February 28, 2018

Senate Majority Leader Mitch McConnell
United States Senate
The Capitol, S-230
Washington, D.C. 20510

Speaker of the House Paul Ryan
United States House of Representatives
The Capitol, H-232
Washington, D.C. 20515

Chairman Thad Cochran
Senate Committee on Appropriations
The Capitol, S-128
Washington, D.C. 20510

Chairman Rodney Frelinghuysen
House Committee on Appropriations
The Capitol, H-305
Washington, D.C. 20515

Dear Speaker Ryan, Leader McConnell, and Chairmen Cochran and Frelinghuysen,

On behalf of National Taxpayers Union (NTU) and our members across the country, I urge you to include relief from the Food and Drug Administration's (FDA) 2016 "Deeming Rule" within the FY18 appropriations omnibus legislation. Congress must take action to update this rule, or else tens of thousands of jobs will be at risk of being lost.

On June 22, 2009, President Obama signed the "Family Smoking Prevention and Tobacco Control Act" (Tobacco Control Act) into law. The Tobacco Control Act gave the FDA the authority to regulate manufacturing, distribution and marketing of tobacco products. The Act also gave the FDA authority to regulate pipe tobacco, cigars, electronic cigarettes and vapor products.

The Deeming Rule requires new products that did not exist on or before February 15, 2007 - the predicate date - to be subject to a burdensome review process that achieves little in the way of protections for public health, yet comes at a very high cost. This arbitrary date in the Tobacco Control Act has placed electronic cigarettes and vapor products in regulatory limbo because they were not widely available in the United States until well after 2007. As a result, there are currently thousands of small businesses that are jeopardized by the FDA's overzealous regulation.

Unless Congress acts to push the predicate date back, the FDA's pre-approval process will stifle a burgeoning marketplace that is providing products that help Americans kick their smoking habits. Left unchanged, the predicate date will effectively serve as barrier to entry for small electronic cigarette and vapor manufacturers who, by the FDA's own estimates, will need to file up to 20 applications, taking at least 500 hours of time per application, and each costing approximately $330,000. The small businesses at the heart of the developing electronic cigarette market simply cannot afford these types of regulatory costs.

Congress should promptly consider a bipartisan proposal introduced last year by Reps. Tom Cole (R-OK) and Sanford Bishop (D-GA). Their solution restricts FDA's deeming regulations and the poorly-conceived Premarket Tobacco Application process to e-cigarette products that first went on sale on or after August 8, 2016, with products introduced before that date being allowed to remain on the market under pre-existing regulations.

As countless studies have confirmed, electronic cigarettes are an integral part of the efforts of millions of Americans to beat smoking addiction. Simply put, these products are much healthier alternatives to cigarettes. Unless Congress stops the FDA's efforts to curb a growing market, many of these products will be regulated out of existence. For these reasons, NTU strongly urges Congress to adopt the language proposed by Reps. Cole and Bishop.

Sincerely,

Brandon Arnold
Executive Vice President

25 Massachusetts Avenue NW, Suite 140 ✱ Washington, DC 20001 ✱ Phone: (703) 683-5700 ✱ Fax: (703) 683-5722 ✱ ntu.org