April 23, 2017

Reining in the Food and Drug Administration's May 2016 "Deeming Rule" to Protect Small Businesses and Consumers from Onerous Regulations

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

House Speaker Paul Ryan
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

We, the undersigned organizations, urge you to provide regulatory relief from the Food and Drug Administration's May 2016 "Deeming Rule" as part of the final FY17 omnibus appropriations package. Without a modernization of a provision of the Family Smoking Prevention and Tobacco Control Act (TCA), the Deeming Rule will kill tens of thousands of jobs in an industry that is helping many American smokers transition to lower risk alternatives to combustible cigarettes.

Language and legislation sponsored by Congressmen Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.) modernizes the "predicate date" for newly deemed products, providing urgent relief to small businesses from an onerous and retroactive pre-approval process imposed by last year's Rule. **House Resolution 1136 and the Cole-Bishop Amendment to the current FY17 Agriculture Bill would provide additional substantive protections for adult consumers without preventing the FDA from imposing more appropriate regulations for the product category in the future.**

Congressional action is necessary to prevent the loss of tens of thousands of jobs created in the last four years. Most of these jobs are the result of domestic manufacturing and new retailers that are providing smokers with potentially effective smoking cessation and/or harm reduction choices that were not available ten years ago.

The Deeming Rule requires new products that did not exist on or before February 15, 2007 – the predicate date – to undergo a burdensome pre-market review process that achieves little in the way of protecting public health at a very high cost. **The FDA's own estimates found that the cost of completing and submitting the required Pre-Market Tobacco Application (PMTA) would exceed $300,000 per product and take at least 500 hours of time per application.** At present, the deadline for the submission of PMTAs for each product manufactured in the United States is August 8, 2018.

There are tens of thousands of vapor products that would have to be processed by the FDA and the Center for Tobacco Products in the months following August of next year, a nightmare for the agencies and small businesses involved. That is, if businesses could even afford an attempt at compliance. **Estimates from the startup industry suggest 99% of all businesses would be wiped out unless Congress moves soon to rein in the Deeming Rule's burdensome barriers to approval for new products.**

This onerous process required of every single vapor product on the market today was one that every single manufacturer of cigarettes in the U.S. avoided when the TCA was signed

into law. Even if businesses could afford this investment, however, the process is designed to end in failure. Many small businesses produce hundreds of these products and would be forced to close their doors as a result of this retroactive federal rule.

In his confirmation hearing as FDA Commissioner two weeks ago, Dr. Scott Gottlieb concluded, "There should be reduced harm products available to consumers to transition them off of combustible cigarettes." Dr. Gottlieb recognizes what numerous international health agencies and bodies have – that vapor products are substantially less harmful than cigarettes and should be embraced by the government as low-risk alternatives for smokers. Without a statutory change to TCA by Congress, however, these tens of thousands of smoking cessation products will be illegal in August of next year.

Time is of the essence for many of these businesses, which cannot afford to wait for an administrative delay in deadlines or delayed Congressional action on the 2016 Deeming Rule. The millions of consumers who currently rely on these products as less harmful alternatives to smoking need your help today.

The Cole-Bishop Amendment and House Resolution 1136 would not weaken the TCA or the ability of the FDA to impose additional product standards or regulations on new products in the future. That is precisely why the efforts are bipartisan, because there is recognition that while regulations that protect consumers are important, the Rule imposed burdens that neither protect consumers, nor acknowledge that the consequence will be the new industry's demise.

The inclusion of the Cole-Bishop Amendment, as it passed the House Appropriations Committee, will provide significant regulatory certainty to tens of thousands of small businesses in the United States. We encourage Congress to adopt the language into the final FY17 omnibus budget.

Sincerely,

Grover G. Norquist
Americans for Tax Reform

Julie Gunlock
Independent Women's Forum

Phil Kerpen
American Commitment

Jeff Stier
National Center for Public Policy Research

Dan Schneider
American Conservative Union

Pete Sepp
National Taxpayers Union

Michelle Minton
Competitive Enterprise Institute

Eli Lehrer
R Street Institute

Tom Schatz
Council for Citizens Against Government Waste

David Williams
Taxpayers Protection Alliance

Adam Brandon
FreedomWorks

Evan Swarztrauber
TechFreedom

Joseph L. Bast
The Heartland Institute