

Opposition to HB1069

1. HB1069 bans 99.9% of Vapor Products and hands the entire industry over to Big Tobacco.

- a. 26 million vapor products have been submitted for FDA approval.¹
- b. Between 2018-2024, the FDA reviewed 99% of the applications and only approved 23 vapor products.^{1,2}
 - i. Only 3 brands have received a marketing authorization – only tobacco flavored vapes made by Big Tobacco and manufactured in China.
 - ii. RJ Reynolds and Altria are 2 of the 3 companies on this list, so it is not surprising that they are heavily lobbying for this bill in nearly every state across the country.
 1. They should not be permitted to use regulations to create a near monopoly by stifling competition from innovative vaping products.
- c. The federal Premarket Tobacco Product Application (PMTA) process was supposed to allow less harmful nicotine products to come to market but exempts deadly cigarettes.
 - i. Between 2018-2024, the FDA approved nearly 900 new cigarettes.³

2. This bill proposes the state of South Dakota use their scarce resources to enforce a broken FDA regulatory scheme.

- a. It is not the state of South Dakota's responsibility to pay millions of dollars annually to enforce this regulation.
- b. Whereas, the FDA has an annual budget of \$750 million and is the administrative body with the authority and discretion to determine whether to target a company for enforcement.
- c. FDA already enforces their regulation through U.S. Customs and Border Patrol to stop illegal products before they enter the United States as well as conducting inspections and issuing civil penalties to manufacturers and retailers of illegal products.
- d. FDA has not released a comprehensive list of products that have received Marketing Denial Orders (MDO), nor those that have received injunctions through the courts to continue marketing their products, making it very difficult for retailers and local law enforcement to know what is legal versus illegal.
- e. The bill imposes a confusing and complicated registration scheme that is dependent on court cases that may change week to week.
- f. The good actors will obey the law and exit the market leaving the industry to be overtaken by bad actors.
- g. Bad actors will not stop selling products which have such high consumer demand. They will only go underground to sell in illicit markets where there are no minimum age requirements, no product safety standards, and no responsible industry practices.

¹ <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted>

² <https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-Jan24.pdf>

³ Vapor Technology Association analysis of FDA Tobacco Products Marketing Orders, last accessed 3/16/23; content current as of 2/23/23.

3. The history of the broken PMTA process.

- a. Understanding the public health benefits of innovative vapor technology in cessation and harm reduction, FDA announced regulatory guidance in 2016 to allow vapor products to come to market.
- b. The regulatory requirements were unnecessarily arduous and estimated to cost more than > \$1 million in fees per product.
- c. At that time, the vapor industry was highly fragmented by thousands of small businesses. Therefore, the FDA promised a pathway for small businesses to be able to file PMTAs. Unfortunately, the FDA never delivered on its promises.
- d. Thousands of vapor businesses hired consultants, scientists, and attorneys to complete their PMTA submissions which were originally due by September 9, 2020, spending millions of dollars each.⁴
- e. On October 5, 2021, the FDA released the Final Rule for Premarket Tobacco Product Applications and Recordkeeping Requirements, over one year after the deadline for submission and did not give manufacturers fair notice of the rule change.⁵
- f. The FDA was overwhelmed by the 26 million product applications they received.
- g. In an effort to expedite the PMTA review process, FDA refused to review the scientific evidence and marketing plans submitted by vapor companies, instead unlawfully implementing a *de facto* flavor ban.

4. Courts are striking down the existing PMTA process calling FDA's actions "arbitrary and capricious."

- a. 5th Circuit Court of Appeals En Banc rejected FDA's implementation of the PMTA process in January 2024 and said that FDA has unlawfully used it to ban all flavored vaping products.⁶ Key findings are as follows:
 - i. FDA's actions were "arbitrary and capricious" and sent manufacturers on a "wild goose chase."
 - ii. FDA changed the PMTA requirements after applications were submitted and "did not give manufacturers fair notice of the rules."
 - iii. FDA ignored the science submitted in support of PMTAs and refused to review it.
 - iv. FDA "acted unlawfully" to implement its "*de facto* flavor ban."
- b. 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."⁶
- c. A direct quote from Judge Oldham of the 5th Circuit Court of Appeals, "Over several years, the Food and Drug Administration sent manufacturers of flavored e-cigarette products on a

⁴ <https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products#:~:text=8%2C%202016%20were%20required%20to,%3F%E2%80%9D%20section%20on%20this%20page.>

⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends#:~:text=The%20final%20rule%20%E2%80%9CPremarket%20Tobacco,%2C%202021%2C%20it%20became%20effective.>

⁶ *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) <https://www.ca5.uscourts.gov/opinions/pub/21/21-60766-CV3.pdf>

wild goose chase. FDA justifies its behavior with two principal arguments. First, FDA argues that its years' worth of regulatory guidance was not worth the paper it was printed on because it was hedged with cautious qualifiers and never guaranteed that any particular submission would be granted. Second, and most disturbingly, FDA argues that its capriciousness should be forgiven as harmless because the agency promises to deny petitioners' applications even if we remand to make the agency follow the law. Today we reject both propositions."⁶

- d. The 11th Circuit Court of Appeals in 2022 also rejected the FDA's PMTA decisions.⁷
- e. Internal memos uncovered during discovery in both trials showed FDA told their reviewers to not spend time reviewing PMTAs for flavored products and "deny all flavored vapes."
- f. These are the only two lawsuits against the FDA to have a final ruling, but more than 30 others have been filed with the courts.
- g. The FDA has appealed the 5th Circuit case to the US Supreme Court. Oral arguments already took place on December 2, 2024 and a ruling is expected by June 2025.
- h. Based on the Chevron⁸ and Cigar Association of America⁹ decisions, the US Supreme Court is expected to rule in favor of the vape manufacturers, thereby revoking FDA's authority over vapor products.
- i. Passing legislation to enforce the FDA's PMTA Registry is premature and could force the state to implement an antiquated regulatory process.

5. HB1069 is not reflective of published FDA regulations nor a balance of power between the branches.

- a. This bill does not allow for synthetic nicotine products which came to market after 2020 even though the FDA created a pathway for all synthetic nicotine products to complete the PMTA process in their Final Rule published in October 2021.
 - i. This would arbitrarily eliminate 99% of disposables which is the highest selling product category in the vapor industry allowing RJ Reynolds a monopoly in this popular product segment.
 - ii. 48% of Generation V's sales are attributed to the disposables product category.
 - iii. Consumers prefer the ease of use and convenience of disposables, especially elderly consumers who have difficulty opening child-resistant caps on e-liquid products.
 - iv. The differential treatment of synthetic nicotine products is currently being challenged in the Southern District Court of Iowa and the state has agreed to hold off on implementing or enforcing the registry until a court ruling has been announced.

⁷ *Bidi Vapor LLC v. U.S. FDA*, No. 21-13340 (11th Cir. 2022)
<https://media.ca11.uscourts.gov/opinions/pub/files/202113340.pdf>

⁸ *Loper Bright Enterprises v Raimondo* https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

⁹ *Cigar Association of America v FDA* <https://law.justia.com/cases/federal/appellate-courts/cadc/23-5220/23-5220-2025-01-24.html>

- b. According to the Office of Management and Budget, all rules with a major impact must undergo an extensive regulatory assessment process.¹⁰
 - i. One of the parameters used to establish if a proposed rule is “major” is if it would have an effect of at least \$100 million on the economy.
 - ii. Implementing a *de facto* flavor ban will eliminate \$7.3 billion of the U.S. economy as economic analysts project flavor bans will cause consumers to:
 - 1. Stop vaping altogether or switch to another tobacco product, likely deadly cigarettes
 - 2. Switch to vaping tobacco flavored products
 - 3. Continue to vape flavored and menthol products, but purchase them through the black market or make their own flavored nicotine products at home
 - iii. Economic modeling conducted by John Dunham & Associates suggests that only 6.4% of users are using tobacco flavored products and expect that to increase 33% to only 8.5% of users if flavored and menthol e-cigarettes are banned.¹¹

6. Banning flavored vapor products will have grave consequences on adult cessation and overall public health.

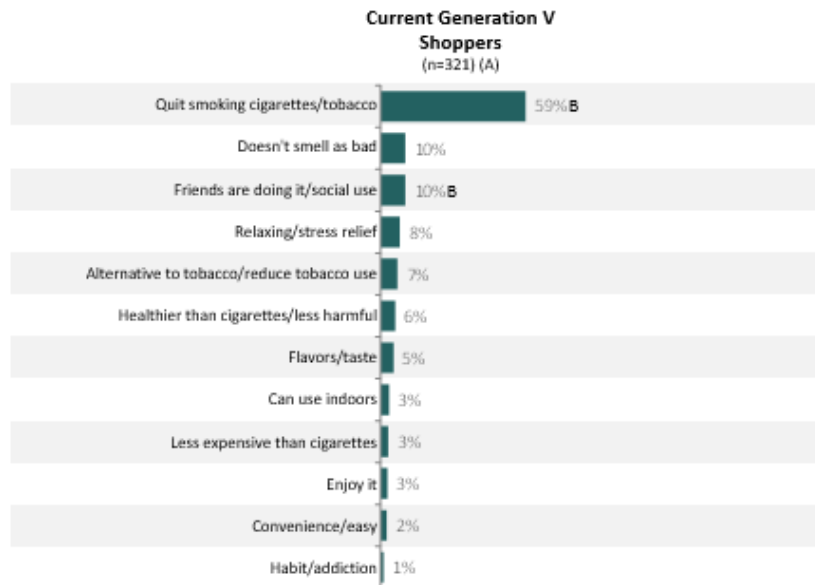
- a. HB1069 is a *de facto* flavor ban as FDA has no intention of approving ANY flavored vapor products, including menthol, as evidenced in *Wages and White Lion Investments, LLC vs FDA*.⁶
- b. At Generation V, tobacco flavored products attribute only 1% of all e-liquid and disposable sales.

Percent Sold	Flavored	Menthol	Tobacco	Unflavored
2024	95.9%	3.1%	1.0%	0.1%

- iii. Tobacco flavored e-liquid uses artificial flavoring to mimic the taste of cigarettes, but tastes horrible.
- iv. 10% of Generation V shoppers reported the smell of cigarettes is what convinced them to switch to vapor products.

¹⁰ Vought, Russell, Memorandum For The Heads Of Executive Departments And Agencies: Guidance on Compliance with the Congressional Review Act, The Executive Office of the President, Office of Management and Budget, Memorandum M-19-14, April 11, 2019.

¹¹ Buckell, John, et. al., Should Flavors Be Banned In E-Cigarettes? Evidence On Adult Smokers And Recent Quitters From A Discrete Choice Experiment, NBER Working Paper 23865, at: <http://www.nber.org/papers/w23865>.



- v. Tobacco flavors can also be a trigger for vapers trying to quit smoking
- c. A national study completed by J.C. Chen in April 2018, found that smokers who used vapor products with one or more non-tobacco/non-menthol flavors were significantly more likely to have reduced or quit smoking over time, thus suggesting that the continued availability of such flavors is important to support smoking cessation efforts.¹²
- d. A study published in the New England Journal of Medicine showed 14% of adults made the switch from vaping to smoking with a tobacco or menthol flavored vapor product, but only 4.6% continue to use those flavors after initiation.¹³
- e. Only 13.5% of minors cited flavors as one of the many reasons for vaping¹⁴
- f. Smoking is the leading cause of preventable death, responsible for 480,000 deaths and 8 million smoking related illnesses per year.¹⁵ Although, 1 in 9 adults still smoke cigarettes.¹⁶
- g. In the 15 years vapor products have been on the market, there have been zero deaths from nicotine vapor products.
- vi. Evidence uncovered during the EVALI crisis showed illness was related to illicit, black market THC vaping products, NOT nicotine vaping products.¹⁷

¹² Chen JC. 2018 Flavored e-cigarette use and cigarette smoking reduction and cessation - A large national study among young adult smokers. Subst Use Misuse. 2018 Apr 6:1-15. doi: 10.1080/10826084.2018.1455704. [Epub ahead of print].

¹³ <https://pubmed.ncbi.nlm.nih.gov/37838658/>

¹⁴ https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm

¹⁵ https://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm#:~:text=Cigarette%20smoking%20is%20the%20leading,death%20in%20the%20United%20States.&text=Cigarette%20smoking%20causes%20more%20than,year%20in%20the%20United%20States.

¹⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10168602/>

¹⁷ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

- h. A study by the Royal College of Physicians shows vapor products are at least 95% less harmful than smoking, but more brands of cigarettes (including menthol) are FDA approved than vapor products.¹⁸
- i. The New England Journal of Medicine Published a study in 2019 showing that vapor Products are nearly twice as effective at helping smoking quit than all other Nicotine Replacement Therapies (NRT) combined (i.e. patch, gum, lozenge, and pharmaceutical drugs).¹⁹
- j. The National Academies of Sciences recently found that there is conclusive evidence that completely substituting e-cigarettes for conventional cigarettes reduces users' exposure to many toxicants and carcinogens present in conventional cigarettes.²⁰

7. HB1069 will have a devastating impact on South Dakota – shuttering hundreds of small businesses.

- a. It is impossible for specialty vape retailers to stay in business selling only 23 products from 3 brands.
 - i. No business can continue to exist were it to lose over 90% of its revenue.
 - ii. Fixed costs, such as rent, insurance, electricity, and interest still must be paid and represent at least 23% of a retail store's operating budget.²¹
- b. An impact study conducted by John Dunham & Associates in 2021 showed the vape industry is providing the following for the state of South Dakota annually.²²
 - i. Revenue Generated: \$74,379,800
 - ii. Jobs Generated: 429
 - iii. Wages Generated: \$26,631,300
 - iv. State and Local Taxes Generated: \$6,131,900
- c. Consumer demand for vapor products is high, promising consumers will find alternate methods for sourcing vapor products:
 - i. Vape shop traffic will go to convenience stores which have a bad history of selling to minors.
 - ii. Consumers will turn to nearby states or online stores to purchase these products.
 - 1. The state will not be able to keep out-of-state e-commerce companies from continuing to sell their products online in South Dakota.
 - iii. HB1069 will create a burgeoning illicit market for flavored vapor products.
 - 1. Bad actors will see a boom in sales as good actors follow the law and close their doors.

¹⁸ <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>

¹⁹ A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. New England Journal of Medicine. February 14, 2019. <https://www.nejm.org/doi/full/10.1056/NEJMoa1808779>

²⁰ <https://www.nationalacademies.org/news/2018/01/new-report-one-of-most-comprehensive-studies-on-health-effects-of-e-cigarettes-finds-that-using-e-cigarettes-may-lead-youth-to-start-smoking-adults-to-stop-smoking>

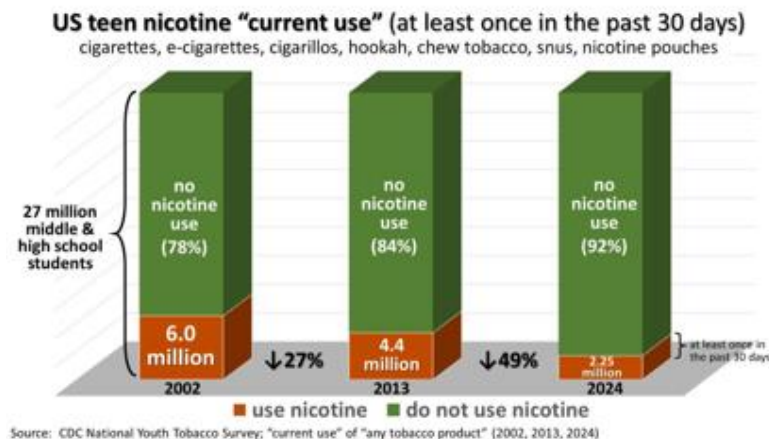
²¹ US Department of Commerce, Bureau of the Census, Annual Retail Trade Survey Detailed Operating Expenses: 2017, Estimated Detailed Operating Expenses of U.S. Retail Firms by Kind of Business, at: www.census.gov/data/tables/2017/econ/arts/operating-expenses.html

²² <https://vaportechnology.org/vaping-impact/>

2. South Dakota will not have the enforcement bandwidth to put a stop to retailers selling products illegally.
3. Consumer safety and public health will suffer as bad actors do not follow the law and will not:
 - a. Enforce minimum age requirements
 - b. Source product from reputable sources
 - c. Conduct quality checks to ensure product safety

8. Youth nicotine use is at an all-time low according to the CDC's National Youth Tobacco Study²³

- a. Only 8% of teens are using nicotine in any form (i.e. cigarettes, vapor products, nicotine pouches), down -49% from 16% in 2013

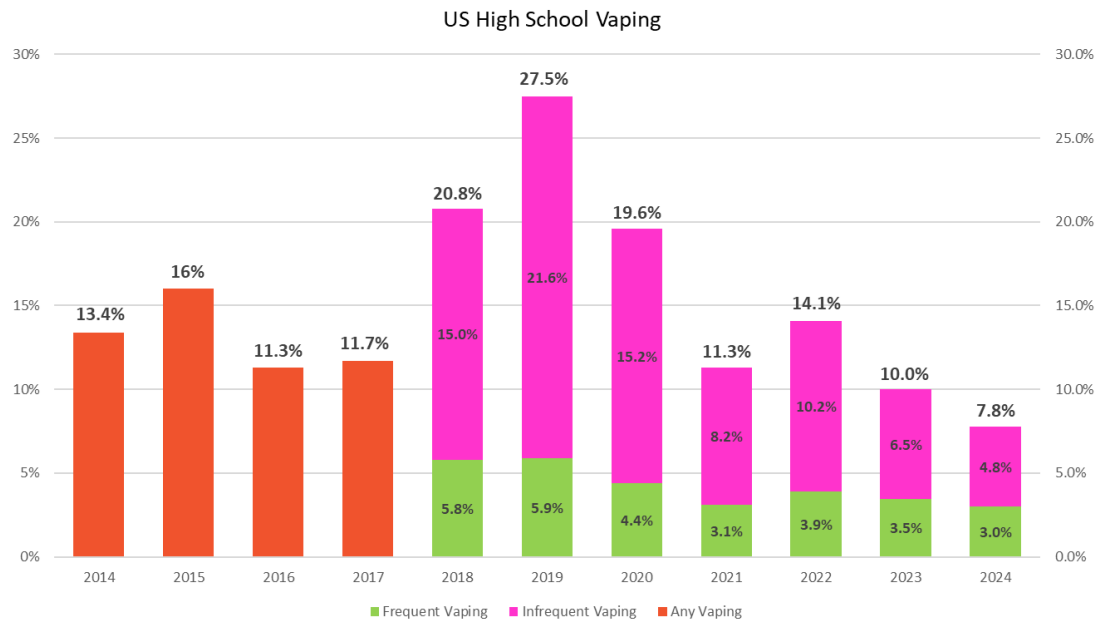


9. Underage vaping has declined 72% since 2019, down to pre-2014 levels according to the National Youth Tobacco Survey.²⁴

- b. Data suggests that vaping is losing its appeal amongst high school students.
- c. Only 7.8% of high school students are vaping at least once per month and only 3% of high school students are vaping frequently, defined as 20 or more times per month.

²³<https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey#2024%20Findings%20on%20Youth%20Use%20for%20E-Cigarette%20Products>.

²⁴<https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey#2024%20Findings%20on%20Youth%20Use%20for%20E-Cigarette%20Products>.



- d. Former Attorney General, Tom Miller, among many others, have asked the FDA to “not exaggerate” the risks of vaping as teens face other issues which are much more serious.
- e. Journal of the National Cancer Institute published new evidence in January 2019 which found no evidence that vaping is a gateway to smoking among youth²⁵
- f. Vaping is minor compared to other teen risks²⁶
 - i. Adolescents engage in many far more harmful behaviors than nicotine use
 1. 23% currently use alcohol
 2. 16% currently use marijuana
 3. 13% ever used illicit drugs
 4. 12% ever misused prescription opioids
 5. 6% currently misuse prescription opioids
 6. 11% experienced sexual violence by anyone
 7. 22% seriously considered suicide
 8. 10% attempted suicide
 - ii. In this context, e-cigarette use, especially non-daily use, is a relatively minor risk among adolescents

10. Alternative solutions to limit access and appeal to teens.

- a. Limiting the sale of flavored vapor products to 21+ only stores that check for IDs and don’t sell to minors or adult only sections of stores where they are not visible to minors.
- b. Ban sales of vapor products that are made to look like other household items (i.e. highlighters).

²⁵ JNCI: Journal of the National Cancer Institute, djz006, January 25, 2019. <https://doi.org/10.1093/jnci/djz006>

²⁶ https://www.cdc.gov/healthyyouth/data/yrbs/yrbs_data_summary_and_trends.htm

- c. Ban sales of vapor products on third-party marketplaces (i.e. Alibaba, Amazon, Ebay, and Craigs List) as well as social media (i.e. Instagram, Facebook, Snapchat, TikTok, and Let Go) as none of these require age verification.
 - i. Social media is now one of the primary places teens purchase illegal drugs and other substances like nicotine vapor products.
- d. Tougher penalties for retailers cited for selling to minors.
 - i. “Three strikes, you’re out” rule for revoking tobacco permits for any retailer accumulating three violations within three years for selling nicotine vapor products to minors.
 - ii. Increased fines for retailers selling to minors.
- e. Require retailers of nicotine vapor products to carry a non-nicotine 0mg vapor product to ensure they offer a step-down method for decreasing consumers’ nicotine intake and eventually quitting nicotine addiction.
 - i. Vapor stores already carry many options with zero nicotine and actively encourage customers to step-down their nicotine intake in order to help them quit vaping entirely.
- f. Require nicotine vapor product retailers to display warning signs indicating a) “Unaccompanied Minors Are Not Allowed on Premises”, b) “Products are Not for Sale to Minors”, or c) “Underage Sale Prohibited”.
 - i. Vapor stores already have such messaging displayed to dissuade minors from trying to make a purchase.
- g. Increasing the fines for “straw man” sellers who sell to minors without a tobacco permit.
 - i. Currently, their fines are half that of retailers. Only \$50 first offense, \$100 second offense, and \$250 third offense.
- h. Install vapor particulate detectors in school bathrooms.
 - i. This would be a great use for MSA funds.

11. HB1069 is NOT about protecting South Dakota, it’s all about Big Business.

- 12.** The bill is not about protecting youth. According to the CDC, since 2019, e-cigarette use among students has plummeted by 72%, reaching its lowest level ever!
- 13.** This bill is not about protecting public health. Removing all flavored vaping products from the market will only increase cigarette sales.
- 14.** This bill is not about enforcing laws. HB1069 just makes South Dakota the unwitting accomplice and enforcer of FDA’s overreach and illegal actions, while costing South Dakota taxpayers millions, shuttering hundreds of small businesses, and throwing thousands of people in South Dakota out of work.