AMERICANCOMMITMENT

March 5, 2018

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

THE AMERICAN CONSERVATIVE UNION

AMERICANS for TAX REFORM

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

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

House Speaker Paul Ryan
The Capitol, H-232
Washington, D.C. 20515

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

Dear Republican Leaders and Appropriations Committee Chairmen,

COMPETITIVE ENTERPRISE INSTITUTE

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 FY18 omnibus appropriations package. Without a modernization of a provision of the Family Smoking Prevention and Tobacco Control Act, the Deeming Rule will kill tens of thousands of jobs in an industry that is helping many American adult smokers transition to lower risk alternatives to combustible to cigarettes.

FreedomWorks

Language and legislation sponsored by Congressmen Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.) modernizes the "predicate date" for newly deemed tobacco products, providing regulatory certainty for small businesses against an onerous and retroactive pre-approval process imposed by the 2016 Rule. **The Cole-Bishop Amendment to the current FY18 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.**

FRONTIERS of FREEDOM
Securing the blessings of liberty

Congressional action is necessary to prevent the loss of tens of thousands of jobs created in recent 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, 2022.

independent™ women's forum

When FDA Commissioner Scott Gottlieb extended the deadlines for the submission of PMTAs last year, he explained that it was done in part "to allow the FDA to encourage innovation that has the potential to make a notable public health difference—and to inform

The JAMES MADISON INSTITUTE

future policies and efforts that will protect kids and help smokers quit cigarettes." Gottlieb has also argued that "there should be reduced harm products available to consumers to transition them off of combustible cigarettes," consistent with the international consensus that vapor products are significantly less harmful than cigarettes. **Without a statutory change to TCA by Congress, however, countless smoking cessation products currently on the market will be illegal in 2022.** The ball is in Congress's court and further inaction only stands to harm public health.

The onerous PMTA 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.

The Cole-Bishop Amendment would not weaken the TCA or the ability of the FDA to impose additional product standards or regulations on new products in the future. **In fact, the FDA is already moving forward on additional rulemaking for newly deemed products and this amendment would make the agency's new regulatory objectives, which include preventing youth initiation, attainable.** 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 millions of adult consumers who currently rely on these products as less harmful alternatives to smoking need your help today. The inclusion of the Cole-Bishop Amendment, as passed by 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 FY18 omnibus budget.**

Sincerely,

Phil Kerpen
American Commitment

Julie Gunlock
Independent Women's Forum

Joshua H. Crawford
Pegasus Institute

Daniel Schneider
American Conservative Union

Dr. Bob McClure
James Madison Institute

Carrie Wade
R Street Institute

Grover Norquist
Americans for Tax Reform

Gregory T. Angelo
Log Cabin Republicans

David Williams
Taxpayers Protection Alliance

Michelle Minton
Competitive Enterprise Institute

Pete Sepp
National Taxpayers Union

Ashkhen Kazaryan
TechFreedom

Jason Pye
FreedomWorks

Jonathan Small
Oklahoma Council of Public Affairs

Tim Huelskamp
The Heartland Institute

George Landrith
Frontiers of Freedom