July 16, 2018

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm 1061
Rockville, MD 20852
Via https://www.regulations.gov

Re: Docket No. FDA-2017-N-6189: Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

This submission is in response to the Advance Notice of Proposed Rule Making on Tobacco Product Standards for Nicotine Levels of Combusted Cigarettes. We provide information relevant to A. Scope, specifically the following sections of the ANPRM:

**IV.A.1.** If FDA were to propose a product standard setting a maximum nicotine level, should such a standard cover other combusted tobacco products in addition to cigarettes? If so, which other products? What criteria should be used to determine whether, and which, products should be covered?

**IV.A.2.** Some suggest that large cigars and those cigars typically referred to as “premium” cigars should be regulated differently from other cigars, asserting that they are used primarily by adults and their patterns of use are different from those of regular cigars (81 FR 28973 at 29024). FDA requests information and data on whether large and/or so-called premium cigars should be excluded from a possible nicotine tobacco product standard based on asserted different patterns of use, and whether large and/or so-called premium cigars would be migration (or dual use) candidates if FDA were to issue a nicotine tobacco product standard that excluded premium cigars from its scope. FDA also requests data and information on whether and how there is a way that, if FDA were to exclude premium cigars from the scope of a nicotine tobacco product standard, FDA could define “premium cigar” to include only unlikely migration or dual use products and thereby minimize such consequences.

Along with cigarettes, the nicotine product standard should include additional combusted tobacco products regulated by the FDA. Given that that inhalation of smoke from burning tobacco remains the most dangerous tobacco use behavior and that cigarettes are not the only form of combusted tobacco use, the nicotine product standard should include other combusted tobacco products regulated by the FDA. While the current proposal includes only cigarettes, FDA acknowledges that "some number of addicted smokers could migrate to other similar combusted tobacco products to maintain their nicotine dose (or engage in dual use with other combusted tobacco products), potentially reducing the positive public health impact of such a rule."[1]

An important criteria for the inclusion of specific tobacco products in a low nicotine standard should be the extent to which the product is likely to be used as substitutes for traditional cigarettes. Many of the combusted products on the market should be regulated to levels like those proposed for cigarettes given their potential to act as substitutes for cigarettes. In their modeling of the impact of the low nicotine standard, FDA

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researchers included roll your own tobacco (RYO), pipe tobacco and mass produced cigars as cigarette substitutes, but did not consider hookah or premium cigars. A robust literature on cigarettes and product substitutions exist largely in the context of cigarette price and taxation. Most recently, Huang et al., using multiple years of Nielsen market scanner data found that RYO tobacco, pipe tobacco, filtered cigars, and cigarillos are all substitutes for cigarettes. Based on the criterion of substitutability, we suggest these products should be included:

**Roll your own and pipe tobacco are highly likely substitutes for traditional cigarettes and should be included in a low nicotine standard.** That RYO as well as pipe tobacco are substitutes for cigarettes is evident given that the product is easily utilized to make man made cigarettes and the internet provides the consumer with step by step instructions on how to do so. Consumption of RYO and pipe tobacco “man-made” cigarettes has been shown to increase when the price of traditional factory made cigarettes are increased. Additionally, to exclude RYO or pipe tobacco could give the public the false impression that somehow hand-rolled cigarettes are not as harmful as machine-rolled cigarettes.

**Little and filtered cigars are highly likely substitutes for traditional cigarettes and should be included in a low nicotine standard.** Obvious tobacco product for cigarette substitution are little and filtered cigars. Often made on the same rolling machines as cigarettes, these cigars have features common to cigarettes, such as shape, size (length 70-100 mm), and cigarette-like tipping paper and filters, including ventilation in filters similar to "light" cigarettes. Moreover, recent data from the PATH survey reveal that filtered cigar smokers are especially likely to be dual cigarette smokers and they endorse affordability as a primary reason for smoking filtered cigars.

**Cigarillos and non-premium cigars are likely substitutes for traditional cigarettes and should be included in a low nicotine standard.** Until fairly recently, despite a wide variety of cigar products on the market-ranging from little filtered cigar to midsize cigarillos to large premium cigars, tobacco research has predominately lumped these products into one category. As such, there is limited data on mass produced cigarillos, which are slightly larger than traditional cigarettes but are small enough that they can be smoked similarly to cigarettes. One of the few econometric studies that disaggregates the cigar market finds a positive cross-price elasticity between cigarettes and cigarillos, indicating potential substitution between the two products. Population data on patterns of use can also be valuable. The potential for cigarette substitution is

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5 Brown AK, Nagelhout GE, van den Putte B, Willemse MC, Mons U, Giugnard R, Thompson ME. Trends and socioeconomic differences in roll-your-own tobacco use:findings from the ITC Europe Surveys. Tob Control. 2015
6 Byron, M., Strasser, A., & Delnevo, C. (In Press) Little and filtered cigars meet the legal definition of cigarettes and should be included in nicotine reduction regulation. Tobacco Control.
high when different tobacco products can be utilized in a similar fashion. Dual use patterns can reveal this potential product substitution. According the 2014 National Survey on Drug Use and Health, 11% of past 30-day cigarette smokers in the United States are dual users with cigars and a high proportion of these users report smoking Black & Mild and Swisher Sweet (popular cigarillo brands). This data is in accord with other studies which suggest that roughly 1 in 10 cigarette smokers are dual users of cigars.¹⁰

**We caution that if a low nicotine standard is not extended to likely combustible tobacco cigarette substitutes, the industry will leverage regulatory loopholes, which will compromise the intent and public health goal of the standard.** The history of the filtered cigar provides the FDA with an important lesson learned about unintended consequences. We have published extensively on this issue and briefly highlight the importance of avoiding a low nicotine regulatory loophole. As a tobacco product class, filtered cigars have historically had a number of policy and regulatory advantages compared to cigarettes.¹¹ In the context of these differences, the tobacco industry has exploited legislative and policy loopholes to market their products as cigarette substitutes. Indeed, in the 1970s, R. J. Reynolds created a filtered little cigar, explicitly for cigarette smokers, to circumvent the broadcast ban for cigarette on television; in the early 2000s, filtered cigar companies explicitly marketed their products as cigarette substitutes and leveraged price differentials given Master Settlement Agreement escrow payments and high taxes on cigarettes; and more recently a clove cigarette company circumvented the FDA ban on flavored cigarettes by creating a clove filtered cigar.⁷,¹²,¹³ The tobacco industry has historically shown resourcefulness and skill in minimizing the effects of regulations. Moreover, the filtered cigar industry has repeatedly shown that any loophole or exemption will be exploited. As such it is highly probable that in the context of a low nicotine standard for cigarettes, filtered cigar companies will leverage the opportunity to widely promote their more addictive and less regulated product.

If FDA determines it appropriate to exclude premium cigars from the scope of a nicotine tobacco product standard- it is essential that the definition is tightly-defined to exclude mass merchandise cigars. The cigar industry has in the past manipulated their products to avoid higher taxation.¹⁴ If FDA were to exempt premium cigars because they are not likely cigarette substitutes, it is important that the definition of premium did not promote product manipulation to avoid regulation. During the deeming process, FDA proposed a definition for premium cigar. This definition required that the cigar would be (1) wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains primarily long filler tobacco; (4) is made by combining manually the wrapper, filler, and binder; (5) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; (6) has a retail price (after any discounts or coupons) of no less than $10 per cigar (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.¹⁵

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¹³ Delnevo CD, Hrywna M. Clove cigar sales following the US flavoured cigarette ban. Tob Control 2015;24(e4):e246-250.
While not common, we find numerous cigars sold in convenience stores, according to Nielsen market scanner data that are close to the $10 per stick price point and we think this price point is too low. Additionally, we believe the weight is also too low as it captures many mass produced cigarillos as shown below.

<table>
<thead>
<tr>
<th>Name</th>
<th>Weight (Lbs., per 1000 cigars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dutch Masters</td>
<td>19.39</td>
</tr>
<tr>
<td>Garcia y Vega Game</td>
<td>16.82</td>
</tr>
<tr>
<td>Middleton's Black &amp; Mild (plastic tip)</td>
<td>9.42</td>
</tr>
<tr>
<td>Dutch Masters Master's Collection Cigarillo</td>
<td>8.51</td>
</tr>
<tr>
<td>White Owl Cigarillo</td>
<td>7.38</td>
</tr>
<tr>
<td>Swisher Sweets (plastic tip)</td>
<td>6.95</td>
</tr>
<tr>
<td>Garcia y Vega Game Cigarillo</td>
<td>6.84</td>
</tr>
<tr>
<td>Middleton's Black &amp; Mild Cigarillo</td>
<td>6.56</td>
</tr>
<tr>
<td>Backwoods</td>
<td>6.47</td>
</tr>
</tbody>
</table>

--- FDA PROPOSED DIVIDING LINE--- 6 lbs.

Instead, we propose that the definition of premium cigars be set at **$20.00 per cigar**, and that this price be **automatically increased annually to account for inflation**. Regarding weight, based on the products currently on the market, **15 lbs. per 1000** would be an appropriate weight to separate cigarillos from full size cigars.

The inclusion of likely cigarette-substitutes in the nicotine reduction policy, and the proper definition of "premium" cigars will be important to maximizing the impact of the policy in protecting public health, and minimizing the use of loopholes that would ultimately harm the public.

Sincerely,

Cristine Delnevo, PhD, MPH, Professor & Director, Rutgers School of Public Health-Center for Tobacco Studies (signing on behalf of Andrew A. Strasser, PhD, Perelman School of Medicine - University of Pennsylvania; Justin Byron, Ph.D., University of North Carolina School of Medicine; Mary Hrywna, MPH, Rutgers School of Public Health-Center for Tobacco Studies, Kevin Schroth JD, Rutgers School of Public Health-Center for Tobacco Studies)