

United States Senate

WASHINGTON, DC 20510

April 18, 2016

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Director Donovan:

It has been nearly seven years since the *Family Smoking Prevention and Tobacco Control Act* (*Tobacco Control Act*) was signed into law. It has been five years since the Food and Drug Administration (FDA) first indicated it would take action to regulate all tobacco products. It has been two years since the FDA formally proposed a rule, called the deeming rule, to extend its authority over all currently unregulated tobacco products, including e-cigarettes and cigars. It has been six months since the FDA sent that rule to the Office of Management and Budget (OMB) for final review, which is past the standard 90 day period for OMB review.

Finalization of this rule is long overdue and we request that OMB complete its review of the FDA's final tobacco deeming rule as soon as possible. Every day that we wait further imperils the health and wellbeing of our nation's children. In just the past two years, e-cigarette use among middle and high school students increased by 2.23 million youth. Your leadership is needed to finish the task and ensure that all tobacco products are regulated.

When the *Tobacco Control Act* was signed into law in 2009, FDA was given the tools to significantly reduce the 480,000 deaths caused by tobacco products each year and the \$170 billion in annual health care costs attributable to treating tobacco-caused disease. The *Tobacco Control Act* gave the FDA immediate authority over cigarettes, smokeless, and roll-your-own tobacco, and it authorized the Department of Health and Human Services (HHS) to deem other tobacco products subject to FDA's jurisdiction. Yet it is now seven years since the law was enacted and the Administration has yet to assert its regulatory authority over e-cigarettes, cigars, and other tobacco products that have serious public health consequences.

Without the assertion of FDA authority under the deeming rule, we have seen irresponsible marketing of products and the use of sweet flavors, like cotton candy, gummy bear, and bubble gum, that clearly appeal to youth. With more than 7,000 of these flavors, it is no wonder that use of e-cigarettes by youth has skyrocketed. According to the Centers for Disease Control and Prevention (CDC) and the FDA, there has been a ten-fold increase in youth use of e-cigarettes between 2011 and 2015, from 1.5 percent to 16.0 percent among high school students and from 0.6 percent to 5.3 percent among middle school students. The CDC estimates that there were 3 million youth e-cigarette users in 2015.

Some in the unregulated cigar industry are also using candy and fruit flavors to make their products more attractive to youth. High school boys now smoke cigars at higher rates (11.5

percent) than cigarettes, making cigars the second most common form of tobacco for this population. Each day, more than 2,500 kids under 18 years try cigar smoking for the first time, and the National Institutes of Health (NIH) recently found that there was a 26 percent increase in large cigar use by 8th graders between 2014 and 2015.

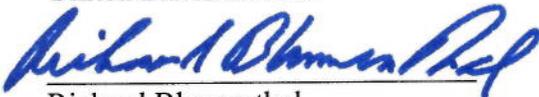
The Administration's final regulation asserting jurisdiction over all tobacco products is long overdue and the health of our nation's youth is being harmed by this delay. Such a long review period may inadvertently serve the interests of big tobacco companies, which have a history of using product design and marketing tactics to attract children to harmful and addictive products.

We ask for your immediate attention and leadership in ensuring prompt action to finalize this regulation in the interest of the public health and especially for the protection of our children. We also ask that the final rule does not carve out or weaken core public health elements of the proposed rule, including those related to flavorings, marketing, minimum age standards, health warnings, manufacturer registration, and new product approval date.

Sincerely,



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator



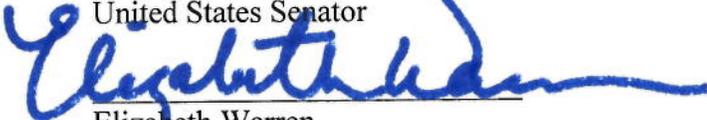
Jack Reed
United States Senator



Tom Udall
United States Senator



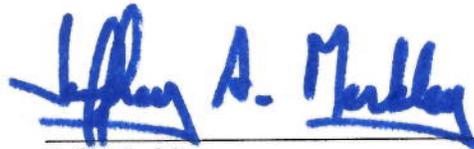
Patty Murray
United States Senator



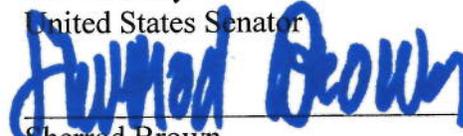
Elizabeth Warren
United States Senator



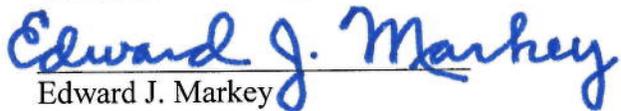
Al Franken
United States Senator



Jeff Merkley
United States Senator



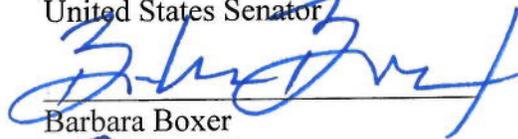
Sherrod Brown
United States Senator



Edward J. Markey
United States Senator



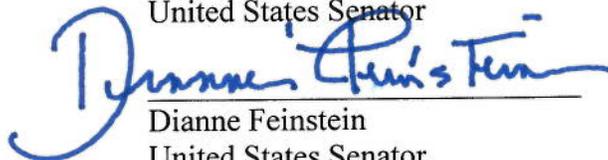
Sheldon Whitehouse
United States Senator



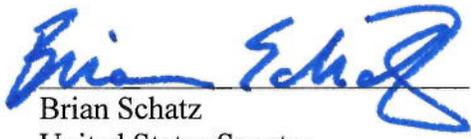
Barbara Boxer
United States Senator



Charles E. Schumer
United States Senator



Dianne Feinstein
United States Senator

A handwritten signature in blue ink, appearing to read "Brian Schatz", written over a horizontal line.

Brian Schatz
United States Senator