



October 18, 2022

The Honorable Robert Califf, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Future Nicotine Standard

Dear Dr. Califf:

We write to thank you and your agency for the inclusion in the recent Unified Federal Agenda that the Food and Drug Administration intends to issue a proposed rule to reduce the nicotine level in cigarettes to non-addictive or minimally-addictive levels. Reduced nicotine levels in tobacco products would have significant public health benefits, and we are glad to see FDA's intention to address this issue.

As the leading medical and public health respiratory organizations in the U.S., our organizations strongly recommend as FDA moves forward that any proposal be broadened to include all tobacco products, including cigars, e-cigarettes and smokeless tobacco, so that the nicotine in all tobacco products is reduced to non-addictive or minimally addictive levels. We are especially concerned about the potential impact reduced nicotine levels in just cigarettes or combusted tobacco products could have on youth tobacco product initiation with e-cigarettes. Our organizations are also concerned about initiation or potential switching in lieu of cessation to other tobacco products with higher nicotine levels.

Tobacco use continues to be a leading cause of preventable death and disability in the U.S. Tobacco use kills more than 480,000 Americans each year. Over 30 million Americans currently smoke and an estimated 2.55 million middle and high school students use at least one tobacco product, including e-cigarettes. The U.S. spends more than \$225 billion annually on tobacco-related medical care for adults.

Applying a low-nicotine standard to all tobacco products, including e-cigarettes, will have significant public health benefits, including reduced youth initiation, reduced adult tobacco use and increased success at tobacco cessation attempts. Implementing a well-crafted low-nicotine tobacco product standard will save lives. In order to protect Americans from the dangers of all tobacco products, as is the responsibility of FDA, it is necessary for a low nicotine proposed rule to include all tobacco products.


As noted by several recent National Youth Tobacco Survey studies, e-cigarettes are by far the most popular tobacco product among middle and high school students and the nicotine gateway

product of choice for youth. A low-nicotine product standard that applies only to combusted tobacco products will leave our youth vulnerable to the lure of tobacco addiction. Further, applying a low nicotine product standard to combusted tobacco products while leaving other tobacco products with higher nicotine levels on the market could push tobacco users to the higher nicotine products.

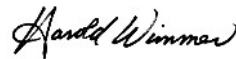
We also note with concern, and some frustration, that there are no FDA approved nicotine cessation medications for youth. The e-cigarette epidemic has created a new generation of youth nicotine users for which clinicians have no highly effective pharmaceutical interventions. While the harms of long-term e-cigarette use are yet to be fully described, pulmonary physicians continue to see cases of severe lung disease caused by e-cigarette use – including cases unrelated to vitamin E-acetate, the main cause of the spike in cases during the 2019 E-Cigarette, or Vaping Product, Use Associated Lung Injury or EVALI crisis. Physicians are treating young patients who want to quit, who know why they should quit, and have parents desperate to help them quit but are struggling due to the powerful hold of nicotine addiction in many cases due to e-cigarettes with extremely high levels of nicotine. A low nicotine product standard that addresses all tobacco products would maximize the benefit to the public health.

We thank you for your time and attention to this issue and urge you to keep these patients in mind as FDA moves forward with a low-nicotine product standard that should include all tobacco products.

Sincerely,



Karen J. Collishaw, MPP CAE  
Chief Executive Officer  
American Thoracic Society



Harold P. Wimmer  
President and CEO  
American Lung Association