Federal Enforcement and the Alternative Nicotine Products Marketplace

Food & Drug Law Institute Annual Conference

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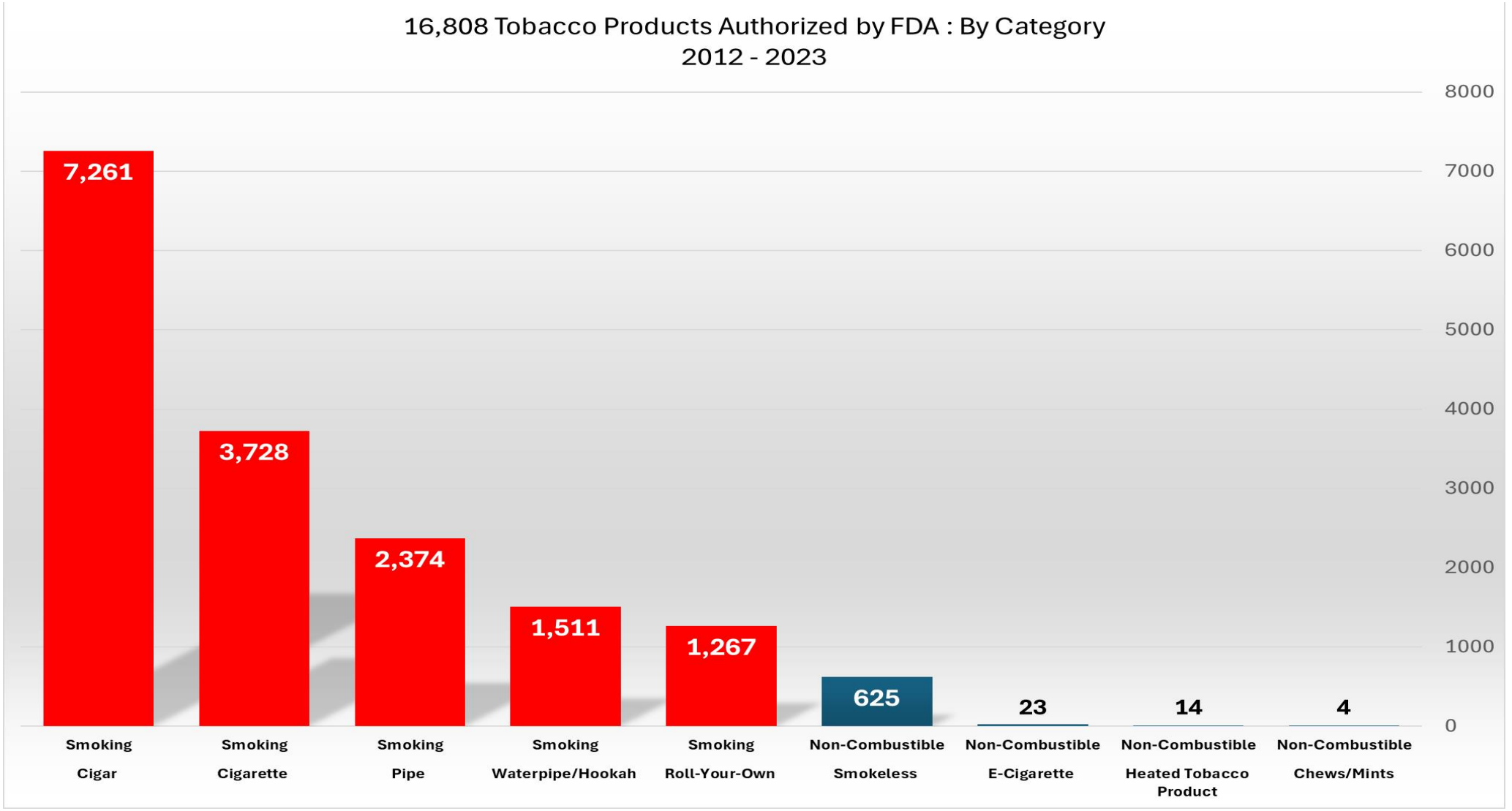
Vapor Technology Association

Topics

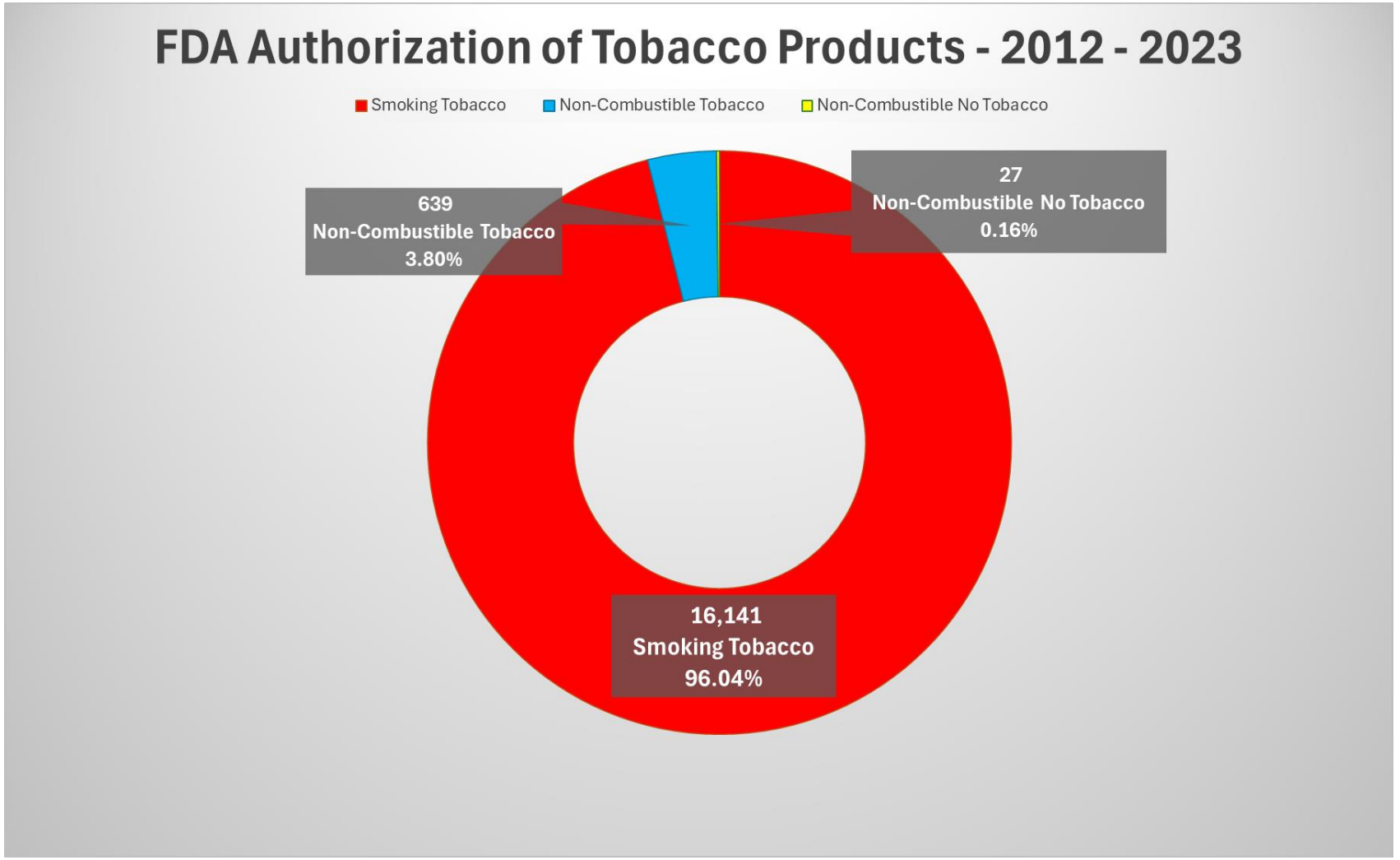
- Tobacco Product Marketplace
- FDA's Ban on Less Harmful Nicotine Products
- How Did We Get Here?
- Perspectives on Enforcing a Broken Regulation

The Marketplace of Tobacco Products

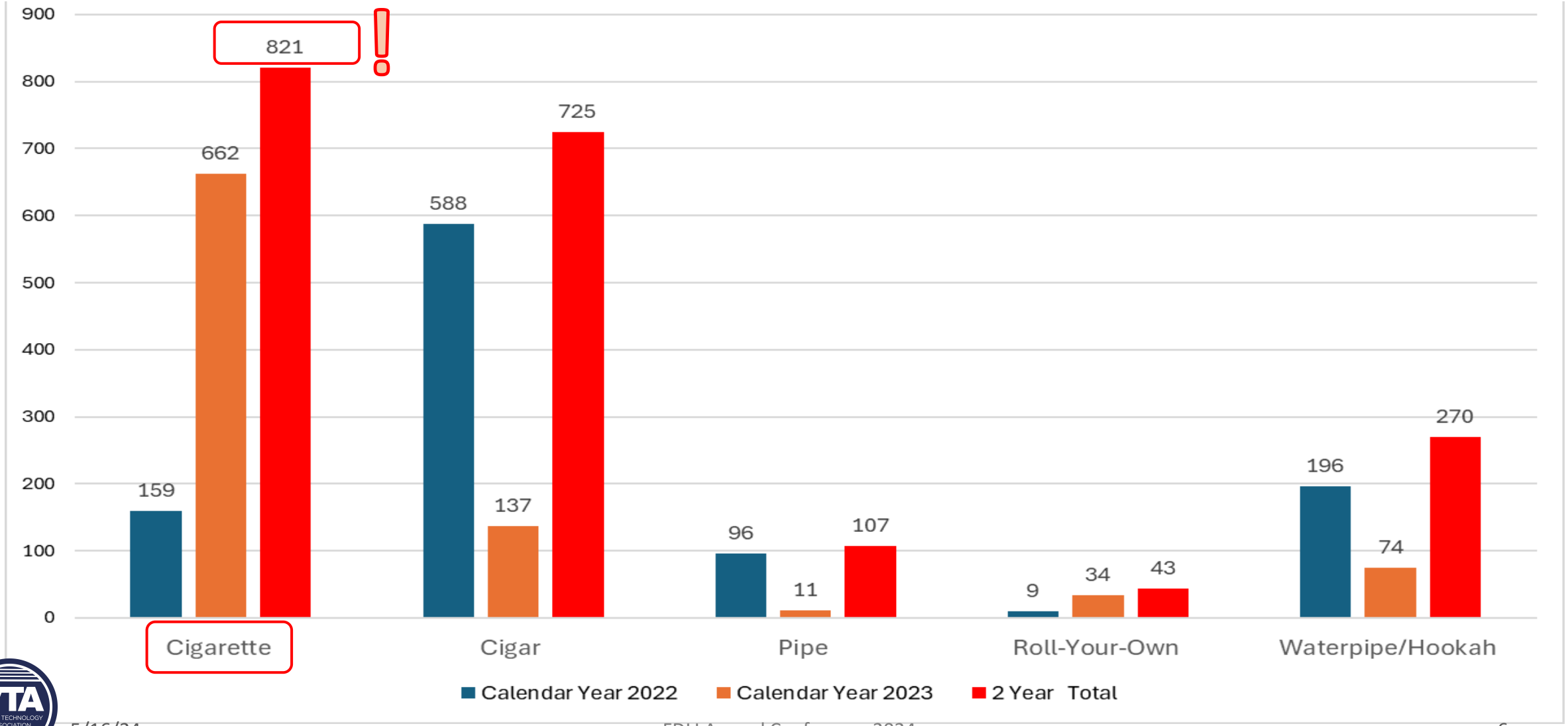
Post-TCA Marketplace Created by FDA



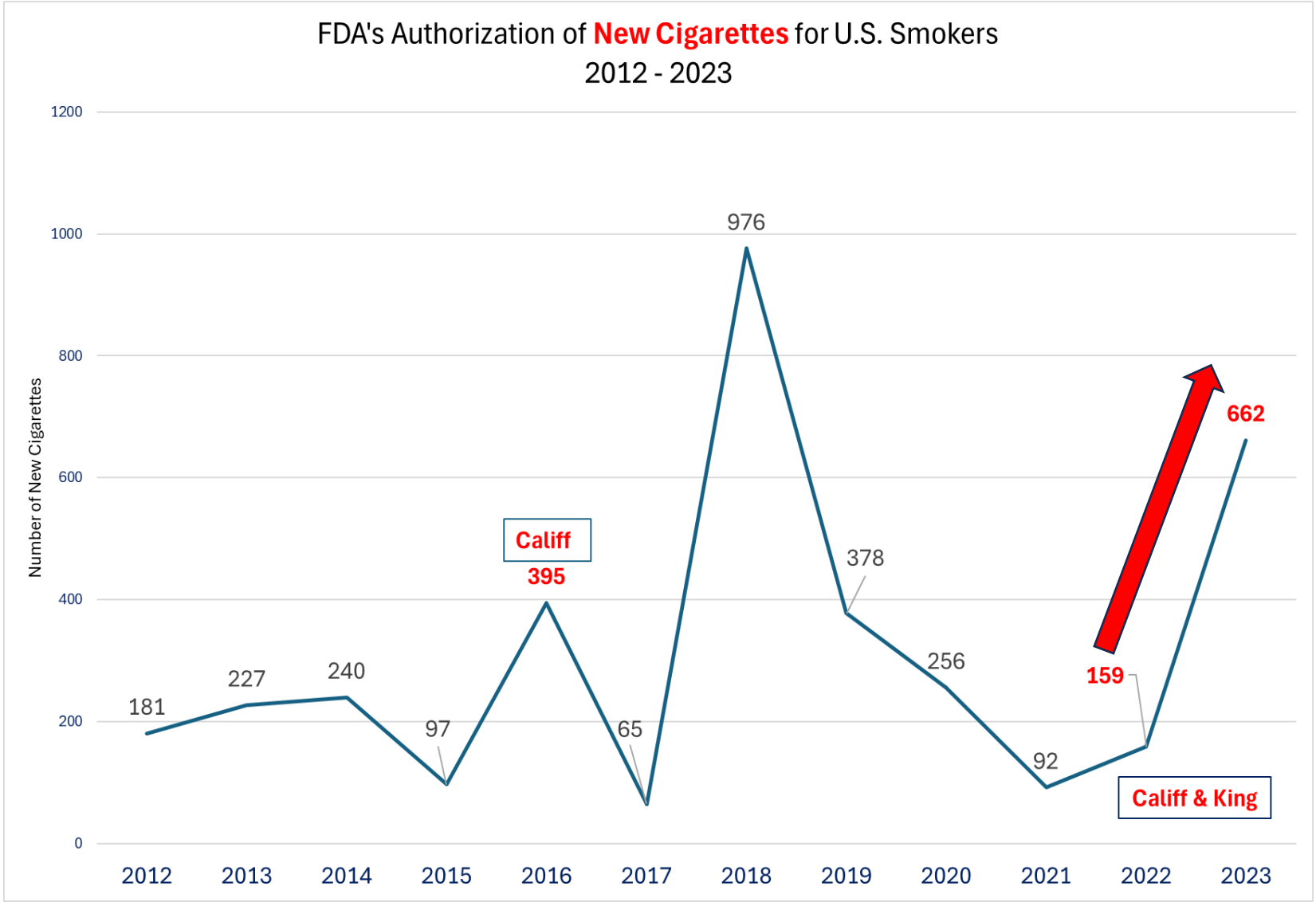
Smoking v. Nonsmoking v. Nicotine



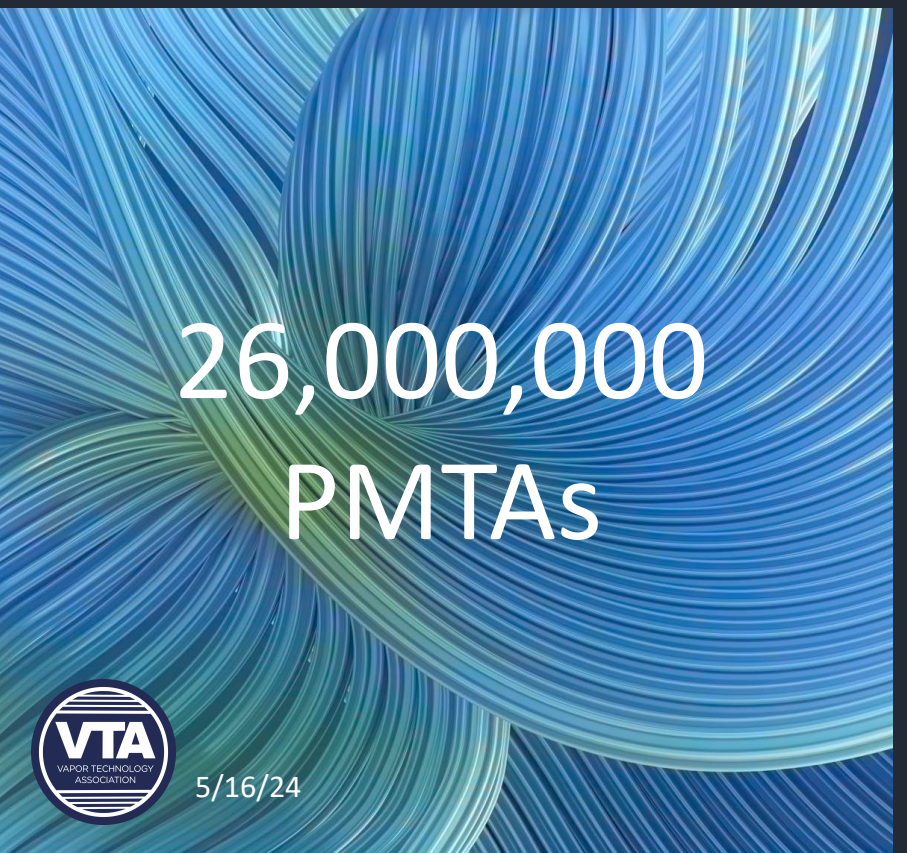
Current FDA/CTP Trajectory: Combustion Reigns



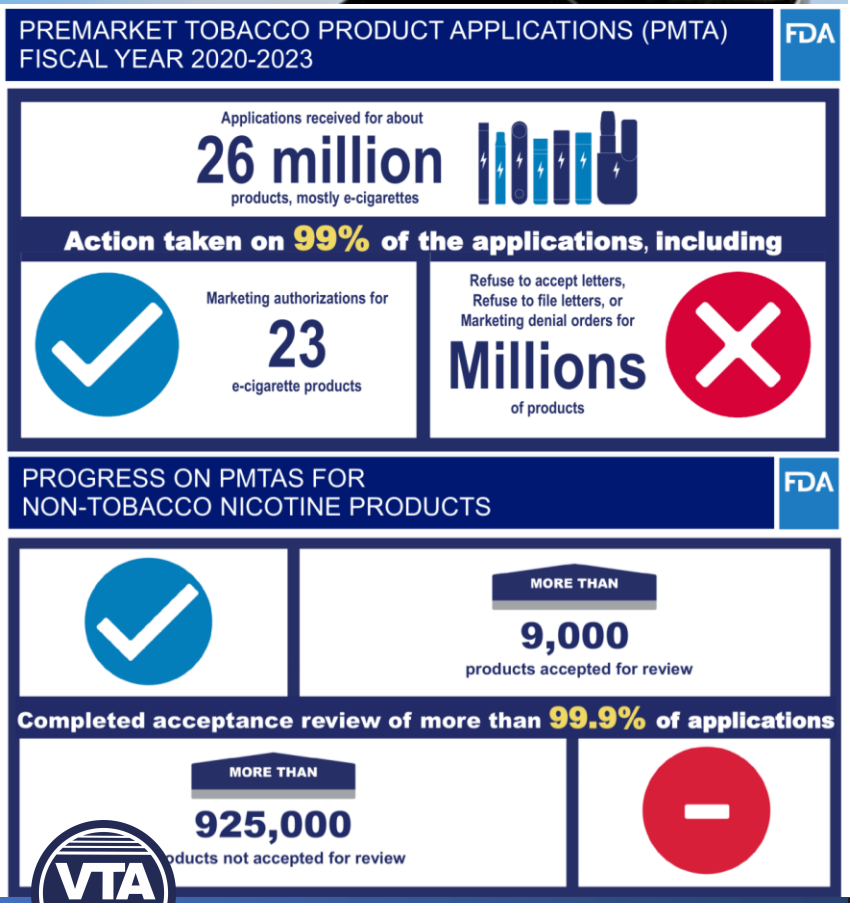
Cigarette Renaissance?



PMTA Used to Authorize 45 Less Harmful Alternatives



- 4 nicotine mints/chews
- 8 snus
- 8 heat-not-burn
- 23 ENDS



PMTA Pathway…to Nowhere

- 23 = 8* ENDS options for smokers
  - Tobacco flavor only
- 23 = 0.00000008% ENDS authorized
- *Zero* open system devices
- *Zero* open system e-liquids
- *Zero* nicotine pouches
- *Zero* flavored products (including menthol)

FDA's Ban on Less Harmful Nicotine Products

Every Product *NOT* on this List is "Illicit" and may not be sold in the U.S.

E-Cigarettes Authorized by the FDA

As of Jan. 2024, these are the only e-cigarettes authorized to be sold in the U.S.

Manufacturer	Product Name
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package
	Logic Vapeleaf Cartridge/Capsule Package
	Logic Vapeleaf Tobacco Vapor System
	Logic Pro Tobacco e-Liquid Package
	Logic Pro Capsule Tank System (1)
	Logic Pro Capsule Tank System (2)
	Logic Power Tobacco e-Liquid Package
	Logic Power Rechargeable Kit
NJOY LLC	NJOY DAILY Rich Tobacco 4.5%
	NJOY DAILY EXTRA Rich Tobacco 6%
	NJOY ACE Device
	NJOY ACE POD Classic Tobacco 2.4%
	NJOY ACE POD Classic Tobacco 5%
	NJOY ACE POD Rich Tobacco 5%
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)
	Vuse Vibe Tank Original 3.0%
	Vuse Vibe Power Unit (2)
	Vuse Ciro Power Unit (1)
	Vuse Ciro Cartridge Original 1.5%
	Vuse Ciro Power Unit (2)
	Vuse Solo Power Unit
	Vuse Replacement Cartridge Original 4.8% G1
	Vuse Replacement Cartridge Original 4.8% G2

For the most up-to-date list of authorized e-cigarettes, visit the Premarket Tobacco Product Marketing Granted Orders webpage.

While these products are authorized to be sold in the U.S., it does not mean these products are safe nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.

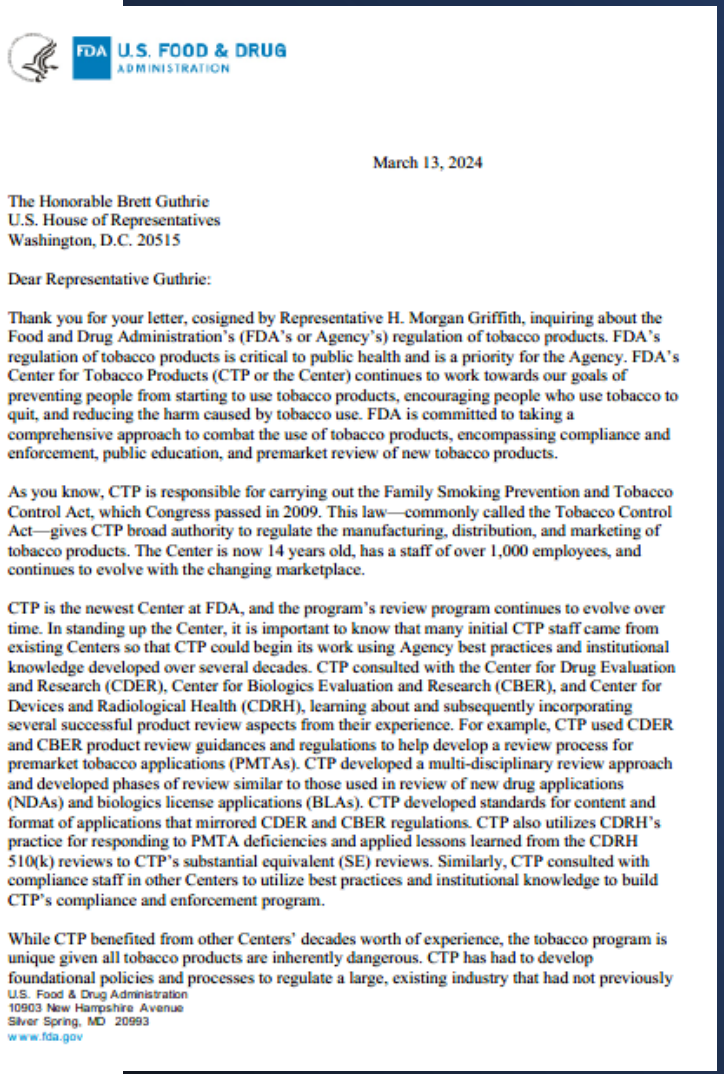
Civ Law 101: Illicit = Illegal

No Safe Harbor for PMTA

Commissioner to Congress – March 2024

"FDA has been clear that unless an e-cigarette product has received a marketing granted order, the product is on the market illegally."

"For unauthorized e-cigarettes, the **pendency of a PMTA does not create any sort of safe harbor to sell that product.**"



U.S. FOOD & DRUG ADMINISTRATION

March 13, 2024

The Honorable Brett Guthrie
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Guthrie:

Thank you for your letter, cosigned by Representative H. Morgan Griffith, inquiring about the Food and Drug Administration's (FDA's or Agency's) regulation of tobacco products. FDA's regulation of tobacco products is critical to public health and is a priority for the Agency. FDA's Center for Tobacco Products (CTP or the Center) continues to work towards our goals of preventing people from starting to use tobacco products, encouraging people who use tobacco to quit, and reducing the harm caused by tobacco use. FDA is committed to taking a comprehensive approach to combat the use of tobacco products, encompassing compliance and enforcement, public education, and premarket review of new tobacco products.

As you know, CTP is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act, which Congress passed in 2009. This law—commonly called the Tobacco Control Act—gives CTP broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. The Center is now 14 years old, has a staff of over 1,000 employees, and continues to evolve with the changing marketplace.

CTP is the newest Center at FDA, and the program's review program continues to evolve over time. In standing up the Center, it is important to know that many initial CTP staff came from existing Centers so that CTP could begin its work using Agency best practices and institutional knowledge developed over several decades. CTP consulted with the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH), learning about and subsequently incorporating several successful product review aspects from their experience. For example, CTP used CDER and CBER product review guidances and regulations to help develop a review process for premarket tobacco applications (PMTAs). CTP developed a multi-disciplinary review approach and developed phases of review similar to those used in review of new drug applications (NDAs) and biologics license applications (BLAs). CTP developed standards for content and format of applications that mirrored CDER and CBER regulations. CTP also utilizes CDRH's practice for responding to PMTA deficiencies and applied lessons learned from the CDRH 510(k) reviews to CTP's substantial equivalent (SE) reviews. Similarly, CTP consulted with compliance staff in other Centers to utilize best practices and institutional knowledge to build CTP's compliance and enforcement program.

While CTP benefited from other Centers' decades worth of experience, the tobacco program is unique given all tobacco products are inherently dangerous. CTP has had to develop foundational policies and processes to regulate a large, existing industry that had not previously

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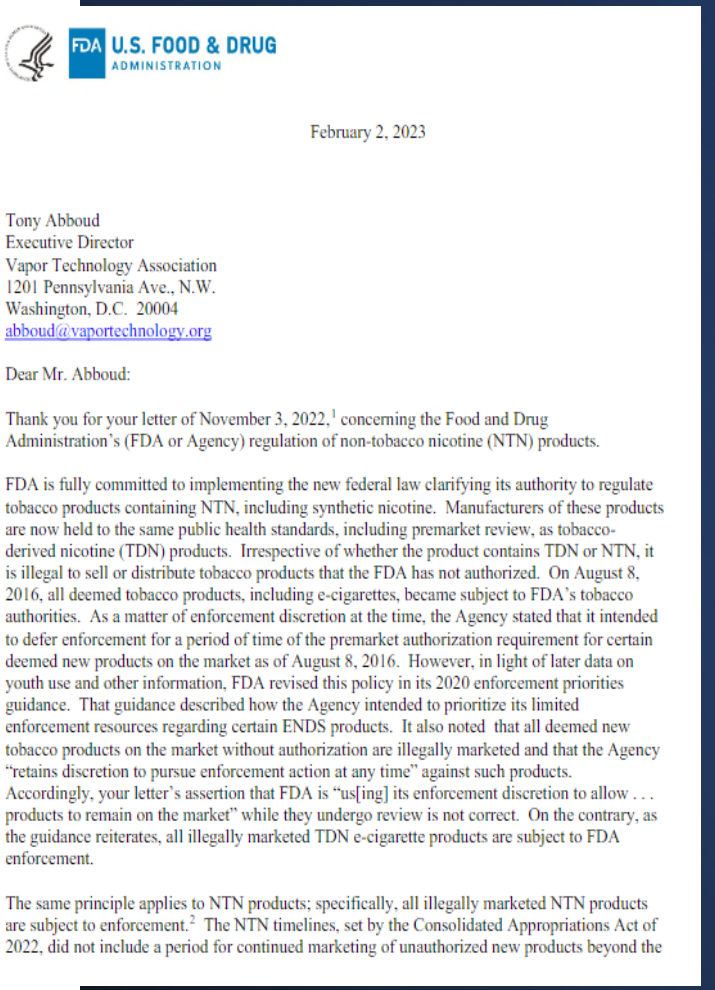
Silver Spring, MD 20993
www.fda.gov

No Enforcement Discretion

CTP Director Brian King – Feb 2023

"Your letter's assertion that FDA is 'us[ing] its enforcement discretion to allow…products to remain on the market' while they undergo review is not correct."

"FDA has not adopted a broad policy of enforcement discretion with respect to TDN or NTN e-cigarette products that lack the required premarket authorization."



FDA U.S. FOOD & DRUG ADMINISTRATION

February 2, 2023

Tony Abboud
Executive Director
Vapor Technology Association
1201 Pennsylvania Ave., N.W.
Washington, D.C. 20004
abboud@vaportechnology.org

Dear Mr. Abboud:

Thank you for your letter of November 3, 2022,[1] concerning the Food and Drug Administration's (FDA or Agency) regulation of non-tobacco nicotine (NTN) products.

FDA is fully committed to implementing the new federal law clarifying its authority to regulate tobacco products containing NTN, including synthetic nicotine. Manufacturers of these products are now held to the same public health standards, including premarket review, as tobacco-derived nicotine (TDN) products. Irrespective of whether the product contains TDN or NTN, it is illegal to sell or distribute tobacco products that the FDA has not authorized. On August 8, 2016, all deemed tobacco products, including e-cigarettes, became subject to FDA's tobacco authorities. As a matter of enforcement discretion at the time, the Agency stated that it intended to defer enforcement for a period of time of the premarket authorization requirement for certain deemed new products on the market as of August 8, 2016. However, in light of later data on youth use and other information, FDA revised this policy in its 2020 enforcement priorities guidance. That guidance described how the Agency intended to prioritize its limited enforcement resources regarding certain ENDS products. It also noted that all deemed new tobacco products on the market without authorization are illegally marketed and that the Agency "retains discretion to pursue enforcement action at any time" against such products. Accordingly, your letter's assertion that FDA is "us[ing] its enforcement discretion to allow . . . products to remain on the market" while they undergo review is not correct. On the contrary, as the guidance reiterates, all illegally marketed TDN e-cigarette products are subject to FDA enforcement.

The same principle applies to NTN products; specifically, all illegally marketed NTN products are subject to enforcement.[2] The NTN timelines, set by the Consolidated Appropriations Act of 2022, did not include a period for continued marketing of unauthorized new products beyond the

How Did We Get Here?

FDA Broke the PMTA Process

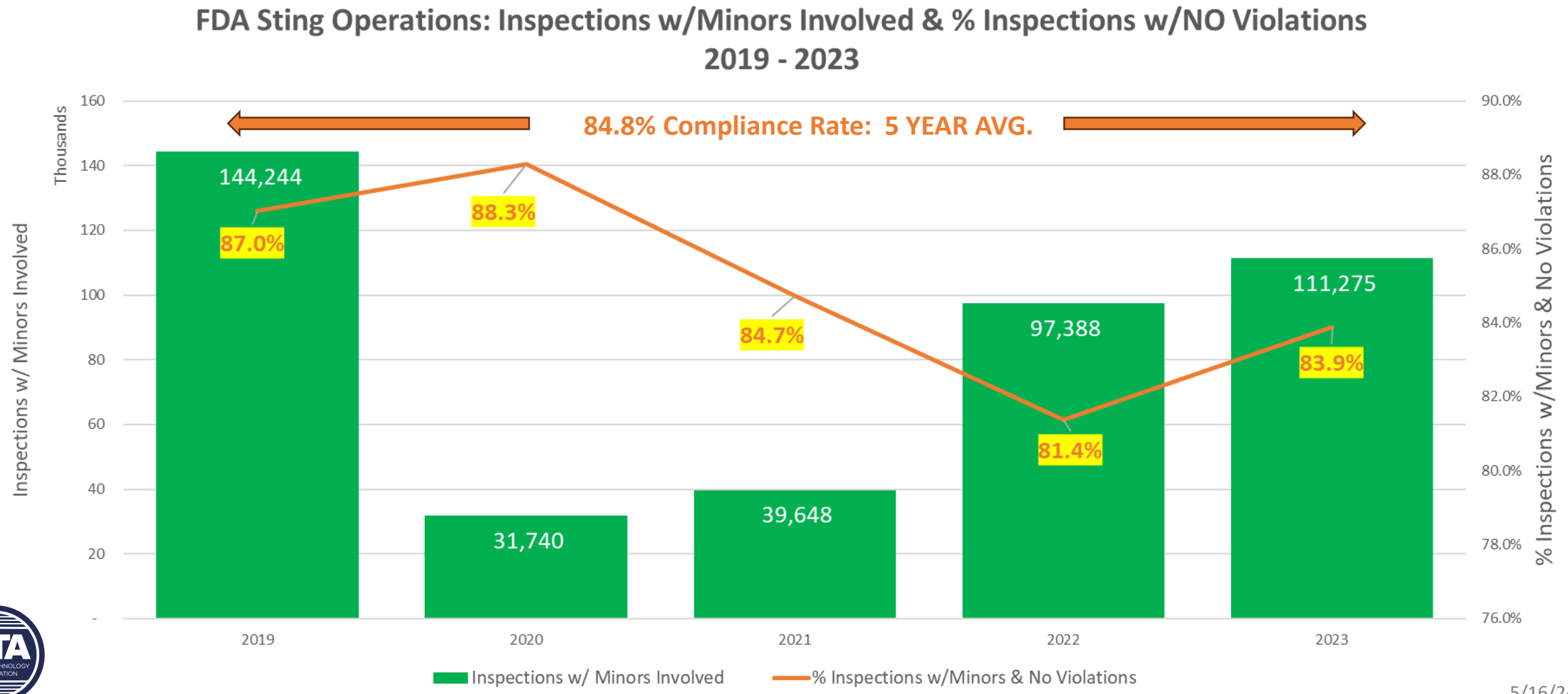
- Acting Commissioner: Overrode Scientists
  - Forced reversal of Office of Science priorities and process
  - Fatal Flaw memo targeted flavored products; small companies
  - Rejected millions of ENDS *without* review
- Reagan-Udall: Process is broken
  - No clarity on science need to prove APPH or how APPH is applied
  - CTP continued issuing MDOs *based on broken process*
  - Strategic Plan silent on APPH & Harm Reduction
- Plunged the agency into litigation
- CTP refuses to publish a list of pending PMTAs
- Agency handcuffed itself - SCOTUS

Perspectives on Enforcing a Broken Process

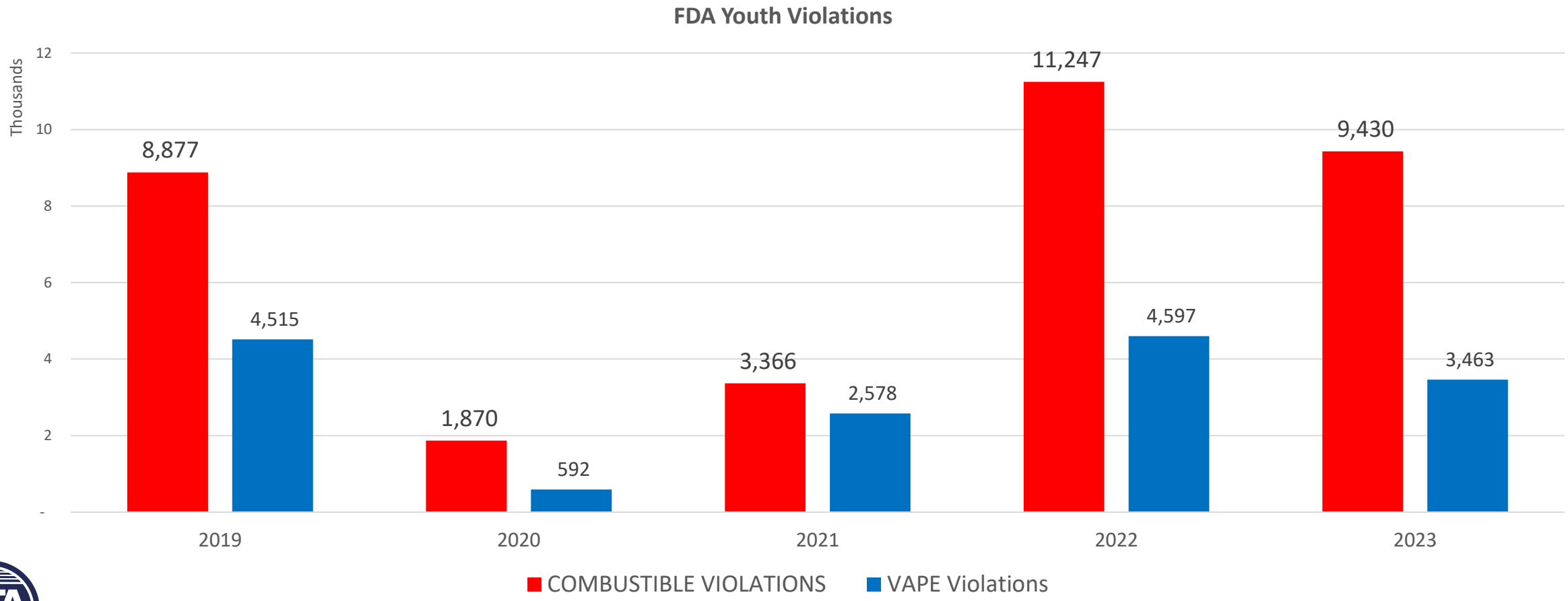
FDA Enforcement on ENDS: Not Viable, Efficient or Effective

- Government can't enforce a *ban*
- CTP is regulatory center, not a police force
- CTP entirely dependent on third parties
  - DOJ has MUCH bigger issues to deal with
- No amount of user fees will change this

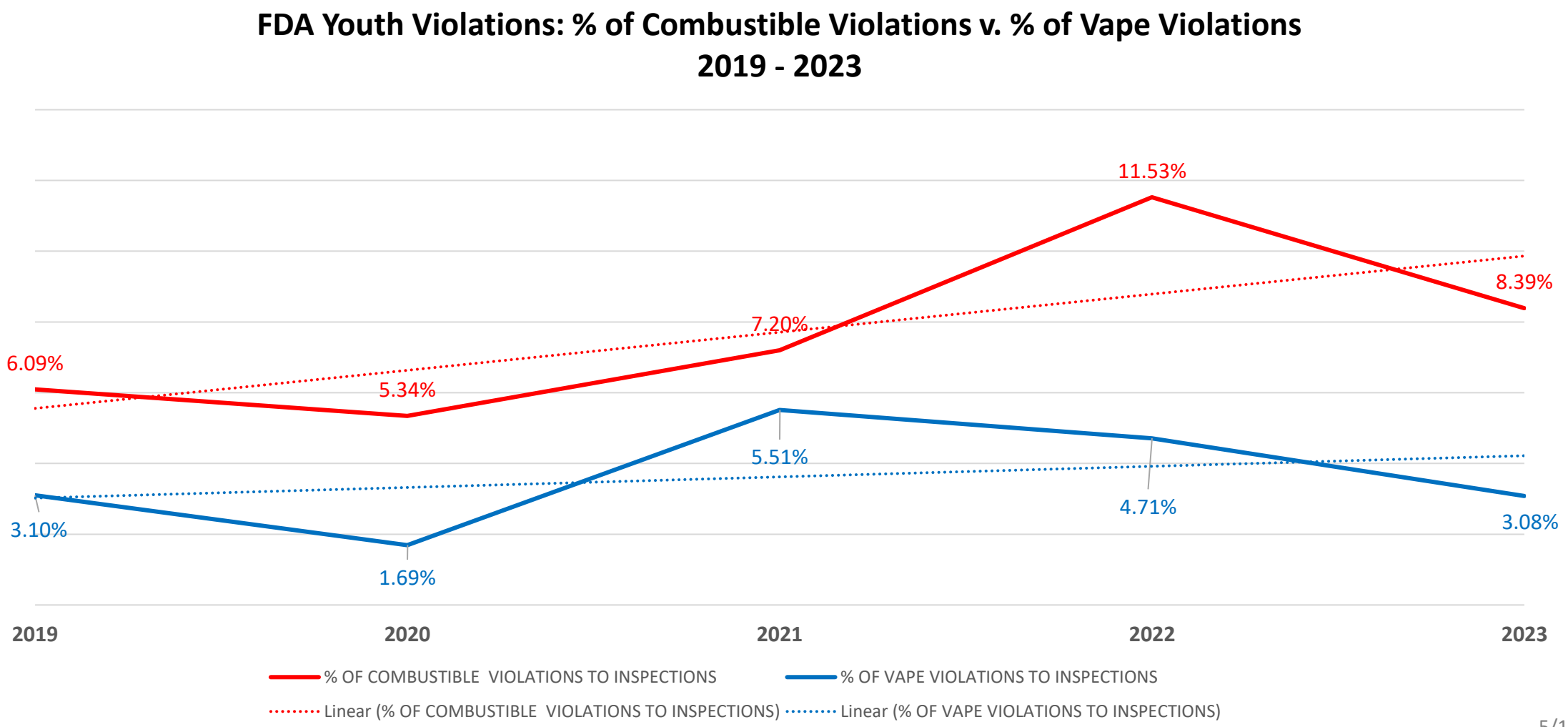
Millions $ Spent FDA Retail Stings Effectiveness?



Youth Violations: Combustible v. Vape



Combustible Youth Violations 2x Vape Youth Violations



Whose Interests Does FDA ENDS Enforcement Serve?

CTP's misguided narrative on youth & flavors

- Every MDO cites youth regardless of product specific youth data
- Every enforcement action cites youth

CTP's need to placate politicians & prohibitionists

- CTP political cover; shows activity

Companies with authorized ENDS

- Creates market advantage

Whose Interests Does FDA ENDS Enforcement NOT Serve?

30M Adult Americans who smoke

13M Adult Americans who want flavored vapes

American businesses which cater to vapers

Not Public Safety or Public Health

- Current state: An FDA regulated grey market
  - Products sold through licensed distribution channels
- Full enforcement: pure black market
  - Removes products from licensed distribution chain
  - Spawn criminal markets that companies have

A Prophetic Warning Not Heeded

"Mass market exit of [vaping] products present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products"

"I am concerned that these declines [in cigarette smoking] could be slowed or reversed in the case of very sudden and very dramatic reductions in availability."

"Mass market exit" is "a public health outcome that should be avoided if at all possible."

Declaration of Mitch Zeller, Director, Center for Tobacco Products, *AAP v. FDA*, March 20, 2020

Banning ENDS = Increases Smoking

1. *Friedman et al.*:
   Flavored vape bans *increase* cigarette sales; youth

2. *National Youth Tobacco Survey 2023*:
   Cigarette use by 12th graders increased from 5.7% - 7.5%

3. *Carpenter et al.*:
   Mere access to e-cigarettes *causes* Americans to quit smoking

4. Cigarette Companies:
   Illicit flavored e-cigarettes depressing cigarette sales

Real Lives Are At Stake

Americans Dying from Smoking
Since February 17, 2022

1,061,119.758

Thank you.