

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

CC: United States Senate Committee on Appropriations Members



May 4, 2018

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 Aderholt and Ranking Member Bishop:

As your Subcommittee 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 manufacturer, 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 your Subcommittee 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 were disappointed that your Subcommittee included restrictions on FDA's authority under the TCA in its FY 2018 bill and urge the Subcommittee to not restrict this authority in its FY 2019 bill. As you know, two policy riders in last year's House Agriculture-FDA Appropriations bill would have substantially weakened FDA's authority over certain tobacco products. One provision would have exempted thousands of e-cigarettes and cigars now on the market 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 have made it much harder for FDA to address concerns about tobacco companies' use of kid-friendly flavors, made the thousands of sweet-flavored products that entered the marketplace in recent years the accepted industry standard by which future products would be evaluated, and left important questions about the effect of e-cigarettes on public health unanswered. Regrettably, FDA has significantly delayed enforcement of this product review requirement. The House rider would have gone beyond this delay and permanently exempted thousands of tobacco products from a product review by FDA.

The other provision would have completely excluded "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 defined "large and premium cigars" so broadly that it would have created a loophole that invited tobacco companies to modify their products to qualify for this exemption, including cheap, machine-made, flavored cigars that appeal to youth. We appreciate that the FY 2018 Consolidated Appropriations Act did not include these provisions and urge the Subcommittee to not include restrictions on FDA's authority over tobacco products in its FY 2019 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 Subcommittee, 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 Action on Smoking and Health 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 Cancer Research American Association for Respiratory Care American Cancer Society Cancer Action Network American College of Cardiology American College of Obstetricians and **Gynecologists** American College of Physicians American College of Preventive Medicine American Dental Association American Dental Education Association American Heart Association American Lung 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 Americans for Nonsmokers' Rights Asian Pacific Partners for Empowerment, Advocacy and Leadership Association of Maternal & Child Health Programs Association of Schools and Programs of Public Health Association of State and Territorial Health Officials

Association of Women's Health, Obstetric and **Neonatal Nurses Big Cities Health Coalition** Campaign for Tobacco-Free Kids ClearWay Minnesota<sup>SM</sup> 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 National African American Tobacco Prevention Network National Association of County and City Health Officials National Association of Pediatric Nurse Practitioners National Association of School Nurses National Association of Social Workers National Hispanic Medical Association **Oncology Nursing Society Prevention Institute Public Health Solutions** 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 United Methodist Church – General Board of Church and Society

CC: United States House of Representatives Committee on Appropriations Members