Vapor Products: Overall Health Impact, Restricting Youth Access, and the Premarket Tobacco Application(PMTA) Process

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Tobacco Harm Reduction (THR)

Tobacco harm reduction (THR) is a public health strategy to lower the health risks associated with tobacco use. Smoking tobacco is widely acknowledged as a leading cause of illness and premature death. Nicotine alone is relatively safe as evidenced by the existence of Nicotine Replacement Therapies (NRT) such as the gum, patch, and lozenge. THR focuses on reducing or eliminating the use of combustible tobacco by switching to safer, smoke-free products, including:

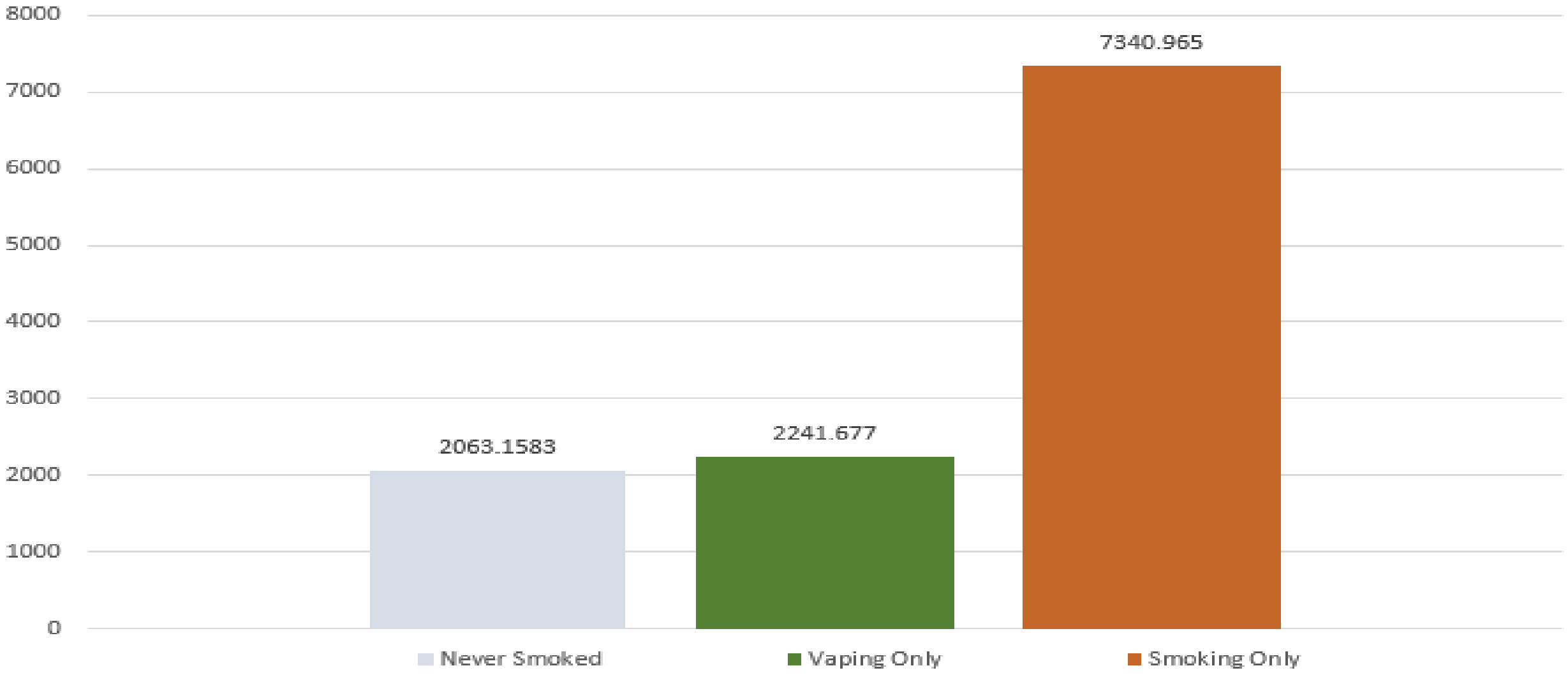
- Smokeless tobacco products
- Electronic cigarettes and vapor products
- Nicotine replacement therapies

E-Liquid Safety

The UK Royal College of Physicians 2016 report "Nicotine without smoke: tobacco harm reduction," underlined that people smoke because they are addicted to nicotine, but are harmed by the other constituents of tobacco smoke, and that provision of the nicotine without the other harmful components can prevent most of the harm from smoking. The report noted that "the hazard to health arising from long-term vapour inhalation was unlikely to exceed 5% of the harm from smoking tobacco."

* Additional studies are available upon request

Comparison of Total Toxicant Exposures*



*Exposure amounts (excluding nicotine markers) from
"Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes"
Maciej L. Goniewicz, PharmD, PhD1; Danielle M. Smith, MPH1; Kathryn C. Edwards, PhD2; et al
JAMA Netw Open. 2018;1(8):e185937. doi:10.1001/jamanetworkopen.2018.5937

Importance of Flavors in Vapor Products

Any proposal to ban the sale of open-system vapor products sold in flavors other than tobacco will deny former adult smokers from the experience that helped them to transition from smoking to vaping

- People who vape prefer flavors and many find tobacco flavors unappealing. Some people experience tobacco flavored vapor products as a relapse trigger.
- Vape shops financially rely upon the sales of flavored e-liquid.
- Any flavor ban will lead to black market sales of e-liquid and pressure many people to make their own at home.

EVALI and ENDS

There is no conclusive evidence to suggest that conventional nicotine vapor products were the cause of the recent deaths and illnesses due to lung injuries. Those illnesses were caused by illicit THC cartridges manufactured and sold on an underground market.

The CDC updated it's advisory on this issue in mid-November 2019 by stating that

> "We do know that THC is present in most of the samples tested to date, and most patients report a history of THC-containing products. The latest national and state findings suggest products containing THC, particularly those obtained off the street or from other informal sources (e.g. friends, family members, illicit dealers), are linked to most of the cases and play a major role in the outbreak. As such, we recommend that you do not use e-cigarette or vaping products that contain THC."

“Popcorn lung” and Vaping

Bronchiolitis obliterans (a.k.a. “popcorn lung”) was discovered after workers from a popcorn factory developed a possibly fatal lung condition caused by inhaling dust from the butter flavoring in high amounts for months or years of 40 hour work weeks without proper ventilation. The chemical used to make the butter flavoring is diacetyl.

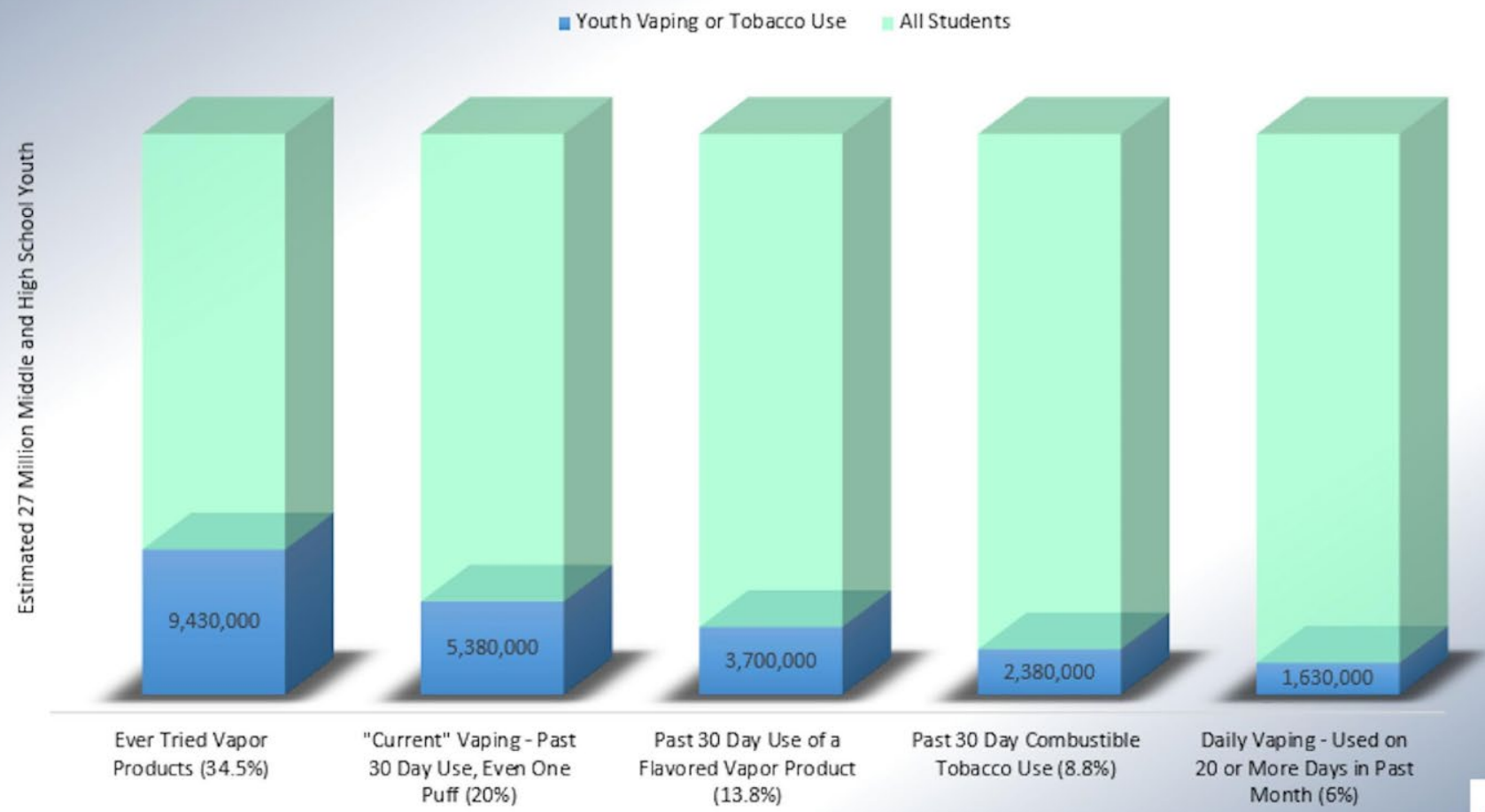
Some e-liquids contain extremely lesser amounts of the culprit, diacetyl, and even contain less than a combustible cigarette.

Note that, after more than a decade of vapor product use worldwide, there are no confirmed cases of popcorn lung related to nicotine vapor products.

Youth Access

- It is vital that any critical conversation about youth use of nicotine relies on an honest and accurate description of national survey data.
- The current debate over youth use of vapor products is being driven by data that focuses on experimentation and ever-use.
- In order to implement real solutions, particular attention must be given to underlying motivating factors of risky behavior including regular and habitual use of tobacco and nicotine products by young people.

A Visual Perspective on 2019 Youth Vaping "Epidemic" with Combustible Tobacco and Flavor Use Data*



*Data and estimates for combined middle and high school use are taken directly from the CDC Report on the 2019 National Youth Tobacco Survey. Based on CDC-estimated use numbers and percentages, we calcuated the total middle and high school youth popuation to be approximately 27 million.

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Youth Access and Vape Shops

The cottage vaping industry is the true "gatekeeper" against youth access to vaping products.

FDA data from their underage sting operations shows that vape shops have the highest compliance rates in Maryland compared to convenience stores, gas stations, etc.

Vape shops serve a vital role in providing products and education to people who smoke with the intent of transitioning them to less risky, smoke-free products.

Vape Shops' Compliance with Minimum Sales Age Laws

According to the FDA Compliance Check Inspection of Tobacco Product Retailers (through November 30th, 2019**), out of 222 violations, not a single vape shop was cited for selling vapor products to minors (**or those over 21 after October 1st, 2019 (MD T21)**).**

The vast majority of the violations were from gas stations, convenience stores, grocery stores, and liquor stores.

Effective Strategies for Restricting Youth Access

- **Education - for parents, teachers, and students**
- **Meaningful penalties for selling to minors**
- **Tobacco 21 (recently adopted as federal law,**
- **Checking ID for anyone under 30**
- **Restricting vapor product sales to adult-only establishments**
- **Requiring all vapor products to be displayed behind counters or in cases accessible only to employees**
- **Enforcing the already established MD ENDS licensing laws**
- **Restricting marketing and advertising of vapor products to adult-only demographics**
- **Age verification for internet sales**

Ineffective Strategies for Restricting Youth Access

Flavor Bans - E-liquid is "open-source" and with a minimal investment entrepreneurial black market sellers can quickly scale up operations to meet the demand created by short-sighted policies.

Taxes - Vapor products are already expensive and enacting new taxes will more likely drive people back to smoking or discourage them from switching in the first place. Excessive taxes also motivate people to seek out untaxed products from black market sources.

Public Use Bans - There is no imminent threat to bystanders from someone who is vaping. Private businesses are free to establish and enforce their own workplace vaping policy. Allowing vaping in public spaces and workplaces normalizes quitting smoking.

Increased Demand for Flavors due to Recent Federal Executive Action?

The Food and Drug Administration recently announced a ban on all flavored vapor products sold as non refillable, closed-systems. Flavors other than tobacco and menthol will still be allowed for sale in refillable, open-system vapor products--almost exclusively sold by specialty vapor retailers.

This ban will likely pressure many people to seek out counterfeit and unregulated pod-based products with which they can use flavored e-liquid.

We may not have the opportunity to evaluate the effectiveness of this policy due to the May 2020 premarket tobacco application deadline which will effectively remove nearly all nicotine vapor products from the market.

Premarket Tobacco Applications (PMTA)

The PMTA process as written will inevitably result in two outcomes:

1. More than 95% of Vapor companies will be put out of business; and,
2. with few exceptions, the large cigarette companies will dominate the market.

Why?

- The FDA's application process is unworkable with no objective framework and the regulatory and financial burden of the PMTA process on vapor businesses--particularly small to medium businesses--will be devastating.

PMTA Limited* Cost Summary

No. Of SKUs	HPHC Testing	Environment Assessment	Stability Testing	All Three Tests Only
1	$65,779	$200,000	$77,168	$342,947
10	$657,790	$200,000	$771,680	$1,629,470
50	$3,288,950	$200,000	$3,858,400	$7,347,350
100	$6,577,900	$200,000	$7,716,800	$14,494,700
500	$32,889,500	$200,000	$38,584,000	$71,673,500

* This summary includes only 2 statutory requirements and 1 FDA requirement•These are actual costs from laboratories•For reference: FDA estimated $300,000 - $500,000 total cost per SKU for entire PMTA in its Regulatory Impact Analysis, May 2016, p. 88.

Additional PMTA Costs

- Literature review
- Clinical Trials
- Other Toxicology Testing
- Behavioral Studies or Surveys on Consumer Perceptions
- Label Comprehension

Questions?