

United States Senate

WASHINGTON, DC 20510

September 11, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and
Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Norman E.
“Ned” Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug
Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

The Honorable Robert
Redfield, M.D.
Director
Centers for Disease
Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Secretary Azar, Acting Commissioner Sharpless, and Director Redfield:

We write with significant alarm about the increase in reports of severe pulmonary disease across multiple states associated with the use of e-cigarette products (devices, liquids, refill pods, and/or cartridges). Six individuals in Kansas, California, Illinois, Indiana, Minnesota, and Oregon have already lost their lives to severe lung disease associated with vaping. E-cigarette use has sickened over 450 people across 33 states, including many adolescents and young adults, with the median age of patients diagnosed with severe pulmonary disease at 19 years.

For years, we have written to you and your predecessors about the dangers of youth use of e-cigarettes, but public health agencies—particularly the Food and Drug Administration (FDA)—have failed to act swiftly and comprehensively to address the epidemic of youth use of addictive e-cigarette products.

FDA’s failure to fully implement and enforce the Family Smoking Prevention and Tobacco Control Act (TCA) and require Premarket Tobacco Applications (PMTA) for all e-cigarette products has allowed e-cigarette companies to flood the market with e-cigarette products that use nicotine salts to deliver high levels of nicotine; products are often accompanied with kid-friendly flavors. By delaying its public health review of products that were on the market as of August 8, 2016, and not rigorously enforcing the public health review requirement for products that entered the market after that date, FDA has permitted thousands of e-cigarettes to enter and remain on the market with no assessment of their health risks, addictiveness, or appeal to youth.

While the cause of the outbreak of severe pulmonary disease is still unknown, FDA’s failure to adequately regulate e-cigarette products on the market has created an environment where dangerous products have flourished and put children’s health at risk. FDA has the authority to regulate all e-cigarette products and components—regardless of the substances and chemicals included or added to them, where and how the products are purchased, and/or whether or not the products are modified. FDA must use this power going forward and play a leadership role in ending this epidemic.

Although your agencies have launched public health awareness campaigns, sent warning letters to some manufacturers whose products have violated the FDA's 2016 "deeming rule," released a recent health advisory, and taken other moderate steps, we believe the spike of more than 450 cases of severe lung disease in adolescents and young adults is a public health crisis that warrants more aggressive and immediate action. This action should include the following: a strong, clear message to the public about what is currently known about the dangers of e-cigarette use; immediate removal from the market of e-cigarette products that have been linked or could be linked to the pulmonary illnesses and deaths; and FDA's immediate enforcement of the required public health review of e-cigarette products with the authority granted to FDA under the Tobacco Control Act. FDA should also immediately take action to remove flavored products from the market, until or unless they have undergone FDA review that shows they are of benefit to the public health.

We stand ready to support your efforts to address this public health crisis, and request your responses to the following no later than Friday, September 20, 2019:

1. Please provide descriptions of all products and samples that FDA is currently analyzing in connection with the severe pulmonary disease, including the type of product and what substances they contain.
2. What is the estimated timeline for completing the investigation and determining if a specific product or substance is linked to pulmonary illness, including the deaths in Kansas, California, Illinois, Indiana, Minnesota, and Oregon?
3. Will e-cigarette products that are linked, or could be linked, to the cases of pulmonary illnesses and deaths be publicly identified and pulled from the market? Why or why not?
4. How are FDA and CDC coordinating with state health departments to address pulmonary illnesses associated with e-cigarettes?
5. What current efforts and considerations are being given to immediately begin enforcing product review requirements or setting more stringent conditions for allowing products to remain on the market prior to a public health review by FDA given the current outbreak of pulmonary illnesses?
6. Will FDA, CDC, and HHS provide weekly teleconference updates to Congressional staff as the investigation continues?

Sincerely,



Jeffrey A. Merkley
United States Senator



Richard Blumenthal
United States Senator

Edward J. Markey

Edward J. Markey
United States Senator

Sherrod Brown

Sherrod Brown
United States Senator

Patty Murray

Patty Murray
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Brian Schatz
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Chris Van Hollen
United States Senator

Dianne Feinstein

Dianne Feinstein
United States Senator

Jack Reed

Jack Reed
United States Senator

Ron Wyden

Ron Wyden
United States Senator

Maggie Hassan

Margaret Wood Hassan
United States Senator

Robert Menendez

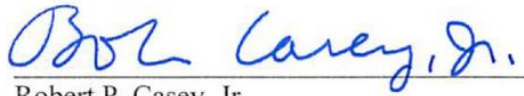
Robert Menendez
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Patrick Leahy

Patrick Leahy
United States Senator

Jeanne Shaheen

Jeanne Shaheen
United States Senator



Robert P. Casey, Jr.
United States Senator



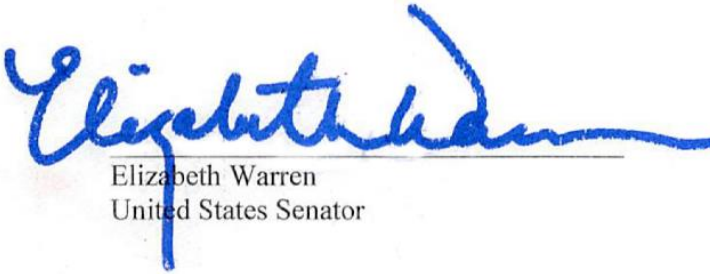
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Kamala D. Harris
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Cory A. Booker
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