Congress of the United States Washington, DC 20515

February 23, 2021

Acting Commissioner Janet Woodcock Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002

Dear Acting Commissioner Woodcock:

Congratulations on your recent nomination as Acting Commissioner of the Food and Drug Administration. You begin your tenure as the leader of this agency at a particularly challenging time with the requirement to defeat COVID-19 while also addressing serious public health concerns that pre-dated the arrival of this pandemic. One of those concerns is the unacceptably high rate of nicotine usage by minors which is attributable to electronic nicotine delivery devices or e-cigarettes. This trend will result in significant immediate and long-term negative public health outcomes if it is not reversed. Urgent action is needed to prevent a new generation of youth from becoming addicted tobacco users, and we urge you to make reducing youth use of e-cigarettes and other tobacco products one of your top priorities.

Former Commissioner Scott Gottlieb sounded the alarm in 2018 about the rising number of youth who were using e-cigarettes and in our opinion correctly identified this phenomenon an epidemic. He warned that e-cigarettes had "become an almost ubiquitous – and dangerous – trend among teens" and declared, "The disturbing and accelerating trajectory of use we're seeing in youth, and the resulting path to addiction, must end. It's simply not tolerable."

Unfortunately, youth use of e-cigarettes remains high. According to the FDA's National Youth Tobacco Survey, more than 3.5 million youth were e-cigarette users in 2020, including nearly one in five high school students.² This is a dangerous trend. Nicotine can adversely affect adolescent brain development, impacting attention, memory, and learning.³ Additionally, there are also worrying signs that youth are becoming addicted to nicotine from e-cigarette use. The number of high school students who use e-cigarettes frequently (i.e., on 20 or more of the past 30 days) has been growing in recent years and reached 38.9% in 2020.⁴

¹FDA, "Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth Ecigarette Use." September 11, 2018. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use

² Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. E-cigarette Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1310–1312.

³ CDC Office on Smoking and Health, "Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults," March 2019.

⁴ Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. E-cigarette Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1310–1312.

Furthermore, the flavoring of these products plays a crucial role in youth's initial attraction to and continued usage of e-cigarettes. In recent years, e-cigarettes have been sold in thousands of flavors, including kid-friendly flavors. Not surprisingly, flavors have been cited as a key reason for the spike in the use of e-cigarettes by kids. Seven in ten current youth ecigarette users say they use these products "because they come in flavors that I like."⁵

Preventing youth use of e-cigarettes is critical because nearly all tobacco use begins during adolescence. Today's alarming youth e-cigarette use rates are jeopardizing decades worth of hard-fought progress in public health. Tobacco use remains the leading preventable cause of death in the United States, responsible for nearly 500,000 deaths each year. 6 It is also responsible for approximately \$170 billion in health care costs each year, with more than 60% of these health costs paid by government programs like Medicare and Medicaid.⁷

The FDA Commissioner, CDC Director, and National Cancer Institute Director from the previous Administration recently called attention to the nation's tobacco use problem in a commentary in the New England Journal of Medicine. They argued, "It's time we recognize smoking for what it is – our country's longest-running and deadliest epidemic – and treat it with a commensurate sense of urgency."8

By using your authority to oversee tobacco products, the FDA can make great progress in reducing nicotine addiction, preventing tobacco-caused diseases like cancer and heart disease, and saving lives. The FDA has responsibility to curb youth tobacco use. We look forward to working with you to solve this public health crisis.

Sincerely,

Chris Stewart

Member of Congress

Raja Krishnamoorthi Member of Congress

⁵ FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," March 13, 2019, https://www.fda.gov/media/121384/download

⁶ CDC, "The Health Consequences of Smoking – 50 Years of Progress A Report of the Surgeon General 2014," http://www.surgeongeneral.gov/library/reports/50-years-of-progress/50-years-of-progress-by-section.html

⁷ Xu, X et al., "Annual Healthcare Spending Attributable to Cigarette Smoking: An Update," Am J Prev Med, 2014.

⁸ Redfield, Robert R., M.D., Stephen M. Hahn, M.D., Norman E. Sharpless, M.D., "Redoubling Efforts to Help Americans Quit Smoking - Federal Initiatives to Tackle the Country's Longest-Running Epidemic: NEJM," New England Journal of Medicine, October 22, 2020. https://www.nejm.org/doi/full/10.1056/NEJMp2003255

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