RE: HB 2563, increasing the minimum age to purchase or possess cigarettes and tobacco products from 18 to 21; prohibiting cigarette vending machines and flavored vaping products.

Chairman Barker and members of the House Federal and State Affairs Committee:

On behalf of the Vapor Industry businesses in the State of Kansas

I am here to urge the committee to reject HB 2563 unless the ban on flavored vaping products is removed from the bill, and just as important, not add any language to the bill containing reference to requiring vapor products sold in the state of Kansas have an active Premarket Tobacco Application successfully filed with the FDA.

In June, 2009, 134 years after RJ Reynolds was founded, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, giving the FDA the power to regulate the Tobacco Industry. Though cigarette companies were allowed to operate unregulated for over 100 years, killing Millions of Americans, in just a few years after e-cigarettes were commercially available, the FDA announced in 2011, it was going to regulate e-cigarettes the same as combustible cigarettes.

But, it wasn't until May, 2016 that the FDA issued final deeming regulations, to be effective August 2016. By now, the vapor industry had rapidly grown into thousands of manufacturers, suppliers, and retail outlets. But more importantly, millions of Americans had completely transitioned from cigarettes to vapor products.

Even though the only common element between traditional cigarettes and vapor products is that the majority of nicotine base used in vapor products is derived from the Tobacco Plant, the deeming rule gave the FDA the same authority over vapor products.

The only products that would be spared the process of "premarket approval" were those that had been on the market unchanged since Feb. 15, 2007. The FDA admitted that the regulations would cause more than 99 percent of vaping manufacturers to "exit the market," and that the cost of a premarket tobacco application (PMTA) would be higher than all but a few companies (almost exclusively Big Tobacco companies) could bear.

The original PMTA deadline was set for 2022, but a bizarre twist, several anti-vaping groups — including Tobacco-Free Kids, the American Academy of Pediatrics, and the American Cancer Society Cancer Action Network — petitioned two federal courts, asking to take over the defense of the Deeming Rule in two lawsuits. In One, a Maryland Judge issued Judgement in favor of these groups who were asking to move the PMTA enforcement date up to May, 2020.

The FDA still hasn't issued the transparent, standards-based guidelines for vaping manufacturers that were promised in Gottlieb's July 2017 speech. Vaping businesses that hope to remain in this industry long-term are still guessing what a successful PMTA might look like. And until there is some kind of assurance that *any* PMTA could pass muster with the agency, no company is willing to take the plunge. It's been nearly three years since the Deeming Rule was announced, and no vaping industry PMTA's have been submitted.

When then-FDA Commissioner Scott Gottlieb announced in July 2017 a "comprehensive plan" for nicotine regulation, he indicated that the FDA would promptly issue foundational rules governing the process. But FDA has been subject to criticism for failing to issue PMTA rules more than two years after promising to do so.

In January, 2020, Alex Azar said the FDA will not shut down vape shops and small vaping companies in May, when manufacturers must submit Premarket Tobacco Applications (PMTAs), and that the agency will "streamline approval" for small companies.

Asked specifically about the cost of completing a PMTA, Azar said that open-system products like mods and bottled e-liquid are not the FDA's focus, and that the agency would assist small businesses to complete the process.

"We're working with small businesses and the vaping association to actually create pathways that would streamline approval for the open-tank small vape shop-based products," Azar said.

"What we're focused on are the cartridges in the systems with kid-attractive flavors, not the open-tank vaping systems, and as to all products we're committed to working with all actors in the system to get them through the regulatory process that Congress set up as expeditiously as possible. That regulatory process is not something the President created. That was created by Congress back in the Obama administration. We just have to implement it." The agency has promised before to "work with" small companies to help shepherd their applications through the process. However, the regulators (FDA) have never created a set of published standards and specific requirements for an approved application, let alone a streamlined pathway to approval.

Then yesterday, February 10, 2020, the Trump administration proposed creating a new federal agency to regulate tobacco products while removing that authority from the FDA.

The White House proposes making the Center for Tobacco Products independent of the FDA, with the director to be confirmed by the Senate.

Joe Grogan, head of the White House Domestic Policy Council stated, “Tobacco Regulation is a huge distraction for the FDA”.

In Conclusion

The FDA got bogged down, trying to apply a PMTA system that was originally designed for traditional tobacco products to a completely opposite set of products in the Vapor Industry. The FDA has failed for over three years to publish requirements for an approved application process that integrates vapor products.

Both President Trump and Alex Azar have publicly stated that the current PMTA process and the FDA are not a good fit to administer the vapor industry at the federal level.

It makes no sense, to include any PMTA language in state level legislation.