RICHARD J. DURBIN
ILLINOIS
DEMOCRATIC WHIP

United States Senate
Washington, DC 20510–1304

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
COMMITTEE ON APPROPRIATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

August 27, 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

Mitch Zeller, JD
Director
Center for Tobacco Products
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Sharpless and Director Zeller:

For years, I have joined with public health groups in sounding the alarm about the dangers associated with youth use of e-cigarettes, like JUUL. For reasons that are inexplicable to me, the Food and Drug Administration (FDA) has refused to act swiftly or comprehensively to protect our nation's children from the dangers of e-cigarettes, despite having the authority to do so and despite skyrocketing rates of youth use of these addictive products. Instead, the FDA has allowed e-cigarettes—and the accompanying kid-friendly nicotine flavors—to proliferate on the market completely unregulated. And now, an individual in Illinois who had recently vaped, and was hospitalized with severe respiratory illness, has died. This death happened on your watch.

According to the Illinois Department of Public Health (IDPH), a total of 22 people in our state—ranging in age from 17 to 38 years—have recently experienced respiratory illness after using e-cigarettes or vaping. Over the past week alone, the number of cases of people reported to IDPH who have used e-cigarettes or vaped and subsequently been hospitalized with respiratory symptoms has doubled. Thankfully, experts from the Centers for Disease Control and Prevention (CDC) have been brought in to help address this epidemic in Illinois, but this burgeoning public health crisis extends beyond any state. According to the CDC, 193 possible cases of severe lung illness linked to vaping were recently reported across 22 states.

As the federal agency responsible for regulating tobacco products, including e-cigarettes, I request answers to the following questions no later than September 10, 2019.

1) What e-cigarette devices have been linked to serious cases of respiratory illness nationwide, including the death in Illinois?

711 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510–1304
(202) 224–2152

230 S. DEARBORN STREET
SUITE 3892
CHICAGO, IL 60604
(312) 353–4952

525 SOUTH EIGHTH STREET
SPRINGFIELD, IL 62703
(217) 492–4062

1504 THIRD AVENUE
SUITE 227
ROCK ISLAND, IL 61201
(309) 786–5173

250 W. CHERRY STREET
SUITE 115–D
CARBONDALE, IL 62901
(618) 351–1122

durbin.senate.gov

2) Will FDA order the immediate removal of e-cigarette products that have been linked to respiratory illness and death from the market?

I recognize that FDA has launched e-cigarette public health awareness campaigns, issued warning letters to the most blatant examples of products violating the FDA's 2016 "deeming rule," and announced new proposed e-cigarette rules and guidances. But, in the face of a public health epidemic—one that has now had deadly consequences—press releases and incremental bureaucratic half-measures have failed. FDA's inaction is alarming and has become dangerous.

FDA did not act forcefully when it became obvious that that e-cigarettes, like JUUL, were causing children to become addicted to nicotine—a substance that has short- and long-term consequences for the developing brain.

FDA did not do enough when it was revealed that children who start vaping often transition to combustible cigarettes—which kill 480,000 Americans every year.

And FDA sat on its hands even after it became obvious that kid-friendly nicotine flavors—such as gummy bear, mint, fruit medley, sugar cookie, and marshmallow—were largely responsible for the popularity of these dangerous and addictive devices in children.

Will FDA act now that 193 people across 22 states have severe lung illness associated with e-cigarettes? Will FDA act now that a person in Illinois has died?

Sincerely,

Richard J. Durbin
United States Senator