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Washington, DC 20510–1304

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

June 19, 2019

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

Dear Secretary Azar:

On May 14, 2019, I met with Dr. Ned Sharpless, the Acting Commissioner of the Food and Drug Administration (FDA), to discuss the public health epidemic of youth e-cigarette use. As I told Dr. Sharpless shortly after we parted ways, it was one of the most disappointing and alarming meetings in my time in public service. It became clear to me in that meeting that the FDA, under Dr. Sharpless' leadership, will not use its existing authority on tobacco products to protect our nation's children from a lifetime of addiction.

As Secretary of the Department of Health and Human Services (HHS)—which oversees the FDA—and as a father to two children, I urge you to put the full force of your agency behind a robust effort to tackle the youth vaping epidemic. To start, there are three very specific actions that you should direct FDA to take today, not years from now.

First, the FDA must immediately act to ensure that flavored e-cigarettes and cigars are subject to the public health review required by the Tobacco Control Act, following the recent ruling by a federal judge striking down the 2017 decision by FDA to give manufacturers a "holiday" (in the judge's words) from that review from 2018 until 2022. Over the last year alone, our nation saw a 78 percent increase in the number of high-school children using e-cigarettes, and a 48 percent increase in the number of middle-school children using these insidious and addictive products. Today, nearly four million children are vaping. We know that kids are attracted to these products because of the kid-friendly flavors that FDA is currently, and inexplicably, refusing to regulate. As Secretary of HHS, you could intervene and end FDA's senseless decision to suspend, for years, public health review of e-cigarettes and cigars.

Next, it remains incomprehensible to me why the FDA is refusing to enforce their "deeming rule." This rule, which was finalized by FDA in May 2016, prohibits any new e-cigarette product from coming to market after August 8, 2016, without FDA approval. As I have mentioned to FDA on numerous occasions, new products are coming to market seemingly daily without FDA approval, in complete and total violation of the "deeming rule." And yet, based on what Dr. Sharpless told me, FDA has only ordered the removal of one product for this violation.

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As head of HHS, you could and should intervene and direct FDA to order the immediate removal of all e-cigarette products that were not widely and commercially available before August 8, 2016, in violation of the deeming rule. You should also direct FDA to make publicly available a complete listing of all e-cigarette products and flavors that were on the market prior to the August 2016 cut-off date. If such a list were made available, we would better be able to police products that are on the market illegally.

Finally, it defies logic that FDA has not already acted to stop JUUL from claiming to be a smoking cessation device. JUUL's current marketing campaign urges smokers to "Make the switch" from cigarettes. This is, unmistakably, a smoking cessation claim from JUUL—a product that FDA has found to be largely responsible for the current epidemic of youth use of addictive e-cigarettes and which has never been approved by FDA as a smoking cessation device. In fact, JUUL has conducted zero clinical trials in the U.S. proving their products help adults quit smoking cigarettes. They should not be making this claim, and FDA has the authority to stop this deceptive marketing campaign. Make them use it.

On May 10, 2018, at a hearing of the Senate Appropriations Committee, you testified that you were "completely aligned" with me regarding concerns about youth use of e-cigarettes and that, under your leadership, HHS "will be uncompromising in terms of any kind of entry path for children … and very vigorous in going after any bad actors that are trying to market or aiming toward entry points for children into addiction." At that hearing, which occurred over a year ago, I cautioned that inaction in the face of rising youth e-cigarette rates would be part of your Department's legacy.

I was therefore pleased that, in a March 20, 2019, *Washington Post* op-ed, you and then-FDA Commissioner Gottlieb wrote, "The e-cigarette craze among teenagers has become an epidemic … though the FDA's leadership will change at the end of the month, the agency's focus on the dangers to young people from e-cigarettes will carry on with the same vigor." Based on my meeting with Acting Commissioner Sharpless—in which he indicated that FDA would not be doing anything on e-cigarettes until 2021 at the earliest—I remain extremely skeptical that this will be the case. Which is why you, as Secretary of HHS, must intervene and force FDA's hand.

Will you use your authority to protect our children?

Sincerely,

Dick Durbin

Richard J. Durbin
United States Senator