United States Senate
WASHINGTON, DC 20510

September 20, 2019

The Honorable Norman E. "Ned" Sharpless, M.D.
Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless:

Last week, the Food and Drug Administration (FDA) announced that, by the end of this year, all non-tobacco e-cigarette flavors—including mint and menthol—would be banned in the United States. We commend you for this long overdue action, given that e-cigarette flavors play an integral role in addicting children to nicotine, have never been proven to help adults quit smoking cigarettes, and have unknown short- and long-term health consequences. However, in light of the recent spate of illnesses and deaths associated with vaping devices, we believe additional action is urgently needed to protect Americans nationwide. Specifically, we urge the FDA to immediately remove all pod- and cartridge-based e-cigarettes from the market, unless or until they can prove that they benefit the public health.

Nationwide, the Centers for Disease Control and Prevention (CDC) has confirmed 530 cases of vaping-related lung disease, as well as eight deaths. According to reports, many of these cases—but not all—involve vaporized liquids that contain ingredients derived from cannabis, such as tetrahydrocannabinol (THC). While no one substance or chemical has been conclusively linked to all the illnesses, it does appear that a significant number of young people are tampering with e-cigarette devices to vape products other than, or in addition to, nicotine.

There are primarily two distinct types of e-cigarette devices currently available for sale in the United States: cartridge- or pod-based systems and open tank systems. Unlike open tank systems, which are typically sold in vape shops, cartridge- or pod-based systems—such as JUUL and Vuse—are widely available in convenience stores nationwide and are incredibly popular among children. These cartridge- or pod-based systems comprise more than 70 percent of the overall e-cigarette market and their sleek design, as well as their easy-to-use features, appeal distinctly to youth. Of course, neither types of e-cigarette devices are on the market with approval from the FDA, nor are they safe. According to former FDA Commissioner Scott Gottlieb, "data show that refillable liquid vaping devices—so-called 'open' systems—are primarily used by adults while disposable, cartridge-based e-cigs—'closed' systems like JUUL—are favored by minors." Unfortunately, many cartridge-based systems are easily able to be opened and modified, exposing adolescents to the additional dangers associated with refillable, and modifiable, e-liquids.

The proliferation of cartridge-based e-cigarettes—and their ever-increasing popularity with children—is primarily due to the FDA's years-long refusal to regulate any e-cigarette devices or impose common-sense design standards preventing against adulteration, despite having the authority to do so. On its own, it is concerning that the FDA has not acted to protect children from e-cigarettes, given that nicotine is a toxic and highly addictive substance that increases the risk of heart disease, addiction, mood disorders, and lowering of impulse control. But now—in the face of FDA inaction—we have the added acute concern of children using their cartridge-based e-cigarettes to vape substances other than nicotine, substances which may present their own set of serious health risks.

The American Medical Association (AMA) recently called upon the FDA to "remove all unregulated [e-cigarette] products from the market." The American Lung Association similarly urged the FDA to "remove all unauthorized products from the market." Make no mistake: none of the e-cigarettes, including cartridge based e-cigarettes, currently on the market have gone through the FDA approval process. They have not demonstrated that that they are safe and effective for helping adults quit smoking cigarettes. They are hooking our children on nicotine at alarming rates. And, lacking tamper-proof technology, they may be to blame for the recent cases of serious respiratory illness and death.

Five million children are now vaping, including one in four high school students—an increase of 135 percent over the past two years alone. The FDA announced it would remove e-cigarette flavors from the market because they were contributing to this youth e-cigarette epidemic. Further, the FDA announced that flavored e-cigarette products would not be allowed back on the market unless or until they can prove a "net public health benefit." The FDA should apply this standard to all e-cigarettes through a pre-market review process, and given the unique popularity and threat posed to children, the same reasonable restrictions and presumption of public health impact that are being imposed upon flavored products, should immediately be imposed upon cartridge-based e-cigarettes.

Sincerely,

Richard J. Durbin
United States Senator

Lisa Murkowski
United States Senator

Jeffrey A. Merkley
United States Senator

Richard Blumenthal
United States Senator