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United States Senate

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WASHINGTON, DC 20510
125 S. STATE STREET
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SALT LAKE CITY, UT 84138

September 11, 2019

The Honorable Alex Azar
Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar,

The escalating national outbreak in severe pulmonary disease associated with the widespread use of electronic cigarettes now stands at 450 possible cases, including 35 cases in Utah, and as many as six deaths nationwide. I write today with strong concern regarding this pervasive public health crisis.

I appreciate that the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are investigating severe illnesses associated with e-cigarettes. However, these devices are already in the hands of millions of users—including an increasing number of young people—and health experts do not yet have a full understanding of the causes of these devastating health outcomes.

During a briefing on September 6, 2019, the CDC's Dr. Dana Meaney-Delman advised, "[w]hile this investigation is ongoing, people should consider not using e-cigarette products." In light of this guidance, and as investigations continue into reported illnesses and deaths, I urge the agencies to strongly consider whether these devices meet the recall classification standards of dangerous products that predictably cause serious or temporary health problems. I also believe the agencies should consider additional actions, outlined below, to strengthen public education efforts, review tobacco product standards, and evaluate possible modifications to e-cigarette devices.

We have a responsibility to protect the health and safety of our citizens, especially our young people, who are particularly susceptible to addiction. In my home state of Utah, e-cigarette use has nearly doubled in the last five years; their proliferation has led to an increase in younger and younger Utahns becoming dependent on nicotine. A 20-year-old Provo man who nearly lost his life to a vaping-related illness told the [Washington Post](#) he was unaware of the potential dangers: "I didn't think it would lead to me literally being on my death bed." I am increasingly concerned that a generation of young people has been deceived into thinking e-cigarettes are a safe alternative to smoking.

With these concerns in mind, I respectfully request responses to the following:

- 1.) When products on the market are defective or potentially harmful, recalling those products can be among the most effective means for protecting public health. FDA has the authority to recall products it regulates. As you know, FDA took over regulatory authority for all electronic nicotine delivery systems, including e-cigarettes, in 2016. Is it the agency's determination, based on its recall classification guidelines, that e-cigarettes are dangerous and may cause serious or temporary health problems? If so, does FDA believe a recall is appropriate at this time?

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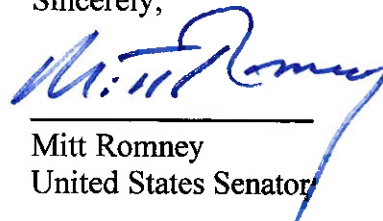
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- 2.) Electronic devices pose unique challenges, including the device structure (refill pods), pop culture ubiquity, and virtual inability to be detected in schools. As FDA continues to wage its public information campaign on associated risks, I ask that you share with the relevant congressional committees early progress or roadblocks so that we might act swiftly to provide clearer legislative pathways, as needed.
- 3.) As you know, the 2009 Tobacco Control Act gave FDA authority to set the tobacco standards to protect public health, including reducing nicotine yields or other harmful components of the product, and FDA periodically reviews tobacco product standards. With 450 outbreak cases across half the United States has FDA considered what standards may be necessary for e-cigarettes to protect the public health?
- 4.) While FDA continues to evaluate the safety of these devices, I also encourage the agency to consider whether these devices should have refill pods or whether they should be limited to single-use. I have heard from my constituents and seen across the United States e-cigarette users modifying pods to include other illicit and harmful substances. What, if anything, is FDA considering to ensure the safety of refill pods?

Urgent responses to these questions and considerations are justified given the escalating public health crisis and the widespread availability and demand of these products. I further urge FDA and CDC to report to Congress and to the public any new findings related to the investigation into severe pulmonary disease, or other diseases, stemming from the use of e-cigarettes. I appreciate your attention to this matter and look forward to your prompt response.

Sincerely,



Mitt Romney
United States Senator

CC: The Honorable Gary Herbert, Governor, Utah
The Honorable Robert Redfield, M.D., Director, U.S. Centers for Disease Control and Prevention
The Honorable Norman "Ned" Sharpless, M.D., Acting Commissioner, U.S. Food and Drug Administration