Congress of the United States

Washington, DC 20515

July 9, 2025

Dr. Marty Makary Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993-0002

Dear Commissioner Makary:

We believe that reducing tobacco use is an important way to reduce chronic disease and protect the health of our nation's young people. In your testimony in May before the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, you expressed concerns about illegal e-cigarettes addicting kids and stressed that addressing illegal e-cigarettes is a top priority for the administration. We share these concerns. We also appreciate the recent seizure of nearly \$34 million worth of illegal e-cigarettes as a result of a joint enforcement operation with U.S. Customs and Border Protection. In your new capacity, we urge you to continue prioritizing efforts to reduce youth use of e-cigarettes and other tobacco products.

We are deeply concerned about the unacceptably high levels of youth e-cigarette use, which pose a serious threat to the health of our youth. In 2024, more than 1.6 million youth, including nearly 7.8% of high school students, used e-cigarettes. Additionally, 42% of high school e-cigarette users reported frequent or daily use,¹ an indication that youth are becoming addicted. As you know, nicotine is a highly addictive drug that can have lasting damaging effects on adolescent brain development, impacting parts of the brain responsible for attention, learning, mood, and impulse control.² Some of the latest e-cigarette products contain as much nicotine as 200 cigarettes, putting kids at risk of quick and severe addiction.

E-cigarette products are marketed to be especially appealing to youth. These products come in a large variety of youth-appealing flavors, such as pink lemonade, cotton candy, and bubblegum, which undoubtedly drive youth use. In fact, in 2024, 87.6% of youth e-cigarette users reported using flavored products in a wide variety of flavors.³ Further, 70.3% of youth e-cigarette users say they use e-cigarettes "because they come in flavors I like."⁴ Additionally, some of the latest e-cigarette products now have built-in video games and smartphone-like features, allowing kids to play video games, send text messages, and use social media.

FDA has recognized that flavored e-cigarettes have an additional level of risk because flavors are much more appealing to youth than tobacco-flavored products. Because of this higher risk, FDA has denied applications for most flavored e-cigarettes. As FDA continues to review applications, we hope FDA continues to be mindful of the risks that flavors pose to youth.

¹ Park-Lee, E., et al., "E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024," *MMWR* 73(35):774-778, September 5, 2024, <u>https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf</u>.

² HHS, *The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General*, CDC, Office of Smoking and Health (OSH), 2014, <u>http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html</u>. See also: CDC Office on Smoking and Health, "Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults," March 2019. Accessed August 9, 2019.

³ Park-Lee, E., et al., "E-Cigarette and Nicotine Pouch Use Among Middle and High School Students — United States, 2024," *MMWR* 73(35):774-778, September 5, 2024, <u>https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7335a3-H.pdf</u>.

⁴ FDA, "Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry, Draft Guidance," March 13, 2019, https://www.fda.gov/media/121384/download. While the methodology is not comparable to the PATH study, the 2019 NYTS found that 68.8% of middle and high school e-cigarette users had used a flavored tobacco product in the past month. Wang, TW, et al., "Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019," *MMWR*, 68(12): December 6, 2019, https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf.

During previous administrations, many members of Congress on a bipartisan basis also expressed their concerns to the FDA regarding the alarmingly high prevalence of illegal e-cigarettes on the market in the U.S. To date, the FDA has authorized the sale of 34 e-cigarettes, which are the only e-cigarette products that may be legally sold in the U.S., but more than 6,000 youth-appealing flavored e-cigarettes remain available for sale in stores and online.⁵ We look forward to working with you to ensure the FDA can successfully leverage every enforcement tool at its disposal to tackle this pervasive problem.

Finally, we were alarmed to hear of the recent layoffs within the Center for Tobacco Products at FDA as part of a large-scale reorganization of the Department of Health and Human Services. Given the concerning number of unauthorized products on the market and the premarket tobacco product applications that remain under review, it is more important than ever that FDA has the resources needed to effectively address these issues.

Using your authority to oversee tobacco products, FDA can make great progress in reducing nicotine addiction, preventing tobacco-caused chronic diseases such as cancer, heart disease, stroke, and COPD, and saving lives. The FDA has the responsibility to address youth tobacco use. We look forward to working with you to protect our youth and resolve this continued public health crisis.

Sincerely,

Raja Krishnamoorthi Member of Congress

Stake D. Moore

Blake D. Moore Member of Congress

Lloyd Doggett Member of Congress

Jeblie Wasserm Sch

Debbie Wasserman Schultz Member of Congress

Celeste Malov

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Lauren Underwood Member of Congress

Page 2

⁵ CDC Foundation, "Monitoring U.S. E-Cigarette Sales: National Trends," <u>https://tobaccomonitoring.org/</u>.