Congress of the United States
Washington, DC 20515

November 24, 2014

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, DC 20201

Dear Secretary Burwell:

We are writing to express our interest in the proposal by the Food and Drug Administration (FDA), published on April 25, 2014, to subject cigars, e-vapor products, and other tobacco products (so-called "deemed tobacco products") to the Tobacco Control Act provisions of the Federal Food, Drug, and Cosmetic Act.

Specifically, we have concerns that the proposed rule's February 15, 2007 grandfather date for newly deemed tobacco products will impede innovation and impose unnecessary regulatory burdens on both the FDA and regulated industries. We request you to consider that it would be inappropriate to apply the current February 15, 2007 grandfather date to newly deemed products.

Importantly, February 15, 2007 was selected as the grandfather date for originally regulated products simply because it was the date the Tobacco Control Act was introduced in the 110th Congress. Should February 15, 2007 remain the grandfather date in the final rule, FDA will create an inequity between currently regulated tobacco products and newly deemed tobacco products.

Because of the passage of time, many pre-February 15, 2007 cigars are unavailable for regulatory comparison. Additionally, most e-vapor products did not exist at that time, meaning there will be virtually no "predicate" products in these categories. Further, FDA did not even consider e-vapor products to be tobacco products until 2011.

Even if such "predicate" products could be found, manufacturers would still be required to file Substantial Equivalence applications with FDA, adding dramatically to FDA's enormous backlog of such applications. As a practical matter, many newly deemed products could be removed from the market. And for those products lacking a "predicate," the cost and barriers surrounding a new product submission would largely prevent new entries, posing an unwarranted regulatory barrier to innovation.

Cigarettes, smokeless tobacco and roll-your-own tobacco did not face this type of barrier to entry because the grandfather date for these products (2007) was about two years prior to regulation (the Tobacco Control Act was enacted in 2009). In contrast, if FDA publishes a final rule next

year, the grandfather date for newly deemed products will be eight years prior to regulation (2015 to 2007).

This is a critical issue, and we request that manufacturers of newly deemed tobacco products have the same market entry opportunities as manufacturers of cigarettes and other currently regulated tobacco products. Specifically, manufacturers of these products suggested in comments to FDA that the grandfather date for them be set at either April 25, 2014 (the date the proposed deeming regulation was published) or the date the final rule is published. We believe either is preferable to the current proposal, as it will treat equally those products regulated in 2009 and those FDA seeks to regulate now. Any final provision on this issue should ensure equity among all regulated tobacco products and encourage innovation while achieving the purpose of the law.

Sincerely,

John A. Boehner
Speaker of the House

Kevin McCarthy
Majority Leader

Fred Upton
Chairman, Energy & Commerce Committee

cc:

The Honorable Margaret A. Hamburg, MD
Commissioner
United States Food and Drug Administration
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