May 15, 2018

House Committee on Appropriations
H305 The Capitol
Washington, D.C. 20515

Dear Representative,

We, the undersigned organizations, representing millions of our members and supporters, were disappointed to see that H.R. 1136, the FDA Deeming Authority Clarification Act of 2017, was not added as an amendment to the Fiscal Year (FY) 2019 Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies bill in the Agriculture Appropriations Subcommittee mark-up on May 9, 2018. We urge the Appropriations Committee to amend the FY 2019 Agricultural appropriations bill by adding the language of H.R. 1136.

If the committee does not add this language, which would amend the Family Smoking Prevention and Tobacco Control Act (TCA), the FDA's May 2016 Deeming Rule will go into effect and kill an industry that is helping millions of Americans, who smoke cigarettes, transition to a non-combustible alternative, such as Electronic Nicotine Delivery Systems (ENDS), or e-cigarettes and other vaping products, while killing thousands of jobs in the process.

H.R. 1136, co-sponsored by Reps. Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.), would change the predicate date of February 15, 2007, for newly-deemed tobacco products and provide immediate relief to small businesses from an onerous and retroactive FDA pre-approval process imposed by the Deeming Rule. The FDA has determined that the cost of submitting a Pre-Market Tobacco Application (PMTA) would exceed $300,000 per product. However, other estimates are much higher, ranging from $2 million to $10 million per item, according to the regulatory consulting firm SciLucent LLC. Such exorbitant costs would be prohibitive for most, if not all, of these small businesses.

Fortunately, the FDA recognizes that ENDS products present far less risk than smoking. On July 28, 2017, the agency announced a new regulatory framework to strike "an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes." As a result, the FDA delayed the submission of PMTAs for non-combustible products such as ENDS until August 8, 2022. But, delaying compliance is not a permanent solution. Changing the grandfathered date, as the Cole-Bishop bill would do, will enable the FDA to continue regulating newly-deemed tobacco products without having to take sweeping enforcement action that will remove thousands of life-saving products from the market.

The legislation contains other important provisions, such as mandating that ENDS labels contain the phrase, "Keep Out of Reach of Children" and "Underage Sale Prohibited," requiring an accurate statement of nicotine content, enacting marketing restrictions that keep advertising away from young readers, and telling the FDA to develop product standards for batteries.

Again, we strongly urge the committee add the Cole-Bishop language to the FY Agriculture, Rural Development, FDA, and Related Agencies bill during the mark-up.

Sincerely,

Thomas Schatz
President
Council for Citizens Against Government Waste

Grover Norquist
President
Americans for Tax Reform

Eli Lehrer
President
R Street Institute

David Williams
President
Taxpayers Protection Alliance

Stefan Didak
Founder & President
Not Blowing Smoke

Gregory T. Angelo
President
Log Cabin Republicans

Alex Clark
CEO
The Consumer Advocates for Smoke-free Alternatives Association (CASAA)

Pete Sepp
President
National Taxpayers Union

Gregory Conley
President
American Vaping Association

Julie Gunlock
Senior Policy Analyst
Independent Women's Voice