December 2, 2015

The Honorable Paul Ryan
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
Majority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Ryan, Leader McCarthy, Leader Pelosi:

On behalf of the 120,900 members of the American Academy of Family Physicians, and the undersigned organizations representing family physicians from 51 chapters, we strongly urge you to oppose the *FDA Deeming Authority Clarification Act* **(**HR 2058), a bill that would exempt many tobacco products from the requirements for Food and Drug Administration (FDA) review required by the *Family Smoking Prevention and Tobacco Control Act* (TCA), enacted in 2009. The proposed bill would entirely undermine the FDA's ability to review tobacco products, such as cigars and e-cigarettes. As organizations representing family physicians across the nation, we ask you to consider the impacts that FDA's review of these products have on public health.

The TCA gave the FDA the needed authority to regulate the manufacture, distribution, and marketing of tobacco products, while preserving state and local authority to require additional review or restriction. The TCA requires that any new tobacco product introduced, or modified, after February 15, 2007, be reviewed by the FDA before it can be sold. HR 2058 would exempt from review all currently commercially available tobacco products that are not currently regulated by the FDA by changing the statutory "grandfather" date for tobacco products. This would set a concerning precedent for the quality and safety of these products, as well as future products that may enter the market.

Furthermore, the proposed legislation would have far-reaching consequences for states and their ability to regulate tobacco, which furthers our concerns. Many state legislatures have proposed to tie state law to the FDA's deeming authority. Many states look to the FDA for guidance and support in the regulation of tobacco products. Were HR 2058 to pass Congress and be signed into law, the FDA exemptions would extend to state-level oversight. Thus the states would lose any ability to regulate or review tobacco products.

Tobacco use is the leading preventable cause of death and illness in our nation. The e-cigarettes industry is largely unregulated even though the liquid used is nicotine based and toxic. In addition, e-cigarettes clearly are being marketed to children and adolescents and may serve as an introduction to tobacco cigarettes. The latest data from the Centers for Disease Control and Prevention (CDC) and FDA revealed that there are currently 2 million high school students using e-cigarettes, a tripling from 4.5 percent in 2013 to 13.4 percent in 2014 (it was just 1.5 percent in 2011).[1] A recent study in *JAMA: the Journal of the American Medical*

[1] *E-Cigarette use triples among middle and high school students in just one year* (April 16, 2015). Centers for Disease Control and Prevention. Retrieved from http://www.cdc.gov/media/releases/2015/p0416-e-cigarette-use.html.

Association found that students who used e-cigarettes before starting ninth grade were more likely than their nonuser peers to start smoking traditional cigarettes and other combustible tobacco products within the next year.[2] Because e-cigarette manufacturers are not yet required to undergo FDA review prior to introducing new products to the market, the FDA is 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 is a crucial for the protection of public health. Since these products have entered the market, there has not been an 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 if they will have a detrimental effect on the nation's health. The decision to market a potentially addictive and harmful product should not be left to manufacturers alone; an independent science-based assessment by the FDA is essential.

The FDA has worked 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 the FDA is conducting its review. Instead, the FDA has proposed allowing 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 the FDA completes its review of the required applications and issues appropriate orders.

We urge you to oppose HR 2058, exempting these products from FDA review could have an impact on the FDA's ability to address the safety of products and have a potential effect on public health. For any questions you might have please contact Kevin Burke, Director of Government Relations, at 202-232-9033 or kburke@aafp.org.

Sincerely,

American Academy of Family Physicians
Alabama Academy of Family Physicians
Alaska Academy of Family Physicians
Arizona Academy of Family Physicians
Arkansas Academy of Family Physicians
California Academy of Family Physicians
Colorado Academy of Family Physicians
Connecticut Academy of Family Physicians
Delaware Academy of Family Physicians
District of Columbia Academy of Family Physicians
Florida Academy of Family Physicians
Georgia Academy of Family Physicians
Hawaii Academy of Family Physicians

[2] Leventhal, Adam M., PhD; et al. (Aug. 18, 2015) Association of Electronic Cigarette Use With Initiation of Combustible Tobacco Product Smoking in Early Adolescence. *JAMA: The Journal of the American Medical Association,* Vol 314, No 7. Retrieved from: http://jama.jamanetwork.com/article.aspx?articleid=2428954.

Idaho Academy of Family Physicians
Illinois Academy of Family Physicians
Indiana Academy of Family Physicians
Iowa Academy of Family Physicians
Kansas Academy of Family Physicians
Kentucky Academy of Family Physicians
Louisiana Academy of Family Physicians
Maryland Academy of Family Physicians
Massachusetts Academy of Family Physicians
Michigan Academy of Family Physicians
Minnesota Academy of Family Physicians
Mississippi Academy of Family Physicians
Missouri Academy of Family Physicians
Montana Academy of Family Physicians
Nebraska Academy of Family Physicians
Nevada Academy of Family Physicians
New Hampshire Academy of Family Physicians
New Jersey Academy of Family Physicians
New Mexico Academy of Family Physicians
New York Academy of Family Physicians
North Carolina Academy of Family Physicians
North Dakota Academy of Family Physicians
Ohio Academy of Family Physicians
Oklahoma Academy of Family Physicians
Oregon Academy of Family Physicians
Pennsylvania Academy of Family Physicians
Puerto Rico Academy of Family Physicians
Rhode Island Academy of Family Physicians
South Carolina Academy of Family Physicians
South Dakota Academy of Family Physicians
Tennessee Academy of Family Physicians
Texas Academy of Family Physicians
Utah Academy of Family Physicians
Vermont Academy of Family Physicians
Virginia Academy of Family Physicians
Washington Academy of Family Physicians
West Virginia Academy of Family Physicians
Wisconsin Academy of Family Physicians
Wyoming Academy of Family Physicians

CC: United States House of Representatives