



Brian King, PhD, MPH  
Director, Center for Tobacco Products  
U.S. Food and Drug Administration

July 26, 2023

Dear Dr. King:

As governmental public health leaders from 24 of the nation's largest cities, we write to urge the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products to take quicker and more direct action to address the widespread availability of illegally marketed e-cigarettes, including seizing such products at ports of entry and shutting down domestic distributions for those without approved marketing orders. We were pleased to see the import alerts issued by the FDA in mid-May 2023 and look forward to your agency's issuance of additional alerts when necessary.

**Unauthorized products are widely available and being used by youth.** To date, your Center has authorized only 23 e-cigarette products and devices, and only those that are solely tobacco-flavored. FDA has issued marketing denial orders to more than 250 companies, which should have resulted in those companies ceasing to make their products commercially available in the United States. Nonetheless, hundreds if not thousands of unauthorized e-cigarette products have been found on shelves of American retailers. And, despite state and local prohibitions on the sales of flavored e-cigarettes, these unauthorized products remain readily available in nearly every big city across the country. For example:

- In NYC, AirBar, Myle, Fume, Elfbar, Puff Plus, and Hyde are among the leading e-cigarette products. These brands' products were noted in violations for flavored product sales a combined 10,998 times in 2022.
- While local Los Angeles retail data are sparse, there have been some reports of the tobacco industry continuing to look for new ways to encourage e-cigarette use, including introducing products that have ambiguous flavors. In addition, brands like AirBar, Flum, El Bars, and Puff Bars, while restricted under local ordinances, are available online and across state lines.
- Multnomah County (Portland, OR) has experienced a 25% tobacco product sales rate to youth in their locally licensed stores post-pandemic. This after years of work toward reducing youth use and youth access through active tobacco retail licensing, counter-marketing, and a soon-to-be-implemented local prohibition on the sale of all flavored tobacco products. Despite these local public health advancements, the mass marketing of flavored e-products nationwide and the continued passive allowance of their sale feeds a new nicotine-addicted generation.

- In April 2023, 112 tobacco retail store audits (STARS assessments) were conducted using a convenience sample in Mecklenburg County (Charlotte, NC); data revealed that 71% of the tobacco retailers were located within a half-mile radius of a school. Of retailers that sold e-cigarettes, 91% sold flavored e-cigs. The predominant e-cigarette brands sold were Elf Bar (most), Hyde, and Lost Mary (owned by Elf).
- As many as 20% of San Francisco Unified School District (SFUSD) high school students have ever tried an e-cigarette, and 8% currently use e-cigarettes. These rates have decreased significantly since 2019 – 31% and 16% respectively, according to the 2019 Youth Risk Behavior Survey (YRBS) – likely due to local tobacco control policy measures restricting the sales of flavored tobacco products and e-cigarettes.

As the above examples illustrate, federal actions to decrease widespread availability of illegally marketed e-cigarettes – such as seizing e-cigarettes at ports of entry and shutting down domestic distributors of products without approved marketing orders – could be invaluable for tobacco control efforts across the U.S. These actions are generally beyond the authority/capability of local jurisdictions. The problem is acute and demands immediate action at the federal level. The widespread availability of products has led to increased vaping usage among middle- and high-school students, usage that often lasts into adulthood. For example:

- In 2021, 11.1% of NYC public high school students reported currently using e-cigarettes. As the teenagers who started using these products when they were first introduced become young adults, the rates of adult use continue to rise, with 12% of NYC young adults ages 18 to 24 now reporting current e-cigarette use. Almost all youth who use e-cigarettes and a substantial portion of adults who use e-cigarettes (over 40%) in NYC never previously smoked and are not using these products to help them quit smoking.
- In Cleveland, one-in-seven high students and nearly 1 in 10 middle school students reported using at least one form of tobacco product, with vaping and flavored cigar products being the most common.
- In Las Vegas/Clark County, over 15% of high school students reported currently using e-cigarettes in 2021.
- In 2017-18, about 10% of high school students in Los Angeles County reported current use of e-cigarettes. In response to this rising pattern of use, LA County government strengthened its tobacco ordinance in 2019 to prohibit the sale of e-cigarettes and flavors contained in these products. By 2020, the prevalence of current e-cigarette use has started to decline in the county: the 2019-20 CSTS showed that current use of e-cigarettes among high school students was about 6%.
- In 2021, 9.7% of Boston public high school students reported currently using e-cigarettes. Reported e-cigarette use was significantly higher for Latinx students (13.5%) and students identifying as lesbian, gay, or bisexual (19.2%)
- In Philadelphia, nearly 4 in 10 (38.9%) high school students had ever used an electronic vapor product according to the most recent (2021) YRBS data. This represents a 4.4% increase since 2017.

- In central Oklahoma (Oklahoma City-County health department's local area), the rate of current users of e-cigarettes or vapor devices (25.5%) is highest among young adults aged 18-24 years. Between 2020 and 2021, the percent of adults aged 18-24 years who reported currently using e-cigarettes rose by 20% in central Oklahoma.

Big city health departments and other city agencies are taking local action to enforce our laws, including providing education on the legal requirements and penalizing businesses that are found in violation of state and local laws. However, these strategies cannot fully address the challenge of large corporations making these products widely available and profiting from their sale. And local action puts a heavy burden on many small businesses, often owned by people from marginalized communities. A few licensed retailers report purchasing flavored products from licensed tobacco distributors, while most others order them directly from the manufacturers, from local stores, or from online distributors.

**Additional action from FDA is needed** to adequately address the suppliers and distributors of the illegal e-cigarette products flooding into our cities.

While it is encouraging to see FDA increasing their scope to limit the unauthorized e-cigarettes reaching our marketplaces, the above data points clearly show that we need an even more comprehensive, systematic, and aggressive course to stop the flow of flavored products from manufacturers to local retail stores, including those not licensed to sell tobacco products. Recently published research examining e-cigarettes on the market from 2017 to 2022 demonstrates that the level of nicotine delivered by the products continues to rise, making it even more likely that users will rapidly become dependent on nicotine, and lifelong customers.

For years, FDA sent warning letters to manufacturers of many of the most common e-cigarette brands, without significant effect. While FDA has stated that “all new tobacco products, including all e-cigarettes, on the market without the statutorily required premarket authorization are marketed illegally and are subject to FDA enforcement action,” multi-national companies continue producing and distributing these products. We look forward to more direct and effective actions.

**Local efforts need federal support to succeed.** As states and some localities begin to receive settlements from Juul, some jurisdictions have recently filed or are preparing lawsuits against other e-cigarette manufacturers and distributors, to begin to address this issue. Unfortunately, these – like so many local efforts – will have limited effects as long as the products continue to be available throughout the country.

**We urge FDA's Center for Tobacco Products to go beyond the two recently issued import alerts to take more direct action, including seizing e-cigarettes at ports and shutting down domestic distributors of products without approved marketing orders.** Similar to the decision recently announced in Australia, stopping the import of these products is critical to limiting their use and protecting the health of our youth from the predatory actions of commercial interests.

We, the leaders of big city health departments listed below, are fully committed to local action to limit youth access to flavored products that lead to nicotine dependence. Without additional federal action, however, we are destined to fall short of what is needed to protect youth. To prevent retailers from continuing to sell products that lack marketing authority, we need strong, consistent actions by the FDA Center for Tobacco Products to remove unauthorized tobacco products from the market.

You may reach us collectively through Maura Kennelly, Deputy Commissioner, External Affairs at the New York City Department ([mkennell@health.nyc.gov](mailto:mkennell@health.nyc.gov)) or Chrissie Juliano, MPP, Executive Director at Big Cities Health Coalition ([juliano@bigcitieshealth.org](mailto:juliano@bigcitieshealth.org)). We look forward to hearing from you.

Sincerely,

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