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COMMITTEE ON THE BUDGET

September 9, 2019

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Norman E. Sharpless, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Azar and Acting Commissioner Sharpless:

I write today with grave concern regarding the Food and Drug Administration's (FDA) reckless and inadequate oversight of e-cigarettes, which has resulted in a public health crisis. Enough is enough: FDA must immediately enforce existing law and ban the sale of all harmful e-cigarette products that have not undergone a premarket review of their health risks.

On Friday, September 6, the Centers for Disease Control and Prevention (CDC) released an alarming update on their nationwide investigation of severe lung disease among e-cigarette smokers. To date, 450 possible cases of this disease have been reported across 33 states, including my home state of Connecticut. CDC has also confirmed five deaths. These numbers are expected to increase in the coming weeks. Along with this outbreak, the FDA is currently investigating the link between e-cigarettes and seizures.

In 2009, Congress passed the bipartisan *Family Smoking Prevention and Tobacco Control Act* (TCA). The TCA gave FDA the authority to regulate new tobacco products before they enter the market, including e-cigarettes.

Yet, in the ten years since the TCA was enacted, FDA has failed to adequately regulate e-cigarette products. Myself, my colleagues in Congress, and public health advocates have been vocal critics of illegal FDA actions that have delayed, and essentially exempted, e-cigarette manufacturers from the premarket review process. As a consequence, today there are now thousands of e-cigarette products on the market without any independent, science-based assessment of their long-term health risks, the safety of their ingredients, or their impact on youth tobacco initiation.

Additionally, the FDA has continued to allow e-cigarette companies, many of which are now little more than a front for Big Tobacco, to lie to the American public about the safety of their

products. Their tactics include enticing advertising campaigns and industry-funded research, echoing the early days of the tobacco industry. Even industry preferred terms like "vaping" and "vapor products" are deceptive. In reality, these are dangerous aerosol products that contain high concentrations of nicotine and other chemicals.

From when e-cigarettes first came to market until now, FDA has continually shirked its regulatory authority and failed in its mission to protect public health. While many of these mistakes predate both of your tenures, they can be rectified under your watch. In his testimony earlier this year before the House Agriculture Appropriations Subcommittee, former Commissioner Scott Gottlieb, M.D. stated, "I am willing to pull them [e-cigarettes] off the market if we continue to see the trends going in the direction that they are." Since then, the public health impact from e-cigarettes has grown, yet FDA has failed to act.

In your September 5 opinion piece with CDC Director Dr. Robert Redfield, you wrote "any opportunity for electronic cigarettes… must not come at the expense of children." However, as the leaders of our nation's premier public health agencies, you should instead commit to ensuring that e-cigarettes do not come to market at the expense of *anyone*.

I urge you to act and uphold the mission of the FDA, as well as the Department of Health and Human Services, by immediately banning all e-cigarette products until they have been properly reviewed by the Agency.

Sincerely,

ROSA L. DeLAURO
Member of Congress