



May 23, 2018

The Honorable Richard Shelby
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

The Honorable Patrick Leahy
Vice Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Chairman Shelby and Vice Chairman Leahy:

As the Appropriations Committee moves forward with the FY 2019 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations bill, we urge you to approve the authorized level of user fees for the Food and Drug Administration's (FDA) oversight of tobacco products and to oppose any effort to limit the authority that Congress granted the FDA under the Family Smoking Prevention and Tobacco Control Act (TCA).

Prior to 2009, tobacco products were virtually unregulated even though they were known to be highly addictive and dangerous to health. Congress, on a bipartisan basis, recognized that tobacco products should be overseen by an agency with expertise in assessing health risks and experience promulgating science-based regulation. The TCA gave the Center for Tobacco Products at FDA the authority to oversee the manufacture, marketing, distribution and sale of tobacco products in a manner appropriate for the protection of public health.

We appreciate that every FDA appropriations bill approved by Congress since the enactment of the TCA has contained the full authorized amount of user fees. This year, we urge the Appropriations Committee to approve the \$712 million in user fees that the TCA authorizes FDA to collect and spend for tobacco-related activities for FY 2019.

We also appreciate that the Committee did not include any restrictions on FDA's authority under the TCA in its FY 2018 bill and urge the Committee to not restrict this authority in its FY 2019 bill. Regrettably, the House Agriculture-FDA Appropriations bill approved by the House Appropriations Committee last week would substantially weaken FDA's authority over certain tobacco products. It would completely exclude "large and premium cigars" from FDA oversight. We agree with FDA's conclusion in 2016 that there is no appropriate public health justification for exempting premium cigars from FDA oversight. FDA's scientific review found that all cigars pose serious negative health risks, including about 9,000 premature deaths a year, and that all cigars are potentially addictive. We also are concerned that the rider defines "large and premium cigars" so broadly that it would create a loophole that invites tobacco companies to modify their products to qualify for this exemption, including cheap, machine-made, flavored cigars that appeal to youth.

The House bill also would exempt all other cigars and pipe tobacco that were on the market prior to April 25, 2014 from a scientific review of their health risks and whether they appeal to kids. By eliminating the obligation of manufacturers to submit these products for review by FDA, the provision would make it much harder for FDA to address concerns about tobacco companies' use of kid-friendly flavors.

In addition, the House bill would make it easier for manufacturers to bring new tobacco products to market in the future. By changing which products can serve as "predicate products," it would enable more e-cigarettes, cigars, and other tobacco products to be eligible for a less rigorous "substantial equivalence" review by FDA instead of a full review of these products' effect on public health.

We urge the Committee to continue to exclude any restrictions on FDA's authority over tobacco products from this appropriations bill.

Tobacco use remains the leading preventable cause of death in the United States and is responsible for more than \$170 billion in health care costs every year. More than 16 million Americans currently suffer from smoking-caused illness and more than 480,000 die each year from cigarette smoking and exposure to secondhand smoke. With the support of your Committee, the FDA will be able to continue its work to reduce tobacco use and the health and economic toll it takes on our nation.

Sincerely,

Academy of General Dentistry
Allergy & Asthma Network
American Academy of Family Physicians
American Academy of Oral and Maxillofacial
Pathology
American Academy of Otolaryngology—
Head and Neck Surgery
American Academy of Pediatrics
American Association for Respiratory Care
American Cancer Society Cancer Action
Network
American College of Cardiology
American College of Obstetricians and
Gynecologists
American College of Preventive Medicine
American Dental Association
American Heart Association
American Lung Association
American Medical Association
American Medical Student Association
American Psychological Association
American Public Health Association
American School Health Association
American Society of Addiction Medicine
American Society of Clinical Oncology
American Thoracic Society
Association of Maternal & Child Health
Programs
Association of Schools and Programs of
Public Health
Association of State and Territorial Health
Officials

Big Cities Health Coalition
Campaign for Tobacco-Free Kids
Community Anti-Drug Coalitions of America
Eta Sigma Gamma - National Health
Education Honorary
International Association for the Study of
Lung Cancer
Lung Cancer Alliance
March of Dimes
Mesothelioma Applied Research
Foundation
National African American Tobacco
Prevention Network
National Association of County and City
Health Officials
National Association of Pediatric Nurse
Practitioners
National Center for Health Research
Oncology Nursing Society
Prevent Cancer Foundation
Prevention Institute
Society for Cardiovascular Angiography and
Interventions
Society for Public Health Education
Society for Research on Nicotine & Tobacco
Students Against Destructive Decisions
The Society of State Leaders of Health and
Physical Education
The Society of Thoracic Surgeons
Trust for America's Health