use prevalence by category and segment among adults aged 21 years or older.

**Jennifer B. Unger, Julia Vassey, Daniel Wood Soto & Artur Galimov (19 Sep 2024): Vaping Devices with Video Games, Substance Use & Misuse, DOI: 10.1080/10826084.2024.2392547, <https://doi.org/10.1080/10826084.2024.2392547>



Since Last Year, the Illicit Market Has...

3 | Engaged in Widespread Mislabeling

Of 12 major illicit vapor brands tested...

9 misrepresented **nicotine type**



10 misrepresented **nicotine concentration**



4 | Expanded to Pouch Products



* This means manufacturers use a different nicotine source than they claim. Specifically, some illicit e-vapor manufacturers claim use of non-tobacco nicotine (NTN) but use tobacco-derived nicotine (TDN). TDN PMTAs were due to FDA by 9/9/20; NTN PMTAs were due to FDA by 5/14/22 and were due to be removed from the market if not authorized by 7/13/22.

Testing commissioned by ALCS (July 2024). For nicotine type testing and nicotine concentration testing, 4 SKUs (i.e., flavors) were selected from each of the 12 brands for using fully validated analytical methods, with one replicate per SKU tested for nicotine type and at least three replicates per SKU tested for nicotine concentration. See backup slides for additional details. Testing was not powered for statistical significance.





Since Last Year...

Enforcement Has Focused on Smallest Actors*...

FDA Act Enforcement Tool	Retailers*	Distributors	Major Mfrs.
Criminal Prosecution	None	None	None
Civil Litigation	Sparse	None	None
CMPs	Active	None	None
Warning Letters	Active	Sparse	Sparse

ALCS analysis of enforcement actions available on FDA.gov. *Retailers include vape shops or other small retail operations FDA characterizes as "manufacturers" due to the nature of the illegal conduct subject to FDA enforcement, including mixing e-vapor liquids in a manner constituting "manufacturing" under the Tobacco Control Act. Several CMP complaints issued to ecommerce sites allege that the respondents "sell and/or distribute tobacco products." While some appear to engage in wholesale distribution, these respondents are principally "online retailers" that sell directly to consumers.

...while PMTA Process Has Resulted in Fewer Legal, Regulated Products...

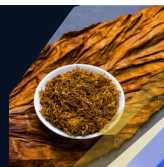
Denied

22,369

Granted

2

(both brands already on the market)



Federal Enforcement Accelerating

PRESS RELEASE

Justice Department and FDA Announce Federal Multi-Agency Task Force to Curb Distribution and Sale of Illegal E- Cigarettes

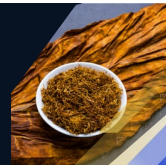
Monday, June 10, 2024

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For Immediate Release

Office of Public Affairs



State Enforcement Accelerating

- ✓ Twelve states have enacted directory or similar legislation
- ✓ Louisiana data shows improved marketplace
- ✓ State AGs becoming more active
- ✓ Ohio AG consumer fraud lawsuit
- ✓ California legislation signals more enforcement

E-Vapor Sales in Louisiana
(4-week moving totals)



Note: totals shown in units sold.

Source: STARS Outbound week ending 07/14/24, not volume equivalized.



Class Action Litigation

Amiel v. EVO Brands, et. al (S.D.N.Y.)

“In March 2022, Congress closed the loophole for synthetically derived tobacco products and banned the sale of all e-cigarettes unless the company received permission from the FDA. Defendants do not have permission to sell the Products, making the sale of these Products illegal.”

“Defendants’ Products have been illegal for sale ... to all consumers throughout the United States since March 2022. Despite this, Defendants continued to market and sell the Products, and allowed and encouraged resellers to do the same, even in the face of their illegality.”

Case 7:24-cv-07327 Document 1 Filed 09/27/24 Page 1 of 42

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	
HAYLEY AMIEL, on behalf of herself and all others similarly situated, Plaintiff, v. EVO Brands, LLC d/b/a Puff Bar, 1750 Santa Fe Ave., Unit 420, Los Angeles, CA 90021, and PWS2, LLC d/b/a Puff Bar, 777 S Alameda St., 2nd Floor, Los Angeles, CA 90021, Defendants,	Case No. 24-7327 CLASS ACTION COMPLAINT <u>DEMAND FOR JURY TRIAL</u>

SUMMARY

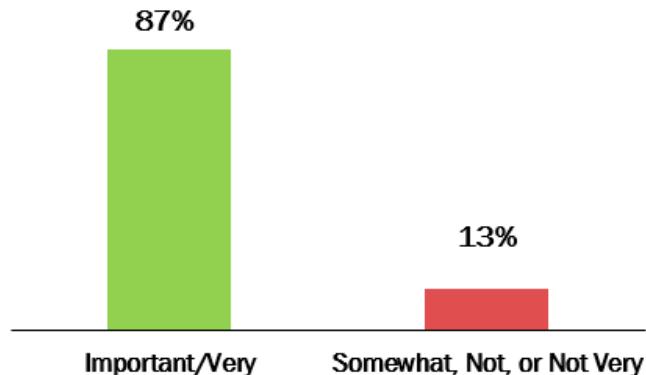
This case seeks relief for consumers who have been misled about the nature and safety of Puff Bar disposable electronic cigarettes. Getting young people hooked on nicotine creates a lifetime of revenue for the tobacco industry. As traditional tobacco products like combustible cigarettes have gone out of style, tobacco companies have reinvented themselves and created a marketplace sensation with electronic cigarettes, also known as vapes. Defendants in this case market their electronic cigarettes to young people, mislabeling them as to the fact that it is illegal in all states to sell these products to people younger than 21 years of age. Defendants market and have sold, and allow resellers to advertise and sell, Puff Bar nicotine products when these products are illegal, which is misleading and unfair to consumers. Puff Bar electronic cigarettes display “3%” nicotine labels, which misleads consumers into thinking the additive nature of

1
CLASS ACTION COMPLAINT

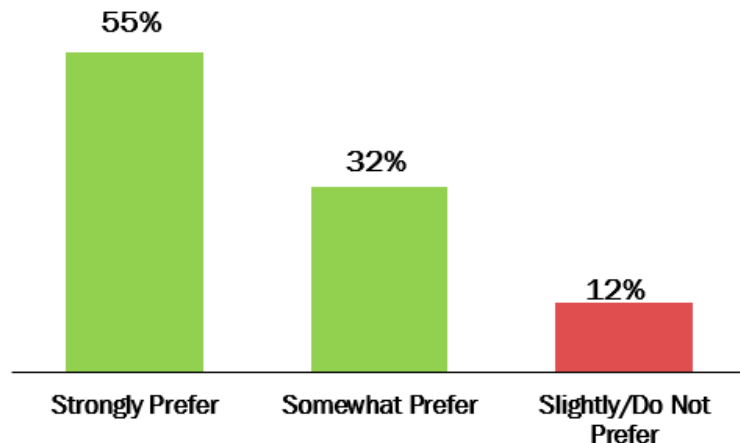


Adult Vapors Want Authorization and Regulation

How important is it that the FDA accelerate authorization so that regulated products replace demand for illicit alternatives?



Would you prefer to know products are FDA-authorized and lawfully regulated versus uncertainty about which products are illicit?

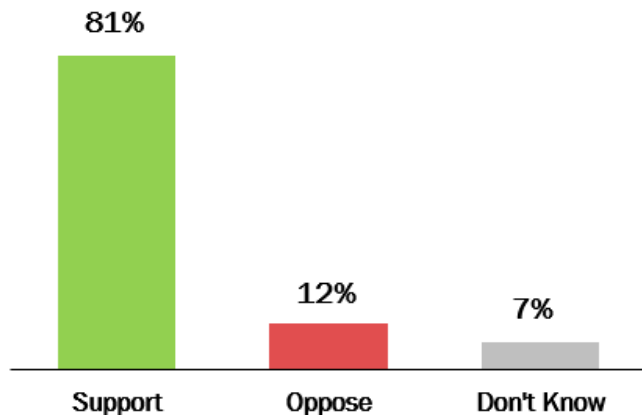


Nationwide survey conducted online among n=408 Adults that Use Vapor Products age 21+ (m.o.e. +/- 4.5%) from 7/29 – 8/11, 2024 by Illuminate Research for Altria Client Services LLC. Question text summarized for brevity.



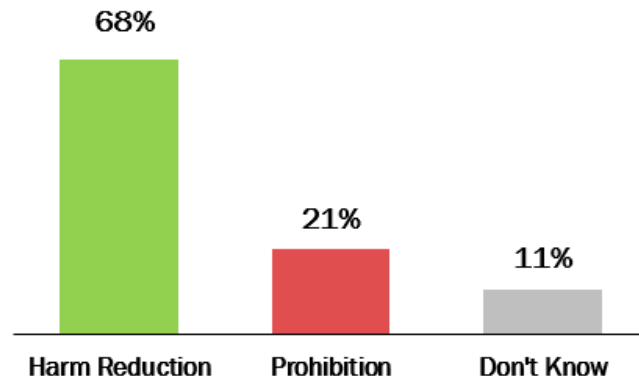
Americans Want a Course Correction

Do you favor or oppose stronger enforcement of existing FDA e-vapor regulations?

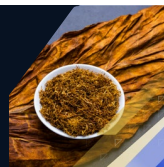


Nationwide survey conducted online among n=1,000 Registered Voters age 21+ (m.o.e. +/- 2.9%) from 3/4 – 3/13, 2024 by Illuminate Research for Altria Client Services LLC. Question text summarized for brevity.

Which do you feel is the better approach for the FDA to focus on when it comes to tobacco?



Nationwide survey conducted online among n=1,503 General Population adults age 21+ (m.o.e. +/- 2.3%) from 10/31 – 11/20, 2023 by Illuminate Research for Altria Client Services LLC. Question text summarized for brevity.



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