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The mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health.

June 22, 2018

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

RE: Regulation of Premium Cigars [FDA-2017-N-6107]

Dear Commissioner Gottlieb:

The American College of Cardiology (ACC) is pleased to submit comments to the Food and Drug Administration (FDA) on the regulation of premium cigars. 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 risk of coronary heart disease 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 it 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.

In 2016, the FDA published the final rule deeming a range of tobacco products, including premium cigars, under the Agency's regulatory authority. While the FDA considered exempting premium cigars, no appropriate public health justification was determined.

¹ Warren GW, Alberg AJ, Kraft AS, Cummings KM. "The Health Consequences of Smoking: 50 Years of Progress". A Report of the Surgeon General; 2014. Accessed June 1, 2018. <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.

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. Accessed June 1, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/21452462>.

Specifically, the Agency concluded that all cigars pose negative health risks, and available evidence did not provide a basis that premium cigars sufficiently reduce health risks to warrant exclusion. Following lengthy scientific review, the FDA also concluded that while some premium cigar smokers may smoke infrequently or do not fully inhale, the behaviors do not fully negate the adverse effects of tobacco smoke or related secondhand smoke. No evidence has been generated indicating that a change in this regulation is warranted.

Instead, exempting “premium cigars” from regulation communicates the dangerous message that premium cigars are less harmful than other cigars. The evidence is clear – all cigars are harmful and potentially addictive to users and pose health hazards to bystanders in the form of secondhand smoke. Tobacco use has been linked to a wide variety of hazardous health conditions that do not distinguish between those who can afford more expensive tobacco products and those who cannot. There is no evidence-based public health justification to exempt any tobacco products from the purview of the FDA. **The ACC urges the FDA to exert its regulatory authority over all tobacco products, including cigars of all varieties.**

The ACC stands in strong support of regulating all cigars, including premium cigars, in the interest of public health. 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