

July 25, 2018

Scott Gottlieb, M.D., Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. ID: FDA-2017-N-6107 Regulation of Premium Cigars

Dear Commissioner Gottlieb:

Reason Foundation is grateful for the opportunity to submit this comment regarding the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking on the Regulation of Premium Cigars.

Reason Foundation's nonpartisan public policy research promotes choice, competition and a dynamic market economy as the foundation for human dignity and progress.

Introduction

FDA has requested comments relating to the definition of premium cigars, use patterns, and other public health considerations associated with premium cigars. FDA faces a number of challenges when assessing any tobacco or nicotine product. Premium cigars present a special challenge as they are not a reduced risk nicotine product such as Electronic Nicotine Delivery Systems or a consistent cause of death for hundreds of thousands of Americans.

FDA has recognized there are a series of considerations that mark out premium cigars in the tobacco market. The high price point, unique user experience, confined and limited consumption, and lack of appeal to youth are all factors distinguishing premium cigars from other tobacco products. Unlike other tobacco products, little concern has been raised either by the FDA or by public health bodies about the marketing of practices of premium cigars. Premium cigar marketing tends to be restricted to select publications and venues that target adults and have little to no interaction with minors.

Given the unique profile premium cigars enjoy in the tobacco market and the lack of a distinguishable threat to public health it is proper that premium cigars be treated differently from other tobacco products when it comes to FDA regulation. For instance, it would be wholly inappropriate to apply a maximum nicotine standard to premium cigars, as nicotine is not, for most consumers, the main appealing ingredient in these products and premium cigars would be a costly and burdensome way to satisfy nicotine addiction, especially if safer and more affordable alternatives are available.

Given the remarkably low use rates, which are almost entirely confined to informed adults, with no market failures apparent, FDA has little reason to impose new regulations on premium cigars. Moreover, doing so would only serve to damage U.S. cigar companies and reduce consumer welfare for no discernable public health benefit.

Definition of Premium Cigars

FDA draws attention to the fact that the existing scientific literature is inconsistent when it comes to the definition of what counts as a premium cigar. This is concerning both for purposes of research and possible regulation. There is no doubt, however, that there are several characteristics which distinguish premium cigars from other cigar products. When considering any possible definition of premium cigars, it's important that such a definition is based on the characteristics of the product itself, not on measures outside the product such as price or use patterns. Basing a product definition on anything outside the characteristics of the product itself could threaten legitimate products with exclusion from the definition, would need constant updating and adjustment, monitoring and oversight, and would fail to account for market dynamics.

There is little need for either price or use patterns be accounted for when defining premium cigars, as the product characteristics themselves are a major factor in the price, which is substantially higher than non-premium cigar products, and use patterns, which are low and concentrated among adults.

There are several factors which could contribute to the definition of a premium cigar. FDA has itself listed what these may be when it published an ANPRM regarding the Deeming Rule in April 2014. To count as a premium cigar, FDA suggested it would have to be wrapped in whole tobacco leaf, contain a 100 percent leaf tobacco binder, contain primarily long filler tobacco, is made by combining manually the wrapper, filler, and binder, has no filter, tip, or non-tobacco mouthpiece and is capped by hand, has a retail price (after any discounts or coupons) of no less than \$10 per cigar, does not have a characterizing flavor other than tobacco and weighs more than 6 pounds per 1000 units.¹

In addition to these considerations, FDA should take account of what the industry itself recognizes as a premium cigar, which would include the humidity needed to store such cigars. Premium cigars generally need to be stored in 65-70 percent humidity. New Hampshire law

¹ Food and Drug Administration. "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products." April 25, 2014.

<https://www.federalregister.gov/documents/2014/04/25/2014-09491/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the>

makes a similar distinction stating that “these [premium] cigars shall be kept in a humidor at the proper humidity.”²

Many of the characteristics listed by FDA give an accurate profile of what should be considered a premium cigar. However, using a retail price as part of a product definition is wholly inappropriate. While it’s certainly true that premium cigars retail for significantly more than their non-premium competitors, there is a wide range of prices within the industry and it is by no means clear the majority or even a plurality of premium cigars retail for \$10 or more. According to analysis by Econostat, the median price paid per premium cigar is \$7.49. Handcrafted cigars on the lower end of the market can price at \$5-\$8, while at the high end they can sell for \$40-\$50 per cigar, or more.³

Requiring a minimum retail price for premium cigars would unfairly disadvantage some companies over others and reduce competition. Furthermore, it would present difficulties for FDA as to how such a price is to be measured. Would such a price standard apply before or after state tobacco taxes, for example?

Patterns of use

FDA has noted that use patterns of premium cigars differ substantially from other tobacco products, particularly combustible cigarettes. The primary appeal of premium cigars is neither nicotine or price but rather their flavor and the broader user experience. This should be taken into account when considering the propriety of any possible regulation.

Based on the 2017 census data, it is estimated that the prevalence of premium cigar consumption among adults is 0.7 percent, amounting to a total of 1.7 million people.⁴ Of these, 6.7 percent are daily premium cigars smokers, meaning just 0.05 percent or 113,900 adults are daily premium cigar smokers.⁵ This makes premium cigars one of the least used tobacco products on a daily basis. Regular and daily premium cigar use is almost exclusively confined to a small section of the adult population who are enthusiasts for these products.

In terms of dual use, the 2012-2013 National Adult Tobacco Survey shows 35.1 percent of premium cigar smokers currently smoke cigarettes, 23 percent are former cigarette smokers,

² Rutherford, Charlie. “Our Thoughts On What Makes a Cigar "Premium." Boveda.
<https://bovedainc.com/thoughts-makes-cigar-premium/>

³ Holt’s Staff. “How Much Do Cigars Cost?” *Holt’s Clubhouse*. Nov. 2, 2017.
<https://www.holts.com/clubhouse/cigar-culture/cigar-prices-how-much-do-cigars-cost>

⁴ Corey, C.G., Anh B. Nguyen, Cristine D. Delnevo, et al. “US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014.” <https://www.ncbi.nlm.nih.gov/pubmed/29059423>

⁵ Corey, C.G., Brian A. King, Blair N. Coleman, et al. “Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults—United States, 2012 – 2013.” *MMWR* 63, no. 30 (2014): 650 – 654.

and 41.9 percent have never been cigarette smokers.⁶ Putting that numerically: out of 3.6 million U.S. adults who use premium cigars, 1.26 million currently smoke cigarettes, 828,000 formerly smoked cigarettes, and 1.5 million are never cigarette smokers. The scale of the total premium cigar market is also vastly smaller than that for combustible cigarettes. According to the Cigar Association of America, 330 million premium cigars were imported in 2017,⁷ whereas 249 billion cigarettes were sold in the same years.⁸ While active measures should be taken to prevent youth use of any tobacco product, premium cigars are one of the least used tobacco products by minors. According to a study of wave one data from 2013-14 Population Assessment of Tobacco and Health published in 2017, 2.3 percent of youth reported ever having used a traditional cigar, 0.7 percent reported use in the past 30-days, and there was too little data for daily use to be reliably measured.

Premium cigars are also rarely the first tobacco product ever used by youth.⁹ For 10-14 year-olds who have used any tobacco product, only 1.5 percent report premium cigars as their first tobacco product use. The figure is only marginally higher for 15-17 year-olds, at 4.5 percent. According to the available data, the age of initiation for cigar smoking is substantially higher than for other tobacco products, with 60 percent of cigarette smokers reporting initiation at the ages prior to 18 whereas only 24.6 percent of those who had smoked more than 50 cigars in their lifetime had started prior to age 18.¹⁰

Public Health Considerations

Premium cigars, like any combustible tobacco product, present risks to their users. But the public health risk of premium cigars is fundamentally different from that of combustible cigarettes. Cigars tend toward mouth puffing and as has been discussed are for the most part smoked occasionally rather than daily. Cigarettes, on the other hand, are inhaled and more often than not smoked daily. It is these characteristics of premium cigar smoking, rather than the constituents of the tobacco smoke itself, which account for the dramatic differences in mortality risks seen between cigar smokers and cigarette smokers.

⁶ Ibid.

⁷ Mottola, Gregory. "U.S. Imports 330 Million Premium Cigars In 2017, Most Since 1998; Nicaragua Named Biggest Supplier." Cigar Aficionado. March 21, 2018.
<https://www.cigaraficionado.com/article/u-s-imports-330-million-premium-cigars-in-2017-most-since-1998-nicaragua-named-biggest-supplier>

⁸ Centers for Disease Control and Prevention. "Economic Trends in Tobacco." May 4, 2018.
https://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm

⁹ Soneji, Samir, James Sargent and Susanne Tanski. "Multiple Tobacco Product Use Among U.S. Adolescents and Young Adults." *Tobacco Control* 25 (2016): 174-180.
<https://tobaccocontrol.bmj.com/content/25/2/174>

¹⁰ Gerlach, Karen K. Et al. "Monograph 9: Cigars: Health Effects and Trends." *National Cancer Institute Division of Cancer Control and Population Sciences*. Feb. 1998.
<https://cancercontrol.cancer.gov/brp/tcrb/monographs/9/index.html>

In 2015, a systematic review of the risks of cigar smoking led by FDA showed a modest increase in risks for all-cause mortality from cigar smoking.¹¹ However, mortality risks from cigar smoking varied by level exposure as measured by cigars smoked per day and levels of inhalation. Research conducted by FDA's Center for Tobacco Products shows primary cigar smokers use one and a half cigars per day when they smoke.¹² According to the studies contained within the 2015 review, the relative risks for smoking one to two cigars per day are elevated but not statistically significant.¹³ Exclusive cigar smokers do have an elevated risk of death compared to nonsmokers, but it is five to ten times lower than it is for exclusive cigarette smokers.¹⁴ In terms of marketing, premium cigars advertising is mostly limited to publications and venues which cater to adult cigar enthusiasts like Cigar Aficionado, Cigar Journal, Cigar Press, Sand Cigar Snob. There is no suggestion that premium cigar companies are in anyway marketing to minors.

Regular cigar use is certainly dangerous and occasional cigar may raise still raise risks. But given the unique use patterns of premium cigars and almost exclusive concentration in the adult population, there is little reason for FDA to propose new rules regarding the regulation of these products.

Conclusion

Public Health cannot simply amount to the aggregate private health risks that emerge from the informed preferences and choices of consumers. For FDA to fulfill its duty to regulate tobacco products based on a public health standard that considers the risks and benefits of tobacco products on the population as a whole, there must be some risk to the population as a whole posed by those products. Premium cigars clearly do not fall into that category.

Not only are these products almost exclusively used by adults, they are used by a tiny subset of adults. As of yet, there appears to be no market failure in the premium cigar market for which FDA must act to correct. We urge FDA to refrain from proposing any rules which would disrupt

¹¹ Chang, Cindy M et al. "Systematic review of cigar smoking and all cause and smoking related mortality," BMC Public Health. 24 April, 2015.

<https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-015-1617-5>

¹² Chen J et al. "Biomarkers of exposure among U.S. cigar smokers: an analysis of 1999-2012 National Health and Nutrition Examination Survey (NHANES) data," Cancer Epidemiology, Biomarkers & Prevention. December, 2014.

<https://www.ncbi.nlm.nih.gov/pubmed/25380733>

¹³ Rodu, Brad. "FDA Study: Cancer risks nearly nil for 1-2 cigars per day," R Street Institute. August 24, 2016.

<https://www.rstreet.org/2016/08/24/fda-study-cancer-risks-nearly-nil-for-1-2-cigars-per-day/>

¹⁴ Christensen, Carol H. et al. "Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population," JAMA Internal Medicine. 2018;178(4):469-476.

<https://www.ncbi.nlm.nih.gov/pubmed/29459935>

the current success of the U.S. cigar industry and damage the welfare of adult cigar smokers for no clear public health gain.

Sincerely,

Guy Bentley, Research Associate