



April 18, 2016

The Honorable Harold Rogers  
 Chairman  
 Committee on Appropriations  
 United States House of Representatives  
 Washington, D.C. 20515

The Honorable Nita Lowey  
 Ranking Member  
 Committee on Appropriations  
 United States House of Representatives  
 Washington, D.C. 20515

The Honorable Robert Aderholt  
 Chairman  
 Subcommittee on Agriculture, Rural  
 Development, Food and Drug Administration,  
 and Related Agencies  
 Committee on Appropriations  
 United States House of Representatives  
 Washington, D.C. 20515

The Honorable Sam Farr  
 Ranking Member  
 Subcommittee on Agriculture, Rural  
 Development, Food and Drug Administration,  
 and Related Agencies  
 Committee on Appropriations  
 United States House of Representatives  
 Washington, D.C. 20515

Dear Chairman Rogers, Ranking Member Lowey, Chairman Aderholt, and Ranking Member Farr:

We are writing to express our strong opposition to Section 749 of the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for Fiscal Year 2017. This provision would prevent FDA from implementing a pending rule that gives the agency authority to oversee cigars, e-cigarettes, and certain other tobacco products unless that rule exempts

“large and premium” cigars - which could also exempt some inexpensive and flavored cigars - entirely from FDA oversight. When the Appropriations Committee marks up this bill, we urge you to support efforts to strike this provision and to oppose any amendments that would weaken FDA’s current authority to regulate tobacco products.

In 2009, Congress gave FDA authority over the manufacture, sale, and marketing of all tobacco products in order to reduce the disease and premature death caused by these products. Under that authority, FDA issued a proposed rule in April 2014 that would enable it to begin to oversee cigars, e-cigarettes and other tobacco products that the agency does not currently regulate. A final rule is expected soon. Section 749 of this bill would block FDA from using funds to “finalize, implement, administer, or enforce” this rule unless the rule excludes “large and premium cigars” from FDA oversight.

No tobacco product should be exempt from regulation. We are also concerned that under this bill’s definition of “large and premium cigars” some machine made cigars, including some that may cost as little as \$1.00, would be exempted from FDA oversight and that some flavored cigars could qualify for an exemption. Moreover, we are concerned that the number of cigars exempted from FDA oversight under this definition would increase over time as cigar manufacturers modify their products to qualify for the exemption. Tobacco manufacturers have a history of modifying their products to avoid public health protections or attain lower tax rates and, because of Section 749, would have a strong incentive to do so again.

Exempting certain cigars from FDA oversight will have serious consequences. There are known health risks linked to cigar smoking, including several types of cancer as well as lung and heart disease. Exempting large and premium cigars could also inaccurately imply that they are safe to use and pose no harm. In addition, cigar smoking is not limited to adults. High school boys smoke cigars at the same rate as cigarettes. Section 749 would create a regulatory loophole that will enable manufacturers of some cheap, fruit- and candy-flavored cigars to escape from FDA oversight and prevent FDA from implementing common sense rules for all cigars.

We also urge you to oppose any amendment that would weaken FDA’s existing authority to oversee tobacco products. Specifically, we are concerned about a possible amendment that would change the so-called “grandfather date” to exempt e-cigarettes, cigars, and other currently unregulated tobacco products from an important product review requirement. The Committee included such a provision in last year’s agriculture appropriations bill.

Under current law, manufacturers are required to provide information to the FDA so that the agency can assess the risks to public health of new tobacco products, which are defined as products introduced to the market after February 15, 2007. Changing this date would exempt e-cigarettes, cigars and other products now on the market from this FDA review and would significantly weaken FDA’s ability to take prompt action to protect children from the thousands of fruit- and candy-flavored e-cigarettes and cigars that have flooded the market in recent years. Youth use of e-cigarettes has increased dramatically in recent years and now exceeds youth use of regular cigarettes. An amendment that

would exempt these products from an FDA review would take away an important tool the agency could otherwise have to address this problem.

Assessing the risks to public health of different types of tobacco products and determining how they are regulated is best determined by FDA. Tobacco use remains the leading preventable cause of death in the United States and is responsible for an estimated \$170 billion in health care costs each year. The Committee should not make it more difficult for FDA to address this public health problem.

Sincerely,

Action on Smoking and Health  
American Academy of Otolaryngology - Head and Neck Surgery  
American Academy of Pediatrics  
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 Preventive Medicine  
American Congress of Obstetricians and Gynecologists  
American Heart Association  
American Lung Association  
American Medical Association  
American Psychological Association  
American Public Health Association  
American School Health Association  
American Society of Clinical Oncology  
American Thoracic Society  
Association of Schools and Programs of Public Health  
Association of State and Territorial Health Officials  
Big Cities Health Coalition  
Campaign for Tobacco-Free Kids  
ClearWay Minnesota  
Community Anti-Drug Coalitions of America  
Eta Sigma Gamma - National Health Education Honorary  
March of Dimes  
National African American Tobacco Prevention Network  
National Association of County & City Health Officials  
National Network of Public Health Institutes  
Oncology Nursing Society  
Society for Research on Nicotine & Tobacco

CC: House of Representatives Appropriations Committee Members