



May 26, 2015

U.S. House of Representatives
Washington, DC 20515

Dear Representative:

We are writing to express our opposition to H.R. 2058, a bill that would exempt many tobacco products from the requirements for Food and Drug Administration (FDA) review in the Family Smoking Prevention and Tobacco Control Act (TCA), which Congress enacted in 2009. The bill would undermine FDA's ability to protect the public's health from cigars (including little cigars and cigarillos), e-cigarettes, and other tobacco products that are on the market but are not yet under FDA's jurisdiction. It would take away an important tool that FDA could use to make sure that candy- and fruit-flavors now on the market do not increase the number of youth who use these products and make sure that these products meet quality standards. The bill appears to be based on the inaccurate assumption that these products would have to be immediately removed from the market once FDA asserts jurisdiction over them. In fact, FDA has proposed a process that would allow these products to remain on the market until FDA completes its review.

The TCA requires any new tobacco product introduced to the market, or modified, after February 15, 2007, to be reviewed by FDA before it can be sold. By changing the statutory "grandfather" date for tobacco products, H.R. 2058 would exempt from review all currently commercially available tobacco

products that are not yet regulated by FDA. This would be extremely concerning because these products are not subject to any quality controls, and many of these products, including the vast majority of e-cigarettes, are made overseas in countries with no regulatory requirements. There has been no independent assessment of the health risks of the substances these products contain and emit, the amount of nicotine they deliver, the quality of the manufacturing processes used, the effect of flavors on youth, or other factors to determine whether they will have a detrimental effect on the nation's health. This is particularly alarming because use of some of these unregulated products has skyrocketed, particularly among youth. The latest data from the Centers for Disease Control and Prevention (CDC) and FDA revealed that 2 million high school students are current users of e-cigarettes, a tripling from 4.5 percent in 2013 to 13.4 percent in 2014 (it was just 1.5 percent in 2011). Because e-cigarette manufacturers were not required to undergo FDA review prior to introducing new products to the market, FDA was not able to assess whether the thousands of flavors used in these products would likely contribute to the rise in youth e-cigarette use or present other health concerns. This situation clearly illustrates why FDA review is needed.

Review of new tobacco products was included in the TCA because it is a crucial public health protection. The decision to market a potentially addictive and harmful product should not be left to manufacturers alone; an independent science-based assessment by FDA is essential. Cigars (including little cigars and cigarillos), e-cigarettes, and other tobacco products that are on the market, but not yet under FDA's jurisdiction, should not be exempted from this requirement.

To address industry concerns about the effect of applying the TCA to currently unregulated tobacco products that are now on the market, FDA's proposed deeming rule provides that newly-regulated tobacco products would not have to be pulled from the market while FDA is conducting its review. Instead, FDA's proposed rule would allow all cigars, e-cigarettes and other currently unregulated tobacco products to remain on the market as long as manufacturers file an application within two years after the final rule is issued. Companies would also be able to introduce new products during this two-year period. All of these products would be able to stay on the market until FDA completes its review of the required applications and issues appropriate orders.

Congress required every new tobacco product to be reviewed by FDA because even seemingly small changes to a tobacco product can make it easier to use, more appealing to kids, harder to quit, or more harmful. Prior to 2009, when cigarette manufacturers were free to introduce new products without prior review by FDA, cigarettes became more addictive and deadly over time, and "innovative" products like filtered and low-tar cigarettes deterred smokers from quitting while providing no benefit to smokers' health.

Under H.R. 2058, all cigars, e-cigarettes, and other currently unregulated tobacco products that are now on the market would be exempt from having to submit an application to FDA that contains information about the product, how it will likely be used, and by whom. Exempting these products from FDA review would likely make it more difficult for FDA to take timely action to remove a dangerous product from the market, correct an inaccurate label before consumers are misled, or protect Americans from harm.

We urge you to oppose this legislation.

Sincerely,

American Academy of Family Physicians

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 Preventive Medicine

American Congress of Obstetricians and Gynecologists

American Dental Association

American Lung Association

American Psychological Association

American Public Health Association

American Society of Clinical Oncology

American Thoracic Society

Association of Women's Health, Obstetric and Neonatal Nurses

Campaign for Tobacco-Free Kids

Cancer Prevention and Treatment Fund

National Association of County and City Health Officials

Partnership for Prevention

Prevent Cancer Foundation

Society for Cardiovascular Angiography and Interventions

Society for Public Health Education

Trust for America's Health

United Church of Christ, Justice and Witness Ministries