



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.<sup>1</sup> Sixteen million Americans are currently living with a tobacco-caused disease.<sup>2</sup> Over 30 million Americans currently smoke, and every day over 1,600 kids try their first cigarette.<sup>3</sup> Approximately half of people who smoke

<sup>1</sup> HHS, *The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General*, 2014 (2014 SG Report).

<sup>2</sup> *Id.*

<sup>3</sup> CDC, “Tobacco Product Use Among Adults—United States, 2020,” *MMWR Morb Mortal Wkly Rep* 2022;71:397–405, March 18, 2022,

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.<sup>4</sup>

We applaud the Administration for taking action to reduce tobacco use as part of its Cancer Moonshot initiative.<sup>5</sup> Cigarette smoking causes about 30 percent of all cancer deaths in the U.S.<sup>6</sup> 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.<sup>7</sup> 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.”<sup>8</sup> 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.<sup>9</sup> 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

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[https://www.cdc.gov/mmwr/volumes/71/wr/mm7111a1.htm?s\\_cid=mm7111a1\\_w](https://www.cdc.gov/mmwr/volumes/71/wr/mm7111a1.htm?s_cid=mm7111a1_w). Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, Results from the 2019 National Survey on Drug Use and Health, NSDUH: Detailed Tables, Table 4.9A <https://www.samhsa.gov/data/report/2019-nsduh-detailed-tables>

<sup>4</sup> 2014 SG Report

<sup>5</sup> 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/>

<sup>6</sup> American Cancer Society. [Cancer Facts & Figures 2022](https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html). Atlanta: American Cancer Society, 2022. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>

<sup>7</sup> CDC, “Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004-2013,” *MMWR* 65(44): 1212-1218, <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6544a3.pdf/>.

<sup>8</sup> 2014 SG Report.

<sup>9</sup> Apelberg, BJ, et al., “Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States,” *New England Journal of Medicine*, published online March 15, 2018. See also, “Tobacco Product Standard for Nicotine Level of Combusted Cigarettes,” Advance Notice of Proposed Rulemaking, 83 Fed. Reg. 11818, 11820 (March 16, 2018)(ANPRM)

(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.”<sup>10</sup> 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.”<sup>11</sup> 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.<sup>12</sup>

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 combusted 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.

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<sup>10</sup> ANPRM, at 11820.

<sup>11</sup> *U.S. v. Philip Morris, Inc.*, 449 F.Supp. 2d, 1, 309 (D.D.C. 2006), *aff’d in relevant part*. 566 F.3d 1095 (D.C. Cir. 2009).

<sup>12</sup> 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