United States Senate
WASHINGTON, DC 20510

July 16, 2018

Dr. Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Docket No: FDA-2017-N-6189

Dear Commissioner Gottlieb,

We write in support of the recent initiative by the Food and Drug Administration (FDA) to reduce the level of nicotine in cigarettes to non-addictive or minimally addictive levels and encourage FDA to expand it to include other combustible tobacco products that could serve as substitutes for cigarettes. We agree with your assessment that this initiative amounts to an "unprecedented public health opportunity"[1] and, as such, we urge FDA to implement it as quickly as possible. We remain concerned, however, about the potential timeline for implementing this initiative, as FDA has repeatedly delayed important tobacco regulations, and again call on FDA to take swift action to further combat the public health consequences of tobacco use, especially among young people. By taking swift and thorough action to reduce nicotine levels, the FDA can help save millions of lives and positively impact public health for generations to come.

For decades, tobacco use has been a scourge on our nation, with the World Health Organization calling the tobacco epidemic "one of the biggest public health threats our world has ever faced."[2] Every year, tobacco use costs the United States over 480,000 lives and billions of dollars.[3] In fact, a 2016 study found that a shocking 28 percent of all cancer deaths in the country can be attributed to cigarette smoking.[4] And, despite the advances that have been made, every day, 2,300 youth under the age of 18 pick up a cigarette for the first time.[5]

The Family Smoking Prevention and Tobacco Control Act, which was enacted in 2009, gave FDA wide ranging authority to regulate tobacco products. This includes the authority to implement standards on the level of nicotine in tobacco products. On March 15, 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) announcing its intention to exercise

[1] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601039.htm
[2] http://www.who.int/news-room/fact-sheets/detail/tobacco
[3] https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm
[4] https://www.nytimes.com/2016/11/01/health/smoking-deaths-cancer.html
[5] https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf

this authority by exploring a product standard that would set the maximum nicotine level in cigarettes at non-addictive or minimally addictive levels.

FDA's own estimates found that reducing nicotine levels in cigarettes could prevent tens of millions of individuals from ever becoming smokers and save eight million lives by the end of the century. Over the next five years alone, a nicotine product standard would help 13 million people quit smoking altogether. As you stated in announcing this ANPRM, the public health benefits of such a move are "undeniable."[6]

However, to fully realize the potentially monumental benefits of reducing nicotine levels, we urge FDA to apply product standards reducing the nicotine level not only to cigarettes, but also to other combustible tobacco products that could serve as substitutes to cigarettes, including all forms of cigar products. This will help ensure that cigarette smokers do not substitute cigarettes for other combustible products that maintain high nicotine levels and will prevent young people from becoming addicted to nicotine through other combustible tobacco products. We concur with FDA's assertion in its ANPRM on this issue, "if a standard were to apply to cigarettes only, it could be substantially less effective."[7]

Further, FDA must move forward on reducing nicotine levels as expeditiously as possible. We have been concerned by FDA's delay in oversight of newly-regulated tobacco products and want to ensure that this initiative, given its life-saving potential, is not unnecessarily delayed, while further ensuring that insufficient oversight of other tobacco products does not continue. To that end, we agree with leading medical and public health organizations that FDA should set hard deadlines for the rulemaking process. Specifically, we urge FDA to issue a final rule within one year of its ANPRM, followed by implementation of the rule one year later in March of 2020.[8]

We thank you for the opportunity to comment on this critical initiative and look forward to working with FDA towards reducing, and eventually eliminating, the massive costs imposed on our country from addiction to tobacco products.

Sincerely,

RICHARD BLUMENTHAL
United States Senate

PATTY MURRAY
United States Senate

[6] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm601039.htm
[7] https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes
[8] Letter from TFK, American Lung, etc.

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