American Lung Association.

August 3, 2021

The President
The White House
Washington DC 20500

Dear Mr. President:

Twelve years ago, President Obama signed the historic Family Smoking Prevention and Tobacco Control Act. This law held the promise to improve the health of the nation and finally curb the scourge of tobacco caused disease, disability and death. Sadly, today that promise remains largely unfulfilled.

The Tobacco Control Act prompted immediate changes including the prohibition of all flavored cigarettes except menthol. Mr. President, earlier this year, your administration took the bold step to announce that rules will be adopted to end the sale of menthol cigarettes and flavored cigars. These rules will save lives, especially in the Black and Brown communities that the tobacco industry has intentionally targeted with menthol. We commend you and we are working hard to ensure these regulations are adopted and implemented.

But for more than a decade, the Food and Drug Administration (FDA) has failed to enforce the law with respect to e-cigarettes and other new products. This failure has allowed candy and ice cream flavored products to addict another generation of children, eroding more than a decade of steady decline of youth tobacco use after the demise of Joe Camel.

Now FDA is under a federal court order to finally enforce the Premarket Tobacco Application (PMTA) process with a September 9, 2021, deadline. FDA must make "the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account -- the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products." Despite the tobacco industry's attempts to overwhelm FDA by filing millions of applications for every conceivable flavor combination, it is critical that this deadline be met.

FDA has indicated that it is prioritizing its review of the most popular products. This brings us to the public health disaster largely created by JUUL. The explosive growth of youth e-cigarette use has been driven by the highly addictive JUUL product that originally came in sweet flavors and has a sleek, easy to conceal design that addicted millions. JUUL's products have been largely responsible for the extraordinary growth in youth e-cigarette use and the growth in the percentage of youth who have become addicted to e-cigarettes—an epidemic which continues to this day.

Because JUUL's products continue to have one of the largest shares of the e-cigarette market, we conclude that based on all of the publicly available evidence, no JUUL product currently on the market can meet the statutory public health standard as they provide no measurable public

health benefit. Therefore, as the Lung Association and our partners previously urged FDA, JUUL should not receive a marketing order for any of its products.

According to CDC's 2020 National Youth Tobacco Use Survey, nearly 1 in 5 high school students or 3.6 million kids continued to use e-cigarettes in 2020, which is 73% higher than four years ago. Additionally, disposable e-cigarette use skyrocketed by 1,000% among high school e-cigarette users (from 2.4% to 26.5%) and 400% among middle school e-cigarette users (from 3.0% to 15.2%). Flavored e-cigarette use among current e-cigarette users also increased from 71.7% to over 84.7% among high school students and from 59.9% to 73.9% among middle school students. In addition, high levels of menthol e-cigarette use were observed with 37.0% of high school students and 23.5% of middle school students using menthol flavored products. The percentage of menthol e-cigarette use was even higher among kids who used cartridge-based e-cigarettes like JUUL.

It is clear that adults are not the target market for these products. Adult use of e-cigarettes remains low at only 4.5% of all adults, according to CDC's 2019 National Health Interview Survey. In addition, about 40% of adult e-cigarette users continue to use cigarettes, referred to as dual use, which keeps a person at the same high risk of smoking-related diseases. We urge your administration to fully enforce the Tobacco Control Act and halt the sale of ALL tobacco products which have not received a premarket authorization by September 9, 2021. These products were never supposed to be on the market without such authorization, so removing unauthorized products is the only lawful approach. FDA should not allow unauthorized, dangerous and kid friendly products to continue to endanger the public.

It is also imperative that no flavored tobacco product receive a PMTA. The Surgeon General's 2016 Report on e-cigarettes concluded that flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults. The CDC data bears this out with over four-fifths of high school student e-cigarette users using flavored e-cigarettes in 2020.

Mr. President, thank you for your steadfast commitment to public health. Please fully and swiftly enforce the Tobacco Control Act to protect the public, especially America's youth.

Sincerely,

Harold Wimmer

Harold P. Wimmer
National President & CEO

cc. The Honorable Xavier Becerra, Secretary, Department of Health and Human Services
Janet Woodcock, MD, Acting Commissioner, U.S. Food and Drug Administration