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September 3, 2021

Hon. Janet Woodcock, Acting Commissioner
Mr. Mitchell Zeller, Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Woodcock and Mr. Zeller,

I write in strong support of the August 18, 2021 letter written by 31 Attorneys General urging the FDA to exercise its regulatory authority to eliminate youth-appealing flavors (including menthol) in all tobacco products, limit nicotine levels, and restrict marketing that targets youth. Further, as the Food and Drug Administration is poised to decide whether to issue marketing orders for thousands of premarket tobacco product applications (PMTAs) for electronic cigarettes and other new tobacco products, I urge FDA to deny marketing orders for any tobacco product applications -- including PMTAs for flavored e-cigarettes, flavored nicotine pouches, flavored gums, and other youth-appealing products -- that do not demonstrate unequivocally that they are not appealing to youth.

I have more than 20 years of experience conducting research on tobacco, media, and social marketing and have studied the tobacco industry's marketing strategies to learn how to improve tobacco control efforts. My research has focused on young adult tobacco use, including the marketing of e-cigarettes and novel tobacco products.

I am Director of the Center for Tobacco Control Research and Education, which has more than 70 affiliated faculty conducting research on a wide range of tobacco-related issues across all four schools at UCSF. In addition, as the principal investigator for the UCSF Tobacco Center of Regulatory Science (TCORS), I am leading a team of more than 45 scientists, researchers, physicians, and economists who have been studying the impacts of new and emerging tobacco products, including e-cigarettes, heated tobacco products, and other new nicotine products. Our investigations include examining the impacts of e-cigarettes and other new tobacco products on lung and cardiovascular disease, the initiation and continued use of these products by youth and young adults, and the products' impacts on vulnerable populations and health care costs. In particular, we have focused on evaluating how specific product characteristics influence health effects and behavior, and have submitted more than 60 public comments to FDA, many of which concern the impact of flavors, nicotine, and marketing on youth initiation and addiction. All of our public comments are available here: https://tobacco.ucsf.edu/list-public-comments-fda-and-other-agencies-ucsf-faculty-and-fellows-and-others-links-comments

Based on my research and that of my colleagues and fellows, I have no doubt that removing flavors from all tobacco products, especially e-cigarettes, would make them less attractive to youth. Most youth report that it is the flavors that first attracted them to use e-cigarettes, and the majority of youth in the US who try tobacco

initiate with flavored tobacco products. There is no rational basis for FDA to exempt menthol-flavored products, since youth are initiating with and using menthol-flavored e-cigarettes (sometimes called “Ice” or other names to evade flavor restrictions), especially now that many candy and fruit flavored e-cigarettes are not available.

New nicotine products such as nicotine pouches and gums are also being marketed to youth in enticing flavors and threaten to sustain nicotine use and addiction in young people. This is highly concerning because nicotine is particularly harmful to developing brains in teens and is associated with both physical and behavioral problems, as well as addiction to other substances. The extremely high levels of nicotine and the modes of delivery that make new nicotine products more addictive and easier to use further threaten the health of young people, and we support the Attorneys General call to limit the amount of nicotine in these products.

Although the marketing and advertising of cigarettes to youth is restricted, the marketing and advertising of e-cigarettes and new nicotine products is essentially unregulated. This “Wild West” environment is a significant reason why young people begin to use these products.

Therefore, I join the Attorneys General in their call on FDA to: (1) prohibit all non-tobacco flavors, including menthol; (2) limit the amount of nicotine in e-cigarette and oral nicotine products; and (3) to ensure that nicotine products (including e-cigarettes, pouches, gums, and lozenges) are not marketed to youth. Further, in its review of PMTAs, I urge FDA to deny marketing orders for e-cigarettes and other novel nicotine products that are flavored, that have excessive levels of nicotine, and that are marketed to youth and that otherwise do not demonstrate that they are appropriate for the protection of the health of all Americans, including youth.

Sincerely,

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cc: Hon. Xavier Becerra
Secretary, Department of Health and Human Services
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