



May 21, 2018

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

Re: Nicotine product standard

Dear Dr. Gottlieb:

The undersigned public health and medical organizations write in strong support of your initiative to move toward a product standard to reduce the nicotine level in cigarettes to non-addictive or minimally addictive levels. Such a standard would have massive public health benefits; indeed, there are few actions FDA could take that would prevent more young people from smoking and save lives. 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 Nearly 38 million Americans currently smoke

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

² *Id.*

and every day about 2,300 kids try their first cigarette.³ Approximately half of continuing smokers will die prematurely as a result of their addiction, losing at least a decade of life on average compared to nonsmokers.⁴

As a Philip Morris researcher once put it, “No one has ever become a cigarette smoker by smoking cigarettes without nicotine.”⁵ 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.”⁶ Thus, reducing the nicotine content in cigarettes to minimally or non-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 adult smokers, making it easier for them to quit.

FDA’s estimates quantifying the public health benefits of this product standard demonstrate the potentially historic lifesaving impact of its implementation. The agency estimates that approximately 5 million additional adult smokers 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 from the current 15 percent to as low as 1.4 percent, **resulting in more than 8 million fewer tobacco-caused deaths through the end of the century.**⁷ The dimensions of this public health benefit make timely implementation of this policy a moral imperative.

Through the public comments received in response to FDA’s Advance Notice of Proposed Rulemaking (ANPRM), FDA will receive valuable information on a host of issues the agency has raised to guide its consideration of a possible nicotine reduction product standard. However, on several pivotal issues, the evidence already establishes the practicality and potential benefits of such a standard.

First, as FDA already has acknowledged in its ANPRM, reducing nicotine in cigarettes is feasible “through tobacco blending and cross-breeding plants, genetic engineering, and chemical extraction.”⁸ 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.

³ CDC, “Current Cigarette Smoking Among Adults – United States, 2016,” *Morbidity and Mortality Weekly Report (MMWR)* 67(2):53-59, January 19, 2018.

⁴ 2014 SG Report.

⁵ Philip Morris, Dun, W Jr., “Motives and Incentives in Cigarette Smoking”; R107, 1972.

⁶ 2014 SG Report.

⁷ 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).

⁸ ANPRM, at 11820.

District Court Judge Gladys Kessler found 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.”⁹ Surely the companies cannot now credibly maintain that they are unable to reduce nicotine levels to no longer sustain addiction.

Second, as FDA also has acknowledged, recent scientific studies do not support concerns that nicotine reduction would cause smokers to compensate by increasing the number of cigarettes smoked or inhaling more deeply to increase nicotine intake. FDA reports studies of very low nicotine cigarettes showing the absence of compensatory smoking, as well as demonstrable reductions in cigarettes smoked per day and in exposure to harmful smoking constituents.¹⁰

However, it is clear that, to realize the potential public health benefits of a nicotine product standard, FDA must extend that standard beyond cigarettes, to other combustible tobacco products, including those currently on the market and those that may come on the market in the future. Exemption of other combustible products would invite tobacco manufacturers to market existing and develop new non-cigarette substitutes that would lead cigarette smokers to substitute those products, like the small flavored cigars the industry introduced after flavored cigarettes 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 to prevent the industry from circumventing the new rule just as they did the ban on flavored cigarettes.

Finally, FDA’s own estimates of the lifesaving potential of your nicotine reduction proposal require a sense of urgency commensurate with that potential. 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. We urge FDA to issue a proposed rule within six months of its ANPRM (by September 16, 2018) and a final rule six months later (by March 16, 2019). We also urge that implementation of the rule be no later than the one-year period provided for in Section 907 of the Family Smoking Prevention and Tobacco Control Act, which would allow the rule to be implemented by March of 2020.

Thank you for your consideration.

⁹ *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).

¹⁰ ANPRM, at 11820.

Action on Smoking and Health
Allergy & Asthma Network
American Academy of Family Physicians
American Academy of Oral and Maxillofacial Pathology
American Academy of Otolaryngology—Head and Neck Surgery
American Association for Cancer Research
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Obstetricians and Gynecologists
American College of Physicians
American College of Preventive Medicine
American Heart Association
American Lung Association
American Medical Association
American Psychological Association
American Public Health Association
American Society of Clinical Oncology
Association of Maternal & Child Health Programs
Association of Schools and Programs of Public Health
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric and Neonatal Nurses
Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Eta Sigma Gamma - National Health Education Honorary
International Association for the Study of Lung Cancer
Lung Cancer Alliance
March of Dimes
National Association of County and City Health Officials
Oncology Nursing Society
Prevent Cancer Foundation
Prevention Institute
Society for Cardiovascular Angiography and Interventions
Society for Public Health Education
Students Against Destructive Decisions
The Society for State Leaders of Health and Physical Education
The Society of Thoracic Surgeons
Trust for America's Health
Truth Initiative
United Methodist Church - General Board of Church and Society