July 11, 2017

The Honorable Rodney Frelinghuysen
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 Sanford Bishop
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 Frelinghuysen, Ranking Member Lowey, Chairman Aderholt, and Ranking Member Bishop:

We are writing to express our strong opposition to Sections 752 and 753 of the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for Fiscal Year 2018. These sections weaken the Food and Drug Administration's (FDA) May 2016 final rule that gives the agency authority to oversee cigars, e-cigarettes, and certain other tobacco products. We urge you to support efforts to strike these provisions from the underlying bill.

Section 752 exempts "large and premium cigars" entirely from FDA oversight. While no tobacco product should be exempt from oversight, we are particularly concerned that Section 752 would create a 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. 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 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 could 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 752, 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. Nearly 10 percent of high school boys smoke cigars – about the same rate as smoke cigarettes.

We also urge you to oppose Section 753, which would exempt the many e-cigarettes and cigars that have come onto the market in recent years from an FDA review and evaluation of their impact on public health. This section would take away one of FDA's most significant tools for removing from the market products that egregiously appeal to kids or pose health and safety risks. Last year, the Committee included very similar language which the New York Times documented was written by Altria, the nation's largest tobacco company.

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 many e-cigarettes, cigars and other products now on the market from this FDA review. These are products that typically deliver nicotine, pose health risks, and are used by millions of young people. Many e-cigarettes are made in China and other places without appropriate manufacturing standards. Without a product review, FDA would be denied information that it needs to assess these products' health and safety risks, addictiveness, and appeal to youth, and its ability to protect kids and public health would be significantly weakened.

The language in Section 753 has been modified slightly from last year's bill and would require FDA to issue a product standard on not just batteries but also characterizing flavors in e-cigarettes within 36 months. While we appreciate that the Committee recognizes the need to address public health concerns about the batteries and flavors used by e-cigarette manufacturers, requiring FDA to issue product standards on these two issues would not offset the negative consequences of taking away FDA's critically important ability to review thousands of products that entered the market prior to August 8, 2016. Removing this review would slow down FDA's ability to remove from the market e-cigarette liquids or e-cigarettes that are sold in clearly kid-friendly flavors like "very berry slushie," "gummy bear" and "cotton candy" or products with batteries that have a record of exploding. In addition, flavors and batteries are not the only public health issues raised by e-cigarettes. E-cigarettes, for example, can also expose users to toxins, including potent carcinogens, and widely varying levels of nicotine. The bill language would prevent FDA from addressing these and other public health issues related to e-cigarettes currently on the market through the product review process. This provision would make the most harmful and youth-appealing e-cigarettes currently on the market the standard by which future products would be evaluated.

In addition, the product standard for flavors required in the bill is limited to e-cigarettes and would not address flavored cigars or other flavored tobacco products. Flavored cigars made up more than half of the

total cigar market in 2015, and 74 percent of youth cigar users say they smoked cigars "because they come in flavors I like." Grandfathering in the many flavored cigars will leave these products on the market for years to come.

Section 753 is not a compromise. The provisions requiring product standards regarding batteries and flavors involve actions FDA can already take under its existing authority. This in no way offsets the damage caused by exempting e-cigarettes and cigars that may already be damaging public health from FDA public health review. FDA can, and should, begin now to develop product standards for e-cigarette batteries and flavors, but not at the cost of losing its authority to take timely action to take the most hazardous products off the market. This rider has only one purpose: to limit the use of one of FDA's most important tools for protecting kids and public health.

We urge you to oppose sections 752 and 753 from this appropriations bill.

Sincerely,

Action on Smoking & Health
American Academy of Family Physicians
American Academy of Oral & Maxillofacial Pathology
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Pediatrics
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action Network
American College of Cardiology
American College of Physicians
American Congress of Obstetricians and Gynecologists
American Heart Association
American Lung Association
American Medical Association
American Psychological Association
American Public Health Association
American Society of Addiction Medicine
American Society of Clinical Oncology
American Thoracic Society
Association of Schools and Programs of Public Health
Association of State and Territorial Health Officials
Association of Women's Health, Obstetric and Neonatal Nurses
Campaign for Tobacco-Free Kids
ClearWay Minnesota
College on Problems of Drug Dependence
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 Pediatric Nurse Practitioners
National Center for Health Research
National Hispanic Medical Association
Oncology Nursing Society
Prevention Institute
Society for Cardiovascular Angiography and Interventions
Society for Public Health Education
Society For Research On Nicotine and Tobacco
Students Against Destructive Decisions
The Society of State Leaders of Health and Physical Education
Trust for America's Health

CC: United States House of Representatives Committee on Appropriations Members