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Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Exempt Premium Cigars – Update "Premium Cigar" Definition - Docket No. FDA-2017-N-6107 for "Regulation of Premium Cigars."

Dear Commissioner Gottlieb,

Thank you for the opportunity to provide comments relating to the Food and Drug Administration's (FDA) Advanced Notice of Proposed Rule Making (ANPRM) under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is correct that there is significant ongoing interest, including great interest in my congressional district and by many members of Congress, in the exclusion of premium cigars from excessive regulation and regulation that runs counter to the aims of the Tobacco Control Act. The legislative intent of the Tobacco Control Act is rooted in the important objective of preventing youth access to tobacco products and the adverse health effects of tobacco and nicotine. As a member of Congress who voted for the Tobacco Control Act, it is clear that the 2016 FDA final deeming rule relating to premium cigars was flawed as the agency did not recognize the evidence that premium cigars rarely are used by youth and that the pattern of use overall is infrequent and thereby warrants exclusion. Thank you for the opportunity to comment specifically on the definition of "premium cigar" and offer for consideration recent studies that demonstrate premium cigars are not marketed towards children and are consumed at a rate that warrants exclusion.

In response the FDA's request in the ANPRM for comments on the definition of "premium cigar", FDA should incorporate the definition of a "premium cigar" that has been developed over a number of years to ensure it excludes tobacco products that are marketed towards children and that are smoked on a frequent basis. Such a definition is contained in legislation that I have sponsored over the last four sessions of Congress and which is currently before the 115th Congress as H.R.564, the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act. It is supported by 145 members of Congress, is grounded in a rational basis and is accepted widely, to wit:

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; and

b. does not include a cigarette or a little cigar

This definition is narrowly-tailored to apply to a very small subset of tobacco items. It purposefully does not contain or allow flavored cigars or little cigars that have been found by FDA to be marketed to children and smoked on a frequent basis. The premium cigar industry is estimated to be roughly 0.01% of the overall tobacco industry according to the Cigar Association of America and the New England Journal of Medicine reports that only 0.4% of the adult population in America smokes traditional (premium) cigars frequently. [1]

In addition to the narrow definition of "premium cigar" that if adopted would limit exclusion to a very small subset of tobacco items, I encourage FDA to recognize premium cigars are consumed in moderation, often infrequently, and have never been marketed to children, and therefore fit neither of the underlying aims of the Tobacco Control Act. By-and-large, premium cigars are sold in small business retail stores, often family-owned, who are proud of their record enforcing existing laws preventing sales of tobacco products to underage individuals. In fact, recent studies support this. A recent report published in the New England Journal of Medicine, written by the Center for Tobacco Products (CTP) and funded by FDA, demonstrated no correlation between premium cigars and underage initiation to tobacco products. Further, another report published in Oxford University Press' Nicotine and Tobacco Research, written by the CTP and funded by the FDA established that 80% of premium cigars are purchased at either specialty stores or cigar bars. Finally, the U.S. Centers for Disease Control and Preventions (CDC) Morbidity and Mortality Weekly Report confirms that premium cigars are smoked infrequently.

FDA also must take into consideration the recent explication of the general issues involved with the 2016 FDA final deeming rule in *CAA v. FDA*. Judge Mehta of the U.S District Court for the District of Columbia, in dicta, expressed skepticism about the broader question of FDA fairness in the continued regulation of premium cigars. Indeed, within the undercurrent of the court's language there is expressed an impatience with the course it must follow as a court of law, when the equities flow towards the plaintiffs. Judge Mehta appraises the reopening of the rule in general, "[A] change in an agency's course in reaction to new information does not indicate that its initial course was *necessarily* arbitrary and capricious when charted." (emphasis added) p.47. Further, the court observes that an agency's reappraisal is not "smoking gun" evidence that its earlier

[1] New England Journal of Medicine Supplementary Appendix to: Kasza KA, Ambrose BK, Conway KP, et al. Tobacco-product use by adults and youths in the United States in 2013 and 2014. N Engl J Med 2017;376:342-53. DOI: 10.1056/NEJMsa1607538

actions were not consistent with evenhandedness. At another point, the Judge expresses his frustration that the court's hands are tied in dealing with the larger question of regulation since the plaintiffs agreed to defer litigating it. Consistent with this other influential dicta, Judge Mehta also writes, "the ANPRM reaffirms that, at the time of the original rulemaking, there was a lack of evidence to justify differential treatment for premium cigars". As you can see above, such studies are available, and it is incumbent on the FDA to take the time to review this information and assess the extent that they fill the deficiencies expressed in launching the ANPRM.

I appreciate the opportunity to offer information for the FDA's consideration. The clear legislative intent of the Tobacco Control Act is to focus on products marketed towards children. The FDA studies cited above and the practices in my district that I have observed for decades establish that premium cigars are not used by or marketed to children and are not used on a frequent basis by adults. This leads to a strong conclusion that premium cigars should be excluded from the Tobacco Control Act's scope. Because regulation of premium cigars, a very small subset of tobacco products on the market, runs counter to the intent of the Tobacco Control Act, FDA should exclude this tiny niche of the market from regulation.

Sincerely,

Kathy Castor

Kathy Castor
U.S. Representative
Florida – District 14