April 13, 2016

The President
The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President:

It has been five years since the Food and Drug Administration first indicated it would take action to regulate all tobacco products and almost two years since the Food and Drug Administration (FDA) formally proposed a regulation to extend its authority over all currently unregulated tobacco products, including e-cigarettes and cigars.

More than a year ago at a Congressional hearing, the Secretary of Health and Human Services indicated that the rule would be finalized by the end of last summer. That did not happen. Last fall, Shaun Donovan, the Director of the Office of Management and Budget, Howard Shelanski, the head of the Office of Information and Regulatory Affairs at OMB, Cecelia Munoz, the Director of the Domestic Policy Council and others met with the leaders of a number of public health organizations and assured us that they understood the urgency of the need to act quickly. More than four months later the rule has not been finalized. Every one of these delays comes with a cost to public health.

Your leadership is needed to finish the task and ensure that all tobacco products are regulated.

Even though we have known for decades the enormous harm that tobacco products cause, until recently FDA was powerless to regulate them. When you signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law in 2009, FDA finally was given the tools to significantly reduce the 480,000 deaths caused by tobacco products each year and the $170 billion in health care costs attributable to treating tobacco-caused disease. Yet it is now seven years since the statute was enacted and your Administration has yet to assert its regulatory authority over all tobacco products.

The Tobacco Control Act gave the FDA immediate authority over cigarettes, smokeless and roll-your-own tobacco, and authorized the Secretary of Health and Human Services to deem other tobacco products subject to FDA's jurisdiction. Until this occurs, there can be no federal oversight of e-cigarettes, cigars and other tobacco products that have serious public health consequences. There are no restrictions in place to protect public health against the risks these products pose, particularly to the health of our children. For example, at present, FDA has no authority to stop manufacturers from using candy and fruit flavors in these tobacco products, or even to disclose their ingredients.

The consequences of not quickly applying FDA's regulatory authority to all tobacco products have been serious. In the absence of regulation, we have seen irresponsible marketing of unregulated products such as cigars and electronic cigarettes and the use of sweet flavors that clearly appeal to youth. E-cigarettes come in more than 7,000 flavors, including cotton candy, gummy bear, bubble gum, and other flavors that appeal to kids. It's no wonder use of e-cigarettes by youth has skyrocketed. According to the Centers for Disease Control and Prevention and the FDA, youth use of e-cigarettes tripled between 2013 and 2014, from 4.5 percent to 13.4 percent among high school students and from 1.1 percent to 3.9 percent among middle school students. The CDC estimates that there were 2.4 million youth e-cigarette users in 2014. The unregulated cigar industry is also using candy and fruit flavors to make their products more attractive to youth. High school boys now smoke cigars at the same rate as cigarettes (10.8 percent for cigars and 10.6 percent for cigarettes).

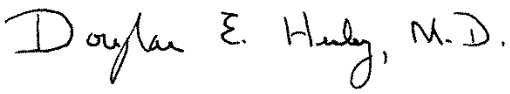
Your Administration's delay in finalizing this regulation has been so great that Congress finally stepped in to address the dramatic increase in poisonings involving liquid nicotine containers for e-cigarettes by enacting legislation to give the Consumer Product Safety Commission the authority to require manufacturers to use childproof packaging for liquid nicotine rather than wait for FDA to respond to this public health concern. The fact that Congress took this action speaks volumes about the level of frustration over FDA's failure to act in a timely manner to protect children.

Your Administration's final regulation asserting jurisdiction over all tobacco products is long overdue. The Office of Management and Budget has been reviewing the final rule for almost six months. This delay is serving the interests of the tobacco companies, which have a long history of using product design and marketing tactics to attract children to harmful and addictive products. We ask for your leadership in ensuring prompt Administration action to

finalize this regulation in the interest of public health and especially for the protection of our children.

Sincerely,

W. Mark Donald, DMD, MAGD
President
Academy of General Dentistry



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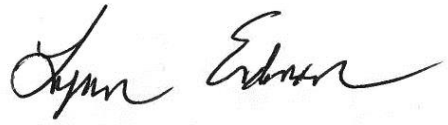

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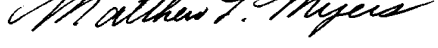

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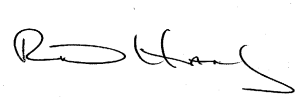

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