United States Senate
WASHINGTON, DC 20510–0905
June 7, 2016

The Honorable Robert Califf, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We write to express our disappointment that the U.S. Food and Drug Administration (FDA) declined to acknowledge the differences between mass market cigars and premium cigars in the recently finalized deeming rule to extend regulatory authority over all previously unregulated tobacco products. While we share your desire to protect the health of the American public and support FDA's efforts to help curtail the use of tobacco products by children, we continue to believe that regulation of premium cigars is misguided.

Many of us cosponsored, as well as voted for, the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"), which provided the FDA with the authority to regulate the manufacturing, marketing and sale of tobacco products. One of the guiding principles behind this law was that it would help combat youth and underage smoking by restricting access to tobacco products and prohibiting marketing campaigns that specifically target children. We continue to agree that we must protect youth against harmful tobacco products. However, we strongly believe that large, premium cigars do not fall into this category.

The final rule imposed a number of new requirements on premium cigar manufacturers and retailers, many of whom are small businesses. For example, the final rule requires manufacturers to pursue one of three pathways for pre-market review for all newly deemed tobacco products first sold after February 15, 2007. Depending on which approval pathway is selected, manufacturers have between 12 and 24 months to submit applications and to allow for FDA review. Absent an FDA determination within the original timeframe, products will receive up to an additional 12 months, during which time the FDA can issue a final decision on the application.

Considering the dramatic increase in expected applications (from premium cigars, e-cigarettes, and all other newly deemed products) filed within the allocated amount of time, premium cigar manufacturers are justifiably concerned that the FDA, through the Center for Tobacco Products, lacks sufficient resources to review these applications in a timely manner.

In light of these concerns and others, we are seeking answers to the following questions:

1. What is the Center for Tobacco Products' current backlog for reviewing pre-market review applications? How many total applications have been submitted and how many

have been completed? Of those completed, how many applications have taken longer than 12 months to complete?

2. How many total applications does the FDA anticipate receiving in the 24 months after the rule's pre-market review requirements go into effect?

3. Does the Center for Tobacco Products have a detailed staffing plan in place to accommodate the increase in pre-market review applications resulting from the finalization of the deeming rule?

4. We are concerned that a failure to process applications in a timely manner will result in market disruption and may result in an effective ban on many products. Is FDA considering extending its period of review for any applications and would the FDA allow products to remain on the market while the Agency arrives at a determination?

5. Under the rule, premium cigars manufacturers will need to place warning labels on their products. Will the FDA require that those changes be printed on the box, or will a clearly visible sticker satisfying all of the other requirements suffice?

6. Under the 2009 Tobacco Control Act, any modification of a tobacco product, including a change in design, constitutes a new tobacco product subject to another pre-market review. Will changes to design required by the deeming rule, such as the inclusion of warning labels, render an item a "new product" requiring pre-market approval?

7. It is our understanding that FDA's existing guidance on which changes trigger a new tobacco product application has been very broad and vague. Will FDA issue guidance specifically with regard to premium cigars to explain which changes from a predicate yield a new product?

8. In the final deeming rule, the FDA commits to providing additional guidance that will set out the terms of compliance with some provisions and clarify compliance with others. Will the FDA announce, in advance, the timelines for these additional documents and keep stakeholders up to date on their progress? Will the FDA accept public input into these crucial additional documents?

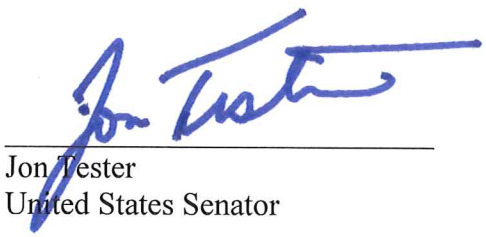
As the FDA begins its work implementing the deeming rule, we urge you to work with the premium cigar industry, many of whom are small business owners, to ensure all parties—manufactures, retailers, consumers, etc.—are able to fully understand and comply with these new rules.

We appreciate your consideration and look forward to hearing from you.

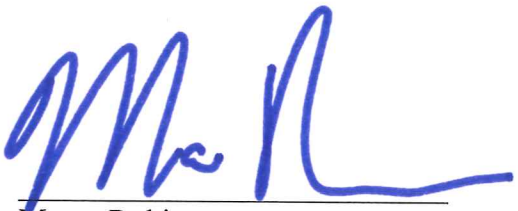
Sincerely,

Bill Nelson
United States Senator

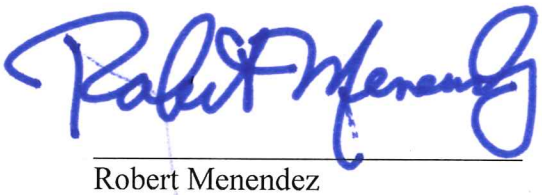
Robert P. Casey, Jr.
United States Senator



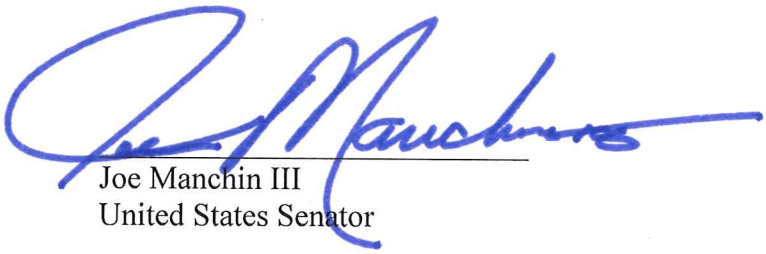
Jon Tester
United States Senator



Marco Rubio
United States Senator



Robert Menendez
United States Senator



Joe Manchin III
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