Support H.R. 2058 – FDA Deeming Authority Clarification Act of 2015

- H.R. 2058 makes an important technical change to the 2009 Tobacco Control Act (TCA), which granted the FDA regulatory authority over tobacco products and products containing nicotine derived from tobacco.

- Without this change, an ambiguity in the TCA threatens to close thousands of businesses that manufacture, distribute, and retail vapor products and electronic cigarettes. Well over 100,000 products will be banned for no reason other than an inability of the manufacturers to afford a multimillion dollar approval process.

2009 Tobacco Control Act – How the FDA Regulates Tobacco Products

* Under the TCA, the FDA was provided immediate regulatory authority over cigarettes, smokeless tobacco, and roll-your-own tobacco. The TCA permits the FDA, by regulation, to bring other tobacco and nicotine products under its purview.

* The TCA defined February 15, 2007 -- the date the TCA was introduced in the 110th Congress – as the "predicate" date for those products Congress intended for the FDA to regulate. If a product was on the market on February 15, 2007, it was permitted to stay on the market without FDA approval, but the FDA could still regulate these products.

* The TCA further provided that any new product that came to market between February 15, 2007 and the date of enactment (June 22, 2009), or during the 21 months following enactment (before March 22, 2011), was permitted to the stay on the market so long as the product manufacturer filed a **substantial equivalence (SE)** application with the FDA. If the SE application was denied, the product was required to be taken off the market.

* An **SE application** requires a manufacturer to show that their new product is substantially similar to a product on the market before February 15, 2007 in such a way that the product does not raise new questions of public health. Manufacturers of cigarette, smokeless tobacco, and roll-your-own products continue to use SE applications today when attempting to bring new products to market.

* If the FDA denies your SE application, you are required to file a **Pre-Market Tobacco Application (PMTA)**.

* **PMTAs are far more burdensome than SE applications and are expected to cost seven or eight figures per product.** To date, the FDA has not accepted a single PMTA application for cigarettes, smokeless tobacco, or roll-your-own products, indicating that the cost may be prohibitive to even large tobacco companies.

The Deeming Regulation

***** On April 25, 2014, the FDA released its proposed "deeming" regulation. The FDA proposes to regulate vapor products as "tobacco products."

* In the proposed rule, the FDA stated that it would maintain the February 15, 2007 date as the "predicate" date for vapor products and all other products it was proposing to regulate.

* FDA acknowledges that because vapor products are a new technology, sufficient "predicate" products (i.e., an e-cigarette product that was on the market on February 15, 2007) may not exist.

*** Without the availability of "predicate" products, every vapor product on the market would be required to retroactively undergo enormously expensive and burdensome "pre-market" review through the PMTA process.**

* Congress never intended for retroactive application of PMTAs. It makes no sense that immediately regulated products -- which Congress decided were most in need of FDA regulation – get such an advantage over later regulated products.

* FDA claims that it lacks the regulatory authority to change the February 15, 2007 date, even though the FDA has regularly exercised enforcement discretion in its regulation of tobacco and other products.

* For 99%-plus of products on the markets, the FDA's deeming "regulation" will translate to a **ban**.

* While the FDA has proposed a 24-month window for companies to come into compliance, for all but a few well-funded tobacco companies, this is just a delay in their execution.

* The FDA does not deny that its regulation would ban the vast majority of vapor products. The FDA's own economic impact statement estimates that approximately 99% of vapor products will be removed from the market. The number will actually be closer to 99.9%, as there are over 100,000 distinctly different products on the market.

What HR 2058 Would and WOULD NOT Do

* HR 2058 would clarify that the "predicate" date for vapor products and other newly regulated tobacco and nicotine products is to be the effective date of the FDA's proposed regulation. All products on the market could remain on the market, but these products would still be subject to regulation.

* New vapor products could be brought to market under the SE pathway. Rather than February 15, 2007, the "predicate" date will be the effective date of the regulation.

* HR 2058 would NOT stop the FDA from regulating vapor products. It merely prevents the FDA from requiring PMTAs from products that were on the market prior to the FDA's assertion of jurisdiction over the product category.

* If HR 2058 passes, the FDA will be free to set rigorous product standards, good manufacturing standards, require product-specific ingredient disclosures, etc. for all current and future products.