United States Senate
WASHINGTON, DC 20510

October 4, 2019

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

Dear Secretary Azar,

As a result of the growing e-cigarette epidemic among adolescents, millions of young people are now suffering under the dangerous grip of nicotine addiction with nowhere to turn. We write today to follow up on a letter sent by sixteen Senators on February 15, 2019, in which we detailed our concern with the Department of Health and Human Services' (HHS) lagging response to the adolescent e-cigarette epidemic and the continued lack of proven nicotine cessation treatments for adolescents. We ask today that HHS advance policies to help prevent more adolescents from getting hooked on e-cigarettes, and prioritize solutions to help America's youth quit e-cigarettes, by expediting and focusing on the development of effective cessation tools.

As you know, according to preliminary 2019 National Youth Tobacco Survey (NYTS) data, just over 25 percent of all high school students report using e-cigarettes in the last 30 days—a 17 percent increase over 2018 use rates.[1] This data represent the continued pervasiveness of youth e-cigarette use, which has become ubiquitous in schools around the country. Unfortunately, as public health experts have warned countless times since the Deeming Rule was delayed in 2017, this epidemic is having real—deadly—consequences.

Since August, there have been 1,080 reported cases of a vaping-related illness that has resulted in lung damage and, in some cases, death. Eighteen individuals have died in Alabama, California, Delaware, Florida, Georgia, Illinois, Indiana, Kansas, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, Oregon, and Virginia.[2] The threat to young people posed by these products is grave, and made worse yet by pervasive marketing by companies like Juul Labs, Inc. and others who claim their product is safe. HHS must expand prevention and education to change this narrative, and FDA must fully utilize its regulatory authority to fully implement the delayed pre-market review provisions of the Deeming Rule and to remove flavored e-cigarettes from the market. However, HHS must also immediately take additional steps to address the consequences of this epidemic that its own failures helped create.

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[1] "Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products," *Food & Drug Administration,* September 11, 2019, https://www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non .

[2] "Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping," *Center for Disease Control and Prevention*, October 3, 2019, https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html .

The Administration must seek out ways to treat now-nicotine dependent youth. Medical professionals lack information about how to treat now-addicted teen e-cigarette users, as there are no nicotine replacement therapies (NRTs) currently approved for youth use.[3] Children, and their families, have been left with little guidance as they deal with nicotine withdrawal, including symptoms like headaches, nausea, and irritability. There have now been reports of teens turning back to cigarettes in order to quit e-cigarettes, a stunning indication of the addictive nature of nicotine.[4] The Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC) need to engage in efforts to develop, investigate, and distribute cessation best practices and products, specifically designed for adolescents.

In your April 12, 2019 response to questions about the Administration's efforts to develop cessation tools, including NRTs and other drug therapies, you noted that National Institute for Drug Abuse (NIDA) recently completed a study on varenicline, otherwise known as Chantix, and is in the process of conducting a study into AppSPIRE, a mobile technology designed to leverage smartphones to support adolescents in tobacco cessation. You also noted that FDA was planning to sponsor additional workshops to gather evidence on cessation approaches for youth. Given these commitments, please provide us with the following:

1. How do FDA and NIH plan on supporting and encouraging research into the development of NRTs, specifically for adolescents?

2. When will the results for NIDA's placebo-controlled trial of varenicline, or Chantix, for adolescents, be available?
    a. Will HHS widely disseminate these results with pediatricians and the public?
    b. Were clinical trial participants users of e-cigarettes or another tobacco product prior to the trial?

3. Where in the process is NIDA in their study of AppSPIRE?
    a. Can you provide more information on the structure and design of AppSPIRE?
    b. Can you provide detailed information on the design of this study? Were study participants users of e-cigarettes or another tobacco product prior to the trial?
    c. Please provide any preliminary findings that may be available.

4. Please share more information about the recent vote by the FDA Nonprescription Drugs Advisory Committee to endorse GlaxoSmithKline Plc's over-the-counter nicotine oral spray for approval.
    a. Were adolescents included in clinical trials associated with this product?

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[3] Natalia Thomas, U.S. Department of Health and Human Services, Food And Drug Administration, "FDA Approach to Evaluating Nicotine Replacement Therapies," Public Hearing, Capital Reporting Company https://www.fda.gov/downloads/NewsEvents/MeetingsConferencesWorkshops/UCM596699.pdf

[4] Ana B. Ibarra, "Vapers seek relief from nicotine addiction in – wait for it – cigarettes," *NBC News*, September 15, 2019, https://www.nbcnews.com/health/vaping/vapers-seek-relief-nicotine-addiction-wait-it-cigarettes-n1054131 .

b. Were e-cigarette users included in these trials?

5. When does FDA plan to hold the next workshop focused on youth nicotine cessation?
   a. Will FDA involve researchers, pediatric care providers, patients, and public health experts in this conversation?
   b. Given the growing urgency, will FDA commit to taking the action on the information provided at future workshops and use it in a concrete and timely manner? How will FDA do that and what is the timeline for action?

6. Will HHS commit to releasing a plan of action providing medical providers, families, and patients with guidance and resources to address adolescent nicotine addiction resulting from e-cigarettes?
   a. If yes, when will this plan of action be shared?
   b. Will HHS work with public health experts, NRT researchers, pediatric care providers, mental health providers, families, and patients in developing this plan of action?

We are hopeful that in addition to taking long overdue steps to prevent the e-cigarette epidemic from growing, HHS will also support children who are desperately seeking to overcome their addiction and quit these dangerous products. Please provide responses to this letter by October 18, 2019.

Thank you,

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