# After two years, senators call for finalization of long overdue tobacco regulations

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– Almost two years ago to the day, the Food and Drug Administration (FDA) proposed a rule expanding its authority to include previously unregulated tobacco products like e-cigarettes and cigars. Today, as Big Tobacco continues to develop, market, and sell those products without federal oversight, fifteen Senators called on Office of

Management and Budget (OMB) Director Shaun Donovan to issue a final rule bringing all tobacco products under the FDA's jurisdiction as soon as possible. The Senators wrote, "Every day that we wait further imperils the health and wellbeing of our nation's children."

The Senators also strongly urged FDA not to exempt products or weaken the draft regulations, and called upon OMB to submit a final rule that protects against marketing to minors, the use of flavors, or online sales of e-cigarettes and other nicotine delivery devices to minors.

The proposed rule has languished at OMB – the last phase of approval for federal rulemaking – for more than twice the standard review period. Today, the Senators warned:**"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."** The evidence shows that those tactics are working. Just last week, the 2015 National Youth Tobacco Survey released data showing that a record 3 million U.S. teenagers used e-cigarettes over the last year.

Today's letter was signed by U.S. Senators Dick Durbin (D-IL), Jeff Merkley (D-OR), Richard Blumenthal (D-CT), Sherrod Brown (D-OH), Jack Reed (D-RI), Edward J. Markey (D-MA), Tom Udall (D-NM), Sheldon Whitehouse (D-RI), Patty Murray (D-WA), Barbara Boxer (D-CA), Elizabeth Warren (D-MA), Charles E. Schumer (D-NY), Al Franken (D-MN), Dianne Feinstein (D-CA), and Brian Schatz (D-HI).

Congress gave the FDA the power to oversee various forms of tobacco products more than six years ago, when Congress passed the Family Smoking Prevention and Tobacco Control Act in June 2009. However, it took until April 2014 for FDA to issue draft "deeming" rules that would bring e-cigarettes, cigars, and other forms of tobacco products under the FDA's jurisdiction, and in the two years since, the rules still have not been finalized. As youth e-cigarette use has skyrocketed, the Senators have repeatedly pressed the Administration to finalize the rules in a timely fashion.

*A copy of the today's letter is available here and copied below.*

*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. TheTobacco 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.*