TO:

Members of the Kansas House of Representatives

RE:

HB 2563 - Concerning the Sale of Flavored Vapor Products

DATE:

February 7, 2020



## Distinguished Legislators:

Logic Technology Development, LLC, ("Logic"), headquartered in New Jersey is one of the largest suppliers of electronic cigarettes/vapor products in the United States.

Our position is clear: minors should not be able to obtain or use electronic cigarettes. We market our products to adult smokers only and we abide by federal and state regulations that govern our industry.

We write to you today regarding a proposal pending before you, (HB 2563) that seeks to prohibit the sale of flavored vapor products throughout the state of Kansas.

We urge you to reject this level of prohibition and instead introduce a measure to limit the sale of flavored vapor products, to those for which a complete Premarket Tobacco Product Application (PMTA) has been submitted to the FDA.

As background, in 2017 the FDA extended its original deadline for manufacturers to submit PMTA's for vapor products from 2018 to 2022. For any vapor product - including flavored products - to be approved and remain on shelves, the manufacturer must demonstrate to FDA that they are "appropriate for the protection of public health" through the PMTA process.

Our position is the decision to extend the PMTA deadline to 2022 was short-sighted and led directly to the proliferation of unregulated products in the market. We have consistently advocated for FDA to carry out its responsibilities and immediately bring forward the PMTA deadline to ensure that only vapor products that are appropriate for the protection of public health remain on the market. Recently, a Federal court ordered the PMTA submission deadline be moved forward dramatically to May 2020.

While we support the court's decision, we also believe that Kansas can act now to remove flavored products from the market for which there is no intention to provide an evidence-based dossier to demonstrate the products' appropriateness.

Our plan would address the debate surrounding flavored products by immediately removing all flavored vapor products from the market, except in cases where specific conditions have been met.

Rather than an outright prohibition on the sale of flavored products in Kansas, our proposal would:

- Prohibit the sale of **all** flavored vapor products in the state, **except** in cases where a manufacturer can prove that a complete PMTA has been submitted to the FDA.
- Allow only flavored products for which a PMTA has been submitted to be offered for sale, up until
  the point that FDA determines whether these products are appropriate for the protection of public
  health and are granted a marketing order.
- In cases where a determination is made in the negative, these products would be immediately
  prohibited from being sold, not just in Kansas, but nationwide.

Critically, for a flavored product to be found to be "appropriate for the protection of public health," FDA must have determined that the evidence submitted in a PMTA demonstrates that the potential benefits of these products outweigh any potential risks.

We believe this proposal is the most effective means by which to address the flavored product debate by removing irresponsible actors from the marketplace in Kansas, who have no intention of going through the rigorous process of submitting a PMTA.

The development of a PMTA is an intense process on the part of the manufacturer that includes clinical and non-clinical tests, as well as significant studies into the impact these products may have on current cigarette smokers, as well as the likelihood that non-smokers, including youth, would gravitate towards using these products.

Any company that is committed to the long-term, responsible operation of the category and is truly serious about regulatory compliance and preventing youth access should have no issue with complying with these requirements if they wish to continue offering electronic cigarettes to adult consumers in Kansas.

Under our proposal, candy flavors and those predominantly intended to appeal to minors would immediately come off the market, as these products have no chance of receiving a marketing order, and it is highly unlikely they would be submitted for premarket approval in the first place.

There are many examples of flavored vapor products playing a significant role in encouraging adults to transition away from combustible products. This proposal would continue to provide an important off ramp for adult smokers looking to try an alternative to combustible products, who do not necessarily want a product that tastes identical to the product from which they are trying to transition away.

If you in your capacity as a lawmaker are serious about advancing legislation that addresses flavored vapor products, you cannot dismiss out of hand the potential role they may play as legitimate alternative to combustible cigarettes. Nor should you be forced to continue to wait for the FDA deadlines to take effect to see the most egregious products removed from the market.

We implore you to be a national leader on this issue and act to ensure that any e-cigarette, flavored or not, that has no long-term place on the market is removed.

Once the federal regulatory requirements take effect in May next year, it is estimated that up to 90 percent of the products currently on the market will disappear, including all of the flavored products that are specifically designed to appeal to youth.

By introducing a measure that codifies the evidence-based process from FDA, it will demonstrate that Kansas takes a balanced approach in addressing public health and the issue of youth access seriously and responsibly.

Yours respectfully,

Rick Chandler

State Government Affairs