



June 8, 2016

United States Senate
Washington, D.C. 20510

Dear Senator:

With Senate consideration of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for Fiscal Year 2017 expected in a few weeks, we urge you to oppose any amendments that would weaken FDA's authority to regulate tobacco products. In particular, we want to express our strong opposition to two provisions in the House version of the bill and urge you to oppose attaching them to the Senate bill. One provision seeks to completely exempt certain cigars from FDA regulation. The other exempts e-cigarettes, cigars, and certain other tobacco products now on the market from an important product review requirement, taking away a powerful and efficient tool to protect children from the candy- and fruit-flavored e-cigarettes and cigars that have flooded the market in recent years.

In May, FDA took an important step to protect children and public health by issuing a final rule that will enable the agency to begin to oversee cigars, e-cigarettes, and other tobacco products that had been outside of FDA's authority. The need for FDA oversight of these products could not be clearer. In April, the Centers for Disease Control and Prevention released the 2015 National Youth Tobacco Survey, which highlighted that the alarming increase in youth use of electronic cigarettes continues. From 2011 to 2015, there was a more than ten-fold increase in current e-cigarette use among high school students – from 1.5 percent to 16 percent. In addition, high school boys now smoke cigars at a slightly higher rate than cigarettes – 11.5 percent for cigars and 10.7 percent for cigarettes. The final rule will enable FDA, for the first time, to oversee the manufacturing, marketing, and sale of these products, providing the

agency with new tools to address the problem of three million middle and high school students using e-cigarettes and 1.4 million using cigars.

However, Section 749 of the House bill would block FDA from using funds to “implement, administer, or enforce” this final rule unless the rule excludes “large and premium cigars” from FDA oversight. FDA specifically examined whether premium cigars should be excluded from FDA oversight and concluded that there was no appropriate public health justification for doing so. 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 are also concerned that the rider defines “large and premium cigars” so broadly that it could also exempt some cheap, machine-made, flavored cigars that are widely used by children. This exemption creates a loophole that invites tobacco companies to modify their products to qualify for this exemption – a loophole that tobacco companies will surely exploit to keep targeting children.

Section 761 of the House bill would change the so-called “grandfather date” in order to exempt e-cigarettes, cigars, and other tobacco products now on the market that FDA is beginning to oversee from an important product review requirement. 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 thousands of fruit- and candy-flavored e-cigarettes and cigars, including products in flavors such as cotton candy, gummy bear and fruit punch that clearly appeal to kids.

Supporters of the “grandfather date” rider have portrayed it as a compromise that modernizes the Tobacco Control Act, but it is no such thing. This rider allows a new generation of tobacco products to be grandfathered in and relieves manufacturers of the responsibility to demonstrate that these products are not detrimental to public health.

Assessing the risks to public health of different types of tobacco products and determining how they are regulated is best determined using a science-based approach 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. We are pleased the Senate Appropriations Committee has continued its tradition of keeping its Agriculture appropriations bill clean of riders that limit FDA’s ability to oversee tobacco products, and we urge the full Senate to reject any amendments that would make it more difficult for FDA to address the public health problems that these products cause.

Sincerely,

Academy of General Dentistry
Action on Smoking and Health
American Academy of Family Physicians
American Academy of Oral Medicine
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 Occupational and
Environmental Medicine
American College of Physicians
American College of Preventive Medicine
American Congress of Obstetricians and
Gynecologists
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
Americans for Nonsmokers' Rights
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
Community Anti-Drug Coalitions of America
COPD Foundation
Eta Sigma Gamma - National Health Education
Honorary
Lung Cancer Alliance
March of Dimes
National African American Tobacco Prevention
Network
National Association of County & City Health
Officials
National Association of Pediatric Nurse
Practitioners
National Association of Social Workers
National Hispanic Medical Association
National Latino Alliance for Health Equity
National Network of Public Health Institutes
Oncology Nursing Society
Oral Health America
Prevention Institute
Society for Cardiovascular Angiography and
Interventions
Society for Public Health Education
The Society of State Leaders of Health and
Physical Education
The Society of Thoracic Surgeons
Trust for America's Health