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The Honorable Thomas Price
Secretary, Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: FDA Deadlines Imposed Upon Vapor and Premium Cigar Product Manufacturers

Dear Secretary Price,

I write today to ask for a delay in all future filing deadlines for newly defined tobacco products under the Food and Drug Administration's (FDA) May 2016 "Deeming Rule." The new rules, imposed upon an expanded list of "tobacco" products, subject products like low risk tobacco-free electronic cigarettes and vapor products to compliance requirements so expensive and onerous that by late next year, more than 15,000 jobs created in the last 4 years will disappear. This does not appear to be an unintended consequence, but instead reflects the abject misunderstanding of innovation and harm reduction by the FDA under President Obama.

The new pre-market review requirements also apply to premium cigars and will have a similarly destructive impact on retailers and manufacturers of these products.

Finalized just shy of the deadline for review under the Congressional Review Act, action will be required of both Congress and the Administration to rein in this federal overreach. In 2009 when Congress passed the Family Smoking Prevention and Tobacco Control Act (TCA) - legislation that you opposed - the FDA was granted authority to impose new regulations upon tobacco products such as cigarettes, smokeless and roll-your-own tobacco. A "predicate date" of February 15, 2007 was established whereby products on the market at or before this date were exempt from pre-market FDA review. That look-back period was just over two years when the TCA was signed in 2009. The look-back period for newly deemed products is ten years.

The FDA's May 2016 Deeming Rule requires products which did not exist in 2007 – such as vapor products – to undergo the pre-market review process set up in the TCA. The process was designed to make it extraordinarily difficult to introduce new products to market, which is why it was supported by organizations like the Campaign for Tobacco-Free Kids. Unfortunately, the free market had something else in mind with regards to helping smokers live healthier than did the TCA. With the emergence of smoke-free vapor products, millions of U.S. adults have successfully quit smoking traditional cigarettes with a variety of products that did not exist in 2007.

The FDA regulatory capture sets up an industry which did not exist a decade ago for prohibition, which would be disastrous for both public health and small businesses across the nation.

The most significant of the requirements imposed by the FDA's new Deeming Rule is a requirement that all manufacturers of vapor products submit every product currently available to consumers for pre-market review, a process that every single manufacturer of cigarettes in the United State avoided when the TCA was signed into law. **The Pre-Market Tobacco Application (PMTA) requires businesses to spend in excess of $300,000 per product and at least 500 hours of time per application.** Even if businesses could afford this investment, 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.

The deadline for the submission of PMTAs for each product manufactured in the United States is August 8, 2018. To date, PMTAs have been granted to only one tobacco product manufacturer. There are tens of thousands of vapor (and cigar) products that would have to be processed by the FDA and the Center for Tobacco Products in the months following August of next year. That is, if businesses could even afford an attempt at compliance.

I am asking you to delay the PMTA filing deadline by at least two years as Congress considers an alternative approach to regulating these very low risk products. There are multiple efforts with bipartisan support aimed at addressing the issues I've outlined, including the Cole-Bishop Amendment to the FY17 House Agriculture Appropriations Bill and House Resolution 1136, also sponsored by Congressman Tom Cole (R-Okla.). It is paramount that Congress acts this year to modernize the February 2007 predicate date for newly deemed products on the market.

Though significantly misguided in their policy proposals, even the anti-innovation head of the Campaign for Tobacco-Free Kids has acknowledged the potential health benefit for smokers transitioning to products like vapor products. In testimony to the Senate Commerce Committee in 2014, Matt Meyers noted, "Responsibly marketed and properly regulated, e-cigarettes could benefit public health if they help significantly reduce the number of people who smoke conventional cigarettes and become sick and die as a result." He continued, "I don't think there is any doubt that there would be a reduction in harm."

He made these statements even before the Royal College of Physicians and Public Health England concluded in 2016 that vapor products are at least 95 percent less harmful than cigarettes and should be embraced by the government as low-risk alternatives for smokers.

Time is of the essence for many of these businesses, which cannot afford to wait until next year for a delay in deadlines or a congressional solution to the regulatory capture presented by the TCA and 2016 Deeming Rule. The millions of consumers who currently rely on these products as less harmful alternatives to smoking need your help.

These products are saving lives at no cost to the government or taxpayers. **An immediate delay of all application deadlines and filing requirements for at least two years will provide some regulatory certainty for the thousands of entrepreneurs helping smokers quit without jeopardizing the long-term goals of harm reduction or the effort to federally regulate new and innovative technology products like electronic cigarettes.**

Sincerely,

Grover Norquist
President
Americans for Tax Reform

Cc: Stephen Ostroff, Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
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