

April 28, 2023

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

On June 23, 2022, after a nearly two-year scientific review, the Food and Drug Administration (FDA) issued a marketing denial order to JUUL, after finding that its premarket tobacco product application “lacked evidence” to prove that the company’s e-cigarette was appropriate for the protection of public health. That denial was subsequently stayed by FDA on July 5, 2022.

FDA’s stay of its denial occurred more than nine months ago. Since then, JUUL has been free to continue addicting children with its unauthorized and dangerous e-cigarettes.

We write to bring your attention to a recent \$462 million settlement between JUUL and six states and Washington, DC, over JUUL’s role in targeting children with deceptive marketing to addict them on vaping products. The settlement provides injunctive relief to prevent JUUL from marketing and selling its products to youth through a number of restrictions. It also bolsters the depository of internal company documents that JUUL must make available.

It is disappointing that it has required action by state attorneys general, rather than our primary federal regulator, to protect public health. JUUL remains one of the most popular e-cigarette brands on the market today, especially among youth.

We urge you to consider any relevant findings and restrictions from this case as FDA weighs important public health matters related to youth e-cigarette use.

Sincerely,



Richard J. Durbin
United States Senator



Kwame Raoul
Attorney General of Illinois