OPPOSE VAPOR DIRECTORY BILLS



TOPLINES:

The proposed vape product directory bills force the state's adoption, ratification, and enforcement of a broken and illegal federal FDA regulatory scheme and use state resources to shutdown hundreds of small-businesses.

Per the CDC, 1 in 7 U.S. adults still smoke cigarettes and 480,000 die from cigarettes while another 8 million suffer from smoking- related illnesses *every year*. The undeniable purpose of this bill is to ban e-cigarettes and eliminate competition with cigarette companies. Do not let cigarette companies deputize the state to enforce illegal federal overreach and extinguish adult access to less harmful nicotine products.

HISTORY OF THE BROKEN PMTA PROCESS:

A premarket tobacco product application (PMTA) is submitted by companies for new tobacco products under section 910(b) of the Federal Food, Drug and Cosmetic Act.

The federal PMTA process was supposed to allow less harmful nicotine products to come to market but **exempts deadly cigarettes**.

In the five years between 2018-2022, the FDA has approved only a handful of ecigarettes (8) in tobacco flavor only, but it has accelerated to the market more than 1,200 new combustible tobacco products including almost 900 new cigarettes.¹

The current PMTA process has been broken and is being used by the FDA to impose a *de facto* ban on e-cigarettes by cigarette companies to eliminate their fiercest competition.

COURTS ARE STRIKING DOWN THE EXISTING PMTA PROCESS

5th Circuit Court of Appeals *En Banc*² just rejected FDA's implementation of the PMTA process and said that FDA has unlawfully used it to ban all flavored vaping products. **Key findings are as follows:**

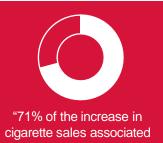
FDA's actions were "arbitrary and capricious" and sent manufacturers on a "wild goose chase." FDA changed the PMTA requirements **after** applications were submitted and "did not give manufacturers fair notice of the rules." **FDA ignored the science** submitted in support of PMTAs and refused to review it. FDA "acted unlawfully" to implement its "de facto flavor ban."

5th Circuit called out the FDA for its treatment of Americans: "No principle is more important than how the Fourth Branch of Government treats the American people."² The 11th Circuit Court of Appeals in 2022 also rejected the FDA's PMTA decisions.³ Importantly, cigarette companies themselves have also filed suits in the 5th Circuit claiming the FDA illegally declared their own products as unlawful.

REMOVING FLAVORED E-CIGARETTES FROM THE MARKETPLACE LEADS TO AN INCREASE IN TRADITIONAL CIGARETTE SALES.

According to the National Institutes of Health, cigarette smoking remains the leading cause of preventable death in the United States.

While increasing smoking will benefit the proponents of the vape registry bills, it will hurt adult consumers and hundreds of small businesses. Research has found that states and localities that remove flavored e-cigarettes from the market have suffered from increased cigarette sales. To be specific, "ENDS flavor restrictions [lead] to an additional 15 cigarettes sold for every 1 less 0.7mL ENDS pod sold suggest increased cigarette sales could partly or more than fully offset any public health benefit of reducing ENDS use by restricting or prohibiting flavors."⁴



cigarette sales associated with ENDS flavor restrictions comes from tobacco-flavored cigarettes."5

VAPE REGISTRY BILLS CREATE A BIG TOBACCO CIGARETTE MONOPOLY.

The proposed vape registry bills rely on a broken FDA system that has been struck down by federal courts.

There are **only eight vaping products** that have FDA approval.

The bill would remove from the market every flavored vaping product giving only products owned by big tobacco companies market domination.

The bill imposes a confusing and complicated registration scheme that is dependent on court cases that may change from week to week.

THIS BILL IS NOT ABOUT PROTECTING CONSUMERS. IT'S ALL ABOUT BIG BUSINESS

THIS BILL IS:

NOT ABOUT PROTECTING YOUTH. According to the CDC, since 2019, e-cigarette use among students has plummeted by 60%, reaching its lowest level since 2014. The bill does nothing to address youth.

NOT ABOUT PROTECTING PUBLIC HEALTH. Removing all flavored vaping products from the market will only increase cigarette sales.

NOT ABOUT ENFORCING LAWS. The same companies pushing these vape registry bills have sued the FDA arguing its actions are illegal. Hence, these bills just make the state the unwitting accomplice and enforcer of FDA's illegal actions, while costing state taxpayers millions, shuttering hundreds of small businesses, and throwing tens of thousands of people out of work.

Sources:

- ¹ Vapor Technology Association analysis of FDA Tobacco Products Marketing Orders, last accessed 3/16/23; content current as of 2/23/23.
- ² Wages & White Lion Investments LLC v. FDA, No. 21-60800 (5th Cir., en banc, 2024). See also Bidi Vapor LLC v. U.S. FDA, No. 21-13340 (11th Cir. 2022)
 ³ Bidi Vapor LLC v. U.S. FDA, No. 21-13340 (11th Cir. 2022)
- ⁴ Friedman, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales, 2023.

REJECT VAPE REGISTRY BILLS & PROTECT PUBLIC HEALTH

