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Written testimony of Susan Walley, MD, MHCM, NCNTT, FAAP

On behalf of the **American Academy of Pediatrics** 

Before the **Senate Judiciary Committee** 

"Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes"

Chairman Durbin, Ranking Member Graham, and members of the committee:

Good morning and thank you for inviting me to speak today on this critical topic for the health of children. My name is Dr. Susan Walley. I am a pediatrician and chief of the Division of Hospital Medicine at Children's National Hospital here in Washington, D.C. I conduct research on adolescent tobacco use and treat children who are addicted to tobacco products. I am here today representing the American Academy of Pediatrics (AAP), where I recently served as chair of the AAP's Section on Nicotine and Tobacco Prevention and Treatment. The AAP is a non-profit professional medical organization representing over 67,000 pediatricians dedicated to the health and well-being of children and adolescents.

E-cigarettes are addictive and they are dangerous for children. We must do all we can to keep them out of their hands. Unfortunately, we are here today because we're not doing enough to protect our youth from a tobacco industry intent on profiting off selling harmful and addictive products to children.

According to the National Youth Tobacco Survey, over 2 million children currently use e-cigarettes. While this number is down from its peak a few years ago, it is still a shockingly and unacceptably high number. What's more, over a quarter of youth e-cigarette users use them every single day – which indicates that these products are both attractive to children and incredibly addictive.<sup>1</sup>

One of the primary reasons children are attracted to e-cigarettes is the sweet fruit, candy, and mint flavors they come in. The flavors smell and taste good and they mask the harshness of tobacco. This makes repeated use more likely, and thereby increases the likelihood of developing nicotine addiction. These products are also often marketed with packaging that can resemble candy, snack food, or even alcohol, are designed to be discrete and easily hidden, and have been routinely pushed by social media influencers.

As a pediatrician, I see all too frequently how nicotine addiction takes hold in my teenage patients who vape e-cigarettes. The brain is more susceptible to nicotine addiction during adolescence. Symptoms of dependence can appear within days to weeks of a teen's first experimentation with e-cigarette use. When the brain does not get the nicotine it craves, teens experience unpleasant withdrawal symptoms such as irritability and anxiety, which leads to continued use. With repeated exposure, tolerance develops quickly, and the user requires more nicotine to just feel normal. For many young people, this is not just sporadic use, but consistent, frequent, and dependent use. Sometimes teens wake in the middle of the night to vape—a sign of intense nicotine dependence. Unfortunately, the trusted adults they usually rely on—parents, teachers, and pediatricians—have limited options to assist in quitting.

I am certified in nicotine and tobacco treatment, which means I have special training on how to help people—including children—quit using tobacco products. But pediatricians like myself have found that helping adolescents stop using e-cigarettes is exceedingly difficult. Many of these children are very addicted and we have limited effective tools in our toolbox to help them because youth tobacco

cessation treatment, particularly for e-cigarettes, is not as well researched as treatment for adults. So the best strategy is to prevent adolescents from using any tobacco products in the first place.

The most effective way to stop youth e-cigarette use is to get the flavored tobacco products off the market. This is where we need the FDA's help. In the Tobacco Control Act, Congress wisely set up a regulatory process at FDA to ensure that dangerous new tobacco products do not enter the market. By law, FDA can only authorize a product for marketing if it is found to be "appropriate for the protection of public health." Central to this determination is analysis to ensure that an authorized product will not be appealing to children. This system of public health review appears, for the most part, to be working as intended. To date, FDA has appropriately determined that no e-cigarettes that are flavored are appropriate for the protection of public health.

This premarket review of e-cigarettes was hard won. The AAP, the Campaign for Tobacco-Free Kids, and other public health partners joined together to sue the FDA in 2018 because—in the middle of a surging epidemic of teen e-cigarette use—the agency was shirking its responsibility under the law to conduct public health reviews of e-cigarettes. At the height of the surge in 2019, one-third of high school students were using e-cigarettes, which has had lasting repercussions on young adult tobacco use today. Thankfully, a federal court ruled in our favor in 2019 and ordered FDA to do its job and begin premarket review.

Subsequently, FDA reviewed millions of e-cigarette applications, and has appropriately rejected the vast majority of them. However, five years after that ruling, FDA still has pending applications before the agency, including for JUUL, the product most responsible for the initial surge in youth e-cigarette use. This delay has complicated efforts to get unauthorized products off the market. While FDA says there is no safe harbor for products with pending applications before the agency, FDA has not taken enforcement action against any of these products.

As of today, FDA has authorized only 23 e-cigarette products. These 23 products are sold under only three brands, and none of these products comes in a flavor other than tobacco. These are the only products that are allowed to be legally sold in the United States. And yet, thousands of illegal flavored e-cigarettes make their way to children every day. Today, 90% of youth e-cigarette users report using a flavored product, despite none of them being authorized by the FDA. Simply put, this is unacceptable.

The solution should start where the problem starts: with the tobacco industry and its supply chain. Manufacturers should end the production of unauthorized e-cigarettes. Distributors should stop distributing them. Retailers like vape shops and convenience stores should stop selling them to the public, where they ultimately land in the hands of children. But history has taught us that the tobacco industry and its partners are unlikely to do the right thing on its own.

Therefore, the federal government must do more to get these illegal products off the market. We are pleased to see that FDA has stepped up enforcement against illegal e-cigarettes in the past year. We also appreciate that FDA and its law enforcement partners announced this week the creation of a

multi-agency task force to specifically address this issue. It is a good start, but it is not sufficient. FDA should issue steeper fines, seize more illegal products, and criminally prosecute bad actors. But we understand that FDA cannot do this alone. It needs the help of the Department of Justice (DOJ), which must prioritize tobacco enforcement. Customs and Border Protection (CBP) must stop the importation of unauthorized products so that they do not enter the country in the first place. We need an all-of-government effort to keep these illegal products away from children.

We understand that enforcement takes resources and that resources are limited. That is why Congress must provide more funding to support e-cigarette enforcement efforts at FDA, DOJ and CBP. Instituting FDA user fees on e-cigarettes and directing this funding toward enforcement can be part of the solution. And lastly, as the federal government works to remove illegal, flavored e-cigarettes from the market, we need to resume efforts to get other flavored tobacco products that drive youth tobacco initiation off the market as well, including menthol cigarettes and flavored cigars.

And while the federal government must do more, let us not lose sight of the real culprit here: a tobacco industry that puts profits over the health of children and adults alike. Large tobacco companies like R.J. Reynolds and Altria claim to care about ending smoking, but they continue to sell billions of deadly cigarettes (still 60 percent of the tobacco market) each year in the United States. They continue to market illegal flavored e-cigarette products. They actively fight local efforts to enact common sense tobacco control policies and instead push policies to preserve their market share.

E-cigarette use in children is a solvable problem with solutions that work. We just need the will to implement these solutions. Thank you for the opportunity to be with you here today. America's pediatricians look forward to working with you to ensure that our children grow up without the harms of tobacco products.

<sup>&</sup>lt;sup>1</sup> Food and Drug Administration. Results from the Annual National Youth Tobacco Survey, https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey.

<sup>&</sup>lt;sup>2</sup> Centers for Tobacco Control and Prevention. Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019, https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm.

<sup>&</sup>lt;sup>3</sup> AAP v. FDA, 399 F. Supp. 3d 479 (D. Md. 2019).

<sup>&</sup>lt;sup>4</sup> FDA. Premarket Tobacco Product Marketing Granted Orders. https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders.

<sup>&</sup>lt;sup>5</sup> FDA. Results from the Annual National Youth Tobacco Survey, https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey.

<sup>&</sup>lt;sup>6</sup> Wall Street Journal. America's cigarette market is up for grabs. April 19, 2024.