

United States Senate  
Washington, DC 20510-1304

September 6, 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:

Our nation is in the midst of a public health crisis that could have been avoided if the Food and Drug Administration (FDA) had acted at any point over the past ten years to properly regulate e-cigarettes and the accompanying kid-friendly flavors and products. To date, the Centers for Disease Control and Prevention (CDC) has reported 450 cases of severe respiratory illness among people using e-cigarettes in 33 states, as well as three deaths (including one in my home state of Illinois). As Acting Commissioner of the FDA, you alone have the power to stop this vaping epidemic, which has now reached the point where children and young adults are getting sick and dying. It is my strong belief that, if you do not take decisive action within the next ten days, you should resign your post. If you continue to refuse to do your job—which is to protect the public health—then it is time to allow someone else to take the helm.

Among some of the decisive actions that you should initiate immediately to combat this vaping-related epidemic, I request that FDA:

- 1) Send a letter to all schools in America warning of the health consequences associated with vaping, and asking each school to ensure this message is conveyed to parents and students alike;
- 2) Immediately ban all e-cigarette flavors other than tobacco; and
- 3) Immediately ban all e-cigarette devices that have not been approved for sale by the FDA, and ensure their immediate removal from stores nationwide.

Further, it is imperative that Senators immediately be briefed on what steps FDA is taking to combat this public health crisis, including what role marijuana-derived products are playing in this epidemic. Therefore, I request that you and Mitch Zeller (Director, Center for Tobacco Products) schedule a time next week to come in and brief any interested Senators on the steps FDA is taking to address and reduce vaping-related illnesses and deaths.

Make no mistake, we saw this storm coming. For years, I have joined with public health groups to warn FDA about the dangers associated with vaping—including sounding the alarm about the skyrocketing rates of youth use of these dangerous and addictive products; bringing to your attention studies which indicate that underage users of e-cigarettes often transition to

combustible cigarettes, which kill 480,000 Americans every year; screaming from the rooftop about the role that kid-friendly flavors—such as fruit medley, mint, cookies ‘n cream, sugar cookie, citra zing, whipped cream, and gummy bear—play in enticing and hooking young people on e-cigarettes; and repeatedly voicing skepticism at Big Vape’s completely unsubstantiated claim that these products are safe and effective at helping adult smokers quit cigarettes.

I have expressed these concerns to you on multiple occasions—in person, on phone calls, and in letters—as well as to your predecessor, Dr. Scott Gottlieb. And yet, FDA has refused to act in any type of meaningful way. If FDA had exercised its authority—granted to you by congress ten years ago—we would not be in this situation today. Many of these e-cigarette devices and flavors would not be on the market, countless numbers of children would not now be addicted to nicotine, regulations would be in place to help prevent against the adulteration of e-cigarette devices, and we would have far better information about the short- and long-term health consequences of vaping.

I look forward to your immediate response to this letter. Thank you.

Sincerely,



Richard J. Durbin  
United States Senator