

United States Senate

WASHINGTON, DC 20510

June 28, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write with regard to the pending rule related to the Food and Drug Administration's (FDA) regulation of premium cigars under the Food, Drug, and Cosmetic Act. We were pleased to see the FDA's recent announcement to extend the comment period for the proposed rule, as it will give the premium cigar industry and its consumers across the country additional time to provide the FDA with the comprehensive data requested.

We remain troubled with the FDA's regulations under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009 as applied to premium, hand-rolled cigars. The 2009 law aimed to protect the health of the American public and prevent the use of tobacco products by children – goals that we all support and share. However, we have consistently heard from those impacted that the FDA's regulation of premium cigars fails to recognize that these cigars are a unique product with a unique consumer base. We are concerned that additional regulation of premium cigars could force small businesses across the country to close and harm historic, American premium cigar manufacturers that use antique machinery.

As the proposed rule accurately noted, the Population Assessment of Tobacco and Health (PATH) Study analyzing findings from the 2013 and 2014 found that the American population's overall consumption of premium, or traditional, cigars is significantly less than that of cigarettes. Moreover, less than one percent of surveyed youth between the ages of 12 and 17 reported trying a traditional cigar in the prior 30 days compared to over 13 percent experimenting with cigarettes. When it comes to daily use, the PATH Study found no statistically significant use of traditional cigars amongst youth.

With that in mind, we respectfully request that the FDA exempt premium cigars from the FDA's regulations under the FSPTCA and use the definition of a traditional cigar provided in the *Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2017*, bipartisan legislation that we support. Specifically, we ask the FDA to define premium cigars to be:

(a) any roll of tobacco that is wrapped in 100-percent leaf tobacco, bunched with 100-percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and—

(1) has a 100-percent leaf tobacco binder and is hand rolled;

- (2) has a 100-percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or
- (3) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100-percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar.

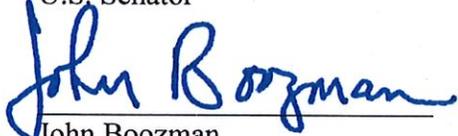
We request that the FDA to exempt premium cigars, as defined above, from these regulations. Any other definition of premium cigars threatens the loss of American jobs. We urge you to provide certainty for manufacturers, retailers and consumers and work with us to maintain this industry's vibrant history in our country.

We thank you for your consideration of this matter and look forward to hearing from you.

Sincerely,



Marco Rubio
U.S. Senator



John Boozman
U.S. Senator



Tom Cotton
U.S. Senator



Joni Ernst
U.S. Senator



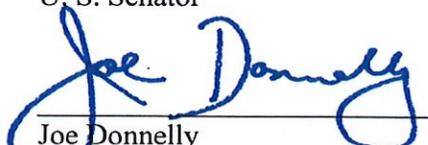
Chuck Grassley
U.S. Senator



Bill Nelson
U. S. Senator



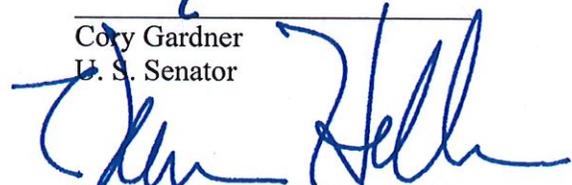
Robert P. Casey, Jr.
U. S. Senator



Joe Donnelly
U. S. Senator



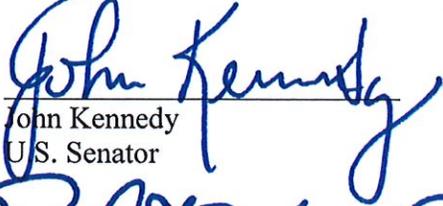
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Dean Heller
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