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Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

San Francisco, New York City, Chicago, and other cities and counties across the country face a crisis: the growing epidemic of e-cigarette use by middle and high school students that has already caused significant harm. Yet while the Food and Drug Administration (“FDA” or “Agency”) has criticized e-cigarette companies for fueling a teen vaping “epidemic,” it has largely failed to take action, giving e-cigarettes a marketplace to grow, resulting in the nicotine addiction of millions of children and teens. The Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act”) grants the FDA exclusive jurisdiction to establish tobacco product standards, but the FDA has failed to conduct the health and safety review federal law requires before any new tobacco product can be placed on the market. We call on the FDA do its job, stop abdicating its statutory duty, and immediately conduct the review that by law was supposed to happen before these products went to market.

Tobacco use is the leading cause of preventable disease and death in the United States. Tobacco kills more than 480,000 people annually—more than AIDS, alcohol, car accidents, illegal drugs, murders, and suicides combined. And nearly all tobacco product use begins during youth or young adulthood. As a result, the Surgeon General, local governments, health advocates and others have undertaken enormous efforts to reduce youth tobacco use. Until recently those efforts were succeeding. Cigarette smoking among youth had steadily declined over the past two decades. The percentage of middle and high school students using conventional cigarettes and other tobacco products was at an all-time low in 2017. But last year tobacco use among youth rose for the first time since the 1990s. According to the Centers for Disease Control and Prevention (“CDC”), the number of middle and high school students who reported being current users of tobacco products increased 36%—from 3.6 million to 4.9 million students—between 2017 and 2018. This dramatic reversal is directly attributable to a nationwide surge in e-cigarette use by adolescents.

The health implications of this disturbing new trend are deeply troubling. Although there is evidence that e-cigarettes have the potential under certain circumstances to benefit adult smokers if used as a complete substitute for regular cigarettes, the Surgeon General has warned that e-cigarettes pose a significant health risk to young people. Nicotine exposure during adolescence can harm the developing brain—adversely impacting learning, memory, and attention—and can also increase risk for future addiction to other tobacco products and other drugs. Moreover, the aerosol that users inhale and exhale from e-cigarettes can potentially expose both themselves and bystanders to other harmful substances,

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including heavy metals, volatile organic compounds, and ultrafine particles that can be inhaled deeply into the lungs and cause long-term cardiovascular and pulmonary health harms.

The FDA has the authority and ability to curb this crisis. To date, it has not.

When Congress enacted the Tobacco Control Act in 2009, it gave the FDA expansive authority to protect public health by regulating tobacco products. Congress required that before a new tobacco product is introduced to the market, the FDA must conduct a premarket review to determine whether the product is beneficial to the population as a whole. If the FDA concludes that the tobacco product is appropriate for the protection of public health, it may issue an order permitting marketing of that product. Unless and until the FDA issues such an order, the product may not be legally marketed.

In 2016, the FDA deemed e-cigarettes a tobacco product subject to the Agency's jurisdiction. At that point, the FDA could have—and given that e-cigarettes were already known to be a gateway product for kids *should* have—removed e-cigarettes from the market until the Agency completed its required public health review. But it did not. Instead, it granted e-cigarette manufacturers until 2018 to submit their applications for premarket review, allowing a class of products that were known to be appealing and harmful to kids to stay on the market without any review. Then, in August 2017, the FDA announced, without any meaningful explanation, that it was extending the premarket review application deadline *another four years* until *August 2022*. The FDA recently issued draft guidance proposing enforcement priorities that it hopes will “prompt[]” manufacturers of *flavored* e-cigarette products to submit their applications a year early, and soliciting comments on whether it should accelerate the compliance date. But the FDA has not actually changed the application deadline, even for these flavored products that have been particularly popular among youth and pernicious to children's health. And even if the FDA did advance it to 2021, the deadline would still be more than two years away.

Accordingly, by the time e-cigarette manufacturers will be required to submit their premarket review applications, e-cigarettes—which first emerged in 2007—will have been on the market for fifteen years without any FDA analysis of their safety and alleged benefit. If current trends continue, up to *six million more* youth will begin using e-cigarettes between now and then. Put simply, due to the FDA's failure to exercise its responsibilities under the Tobacco Control Act, a generation of children will become addicted to nicotine, and thousands will die from preventable diseases.

In the face of the FDA's inaction, we are doing what we can as cities to address this crisis.

For example, Chicago has taken significant legislative action directed at preventing young people from obtaining and using e-cigarettes. Since 2013, Chicago has amended its municipal code to, among other things, prohibit the sale of flavored tobacco products, including e-cigarettes, within 500 feet of a school; prohibit e-cigarette use in all publicly accessible indoor areas, including bars, restaurants, and other workplaces; raise the minimum legal sales age for tobacco products, including e-cigarettes, from 18 to 21; impose a municipal tax on e-cigarettes and liquid nicotine products; and require that all tobacco displays, including of e-cigarette products, be entirely behind the counter. In 2015, through its Department of Public Health, Chicago launched a public education and social media campaign dedicated to informing youth and families about the dangers of e-cigarettes. More recently, Chicago launched an investigation into the marketing and sales of e-cigarettes and “e-juices” to young people, which thus far has resulted in lawsuits against more than thirty online purveyors of e-cigarettes.

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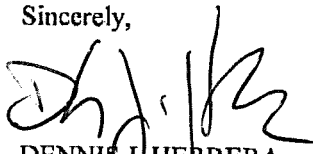
New York City has prohibited the use of e-cigarettes wherever smoking is banned by its Smoke Free Air Act, regulated where they are sold, and prohibited their sale to anyone under the age of 21. And, most recently, it extended its flavor ban to them.

San Francisco has amended its municipal code to, among other things: restrict the sale and use of electronic cigarettes in all places where traditional tobacco products are sold and used; prohibit the sale of all flavored tobacco products, including e-cigarettes, throughout the entire City; raise the minimum age for purchase of all tobacco products to 21; and impose a cap on the number of stores that sell tobacco products, including e-cigarettes, per neighborhood.

But Congress explicitly preempted state and local governments from conducting premarket reviews and preventing products that fail to meet public health standards from entering the national market. Accordingly, cities and counties—which end up shouldering many of the costs of medical care for tobacco related illnesses—need the FDA to do its job and fulfill its premarket review duties. As noted, the FDA's failure to do so has already placed millions of children at risk of addiction and disease. Millions more will follow if the FDA does not act now. The FDA must reconsider its compliance policy for e-cigarettes and immediately conduct the required premarket health and safety review.

Enclosed with this letter is a FOIA request seeking records regarding the FDA's decision to give e-cigarette manufacturers until 2022 to submit their applications for premarket review. We ask that you (1) expedite processing of that request under 28 C.F.R. Section 16.5(e), and (2) respond to this letter within 30 days, so that we may consider whether legal action will be necessary to force the FDA to fulfill its statutory duties and protect our youth.

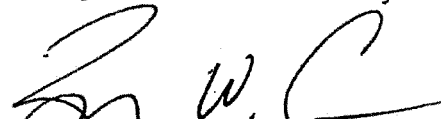
Sincerely,



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ZACHARY W. CARTER
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cc: Mitch Zeller, Director Center for Tobacco Products