



July 7, 2015

Dear Representative:

We are writing in opposition to Section 747 of the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for Fiscal Year 2016.

This rider would weaken the Tobacco Control Act (TCA) and significantly limit FDA's ability to protect Americans, including children from the many unregulated and untested tobacco products that are currently on the market. By changing the so-called "grandfather date" for these products, Section 747 would exempt them from an important product review requirement and leave FDA with far fewer tools to take prompt action to protect children from the thousands of fruit and candy flavored e-cigarettes and little cigars that flooded the market in recent years.

One of the major purposes of the TCA was to end the ability of the tobacco companies to introduce new, addictive products without any review or oversight. The TCA set a new standard for tobacco products introduced in the market after February 15, 2007. Manufacturers are now required to provide information to FDA so that the agency can conduct a science-based assessment of the risks to public health of a new tobacco product before it is sold. While FDA is trying to catch up to a rapidly changing marketplace and is proposing to assert jurisdiction over all tobacco products like flavored e-cigarettes and little cigars, Congress should not make FDA's job of protecting public health more difficult by allowing these products to remain on the market without FDA being able to conduct a thorough review in the future.

In recent years, tobacco manufacturers have introduced an array of cheap, sweet cigars to get around the prohibition on flavored cigarettes approved by Congress as part of the TCA. At the same time, the e-cigarette market has exploded and now includes more than 7,000 flavors. As a result, youth use of e-cigarettes tripled from 2013 to 2014 (increasing from 4.5 percent to 13.4 percent among high school student) and now exceeds youth use of regular cigarettes. In addition, high school boys now smoke cigars at the same rate as cigarettes (10.8 percent for cigars and 10.6 percent for cigarettes). The proposed appropriations language would make it much more difficult for the FDA to address these threats to our children's health. We urge you to not take away tools FDA needs to protect children.

Just because e-cigarettes and cigars are currently on the market does not mean they are safe and does not justify an exemption from a review by FDA when FDA finally asserts jurisdiction over them. For example, FDA has not assessed the chemicals e-cigarettes emit, the amount of nicotine they deliver, the effect of flavors – from gummy bear to ice cream sundae – on use by teenagers, and other factors to determine whether an e-cigarette will have a detrimental effect on the health of the nation. Exempting these products from product review requirements would take away a tool that FDA could use to take timely action to stop the sale of a dangerous product, require a change in an inaccurate label, or place restrictions on how a product is marketed to reduce the likelihood that youth will use it.

Since the TCA passed in 2009, the tobacco industry has been on notice that it would not be able to flood the market with new products without an FDA review to ensure that they do not attract and addict more children or otherwise harm public health. Congress should not now rush in to protect the industry from a full assessment of the public health impact of the new tobacco products companies have chosen to introduce to the market in recent years.

FDA has already addressed the industry's main concern, which was that e-cigarettes and cigars currently on the market would have to be pulled while FDA is conducting its review. Under FDA's proposal, all e-cigarettes and cigars currently on the market would be permitted to stay on the market as long as they file an application within two years. And during this time companies can also introduce new products. These products will be able to stay on the market until FDA completes its review.

This rider takes away FDA's ability to review each of these products and evaluate whether their continued marketing will negatively impact public health. Further accommodation to the industry is not warranted and has significant potential to undermine the public health of the nation.

Requiring new tobacco products to undergo product review by FDA is not only good public health policy but also strongly supported by the public. A recent national poll by Public Opinion Strategies and The Mellman Group found that 86 percent of voters support requiring tobacco companies to submit any new tobacco products to FDA for review.

We urge you to oppose Section 747 of this appropriations bill.

Sincerely,

American Academy of Family Physicians  
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 Association of Nurse Practitioners  
American Cancer Society Cancer Action Network  
American College of Cardiology  
American College of Occupational and Environmental Medicine  
American College of Preventive Medicine  
American Congress of Obstetricians and Gynecologists  
American Dental 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  
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  
Campaign for Tobacco-Free Kids  
Cancer Prevention and Treatment Fund  
Coalition of National Health Education Organizations  
Community Anti-Drug Coalitions of America  
International Association for the Study of Lung Cancer  
Lung Cancer Alliance  
National Association of County & City Health Officials  
National Physicians Alliance  
Oncology Nursing Society  
Pacific Northwest Chapter of Society for Public Health Educators  
Partnership for Prevention  
Prevent Cancer Foundation  
Society for Cardiovascular Angiography and Interventions  
Society for Public Health Education  
Society for Research on Nicotine and Tobacco  
Society of Thoracic Surgeons  
Trust for America's Health