

Congress of the United States
Washington, DC 20515

November 15, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Gottlieb:

While we commend some elements of the Food and Drug Administration's (FDA) newly announced tobacco regulatory framework, particularly the reduction of nicotine levels in cigarettes, we write today to express our strong opposition to FDA's recent announcement that it will delay the review of thousands of e-cigarettes and cigars currently on the market.

As you are aware, tobacco use remains the leading cause of preventable death in our nation, each year killing more than 480,000 Americans and resulting in an estimated \$170 billion in health care expenses. Years of credible research have shown us that tobacco use is primarily established during adolescence, and the CDC estimates that if smoking continues at the current rate among youth, 5.6 million of today's Americans younger than 18 will die early from a smoking-related illness.

We are encouraged by CDC statistics showing that from 2011 to 2016, cigarette smoking rates declined among middle and high school students. Our children should not be using ANY tobacco products, and we as a nation must do everything possible to prevent a new generation of Americans from facing a lifetime of addiction. However, the most recent survey released by the FDA and the Centers for Disease Control and Prevention (CDC) shows that kids are using e-cigarettes, which come in kid-friendly flavors such as vanilla birthday cake and sour apple, at a higher rate than traditional cigarettes. Further, high school aged males smoke cigars, often sold in flavors like chocolate and watermelon, at a higher rate than traditional cigarettes.

Over the last decade, there has been a significant increase in the number of sweet- and candy-flavored tobacco products on the market. A 2014 study cited over 7,700 flavors available and the FDA has acknowledged that e-cigarettes and cigars are being marketed in flavors that appeal to children. As such, we are greatly troubled that your agency plans to delay implementing an important part of the deeming rule: a requirement that e-cigarettes, cigars and other products covered by the rule undergo a scientific review by FDA to ensure that they are not harmful to public health. Instead of requiring manufacturers to submit applications next year, cigar manufacturers would have until 2021 and e-cigarette manufacturers would have until 2022 to submit applications.

This delay endangers our nation's public health and places our kids at unnecessary risk by preventing FDA from removing sweet- and candy-flavored e-cigarettes and cigars from the market as early as next year. In your speech announcing FDA's new regulation, you noted that this delay would allow the agency to put in place a "robust and sustainable framework for regulating the non-combustible forms of nicotine delivery." However, we do not believe this rationale justifies leaving any tobacco product that appeals to kids on the market, and such a justification surely does not apply to small cigars, a combustible product that comes in flavors appealing to children.

Further, we are troubled by your announcement that FDA plans to issue an Advance Notice of Proposed Rulemaking (ANPRM) to examine whether premium cigars should be exempt from FDA oversight. FDA considered this issue during the rulemaking process for the deeming rule and, after a thorough review, determined there is no scientific justification for excluding any cigar from FDA oversight. We strongly believe there is no need to devote limited resources to reexamine this issue.

Despite our serious concerns regarding many aspects of FDA's new tobacco regulatory framework, we strongly support the agency's efforts to promulgate a standard to reduce nicotine levels in cigarettes to non-addictive levels. Such a standard holds great promise to prevent Americans who experiment with cigarettes as children from suffering a lifetime of addiction and tobacco-caused disease. We urge FDA to move forward as soon as possible with a proposed rule regarding nicotine levels in cigarettes and to consider applying that standard to other combustible tobacco products. We also urge you to set a firm deadline for issuing a final nicotine standard.

Finally, we support your call for FDA to issue a product standard regarding characterizing flavors. As FDA's own data have found, characterizing flavors increase tobacco products' appeal to adolescents and are detrimental to public health. Since the agency has already examined and sought public comment regarding the role of characterizing flavors, it is unnecessary and counterproductive for the agency to first issue an ANPRM on this topic. Instead, we encourage you to commit to directly issuing a Notice of Proposed Rulemaking (NPRM) by a date certain.

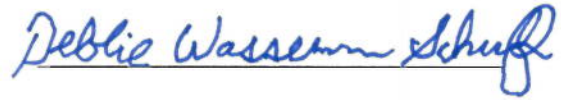
All children deserve a future free of tobacco addiction and the life threatening risks associated with its use. We appreciate your commitment to the health and safety of all Americans and for your attention to this critical matter. We will closely monitor FDA's implementation of its new tobacco regulatory framework to ensure the agency meets our shared goal of protecting our nation's children and the public health of our communities.

Sincerely,



LUCILLE ROYBAL-ALLARD

Member of Congress



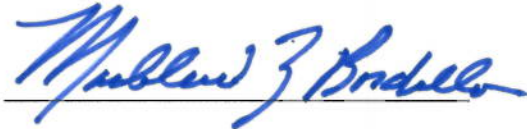
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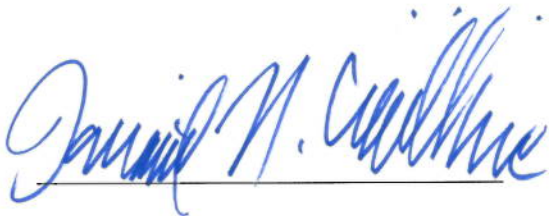
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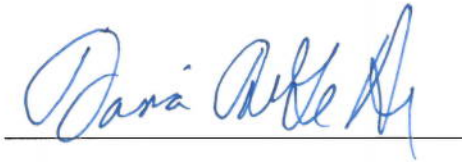
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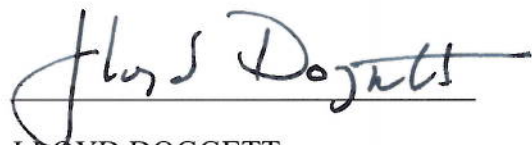
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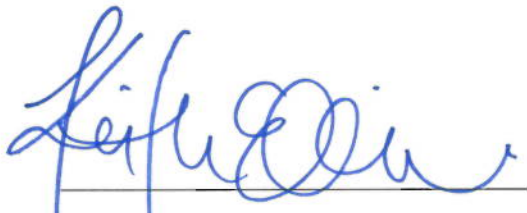
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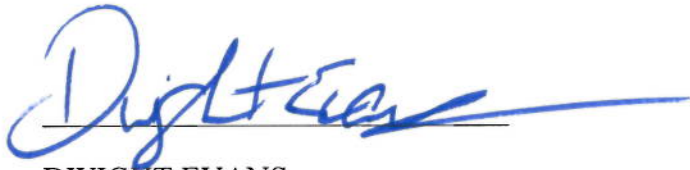
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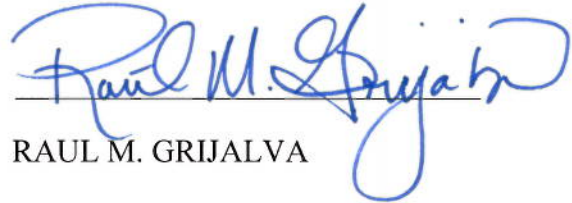
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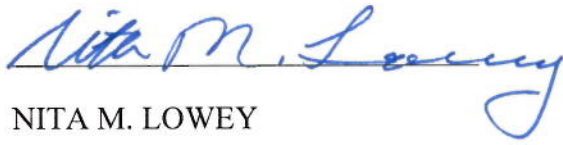
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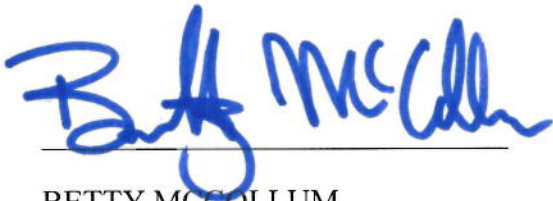
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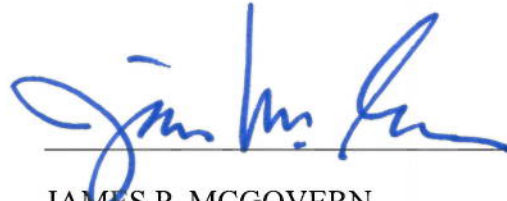
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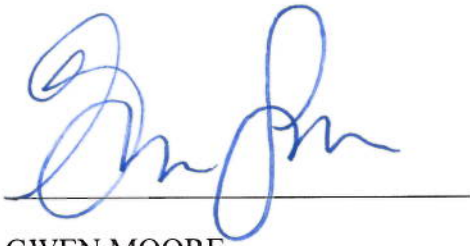
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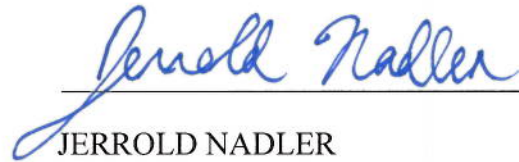
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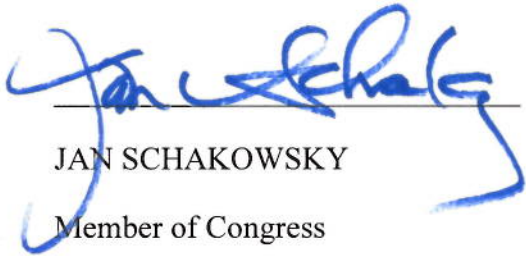
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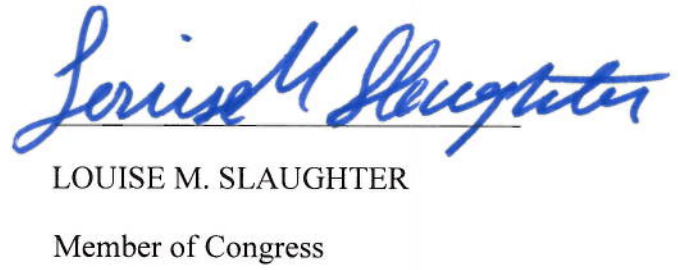


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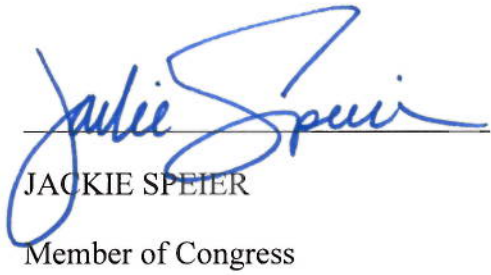
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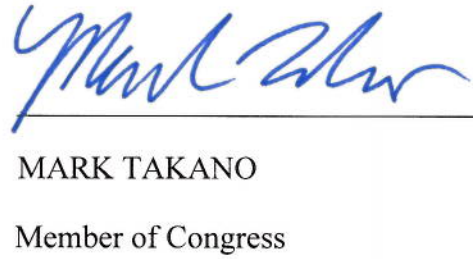
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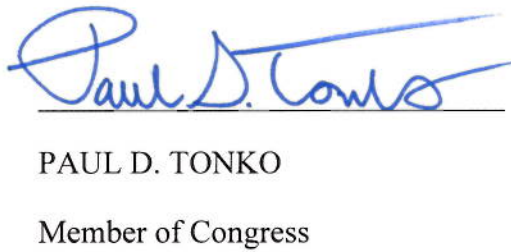
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