

# United States Senate

WASHINGTON, DC 20510

October 21, 2015

Shaun Donovan, Director  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 7<sup>th</sup> Street, NW  
Washington, DC 20503

Dear Director Donovan:

We are writing, more than six years after Congress passed the Family Smoking Prevention and Tobacco Control Act giving the Food and Drug Administration direct authority to begin regulating all tobacco products, to urge the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) to complete its review of the FDA's final tobacco deeming rule as soon as possible. We also strongly urge that the final rule gives FDA authority over all tobacco products, including e-cigarettes, and does not move the "grandfather date" for new products.

As you know, Executive Order 12866 limits to 90 days the period for OIRA review. Yesterday, an FDA spokesman stated that "[w]hile the office has 90 calendar days to review rules, the window could be extended to allow for further interagency discussions." Finalizing this rule cannot wait until 2016. The proposed deeming rule was issued over eighteen months ago on April 25, 2014 and FDA, HHS, and OMB have had ample time to confer.

Every day of further delay is compromising the health of America's youth. According to the Centers for Disease Control and Prevention (CDC) 2014 National Youth Tobacco Survey released in May, e-cigarette use among high school students tripled in the last year, from 4.5 percent in 2013 to 13.4 percent in 2014. In the six years since the passage of the Tobacco Control Act, tobacco and e-cigarette companies have had time to develop new, innovative products, many with candy and fruit flavors, to attract and ultimately addict America's youth.

Due to the impact this rule will have on protecting public health, we urge OIRA to complete its review expeditiously so that FDA can issue the final rule as soon as possible. In Executive Order 13563, President Obama confirmed the need for a transparent and timely review process. Once the deeming rule is final, FDA will be able to regulate new tobacco products in important ways. These include imposing minimum age standards, limits on advertising, and health warnings on the products; requiring the registration of tobacco product manufacturers with FDA; and mandating FDA approval of some novel products.

We urge OMB to work quickly to finalize review of the final deeming rule, ensuring that the rule gives FDA authority over all tobacco products including e-cigarettes and cigars, explicitly bans the use of flavorings and marketing that appeals to children, and mandates child-proof packaging of e-liquids (liquid nicotine). We also implore that the final rule not

move the "grandfather date" for new products (set at February 15, 2007). Altering this grandfather date would exempt a wide range of e-cigarettes and related products from any premarket review to determine whether they constitute threats to public health.

It is critical that the Administration take swift and immediate action to finalize the tobacco deeming rule in order to reduce tobacco's harmful effects on public health, and especially the health of America's youth.

Sincerely,



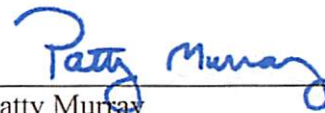
Jeffrey A. Merkley  
United States Senator



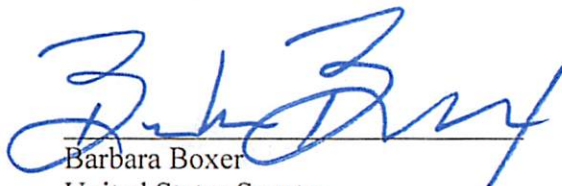
Richard Blumenthal  
United States Senator



Charles E. Schumer  
United States Senator



Patty Murray  
United States Senator



Barbara Boxer  
United States Senator



Edward J. Markey  
United States Senator



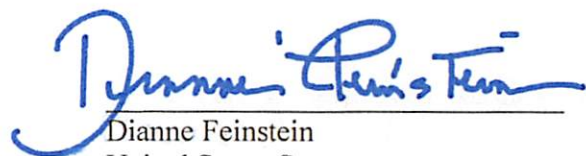
Sherrod Brown  
United States Senator




Richard J. Durbin  
United States Senator



Jack Reed  
United States Senator



Dianne Feinstein  
United States Senator



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Elizabeth Warren  
United States Senator

cc: The Honorable Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services  
Stephen Ostroff, M.D., Acting Commissioner, U.S. Food and Drug Administration