Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Vaping in America: E-Cigarette Manufacturers' Impact on Public Health"

February 5, 2020

Mr. Jerry Loftin, President, Logic Technology Development, LLC.

The Honorable Diana DeGette (D-CO)

1. **Do you expect that the guidance issued by the Food and Drug Administration (FDA) on January 2, 2020, and in effect as of February 6, 2020, will reduce youth use of Logic's products or of e-cigarette products in general? Why or why not?**

   Logic's products do not resonate with youth. This is demonstrated through the evidence provided to the Subcommittee and is detailed in Logic's Premarket Tobacco Applications (PMTAs) submitted to FDA.

   In our opinion, the guidance will not reduce youth use of e-cigarettes. It is not based on science or evidence and opened unnecessary loopholes, including the opportunity for an influx of disposable flavored products that have appeared in the market.

   The only way to meaningfully reduce youth use of ENDS is to ensure that only products that are appropriate for the protection of public health are allowed for sale on the market. This provision of the Tobacco Control Act needs to be supported by the immediate and robust enforcement of the deeming regulations.

   Logic believes that a comprehensive solution to reduced use by minors consists of three pillars:

   1. Enforce the deeming regulations and remove any product that:
      a. has not received a marketing order; or
      b. is not the subject of a PMTA submitted to FDA.

      This immediate action would remove from the market a far greater number of products that are not appropriate for the protection of public health.
   2. Require mandatory age verification for all sales, both in person at retail and online.
   3. Restrict the online sale of ENDS to manufacturer websites with third-party age verification only, cutting out all third-party sales, including unauthorized sales with no age verification.

Irrespective of the January 2020 guidance, Logic does not market to minors. We have taken several actions as a responsible company to ensure Logic does not resonate with youth:

- Logic submitted its PMTAs well before the deadline, so that the appropriateness of its products for the protection of public health can be reviewed and determined by FDA. To our knowledge, these are the first ENDS products to be filed and accepted for substantive scientific review by FDA.
- Logic has had mandatory age verification (over 21 years of age) on its website long before it was legally required.
- Since Logic began, we have placed health warnings on our packaging and website, even before they were legally required. These warnings have always clearly stated that our products contain nicotine, which is addictive, and that our products are not for underage sale or consumption.
- Logic only uses people who are over the age of 30 in our consumer marketing materials.
- Logic does not use celebrities to endorse our products and does not pay or solicit social media influencers to market or promote our products.
- Since January 2016, Logic has supported broad efforts to prevent youth access to all tobacco products and ENDS through our participation in the WeCard program, its secret shopper program, and its Manufacturers' Advisory Council.

2. **Do you believe FDA or other federal agencies have the resources (financial or otherwise) to monitor data and evolving trends with respect to youth use of e-cigarettes? If not, what more needs to be done?**
We support effective, proportionate and evidence-based regulation of ENDS and the enforcement of those regulations by the Center for Tobacco Products.

We believe that resources and activities at FDA and other federal agencies should be prioritized to focus on where these are most needed and where they can have the greatest positive impact. FDA is in the best position to prevent sales to minors because of its undercover buy inspections. FDA has effective enforcement tools to address retailers that repeatedly sell to minors, including warning letters, civil monetary penalties, and no-tobacco-sale orders.

Financially, the Center for Tobacco Products has consistently run a carryover surplus in recent years, of which a portion could be allocated for further market enforcement, including enforcement against the influx of unauthorized products in the market.

The Honorable Brett Guthrie (R-KY)

1. **Currently, the Food, Drug and Cosmetic Act limits the ability of the U.S. Food and Drug Administration (FDA) to disclose receipt of premarket tobacco product applications (PMTA).**

    - **After May 12, 2020, what is your understanding of how distributors, retailers, and other relevant entities will be able to determine which products have a**

PMTA submitted to FDA, and thus can remain on the market while under review, and which products do not have a PMTA submitted to FDA?
As it currently stands, manufacturers are free to communicate with distributors and retailers regarding the submission of their PMTAs. In our opinion, distributors and retailers have a responsibility to secure evidence of PMTA submissions before agreeing to sell a product. For example, manufacturers could provide copies of letters from FDA confirming their PMTAs are accepted for review.

FDA should exercise its authority to send letters to retailers and distributors mandating the removal of certain products that are not subject to a PMTA submitted by May 12, 2020. This would allow retailers and distributors to assist in clearing the market of products that are not subject to a pending PMTA determination.

Although the FDA is currently restricted from releasing certain PMTA-related information, we believe that Congress can amend FDA's ability to communicate with stakeholders, creating a database which includes:

1. A list of products for which a PMTA (submitted by May 12, 2020) is pending or which received marketing authorization. This would let stakeholders know which products can legally be sold, so long as the product was first sold in the United States before August 8, 2016.
2. A list of products for which a PMTA is not pending, either because it was never filed, it was withdrawn, or FDA denied marketing authorization. This would let stakeholders know which products cannot legally be sold**.**

- **Are any regulatory or legislative changes necessary to help inform the public and enforcement authorities about which products will be allowed on the market after May 12, 2020?**
  As we stated above, although the FDA is currently restricted from releasing certain PMTA-related information, we believe that Congress can amend FDA's ability to communicate with stakeholders, creating a database which includes:
  1. A list of products for which a PMTA (submitted by May 12, 2020) is pending or which received marketing authorization. This would let stakeholders know which products can legally be sold, so long as the product was first sold in the United States before August 8, 2016.
  2. A list of products for which a PMTA is not pending, either because it was never filed, it was withdrawn, or FDA denied marketing authorization. This would let stakeholders know which products cannot legally be sold.

  In our discussions, distributors and retailers are ready and willing to assist in clearing the market of products that are not subject to pending PMTAs or marketing authorization. However, distributors and retailers have no guidance beyond what a manufacturer tells them.

  Without clarity from FDA, distributors and retailers must rely on manufacturers, and cannot distinguish between the responsible companies, such as Logic, that submitted

PMTAs or the bad actors that will stay on the market without PMTA submissions until they are caught.

We have concerns with recent statements from FDA and the Department of Health and Human Services about their commitment to enforce the deadline equally across all products. Congress also could pass legislation requiring FDA to update its online list of marketing orders within two business days of issuing the order. We believe the distributor and retail community would work to self-regulate and clear the market of those products in which a PMTA has not been submitted, if properly informed.

2. **During the summer of 2018, FDA conducted an enforcement blitz of retailers nationwide, resulting in more than 1,100 Warning Letters and approximately 130 civil monetary penalties being issued to retailers for underage sale of e-cigarettes. Those cases included the illegal sale of Logic, JUUL, Fontem products to minors. As such, each company received a letter from FDA in September 2018 requesting a meeting with FDA and that each company submit a detailed plan to address and mitigate widespread use by minors.**
    - **What was the result of your company's response to this request from FDA**
      In response to FDA's letter, we submitted a written response, which we shared with the Subcommittee last fall. We also met with former Commissioner Gottlieb, CTP Director Mitch Zeller and staff to propose our comprehensive solution to reduced use by minors:
        1. Enforce the deeming regulations and remove any product that:
            a. has not received a marketing order; or
            b. is not the subject of a PMTA submitted to FDA.

           This immediate action would remove from the market a far greater number of products that are not appropriate for the protection of public health.
        2. Require mandatory age verification for all sales, both in person at retail and online.
        3. Restrict the online sale of ENDS to manufacturer websites with third-party age verification only, cutting out all third-party sales, including unauthorized sales with no age verification.

3. **In addition to the Customs and Border Patrol, does your company have a direct line of communication with other law enforcement entities for reporting illicit products?**
   We take illicit operations, including the counterfeiting of our Logic products, extremely seriously and work with several law enforcement entities. Since 2016, our Anti-Illicit Trade (AIT) Operations team has worked diligently with many national law enforcement entities to identify counterfeit Logic products, including:
    - Customs and Border Patrol
    - Department of Homeland Security
    - Food & Drug Administration Office of Criminal Investigations
    - US National Intellectual Property Rights Coordination Center

- **If so, has information that your company has provided to law enforcement resulted in criminal enforcement actions?**
  From February to November 2016, US Customs & Border Protection made five separate seizures of large amounts of Logic products based on information provided by Logic.

  Once our AIT team identified a possible criminal network group as the source of these counterfeit products, Logic held a series of meetings with the US Department of Homeland Security to take action.

  In 2017, our efforts to battle counterfeit included a counterfeit awareness training held by Logic AIT and our Quality Assurance team, provided to US Customs & Border Protection, Department of Homeland Security and the Food & Drug Administration.

  This effort resulted in a raid of a China-based factory making Logic counterfeits, and officers seized 6,325 Logic Pro devices and eight production molds.

  Also, in July 2019, Logic worked with Nassau County, NY authorities, together with the U.S. Homeland Security B.E.S.T. Task Force, on a lengthy investigation that resulted in three arrests and seizure of $1.5 million worth of counterfeit Logic products.

  In September 2019, Logic worked with the U.S. FDA Office of Criminal Investigations on another lengthy investigation which resulted in raids of three locations found to be selling counterfeit Logic devices.

  Logic regularly sends information regarding counterfeit sellers to the FDA, Homeland Security, and local law enforcement agencies and will continue to prioritize the eradication of counterfeit ENDS products in the marketplace. Logic will partner with law enforcement agencies to ensure illicit operators will be prosecuted.

4. **What does your company do to ensure the safety of the supply chain for your ENDS products?**
   A strictly controlled supply chain and high product quality standards are our top priorities to ensure the safety of our products. On August 19, 2019, Logic submitted its PMTAs to FDA. To our knowledge, these were the first ENDS PMTAs filed and accepted for substantive scientific review by FDA.

   We are now engaged in the substantive review phase and FDA inspectors already visited our contract manufacturing facilities to assess our production methods, staffing and working practices, standard operating procedures, records retention disciplines and many other factors relevant to our supply chain and commercial operations. We are committed to cooperating fully with FDA in order to demonstrate that Logic ENDS are appropriate for the protection of public health.

In parallel with the PMTAs, our global Quality Assurance experts, located in Germany and Hong Kong, perform detailed supplier audits, batch release testing and batch production record reviews to continually improve the capabilities of our contract manufacturers and validate the quality of our products. They have also implemented a change control process for Logic ENDS to reinforce our current internal governance practices. Logic also coordinates the processing of all consumer feedback (including analysis of returned product samples) to identify potential trends and inform any future product development initiatives.

We also have an Anti-Illicit Trade team dedicated to investigating and identifying potential sources of counterfeit Logic ENDS, and who work diligently with US law enforcement authorities to eliminate them. This helps to protect consumers from accessing illegal products which fail to satisfy relevant regulatory requirements and are unsafe.

Finally, and as mentioned in our earlier submission, all Logic ENDS are subject to a routine and ongoing product stewardship program which includes a recurrent and comprehensive review of ingredient toxicity and quality control of all the ingredients we use. This robust and tiered approach takes into consideration material and ingredient assessments, relevant chemicals standards compliance, and quantitative risk assessment of individual chemicals and e-liquid formulations.