



## The Truth About PMTA Directories: Clarifying Misconceptions

Claim	Reality
<p><b>PMTA directories have not led to the closures of small businesses.</b></p>	<p>In the three states that have enacted PMTA directory laws, active enforcement is currently on hold due to litigation and funding challenges for enforcement efforts.</p> <p>The threat of enforcement has caused some businesses to close.</p>
<p><b>PMTA directories enjoy support from public health and free market groups.</b></p>	<p>Public health advocates have opposed PMTA registries and pointed out the influence the tobacco industry has had in writing them.</p> <p>Despite heavy lobbying, numerous prominent national conservative organizations have refused to support these bills.</p>
<p><b>Over 1,000 products appear on PMTA directories in other states, so vape shops can continue to operate.</b></p>	<p>Although directories may list over 1,000 products today, the FDA has committed to completing its review of outstanding PMTAs by June this year.</p> <p>The FDA has not authorized a single vaping product since July 2022. Devastating opinions from the 5th and 11th Circuits have not done nothing to force reforms inside FDA.</p>
<p><b>Products on PMTA directories are safer than those not listed.</b></p>	<p>Most products listed in PMTA directories are bottled e-liquids. Fears of accidental spillage or ingestion by children has led many parents to favor disposable vaping products, which this bill will ban.</p>
<p><b>All vaping products without PMTAs are illegal.</b></p>	<p>Like any regulator, FDA exercises enforcement discretion. FDA has put over 9,000 post-2020 PMTAs into scientific review. Nearly all these products are being sold today.</p> <p>The tobacco industry has demanded FDA enforce against all these products, but FDA has wisely chosen to target specific brands with youth use issues.</p>
<p><b>Youth vaping is an epidemic.</b></p>	<p>Government data shows youth vaping has dropped to its lowest level since 2013. Conversely, adult vaping rates are on the rise, primarily driven by the availability of disposable vaping products.</p>
<p><b>China banned flavors in vaping products to protect children.</b></p>	<p>China owns and operates from the world’s largest combustible cigarette company. Tax revenue from cigarettes is a major source of government funding. The CCP is not focused on health.</p>



February 20, 2024

**Chairman Carpenter and members of the House Federal and State Affairs Committee,**

On behalf of the American Vapor Manufacturers (AVM), a trade group representing a broad spectrum of small business owners within the nicotine vaping industry, I am writing to urge you to reject HB 2801. Importing the Food & Drug Administration's prohibitionist vaping product regulations into the state would lead to negative consequences for small businesses and public health.

HB 2801 would do little to nothing to address youth vaping, as history has shown that young people are more than capable of navigating illicit markets. What HB 2801 will do is shut down responsible small businesses and make it more difficult for Kansas's 180,000 adult vapers to access the products they want to use.

### **Overview of House Bill 1260**

HB 2801 proposes an effective prohibition on all vaping products introduced in the past eight years by establishing a Pre-Market Tobacco Application (PMTA) directory. Placement on the directory would be limited exclusively to manufacturers who submitted a PMTA for a product that was on the market on August 8, 2016, to the FDA by September 9, 2020, and are awaiting or have received authorization.

The corporate proponents of this bill deliberately chose the September 2020 date in a bid to sideline non-tobacco nicotine products, the manufacturers of which were not required to submit their PMTAs until mid-2022. **Consequently, over 9,000 non-tobacco nicotine products under FDA review today will be ineligible for inclusion in the directory.**

The end effect of HB 2801 will be to eliminate over 95% of nicotine vaping products available at Kansas specialty retailers. This will disproportionately benefit large, out-of-state tobacco companies by decimating their competition.

### **Implications for Small Businesses**

Imagine attempting to operate a cell phone store that can only sell iPhone models introduced in the mid-2010s; this analogy mirrors the predicament nicotine vaping businesses would face under HB 2801.

The FDA has already denied over 99% of the 26 million PMTAs it received from vaping manufacturers. Two months ago, the agency informed a federal district court judge that it intends to complete review on the remaining 1% by June of this year. **The 1,000+ vaping products from 2016 that appear on other state registries—none of which have much popularity today—will almost undoubtedly be wiped out.**



Simply put, it will be impossible to both run a profitable business and comply with the law. Passage of this law will put legitimate retailers in the position of deciding between violating state law and shutting down their businesses.

### Unfunded Enforcement Mandate

The proposed \$250 per product fee falls far short of what would be necessary to create even the *appearance* of enforcement. As it stands today, just three manufacturers have received PMTAs from the FDA for 23 products. All are from large tobacco companies and limited to tobacco flavors only. To give an idea of the consumer demand for these products, 3 of the 23 products have already been discontinued.

***Absent an extraordinary change in the FDA's review process, the fee structure proposed in HB 2801 may only generate \$4,000 annually for enforcement of this law.*** This is starkly inadequate compared to the State of Virginia's estimated annual enforcement cost of at least \$2.1 million for a PMTA directory.

### Big Tobacco Protection Act

There is a reason why Altria—America's largest cigarette company—is such a fervent advocate for PMTA registries. Last October, they blamed disposable vaping products for causing their cigarette sales to decline faster than anticipated. The news for Altria has only soured since. Just last week, the investment firm Barclay's predicted that unless disposable vaping products are quickly eliminated, Altria will have to reduce its predicted earnings for FY 2024.

Altria's advocacy suggests their interest in PMTA registries is not about 'fairness' in the market, or even to obtain a competitive advantage for their vaping product. ***Rather, it appears Altria is banking on adult vapers returning to combustible cigarettes.***

### No State Has Successfully Implemented a PMTA Directory

HB 2801's restrictive product directory could push consumers toward unregulated markets, heightening public health risks and fostering crime, including cartel involvement. Both adolescents and young adults will bypass these laws by purchasing products through countless unregulated deals that can easily be found on platforms like TikTok and Snapchat.

Today, not a single state is actively enforcing a PMTA directory law. Legal challenges and enforcement difficulties have plagued these efforts, underscoring the impracticality and inefficacy of such regulations. For instance, a county judge put enforcement of Louisiana's PMTA directory on hold last month. Prior to the Louisiana law being enjoined, our trade group received multiple reports of vaping products being sold out of car trunks in the parking lots of smoke shops.

### Youth Vaping Has Plummeted as Adult Use Has Grown



Contrary to the narrative of a vaping epidemic, the rate of youth vaping has plummeted nationally by 60% since 2019. Usage of vaping by adults, meanwhile, has surged by over 25%. This growth is predominantly attributed to adults opting for flavored disposable vaping products, highlighting a shift towards safer alternatives to smoking.

Youth vaping is at its lowest rate nationally in a decade. Please keep this in mind when proponents claim that these “new” disposable vaping products are targeted at kids.

### **Inappropriate Marketing Does Not Justify Broad Bans**

In hearings across the country, proponents of PMTA registries have engaged in legislative theater by showing off inappropriately marketed vaping products to suggest that action is needed. We support targeted legislation to eliminate market outliers. However, we believe this can be accomplished without resorting to overreaching measures that harm responsible businesses and consumers.

### **Questions for Proponents:**

- (1) If disposables are indeed impacting cigarette sales negatively, isn't it logical to infer that Altria anticipates a rebound in cigarette sales should PMTA registries be enacted and enforced vigorously?
- (2) If the FDA denies the remaining pending PMTAs, how is enforcement going to work with just \$20,000 in annual fees?
- (3) Have any states successfully curtailed illicit sales via social media platforms?
- (4) How will adult constituents and voters respond to being told they can buy cigarettes, but not a fruit-flavored vape?

### **Conclusion**

The American Vapor Manufacturers and Kansas's small businesses are eager to engage in meaningful discussions to devise fair and effective regulatory frameworks for vaping products. We firmly oppose HB 2801 and kindly request your support in defeating this bill.

Thank you for considering our testimony.




Sincerely,

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# 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
<p><i>Logic Technology Development</i></p> <p>Owned by Japan Tobacco International</p> 	<p><i>Logic Regular Cartridge/Capsule Package</i></p> <p><i>Logic Vapeleaf Cartridge/Capsule Package</i></p> <p><i>Logic Vapeleaf Tobacco Vapor System</i></p> <p><i>Logic Pro Tobacco e-Liquid Package</i></p> <p><i>Logic Pro Capsule Tank System (1)</i></p> <p><i>Logic Pro Capsule Tank System (2)</i></p> <p><i>Logic Power Tobacco e-Liquid Package</i></p> <p><i>Logic Power Rechargeable Kit</i></p>
<p><b>NJOY LLC</b></p> <p>Owned by Altria</p> 	<p><i>NJOY DAILY Rich Tobacco 4.5%</i></p> <p><i>NJOY DAILY EXTRA Rich Tobacco 6%</i></p> <p><i>NJOY ACE Device</i></p> <p><i>NJOY ACE POD Classic Tobacco 2.4%</i></p> <p><i>NJOY ACE POD Classic Tobacco 5%</i></p> <p><i>NJOY ACE POD Rich Tobacco 5%</i></p>
<p><b>R.J. Reynolds Vapor Company</b></p> <p>Subsidiary of R.J. Reynolds Tobacco</p> 	<p><i>Vuse Vibe Power Unit (1)</i></p> <p><i>Vuse Vibe Tank Original 3.0%</i></p> <p><i>Vuse Vibe Power Unit (2)</i></p> <p><i>Vuse Solo Power Unit</i></p> <p><i>Vuse Replacement Cartridge Original 4.8% G1</i></p> <p><i>Vuse Replacement Cartridge Original 4.8% G2</i></p>
<p><b>DISCONTINUED</b></p>	<p><del><i>Vuse Giro Power Unit (1)</i></del></p>
<p><b>DISCONTINUED</b></p>	<p><del><i>Vuse Giro Cartridge Original 1.5%</i></del></p>
<p><b>DISCONTINUED</b></p>	<p><del><i>Vuse Giro Power Unit (2)</i></del></p>