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TO: The Honorable C.T. Wilson

Chair, Economic Matters Committee

FROM: Aravind Muthukrishnan

Assistant Attorney General, Office of the Attorney General

RE: House Bill 1197—Business Regulation—Electronic Smoking Devices Manufacturers—

Certifications

The Office of the Attorney General urges the Committee to report favorably on House Bill 1197—Business Regulation—Electronic Smoking Devices Manufacturers—Certifications, with amendments.

House Bill 1197 brings much-needed improvements to Maryland's electronic smoking devices ("ESD") law, Business Regulation Title 16.7. The ESD market is substantially different than it was when Title 16.7 was enacted in 2017; there has been massive growth in the quantity and type of products being sold as well as significant changes in federal landscape regulating ESDs. HB 1197 incorporates improvements recommended by the Comptroller's 2020 Task Force on Electronic Smoking Devices and utilizes a model that has proven effective in controlling the cigarette market in Maryland for over 20 years.

ESD sales have skyrocketed over the past 5 years, while new and unregulated products have flooded the market. From January 2020 to December 2022, total U.S. e-cigarette unit sales increased by 46.6%, from 15.5 million to 22.7 million units. ESDs are the second largest nicotine product category after traditional combustible cigarettes for adults. But for youth, ESD use is over 2.5 times greater than cigarette, cigar, and smokeless tobacco use combined. In 2021, 14.7% of Maryland High School students reported having used ESDs in the prior 30 days, compared with 3.6% reporting using combustible cigarettes during the same period. Among those students who

<sup>&</sup>lt;sup>1</sup> CDC, F.R. Ali et al. "E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022," *Morbidity & Mortality Weekly Report*, vol. 72 no. 25, 672–77 (June 23, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7225a1-H.pdf

<sup>&</sup>lt;sup>2</sup> Maryland Dep't of Health, *Youth Risk Behavior Survey/Youth Tobacco Survey (YRBS/YTS) 2021-2022*, https://health.maryland.gov/phpa/ccdpc/Reports/Pages/State-Level-Data,-2021-2022.aspx.

reported having used ESDs in the prior 30 days, over 95% said that they usually used a flavor other than tobacco. Nicotine is highly addictive and can harm developing brains, and early nicotine exposure can prime the brain for addiction to other drugs. Nearly 90% of adults who smoke daily started by age 18 and 98% by age 25.<sup>3</sup>

As sales and use have risen, changes have also come to the legal landscape. In 2016, pursuant to the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §387 *et seq.* ("Tobacco Control Act"), the U.S. Food and Drug Administration adopted the "Deeming Rule," which provided that ESDs would be treated as "tobacco products." This meant that ESDs were subject to the Tobacco Control Act and regulation by the FDA. Any tobacco product that was first commercially marketed in the United States after February 15, 2007 is required to submit an application, undergo a thorough review of the product, and obtain a marketing authorization order from the FDA *before* it may legally be sold in the United States. The FDA received approximately 26 million premarket tobacco product applications and has rejected over 99% of these products. An unknown number of ESDs still have pending premarket applications, however, and to date the FDA has issued marketing orders for only 23 tobacco flavored e-cigarette products. This process has finally given much-needed clarity regarding what ESDs are authorized for sale under federal law. However, most ESD products currently on the market have not received a marketing order from the FDA.

House Bill 1197 would improve Maryland's regulation of the ESD industry in two main ways. First HB 1197 would only permit ESDs that are in compliance with federal and state law to be sold in the State. It does this by establishing an ESD directory, similar to the cigarette directory that Maryland has had in place for over 20 years. Only ESD products that have received a marketing order from the FDA would be permitted to be included on the Directory, and only products listed on the Directory would be legal for sale in the State. Any ESD product not listed on the Directory would be considered contraband, subject to seizure and forfeiture by the State.

House Bill 1197 will protect Maryland teens and other consumers from ESDs made by unknown manufacturers with unregulated and potentially dangerous products and components. In addition, by creating a published directory of legal products, HB 1197 will enable law-abiding State licensees to avoid selling illegal and dangerous products unknowingly. HB 1197 empowers the Attorney General to obtain information about the companies and their products before allowing their ESDs to enter Maryland. Furthermore, applicants to the directory must obtain a license and either register to do business in the state or appoint an agent for service of process, enabling the state to find these manufacturers and take enforcement actions if there are any violations of the law.

An ESD directory is a commonsense solution to a market that has been flooded with noncompliant products, including disposable and synthetic nicotine products. The Associated Press reports that, according to sales data, since 2020 thousands of unauthorized vapes have entered the market from China. These products come in flavors that are appealing to kids and often "copy each other's

<sup>&</sup>lt;sup>3</sup> U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

designs, blurring the line between the real and counterfeit" products.<sup>4</sup> With so many products entering the market, it is difficult for wholesalers, retailers, and vape shop vendors to know what ESDs are legal for sale, resulting in many illicit products remaining available to consumers. This mirrors the situation that occurred with cigarettes in the early 2000s, when the U.S. was flooded with untold cigarettes from questionable foreign manufacturers that often skirted state laws. Through effective enforcement of the Maryland Tobacco Directory, the State was able to virtually eliminate the sale of these unauthorized cigarette sales.

Additionally, House Bill 1197 grants the Alcohol, Tobacco, and Cannabis Commission ("ATCC") the authority to conduct unannounced inspections of retailers and vape shop vendors to ensure compliance with ESD regulations and the requirement that ESDs may only be sold to individuals aged 21 and older. The ATCC already conducts retail checks for cigarettes and Other Tobacco Products ("OTP"), including directory checks for cigarettes. Giving the ATCC similar authority to check ESD compliance is another way in which HB 1197 seeks to treat ESDs similarly to traditional tobacco products.

The second way in which House Bill 1197 improves Maryland's enforcement of the ESD industry is by making important modifications to Maryland's ESD licensure system. Right now, many entities selling ESDs do not have ESD licenses because they already have a cigarette or OTP license, and the law exempts them from getting a separate ESD license. HB 1197 requires that all businesses obtain a separate ESD license, enabling the State to know exactly which businesses are buying and selling ESDs in Maryland. HB 1197 also requires that all sales be made by and to businesses with Maryland ESD licenses, as is required for traditional tobacco products.

House Bill 1197 would also close a significant loophole in the current law that allows ESD manufacturers to sell their products over the internet or by mail directly to consumers. Under current law, all manner of questionable products, including those that are attractive to youth, may be sold directly to consumers without any oversight. Online sales are not allowed for cigarettes or OTP, and HB 1197 removes this exception for ESDs, instead treating them the same as traditional tobacco products. HB 1197 requires that all purchases by consumers occur in face-to-face sales, allowing Maryland retailers and vape shop vendors to better prevent illegal, underage sales.

The provisions in House Bill 1197 come from the State's long experience with traditional tobacco products as well as the recommendations of the Comptroller's Task Force on Electronic Smoking Devices.<sup>5</sup> The Task Force was made up of 40 appointed members from every region of the State, comprised of educators, ESD retailers, public health experts, concerned parents, and local and state elected officials. After holding four public meetings and soliciting feedback from both industry and the public, the Task Force's 2020 Report made two recommendations found in House Bill 1197: banning all direct-to-consumer internet and mail order sales of ESDs, and requiring separate ESD licenses with higher fees. The Report also recommended obtaining more information from

<sup>&</sup>lt;sup>4</sup> M. Perrone, "Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors," *Associated Press* (June 26, 2023), https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f.

<sup>&</sup>lt;sup>5</sup> Comptroller's Task Force on Electronic Smoking Devices, *Electronic Smoking Devices in Maryland: A Safer Path Forward* (2020), <a href="https://mdlaw.ptfs.com/awweb/pdfopener?md=1&did=31028">https://mdlaw.ptfs.com/awweb/pdfopener?md=1&did=31028</a>.

manufacturers to better "know precisely what e-liquids and ESD devices contain before these products ever reach consumers." House Bill 1197 improves on that standard by requiring that ESDs sold in the State to first submit to intense review and receive a marketing order issued by the FDA.

House Bill 1197 is identical to House Bill 1033, which is also supported by the Office of the Attorney General, with amendments. Our Office has worked closely with Delegate Mireku-North as well as numerous stakeholders to draft amendments which address concerns raised by various constituencies. For the foregoing reasons, the Office of the Attorney General urges a favorable report on House Bill 1197 with amendments.