## Congress of the United States Washington, DC 20515

January 23, 2020

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

Dear Secretary Azar:

We write to you today to express our disappointment with the guidance, "Enforcement Priorities for Nicotine Delivery Systems (ENDS) and other Deemed Products on the Market Without Premarket Authorization" finalized on January 2, 2020.

Youth e-cigarette use in the United States has reached alarming levels. The 2019 *National Youth Tobacco Survey* found that more than 5 million adolescents use e-cigarettes, up from 3.6 million in 2018. On December 18, 2018, the U.S. Surgeon General issued an advisory calling this uptick an "epidemic." E-cigarettes pose a serious threat to the health and wellbeing of American children.

The nicotine in e-cigarettes is a highly addictive substance that can hamper healthy brain development in adolescents. More specifically, it can impact a child's ability to learn and concentrate, skills critical for success in the classroom. Additionally, nicotine exposure at a young age can increase a child's risk of developing other substance use disorders, including drug addiction. Furthermore, the aerosol of e-cigarettes often contains dangerous substances such as volatile organic compounds and heavy metals that pose a danger to children's lung health. It is clear that the substances in e-cigarettes are detrimental to a child's development.

Flavors in e-cigarettes often engender youth use of these tobacco products. The FDA reports that 97% of youth e-cigarette users vaped a flavored e-cigarette and a large share of children that began using these products did so because of their appealing flavors such as mango and cookies 'n cream. Recognizing the role of flavors in e-cigarettes, President Donald J. Trump and you stated an intention on September 11, 2019 to the "clear the markets" of all flavored e-cigarettes. The finalized guidance released on January 2, 2020 falls well short of this and will not help turn the tide in this public health crisis.

We are deeply alarmed that this policy exempts open tank-based products, disposable flavored ecigarettes and certain flavored e-cigarette cartridges, including menthol and even tobacco. These exemptions are all but certain to increase the popularity of refillable flavor pod systems such as Suorin and Smok, which are the most popular flavored e-cigarette products among adolescents after JUUL. In addition, this guidance will not eliminate the nearly 15,000 e-cigarette flavors available on the market—many of which come in kid-appealing flavors such as gummy bear and s'mores—as children will be able to access them through tank-based systems. This short-sighted policy fails to provide the comprehensive response needed to end this public health crisis.

We have the chance to protect the next generation of Americans from the dangers of tobacco and nicotine. We urge you to immediately revise this guidance and remove flavored e-cigarettes from the market.

Sincerely,

Eliot L. Engel	Dissu Jelette Diana DeGette	Jackie Speier
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	Aust Or France	The Laure
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Bonni Waken Colomo	m MMM ONO	Don's Matsur
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Harley Rouda

Member of Congress