Testimony In Opposition to Section 12 of Engrossed HB 1003

Submitted by Patrick Berry of the Vapor Technology Association

March 12, 2025

Chairman Wanzek and members of the Senate Appropriations Government Operations committee, for the record my name is Patrick Berry, and I am appearing before you as a representative of the Vapor Technology Association. I am submitting this testimony through our VTA lobbyists, Alexander Kelsch and Todd D. Kranda, attorneys with the Kelsch Ruff Kranda Nagle & Ludwig Law Firm in Mandan.

The Vapor Technology Association is the leading national trade organization representing manufacturers, wholesalers, distributors, small business owners, and entrepreneurs who have developed innovative and quality vapor products. Our members employ thousands of people around the country and in the State of North Dakota. Any ban or limitation on access to vapor products directly jeopardizes the businesses that North Dakota taxpayers have built and are still building, not to mention the consumers who are reliant upon vapor products as an alternative to combustible cigarettes.

HB 1003 section 12 forces the adoption, ratification, and enforcement of a failed federal Food and Drug Administration (FDA) regulatory scheme, declared illegal by courts, and uses state resources to shut down North Dakota small businesses. The purpose and the implementation of this bill would remove all competition from the electronic cigarette marketplace.

HB 1003 section 12 relies on the Premarket Tobacco Product Application (PMTA) process to achieve its objectives. The PMTA process applies to tobacco products created after February 15, 2009, and is not applied to cigarettes. A recent review of FDA marketing orders found that in the last five years, while the FDA has approved only a handful of e-cigarettes in tobacco flavor only, it has at the same time accelerated the introduction of 1,213 new combustible tobacco products including 892 combustible cigarette products into the U.S. market. Simply put, the current PMTA process protects big tobacco by creating a de facto ban on e-cigarettes while leaving menthol and other combustible cigarettes in the marketplace.

In addition, federal courts have raised concerns and struck down the existing PMTA process. The 5th Circuit Court of Appeals *En Banc* in *Wages & White Lion Investments LLC v. FDA* ruled that the PMTA process is broken, and that the FDA has unlawfully used it to ban all flavored vaping products. The court held that the FDA's actions were "arbitrary and capricious" and sent manufacturers on a "wild goose chase". It further elaborated that the FDA changed the PMTA requirements *after* applications were submitted and "did not give manufacturers fair notice of the rules." Finally, the 5th Circuit called out the FDA's administrative failing stating:

"No principle is more important than how the Fourth Branch of Government treats the American people."[1] A ruling on similar grounds was held by the 11th Circuit Court of Appeals in 2022.[2] The FDA's actions related to the PMTA process are now before the Supreme Court. Oral arguments were heard in *Wages & White Lion LLC v. FDA* on December 2, 2024. The entire premise of HB 1003 section 12, the PMTA process, is currently being heard by the U.S. Supreme Court.

Further, the effects of removing flavored electronic cigarettes from the marketplace are devastating for public health. 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*. Cigarette smoking costs the United States $225 million in direct health care costs annually. 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."[3] To put a finer point on the issue, "71% of the increase in cigarette sales associated with ENDS flavor restrictions comes from tobacco-flavored cigarettes."[4] Clearly, while increasing smoking will benefit those selling traditional cigarettes, it will hurt North Dakota consumers and businesses.

In conclusion, House Bill 1003 section 12 imposes a confusing and complicated registration scheme that is dependent on court cases that may change from week to week. It makes North Dakota the enforcement arm of the federal government requiring the State to monitor all federal court orders and regulations and update its registry daily to ensure products comply.

Accordingly, VTA respectfully asks that you remove section 12, the PMTA registry process provision from HB 1003. Thank you for the opportunity to provide this information. I would be happy to try to answer any questions.

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[1] *Wages & White Lion Investments LLC v. FDA*, No. 21-60800 (5th Cir., *en banc*, 2024).
[2] Bidi Vapor LLC v. U.S. FDA, No. 21-13340 (11th Cir. 2022)
[3] Friedman, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales, 2023.
[4] Friedman, E-cigarette Flavor Restrictions' Effects on Tobacco Product Sales, 2023.