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Via Electronic Submission

July 25, 2018

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

Subject: Regulation of Premium Cigars – (Docket No. FDA-2017-N-6107)

Dear Dr. Gottlieb:

The American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) appreciate the opportunity to provide input on the U.S. Food and Drug Administration's (FDA's) advanced notice of proposed rulemaking on the regulation of premium cigars. The AACR and ASCO are the preeminent scientific organizations for cancer researchers and physicians. The AACR, which has 40,000 members, is the world's oldest and largest professional organization dedicated to preventing and curing cancer through research, education, communication, and collaboration. ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO members are committed to ensuring that evidence-based practice for the prevention, diagnosis, and treatment of cancer are available to all Americans. Our organizations are engaged in promoting the reduction and ultimate elimination of tobacco products and exposure to environmental tobacco smoke to prevent cancer and the numerous other tobacco-caused diseases and thereby improve public health.

We appreciate the FDA's efforts to seek data, research, and other information to inform potential regulatory actions on the sale and distribution of premium cigars. In 2009, the Tobacco Control Act gave the FDA authority to regulate tobacco products, including roll-your-own tobacco, smokeless tobacco, and any

other tobacco products deemed by the Secretary of Health and Human Services.¹ In 2014, the FDA released the Deeming Rule with plans to either include premium cigars in its scope of the rule's definition of tobacco products to be regulated or exempt premium cigars. We applaud the FDA after review of public comments on the Deeming Rule for concluding that there was no public health justification to exclude premium cigars from regulations.² Based on the evidence of public health harms posed by premium cigars, it is our position that FDA's regulatory oversight of tobacco products should not be limited or restricted, and particularly not by the exemption of large and premium cigars.

The 2016 National Youth Tobacco Survey found that high school boys smoke cigars (i.e., large cigars, cigarillos and small cigars) at a slightly higher rate than cigarettes (9.9 percent to 9.1 percent). In addition, cigars are sold in hundreds of flavors, including sweet flavors and names that appeal to kids. Research has found that flavors play a key role in youth use of tobacco products, including cigars.³ In 2014, among past 30-day cigar smokers, 64.7% of high school students and 56.6% of middle school students used a flavored cigar in the past 30 days.⁴ While the patterns of use and the health effects of premium cigars may be different from other tobacco products, cigars are combusted just like cigarettes and cause multiple types of cancer. There is little question that FDA regulation of cigar products will create public health benefits.

A cigar is a roll of tobacco wrapped in leaf tobacco or in a substance that contains tobacco, and most cigars are combustible. Most cigars are composed primarily of a single type of tobacco air-cured and fermented. Cigars vary in size from smaller cigars, such as little filtered cigars or cigarillos, to larger ones, such as large so-called premium cigars. The cigar products available on the market labeled as "little cigars" or "filtered cigars" resemble cigarettes in size and shape.⁵ However, cigars are not a safe alternative to cigarettes and cigar smoke may be as or more toxic as cigarette smoke. Large cigars can deliver as much as 10 times the nicotine, two times the tar, and more than five

¹ Federal Food, Drug, and Cosmetic Act. Subchapter IX – Tobacco Products. 21 U.S.C. <https://www.gpo.gov/fdsys/pkg/USCODE-2016-title21/html/USCODE-2016-title21-chap9-subchapIX-sec387.htm>

² Final Rule: Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. FDA, 2016. <https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>

³ US Department of Health and Human Services. E-Cigarette use among youth and young adults. A report of the Surgeon General. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf

⁴ Corey CG, Ambrose BK, Apelberg BJ, King BA. Flavored Tobacco Product Use Among Middle and High School Students - United States, 2014. MMWR Morb Mortal Wkly Rep. 2015;64(38):1066-1070.

⁵ National Cancer Institute (NCI). Cigars: Health Effects and Trends Tobacco Control Monograph 9. Bethesda, MD: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, National Cancer Institute; 1998

times the carbon monoxide of a filtered cigarette. Cigar wrappers are also less porous than cigarette wrappers. Thus, the nonporous cigar wrapper makes burning of cigar tobacco less complete resulting in higher levels of toxins in cigar smoke.⁶ The impact of reducing nicotine in combustible cigarettes on the uptake of cigar smoking is unclear at this time. We do know that exclusive premium cigar smokers generally exhibit a different pattern of use. Based on what we know about current use patterns, premium cigars may not be relevant substitutes for smokers who are seeking nicotine to replace the levels that were attained from higher nicotine content cigarettes. One important difference is that cigars, and especially premium cigars, tend to have a relatively higher pH which makes the smoke harsh and more difficult to inhale.⁷ We suggest that, in addition to other factors defining cigars as “premium” (e.g. manufacturing processes, cost, etc.), the FDA consider setting a limit on the pH of premium cigars, e.g. premium cigars tend to have a high pH (~ 6.0). A justification for this pH standard is that the tobacco industry may try to label something with a lower pH (i.e. lower than 6.0) as a “premium cigar” but it may have a greater abuse liability relative to the other premium cigar (higher pH) products. If a pH threshold (e.g., > 6.5) is considered by the FDA, the toxicity, abuse liability and pattern of use of associated with this standard would need to be determined.

By 1998, an objective assessment of the evidence demonstrated that cigar smoking can cause oral, esophageal, laryngeal, and lung cancers (9). Further, heavier cigar smoking increases the risk of coronary heart disease and chronic obstructive pulmonary disease (9). Based on this and other evidence, in 2010 cigar smoking was estimated to be responsible for approximately 9,000 premature deaths among US adults age 35 and older.⁸ Cigar smokers directly expose their lips, mouth, tongue, and throat to toxic, cancer-causing chemicals,⁹ so that in addition to oral cancer cigar smoke is also linked to gum disease and tooth loss.⁵ Consistent with this strong evidence of the harms caused by cigar smoking, the FDA requires manufacturers include five warnings covering these and additional health effects for cigar packaging, having added a fifth warning regarding reproductive health effects to the four rotating warnings.

Our organizations believe the FDA should make an evidence-based decision to regulate premium cigars. The evidence clearly demonstrates substantial harms caused by cigar smoking. In the 2014 report of the US Surgeon General the conclusion was made that inhaling tobacco smoke is deadly; the risks for cigarette smoking are greater than for cigar smoking due primarily to the fact that cigars tend to be used less frequently and the smoke inhaled less deeply, but the risks of cigar smoking are clearly of public health significance. Some premium cigars contain tobacco equivalent

⁶ Baker F, Ainsworth SR, Dye JT, et al. Health risks associated with cigar smoking. *Journal of the American Medical Association* 2000; 284(6):735–740.

⁷ Lawler, TS et al., Surveillance of Nicotine and pH in Cigarettes and Cigar Filler, *Tobacco Regulatory Science*, 2107, April; Suppl. 1, 101-116.

⁸ Nonnemaker J, Rostron B, Hall P, MacMonegle A, Apelberg B. Mortality and Economic Costs from Regular Cigar Use in the United States, 2010. *Am J Public Health*. 2014:e1-e6.

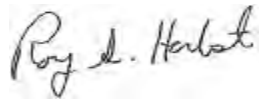
⁹ National Cancer Institute (1998). *Smoking and Tobacco Control Monograph 9: Cigars: Health Effects and Trends*. Bethesda, MD. Retrieved October 21, 2010,

<http://www.cancercontrol.cancer.gov/tcrb/monographs/9/index.html>.

to an entire pack of cigarettes. Cigar smoking carries many of the same health risks as cigarettes smoking, and therefore should be regulated by the agency as cigarettes and other tobacco products.

We appreciate the opportunity to provide the FDA with these comments and data to support the regulation of premium cigars to protect public health. These comments are based on the evaluation of the extant literature on tobacco treatment by the AACR's Tobacco and Cancer Subcommittee (roster attached), ASCO's Tobacco Cessation and Control Subcommittee (roster attached). If we can provide any additional information or assistance to the FDA, please do not hesitate to contact Nicole Boschi, PhD, AACR Senior Science Policy Analyst, at (215) 446-7275 or nicole.boschi@aacr.org or Shimere Williams Sherwood, PhD, ASCO Associate Director, Research and Science Policy at (571) 483-1672 or Shimere.Sherwood@asco.org.

Sincerely,



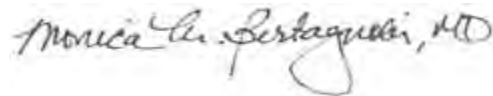
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