Vaping in America: E-Cigarette Companies' Impact on Public Health

Testimony of

Jerry (Jay) Loftin

President

Logic Technology Development, LLC

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Chairwoman DeGette, Ranking Member Guthrie, and members of the Subcommittee, thank you for inviting me to testify at this important hearing, which forms part of your inquiry into Electronic Nicotine Delivery Systems (ENDS). I am Jerry (Jay) Loftin, and I am the President of Logic Technology Development, LLC (Logic), a role which I have held since 2017.

Logic believes that youth should never have access to any tobacco products or ENDS. We, therefore, share the Subcommittee's concerns about the number of minors using ENDS. The primary driver of this phenomenon appears to be the youth appeal of certain products that seem to intentionally target minors. We also believe that these types of products undermine our efforts to demonstrate robust product stewardship, correctly market and represent our ENDS products and self-impose controls aimed at preventing youth appeal and access to ENDS.

For these reasons, we strongly encourage regulators and public officials not to attribute the reckless or unlawful commercial practices of some ENDS manufacturers to all companies that sell ENDS. The business practices of some have caused tremendous damage to the reputation of this important category. Logic believes that a proper balance can be struck between offering adult smokers suitable options and restricting youth access.

Instead of imposing new requirements, such as "one size fits all" flavor bans that unfairly penalize responsible companies and limit consumer choice, we believe that regulators must strengthen enforcement of existing requirements. The Food and Drug Administration (FDA) should immediately enforce premarket authorization requirements for all ENDS products currently on the market and take action against companies that make unauthorized modified risk or smoking cessation claims or who market their products in ways that are uniquely appealing to minors. Failure to do so disadvantages companies that are acting responsibly and distorts the ENDS marketplace to the public detriment.

Below I provide supporting information on:

- Our company and our products;
- Our efforts to market only to adult consumers and to deter youth access;
- Our commitment to regulatory compliance and product stewardship;
- Our views regarding the underlying causes of ENDS youth prevalence; and
- Our proposals for more effective ENDS regulation and enforcement.

Introduction to Logic

Logic was founded in 2010. It became part of the JTI Group of Companies in July 2015. My testimony will, therefore, be based on the time period from July 2015 to the present. Today, Logic is based in Princeton, New Jersey, and is the fifth largest U.S. supplier of ENDS based on sales in traditional retail outlets, such as convenience stores and gas stations, with a market share of 1.8%. Logic sells the Logic Pro, Logic Power and Logic Vapeleaf lines of ENDS products.

Logic Markets Its Products Only to Adult Consumers and Takes Steps to Prevent Youth Access

We have always taken our commitment to youth access prevention seriously, taking steps to ensure minors not gain access to tobacco products or ENDS. We expect this same level of commitment from all our trade partners. For example, Logic will warn any trade partner following a violation and terminate sales to any retailer based on FDA reports of three or more violations.

We have never marketed Logic to appeal to anyone other than adult smokers and vapers and have self-imposed numerous measures that reinforce our commitment to prevent youth from

using our ENDS. Unlike those companies whose irresponsible, youth-appealing campaigns have been highlighted as the cause of increased youth consumption, Logic is a brand that does not resonate with youth or non-smokers. As demonstrated by our sales data from our online store over the past four years, Logic products are most favored by adult consumers over the age of 61 and least favored by adult consumers in the lowest age group between 21-29 years old.

This older adult age profile of Logic consumers is not by chance, but is the result of the responsible steps we have taken, including:

- Always requiring mandatory age verification before Logic sells online to consumers;
- Designing Logic products to appeal to adults and not marketing flavors or using flavor descriptors or imagery in ways that are likely to have unique appeal to minors. We believe that the responsible use and marketing of flavors encourages existing adult smokers to try ENDS. We use ingredients, including flavors, to help ensure that our products meet the taste preferences of these adult consumers;
- Only using people who are over the age of 30 in our consumer marketing materials;
- Not using celebrities to endorse our products or paying or soliciting social media influencers to market or promote our products. On social media, as of January 29, 2020, Logic had a small, age-restricted presence on Facebook (86 adult followers) and Instagram (110 adult followers); and
- Supporting, since January 2016, broader 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.

Logic operates an E-commerce site, www.logicvapes.us, through which we have only sold to verified adult consumers. And, even before the Deeming Regulations took effect, we further restricted sales to those aged 21 and above. When other companies merely required the purchaser to provide a self-declaration of age, Logic mandated third-party age verification before authorizing any purchase. No one has ever been able to purchase from our website without going through a stringent verification system, validated against a database of public records. We also have bulk purchasing restrictions in place to mitigate the risk of unauthorized third-party resales.

Logic is Committed to Regulatory Compliance and Product Stewardship

Logic has always supported effective, proportionate and evidence-based regulation of ENDS. From the moment FDA issued the Deeming Rule regulating ENDS, Logic has been engaged in a robust effort to comply with all FDA requirements, including premarket review requirements. Beginning in May 2016, Logic vigorously pursued a Premarket Tobacco Product Application (PMTA) research program aligned with FDA guidance. Even when FDA announced a lengthy extension of the original PMTA deadline, we pressed forward with our PMTAs in an effort to submit them well before the deadline.

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 the Agency. The PMTAs include almost 50 scientific studies conducted in 18 research facilities, including non-clinical vapor chemistry analyses and toxicology studies and multiple clinical and consumer perception studies. Our PMTAs total more than 200,000 pages. Logic's PMTAs provide an evidentiary basis for FDA to evaluate whether the continued marketing of Logic's products is "appropriate for the protection of public health." Today, the PMTAs are in the substantive review phase with the Agency.

Logic also has a product stewardship program that exists independent of governmental mandates. The program consists of routine and ongoing evaluation of all of Logic's ENDS products, including recurrent review of ingredient toxicity. This robust and tiered approach takes into consideration material and ingredient assessment, relevant chemicals standards compliance and quantitative risk assessment of individual chemicals and e-liquid formulations.

We have always been open and transparent with adult consumers about the potential risks associated with the use of ENDS. Our product labeling, marketing materials and website have carried a health warning, years before it became mandatory. The product labeling and our website warn consumers of the potential health risks of using ENDS, including the potential risks of cancer and reproductive harm. They advise that the product is intended only for adult smokers and adult vapers of legal smoking age, that underage sale is prohibited, and that it should not be used by minors, non-smokers, or people with health conditions. They state that Logic products are not smoking cessation products and are not intended as such. We have never advertised or marketed our products as safer than combusted tobacco products.

Logic's Efforts to Combat Illicit Trade

We have been alarmed by reports of EVALI linked to vaporizers, including ENDS. Although Logic has never received any such reports regarding its products, we have reviewed the matter further and have not identified any link between Logic products and similar consumer health issues. Now that public health authorities have revealed more information about the products that caused these issues, we hope this will prompt a larger discussion regarding illicit, poorly-manufactured and counterfeit products, and underline the importance of regulators' swift enforcement against such products.

Indeed, Logic has committed substantial resources of its own toward eliminating illegal counterfeit products. Working with expert consultants, Logic has shut down 1,859 online sellers of its products on sites such as eBay. We have also had 1,540 posts on social media removed that involve our products. We have sent 681 cease and desist letters to retailers suspected of selling counterfeit products, and working with FDA, the US Department of Homeland Security, Customs and Border Protection and local law enforcement, eight raids have been conducted. To date, this action has removed over three million dollars' worth of counterfeit products from the market. In addition, working with the authorities in China, Logic instigated the closure of a factory that was illegally manufacturing Logic counterfeits.

The Underlying Causes of Youth ENDS Prevalence

Considering Logic's responsible practices and Logic's older consumer demographic, clearly Logic is not the cause of youth consumption of ENDS. We believe that there is a link between youth uptake of vapor products and the combined irresponsible marketing and product characteristics of certain other ENDS. We have expressed to FDA our concerns about these products, in addition to concerns regarding impermissible smoking cessation and modified risk claims. We are disappointed that regulators have not taken more aggressive action, including by accelerating PMTA requirements and enforcing existing prohibitions of smoking cessation and modified risk claims and of new and modified products without FDA authorization. This would have, by now, allowed FDA to be well-advanced in determining whether the products concerned are appropriate for the protection of public health.

Logic's Proposals for More Effective ENDS Regulation and Enforcement

After FDA announced in 2017 that PMTA deadlines would be delayed by four years, Logic consistently called for the deadlines to be brought forward. This was out of a strong concern that

opportunists would exploit a lack of enforcement and regulation, flooding the market with potentially hazardous products.

Logic's proposals, presented to then-FDA Commissioner Gottlieb in 2018, centered around requiring PMTAs to be submitted two years sooner than required at the time (August 2019 versus August 2021), robust enforcement of the regulations, restrictions of online sales to manufacturer websites and mandatory age verification for the sale of any tobacco product, irrespective of location, product type or the age of the prospective purchaser.

We believe that our proposals, had they been implemented, would have halted the rise in youth vaping, prevented the proliferation of low-quality and counterfeit products, and potentially avoided some of the recent and unfortunate cases of respiratory illnesses and fatalities.

Logic has provided FDA with solid evidence of the need for prompt regulatory action and enforcement. Specifically, Logic shared with FDA over forty samples of apparently unauthorized and adulterated "new" ENDS products readily available in the marketplace that had been purchased at local vape stores. A significant number were presented in a manner that was clearly designed to appeal to youth, with statements suggesting that many were compatible with market leading brands and claimed to contain THC or CBD. We were also able to purchase numerous vials of nicotine from various vape stores for as little as one dollar.

As Logic noted some time ago, without immediate FDA action, the situation in the marketplace would continue to deteriorate with respect to ENDS product proliferation and youth access. We believed there was a clear risk of sleepwalking into a public health disaster, words that appear prophetic nearly a year after Logic articulated these concerns to FDA.

We know that there are discussions around levying a federal excise tax on ENDS, and even perhaps establishing FDA user fees. We believe that these discussions are best reserved for a time when only authorized ENDS remain on the market. This would avoid unintentionally legitimizing products that should not be sold and allow for an appropriate and reasonable tax and user fee construct to be considered.

FDA's Recent Guidance on "Enforcement Priorities" for Flavored ENDS

We strongly disagree with the recent FDA guidance that effectively bans most flavored cartridge-based products yet exempts flavored open tank systems and disposable products. We believe that ensuring PMTAs are expeditiously submitted for all products (or otherwise have products removed from the marketplace) would be far more effective than picking and choosing between types of products. Companies such as Logic, whose PMTAs are undergoing substantive review, should not be required to remove their products from the market during this period, especially when companies with no apparent intention of submitting PMTAs can continue selling their products without regulatory scrutiny. Indeed, based on our review of applicable laws and Agency guidance, it is highly unlikely that open tank systems will successfully meet the PMTA requirements or receive FDA marketing authorization. In Logic's opinion, the recent FDA guidance does not represent sound regulation and will not help address youth access, as the problem will simply shift elsewhere.

Open tank systems, by their nature, are highly customizable and variable. They offer the user the opportunity to alter the battery power and "mix and match" the e-liquids employed, customizing every aspect of the liquid, including the amount of nicotine. As a result, these products present many additional risks over closed tank, cartridge-based systems, including dermal contact with or ingestion of nicotine, the creation of higher concentrations of harmful or potentially harmful constituents as a result of higher temperatures, battery failures and venting

due to using different batteries and the consumer's ability to circumvent any fail safes that may be present. Additionally, consumers can order component parts and liquids online and create their own devices and consumables without any assurance of quality or regulatory compliance.

The FDA guidance does not establish a solid or evidence-based foundation for effective regulation or the responsible retailing of ENDS products. Indeed, the guidance presents a substantial risk that many smokers, who have migrated from cigarettes to flavored ENDS, will simply return to cigarettes, turn to flavored open tanks or disposables, or seek out illicit ENDS because their preferred products are now banned.

Conclusion

In summary, the increased rates of youth ENDS consumption cannot be attributed to Logic. Throughout its history, Logic has consistently taken measures to deter youth access that predated legal requirements. It is, therefore, no surprise that Logic products are most favored by older demographics and least favored by adult consumers in the lowest age group. In contrast, the primary influence appears to be the youth appeal of certain products that intentionally target minors. The solution is through the immediate and equal enforcement of the Deeming Rule, which would remove from the market unauthorized, illegal and irresponsibly manufactured, marketed or counterfeit products.

We do not wish to be painted with the same brush as others. We share concerns regarding unlawful products, youth vaping and products that appear to intentionally target minors and products that are impermissibly marketed for smoking cessation or with modified risk claims. We believe that these types of products undermine our responsible efforts to demonstrate robust product stewardship across our portfolio, correctly market and represent our ENDS products to adult consumers and self-impose controls aimed at preventing youth access to ENDS.

We appreciate the opportunity to contribute to this very important discussion concerning ENDS and stand ready to support the Committee with its ongoing work.

Thank you.