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June 5, 2018

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

RE: **Tobacco Product Standard for Nicotine Level of Certain Tobacco Products [FDA-2017-N-6189]**

Dear Commissioner Gottlieb:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on the establishment of a nicotine level tobacco product standard for certain tobacco products. The American College of Cardiology is the professional home for the entire cardiovascular care team. The mission of the College and its more than 52,000 members is to transform cardiovascular care and to improve heart health. The ACC leads in the formation of health policy, standards and guidelines. The College operates national registries to measure and improve care, offers cardiovascular accreditation to hospitals and institutions, provides professional medical education, disseminates cardiovascular research and bestows credentials upon cardiovascular specialists who meet stringent qualifications.

Cigarette smoking increases an individual's risk of cardiovascular disease by two to four times.[1] After one year, smoking cessation is associated with a 50 percent reduction in coronary heart disease risk compared to those still smoking.[2] While significant strides have been made to decrease the prevalence of smoking, tobacco use remains the chief cause of preventable death and disease in the United States. To further reduce the prevalence of cigarette smoking and associated health problems such as heart disease, the FDA must take all appropriate measures within its authority to steer current smokers toward cessation and prevent non-smokers from initiation.

As the primary addictive agent in cigarettes,[2] nicotine presents an immense challenge to both regular smokers attempting to quit and adolescents vulnerable to initiation. Scientific evidence has now emerged that supports lowering nicotine levels in cigarettes to reduce addiction and the toll of death and disease from smoking. Within the Advanced Notice of Proposed Rulemaking (ANPRM), the FDA estimates that the implementation

[1] Warren GW, Alberg AJ, Kraft AS, Cummings KM. The 2014 Surgeon General's report: "The health consequences of smoking--50 years of progress": a paradigm shift in cancer care. Cancer 2014;120:1914-6.
[2] Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention; 2010.

of such a proposal would prevent over 33 million youth from initiating regular smoking and prompt 5 million regular smokers to quit within one year. After five years, they estimate the number of former smokers will rise to 13 million, ultimately saving more than 8 million lives by the close of the century. **Given the immense public health benefits predicted by the FDA, the ACC strongly supports the implementation of a nicotine product standard in cigarettes to a minimally addictive or non-addictive level.**

Rendering cigarettes minimally or non-addictive is estimated to save a groundbreaking number of lives; however, much of this anticipated progress will be lost if not implemented in a swift and timely manner. Given the magnitude of potential public health benefit, rapid implementation of a nicotine product standard is an ethical obligation. Each day the policy is delayed translates into additional children and young adults transitioning into addiction and countless adults still struggling to quit. **The FDA should move quickly to develop and issue a final regulation to maximize the number of lives saved.**

As stated in the ANPRM, cigarettes are the tobacco product category that currently causes the greatest burden of harm to public health. However, if other combustible products are exempted from the nicotine product standard, users may migrate to other tobacco delivery mechanisms to receive additional nicotine intake. As the Agency states within the ANPRM, a standard applied only to cigarettes could be substantially less effective. Exempted products could also create a loophole for manufacturers to market similar combustible products such as cigars or cigarillos as alternatives. **The FDA must extend the nicotine product standard to all combustible tobacco products to prevent users from turning to alternative methods to satisfy their nicotine addiction or allowing exempted products to become a vehicle for youth initiation.** Additional funding should also be allocated from the FDA or other organizations to research and consider implementation of similar product standards in non-combustible tobacco products, including e-cigarettes, to avoid migration or dual use.

Throughout implementation of a nicotine product standard, it is imperative that the FDA conduct thorough post-market surveillance to detect any problematic use patterns or unintended consequences. In the ANPRM, the FDA highlights several potential countervailing effects, including the notion of compensatory smoking. However, the Agency does acknowledge recent studies on very low nicotine cigarettes that indicated users did not turn to compensatory smoking to mitigate the reduction in nicotine. Instead, the studies found that users smoked significantly fewer cigarettes per day and experienced less exposure to other dangerous byproducts of smoking. Smoking and nicotine/tobacco regulation will remain a high-priority focus for academic research; it is likely that any unintended consequences will be recognized and highlighted for the FDA during policy implementation, providing the opportunity to modify these policies.

The ACC stands in strong support of implementing a nicotine product standard for all combustible tobacco products without any further delay. The College appreciates the FDA's openness to stakeholder input throughout its ongoing initiative to lessen tobacco-related harm and welcomes the opportunity to provide further input as needed. Please direct any questions or concerns to Kelsey Creehan, Associate, Advocacy at (202) 375-6625 or kcreehan@acc.org.

Sincerely,

C. Michael Valentine, MD, FACC
President