September 12, 2022

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

Re:  Nicotine Standard

Dear Dr. Califf:

The undersigned public health, medical and professional organizations write in strong support of your recent announcement that FDA will issue a proposed rule to reduce the nicotine level in cigarettes to non-addictive or minimally addictive levels. Such a standard would generate massive public health benefits, preventing millions of young people from smoking and dramatically reducing the number of people who die from tobacco-caused diseases. We urge you to move forward with this proposal as quickly as possible.

Despite great progress in curbing smoking prevalence in recent years, tobacco use – primarily smoking – remains the leading cause of preventable death and disease in the United States, killing more than 480,000 Americans every year.1 Sixteen million Americans are currently living with a tobacco-caused disease.2 Over 30 million Americans currently smoke, and every day over 1,600 kids try their first cigarette.3 Approximately half of people who smoke

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2 Id.
will die prematurely as a result of their addiction, losing at least a decade of life on average compared to those who do not smoke.4

We applaud the Administration for taking action to reduce tobacco use as part of its Cancer Moonshot initiative.5 Cigarette smoking causes about 30 percent of all cancer deaths in the U.S.6 Reductions in tobacco use have already had an impact on cancer rates. According to CDC, 60 percent of the decrease in cancer death rates among men and 40 percent of the decrease among women from their peak in 1990 to 1991 until 2014 were due to declines in tobacco-related cancer deaths.7 More progress can be made and reducing nicotine levels will have a profound impact.

Nicotine is the primary addictive agent in cigarettes and other tobacco products. According to the U.S. Surgeon General, “the addiction caused by the nicotine in tobacco smoke is critical in the transition of smokers from experimentation to sustained smoking and, subsequently, in the maintenance of smoking for the majority of smokers who want to quit.”8 Thus, reducing the nicotine content in cigarettes to non-addictive or minimally addictive levels will prevent experimentation by the young from becoming a lifetime of addiction and tobacco-caused disease. It also will reduce the level of nicotine dependence in adults who smoke, making it easier for them to quit.

Current evidence establishes the potentially historic lifesaving impact of reducing nicotine content in cigarettes to non-addictive or minimally addictive levels. As you know, FDA estimated in 2018 that approximately 5 million additional adults who smoke could quit smoking within one year of implementation and, by the year 2100, more than 33 million people – mostly youth and young adults – would have avoided becoming regular smokers. Smoking rates could drop to as low as 1.4 percent, resulting in more than 8 million fewer tobacco-caused deaths through the end of the century.9 The dimensions of this public health benefit make timely implementation of this policy a moral imperative.

Reducing nicotine levels in cigarettes to achieve these enormous public health gains is technologically feasible. As FDA noted in its earlier Advance Notice of Proposed Rulemaking

4 2014 SG Report
5 The White House, “President Biden Reignites Cancer Moonshot to End Cancer As We Know It,” Fact Sheet. February, 2, 2022, https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/
8 2014 SG Report.
(ANPRM), there are a wide range of available technologies to reduce nicotine in cigarettes, including “through tobacco blending and cross-breeding plants, genetic engineering, and chemical extraction.”\textsuperscript{10} Indeed, the tobacco industry’s own documents show that the industry has a long history of manipulating nicotine levels in cigarettes to make them more addictive. As U.S. District Court Judge Gladys Kessler determined in her landmark opinion finding that the major cigarette companies had violated the federal anti-racketeering statute, “Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction.”\textsuperscript{11} Surely the companies cannot now credibly maintain that they are unable to reduce nicotine levels to no longer sustain addiction.

In addition, FDA has noted that recent scientific studies do not support concerns that nicotine reduction would cause people who smoke to compensate by increasing the number of cigarettes smoked or inhaling more deeply to increase nicotine intake. Studies of very low nicotine cigarettes have not found evidence of compensatory smoking but have found demonstrable reductions in cigarettes smoked per day and in exposure to harmful smoking constituents.\textsuperscript{12}

To realize the full potential public health benefits of a nicotine product standard, FDA must extend that standard beyond cigarettes, to other combustible tobacco products. Exempting other combustible products would invite tobacco manufacturers to market existing, or develop new, non-cigarette substitutes, like the small, flavored cigars the industry introduced after flavored cigarettes (except menthol) were removed from the market. It also would make the exempted products a potential vehicle for youth initiation. Thus, we urge FDA to make any nicotine reduction product standard applicable to other combustible tobacco products.

Reducing nicotine in cigarettes and other combustible tobacco products will complement FDA’s proposed rules to prohibit menthol cigarettes and flavored cigars. By addressing flavors and nicotine levels, FDA will be able to target both what attracts youth to these products and what addicts them. FDA should continue its work to promptly finalize and implement the menthol cigarette and flavored cigar proposed rules. Moreover, FDA should continue to address high rates of e-cigarette use by youth by promptly completing statutorily required premarket reviews and removing from the market those products that are not “appropriate for the protection of the public health.”

Reducing the nicotine content in cigarettes and other combustible tobacco products will dramatically reduce addiction, disease, and premature death from tobacco. We applaud FDA for setting forth a bold plan to protect kids and public health and urge the agency to act quickly to complete the rulemaking process. Every day that passes means more kids moving from experimentation to addiction and more adults who want to quit, and try to quit, but remain addicted to a lethal product.

\textsuperscript{10} ANPRM, at 11820.
\textsuperscript{12} ANPRM, at 11820.
Respectfully submitted,

AASA, The School Superintendents Association
Academy of General Dentistry
Action on Smoking and Health
Allergy & Asthma Network
Alpha-1 Foundation
American Academy of Family Physicians
American Academy of Oral and Maxillofacial Pathology
American Academy of Oral and Maxillofacial Radiology
American Association for Cancer Research
American Association for Dental, Oral, and Craniofacial Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Physicians
American Dental Association
American Heart Association
American Public Health Association
American Society of Addiction Medicine
Americans for Nonsmokers' Rights
Association for Clinical Oncology
Association for the Treatment of Tobacco Use & Dependence
Association of Black Cardiologists

Association of State and Territorial Health Officials
Asthma and Allergy Foundation of America
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
Catholic Health Association of the United States
Center For Black Equity
Children's Health Fund
Commissioned Officers Association of the USPHS
Common Sense Media
Community Anti-Drug Coalitions of America (CADCA)
COPD Foundation
Counter Tools
Dana-Farber Cancer Institute
Emphysema Foundation of America
Family, Career and Community Leaders of America (FCCLA)
First Focus on Children
GLMA: Health Professionals Advancing LGBTQ+ Equality
GO2 Foundation for Lung Cancer
HealthHIV
International Association for the Study of Lung Cancer
Kaiser Permanente
March of Dimes
National Alliance to Advance Adolescent Health
National Association of Hispanic Nurses
National Association of Pediatric Nurse Practitioners
National Association of School Nurses
National Association of Secondary School Principals
National Black Church Initiative
National Black Nurses Association
National Education Association
National Hispanic Medical Association
National LGBT Cancer Network
National Medical Association
National Native Network
National Network of Public Health Institutes
National Tongan American Society

North American Quitline Consortium
Oncology Nursing Society
Parents Against Vaping e-cigarettes (PAVe)
Preventing Tobacco Addiction Foundation/Tobacco 21
Preventive Cardiovascular Nurses Association
Respiratory Health Association
SADD
Society for Cardiovascular Angiography & Interventions
The Center for Black Health and Equity
The Society for State Leaders of Health and Physical Education
The Society of Thoracic Surgeons
Trust for America's Health
Truth Initiative
US COPD Coalition

CC: Dr. Brian King, Director of the Center for Tobacco Products