

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



April 1, 2014

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

Six months ago today, the Food and Drug Administration (FDA) sent a proposed regulation to the White House Office of Management and Budget to give FDA authority over all unregulated tobacco products. Today, our organizations write to ask you to direct the Office of Information and Regulatory Affairs (OIRA) to release this critical public health proposal and begin the public comment period. The proposal is already two months overdue. Under Executive Order 12866, OIRA had ninety days to complete its review of the proposed regulation with a possible extension of no more than 30 additional days.

In September, our organizations and 10 other leading medical and public health organizations sent you the attached letter asking for your leadership in “ensuring that the Food and Drug Administration moves forward promptly with a rule that would assert the agency’s authority over all tobacco products, including e-cigarettes, little cigars, cigars and other tobacco products not currently under its jurisdiction.”

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) gave the FDA immediate authority over cigarettes, smokeless and roll-your-own tobacco and gave the authority to the Secretary of Health and Human Services to deem other tobacco products subject to FDA’s jurisdiction. Until this occurs, there is no federal oversight of these products, nor restrictions in place to protect the public health against risks posed by these products, particularly to the health of our children. For example, at present FDA has no authority to stop the use of candy-and fruit-flavors in other tobacco products and cannot require the disclosure of the ingredients of those products. There is no reason for further delay.

New and very troubling data from the National Poison Data System show that reports of poisonings caused by accidental ingestion of e-liquids, the liquid containing nicotine used to refill e-cigarette cartridges, tripled from 2012 to 2013 – from 459 to 1,414. Yet this e-liquid remains unregulated. In a March 23 *New York Times* article, Lee Cantrell, director of the San Diego division of the California Poison Control System stated, “it’s not a matter of if a child will be seriously poisoned or killed,” as a result of ingesting e-liquid, “it’s a matter of when.” Indeed, 365 cases of e-liquid poisonings were referred to hospitals in 2013, triple the previous year’s number.

In September, the Centers for Disease Control and Prevention (CDC) released alarming new data about e-cigarette use among youth. In just one year (2011 to 2012), the number of students in grades 6-12 reporting having ever used an e-cigarette doubled from 3.3 percent to 6.8 percent. Current use of e-cigarettes among youth in grades 6-12 also increased from 1.1 percent to 2.1 percent. E-cigarettes come in cotton candy and

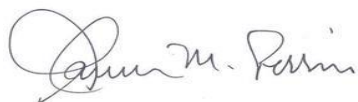
gummy bear, as well as bubble gum, an assortment of children's cereal flavors, grape, apple, strawberry – even in the flavor of Thin Mint, the popular Girl Scout cookie.

There has also been a significant increase – 113 percent – in cigar consumption from 2000 to 2013. Cigar smoking is the second most common form of tobacco use among youth. According to national surveys, 17.8 percent of high school boys currently smoke cigars (i.e., large cigars, cigarillos, and small cigars), and each day nearly 3,000 kids under 18 years old try cigar smoking for the first time. The unregulated cigar and little cigar industry is also using candy and fruit flavors to addict youth.

April also marks the three year anniversary of the issuance of a letter to stakeholders from the directors of FDA's Center for Tobacco Products and Center for Drug Evaluation and Research, when the FDA first publicly indicated that it would propose to expand its authority to include other categories of tobacco products.

This public health regulation is long overdue. We urge you to do everything in your power to enable FDA to initiate the public comment period for this regulation. Further delays will continue to compound the serious public health and medical problems that are occurring as a result of these unregulated tobacco products.

Sincerely,



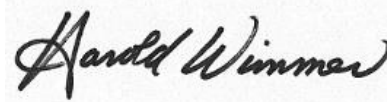
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Harold Wimmer
National President and CEO
American Lung Association



Matthew L. Myers
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Campaign for Tobacco-Free Kids



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Cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
The Honorable Margaret Hamburg, Commissioner, Food and Drug Administration
Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration
Sylvia Mathews Burwell, Director, White House Office of Management and Budget
Howard Shelanski, Administrator of the Office of Information and Regulatory Affairs,
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SAHM
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September 19, 2013

The President
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

We write you today to ask for your leadership in ensuring that the Food and Drug Administration (FDA) moves forward promptly with a rule that would assert the agency's authority over all tobacco products, including e-cigarettes, little cigars, cigars and other tobacco products not currently under its jurisdiction. More than two years ago, FDA announced its intent to take this action, yet no progress has been made. This delay is having very real public health consequences.

This Sunday, September 22, marks, the four-year anniversary of the prohibition of candy-flavored cigarettes. The prohibition of candy-flavored cigarettes was one of the very first measures implemented as a result of the enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which passed the Congress with overwhelming bipartisan majorities and you signed into law on June 22, 2009. As a result, the tobacco industry is no longer able to use candy- and fruit-flavored cigarettes with characterizing flavors such as strawberry, grape, pineapple, chocolate and vanilla to attract and addict our nation's children to cigarettes.

The Tobacco Control Act gave the FDA immediate authority over cigarettes, smokeless and roll-your-own tobacco and gave the authority to the Secretary of Health and Human Services to deem other tobacco products subject to FDA's jurisdiction. Until this occurs, there is no federal oversight of these products, nor restrictions in

place to protect the public health against risks posed by these products, particularly to the health of our children. For example, at present FDA has no authority to stop the use of candy-and fruit-flavors in other tobacco products and cannot require the disclosure of the ingredients disclosure of those products. There is no reason for further delay.

The use of e-cigarettes is increasing, including among youth. The e-cigarette industry is using a number of marketing techniques originally employed by the cigarette companies to addict youth, including the use of candy- and fruit-flavors. E-cigarettes come in cotton candy, gummy bear, bubble gum flavors, Atomic Fireball, orange soda, as well as grape, apple and strawberry. Earlier this month, the Centers for Disease Control and Prevention (CDC) released alarming new data about e-cigarette use among youth. In just one year (2011 to 2012), the number of students in grades 6-12 reporting having ever used an e-cigarette doubled from 3.3 percent to 6.8 percent. Recent use of e-cigarettes among 6-12 year olds increased from 1.1 percent to 2.1 percent. Adults are also reporting greater use of e-cigarettes. CDC estimates that one in five adults have tried an e-cigarette, doubling from ten percent in 2010 to 21 percent in 2011.

Cigarette use declined 33 percent between 2000 and 2011, while the use of large cigars increased 233 percent over this period. Cigar smoking is the second most common form of tobacco use among youth. According to national surveys, 17.8 percent of high school boys currently smoke cigars (i.e., large cigars, cigarillos, and small cigars), and each day more than 3,000 kids under 18 years old try cigar smoking for the first time. Again, the unregulated cigar and little cigar industry is using candy- and fruit-flavored flavors such as Swisher Sweets Sweet Chocolate Blunts, Phillie Sugarillos Cigarillos (described on the box as “when sweet isn’t enough!”), White Owl grape Blunts Xtra, and Optimo peach Blunts.

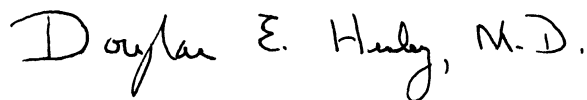
The Tobacco Control Act is already paying health dividends. The FDA has implemented regulations to curb the marketing and sales of cigarettes and smokeless tobacco products to children and is working with states and local governments to enforce the law that prohibits the sale of these products to children. It has also worked to end misleading brand descriptors including light, low and mild. The FDA has also launched a significant research collaboration with the National Institutes of Health to investigate major questions associated with tobacco use.

Given the enormity of the burden of death and disease caused by tobacco products, the public health of our nation cannot afford further delay. FDA must issue a rule to regulate all tobacco products, including cigars, little cigars, e-cigarettes and other tobacco products. We urge you do everything in your power to ensure that FDA takes this action without further delay.

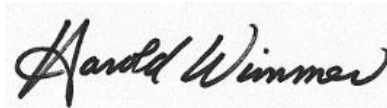
Most respectfully,



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American Academy of Family Physicians



Harold Wimmer
National President and CEO
American Lung Association



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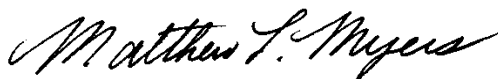
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Cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
The Honorable Margaret Hamburg, Commissioner, Food and Drug Administration
Mitch Zeller, Director, Center for Tobacco Products, Food and Drug Administration