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July 21, 2014

The Honorable Margaret Hamburg, M.D.
Commissioner
The Food and Drug Administration
10903 New Hampshire Avenue
White Oak, RM 322346
Silver Springs, MD 20993

Dear Commissioner Hamburg:

Thank you for your response to my letter expressing concerns regarding the regulation of electronic nicotine delivery devices, including electronic-cigarettes. The subsequent release of the proposed rule that expands the Food and Drug Administration's tobacco authority to cover electronic nicotine delivery devices is a welcomed first step. As you consider the scope and scale of the deeming rule, and subsequent regulation, I encourage you to draft a rule that emphasizes curbing the use of nicotine among our nation's youth.

As you know, recent research indicates that, while cigarette use has fallen among children and adolescents, many more of our young people have sought out alternative sources of nicotine such as hookah, electronic devices, and cigars. Use of these alternative nicotine delivery devices has increased 123% over the past decade.¹ Further, many children falsely believe these nicotine delivery devices are healthier alternatives to cigarettes. The longer we wait for the deeming process to complete, the longer we risk exposing our nation's children to these harmful devices. Accordingly, I urge the adoption of a final deeming rule within 12 months of the issuance of the proposed rule on April 25th so that we can begin curb the growth of nicotine device usage among our youth.

Furthermore, I have several concerns that I urge FDA to consider as the agency moves to finalize its proposed rule. In my initial letter, I highlighted the prolific use of tobacco in "a plethora of flavors attractive to youth such as chocolate, gummy bear, bubble gum, and strawberry," which are commonly found in electronic nicotine devices. Additionally, I noted the use of "celebrity endorsement, sports sponsorship, music artist promotion" in order to appeal to children and adolescents. Due to the growth in child and adolescent experimentation with these alternative delivery systems, I urge FDA to move quickly to ban child-friendly flavorings and youth-oriented marketing practices.

Despite the danger, child-proof packaging is not required for containers of highly concentrated nicotine that are inserted into e-tobacco devices. Currently, nicotine poisoning due to the ingestion of this toxic liquid is on the rise among children. Parents demand common sense rules

¹ Klein, Lorinda. "NYU researchers find 18 percent of high school seniors smoke hookah." *NYU Langone Medical Center / New York University School of Medicine*. American Association for the Advancement of Science EurekAlert!, July 2014. Web. July 7. http://www.eurekalert.org/pub_releases/2014-07/nlmc-nrf070114.php

from FDA which ensure that any container for nicotine liquids is only available on the market in a child-proof design. I ask that you move immediately to address this issue, and require that all nicotine refill cartridges for electronic delivery devices be child proof, before more children are harmed.

Moreover, premium cigars, as with all forms of tobacco, should fall under FDA's direct purview with regard to public health protections and regulatory jurisdiction. According to the Center for Disease Control and Prevention's National Youth Risk Behavior Survey, high school boys now smoke cigars at the same rate as cigarettes, and an alarming 23 percent of male high school seniors smoke cigars. In order to protect our youth from the long-term consequences of tobacco inhalation, these cigars should be subject the same regulatory standards all other forms of tobacco.

The FDA's authority under the Tobacco Control Act is broad, so it is critical that FDA move swiftly to both deem and regulate all nicotine delivery products. Thank you for your attention to this critical issue.

Sincerely,



Rosa L. DeLauro
Member of Congress