

July 25, 2018

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

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

The undersigned Attorneys General of California, Connecticut, New Mexico, and Washington submit this comment in response to the FDA's Advance Notice of Proposed Rulemaking by which it seeks "to obtain information related to the regulation of premium cigars." Regulation of Premium Cigars, 83 Fed. Reg. 12,901, 12,901 (Mar. 26, 2018).

We provide this comment primarily to reiterate the position 29 Attorneys General stated in 2014 that premium cigars should not be exempt from FDA regulation.<sup>1</sup> As explained in that comment, the public health is best served by regulating all cigars under the same regime as other tobacco products.<sup>2</sup> In addition, this comment addresses the specific questions raised by FDA with regard to premium cigar use patterns and public health.

The 2014 comment also explained that a complex definition of premium cigars would be "likely to cause confusion on the part of enforcers, retailers, and possibly others."<sup>3</sup> We again reiterate this point in light of the specific factors identified by FDA as potentially distinguishing characteristics of premium cigars. This comment further addresses the difficulty of establishing methods by which a standard using these characteristics could be enforced and the potential consequences that would flow from such enforcement difficulties.

The state Attorneys General are uniquely positioned in relation to implementation and enforcement of tobacco product regulations in furtherance of the public health, founded on our securing and enforcing the Tobacco Master Settlement Agreement as well as our enforcement of numerous state laws regulating the sale, distribution, marketing, use, and/or taxation of tobacco products. Those laws include state Directory Statutes, cigarette fire-safe statutes, escrow requirements for manufacturers that did not sign the Master Settlement Agreement, excise tax laws, assurances of voluntary compliance with major retailers, consumer protection laws, and laws against sales to minors. As such, the state Attorneys General are well-informed about and familiar with enforcement of tobacco-related laws and their public health consequences.

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<sup>1</sup> 29 State Attorneys General, Comment Letter on Proposed Rule Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act Part IV, at 25–29 (Aug. 8, 2014), <https://oag.ca.gov/sites/all/files/agweb/pdfs/tobacco/2014-08-08-ag-fda-com-re-reg-fin-filed-letter.pdf> [hereinafter 2014 Attorneys General Comment].

<sup>2</sup> *Id.* at 25–26.

<sup>3</sup> *Id.* at 27.

## A. Use Patterns of Premium Cigars (83 Fed. Reg. 12,903)

In August 2014, in response to FDA's 2014 Proposed Deeming Rule,<sup>4</sup> the Attorneys General of 29 states and territories submitted a comment,<sup>5</sup> which included information related to premium cigars. We reiterate portions of that comment in response to FDA's requests at (B) for "information related to the use of premium cigars generally and among youth and young adults specifically." First, "young people . . . , increasingly, consume premium cigars."<sup>6</sup> In fact, "younger people actually use premium cigars at higher rates than older people."<sup>7</sup> Young adults aged 18 to 29 use premium cigars at a rate twice that of adults aged 45 to 64 and six times that of adults aged 65 or older.<sup>8</sup> Second, we note that "overall sales of premium cigars are increasing," and "there is no reason why [even] adult occasional smokers of premium cigars and those in their proximity should not receive the benefits of warnings about health risks."<sup>9</sup>

Additionally, in response to (B)(6), which concerns the impact of "premium cigar labeling, advertising, and marketing efforts . . . compared and contrasted against other cigars" on use patterns, we note that brands are used across different categories of cigars.<sup>10</sup> Even if labeling, advertising, and marketing practices vary between premium and non-premium cigars, the use of a common brand could easily blur the lines between them. Regardless of the prevalence of such cross-segment marketing, distinguishing between premium and non-premium cigars for purpose of regulation will likely invite manufacturers to take advantage of looser regulations for one product to achieve what they cannot for another, skewing use patterns.

The potential for cross-segment marketing also impacts item (B)(7), which addresses the possibility of consumers switching to premium cigars. Though consumers today might have little reason to "switch" to premium cigars beyond personal preference and price, differential treatment of premium cigars will create new incentives for switching and skew any current differential usage of the products. If, for example, nicotine levels are regulated in non-premium cigars, but not regulated in premium cigars, nicotine will likely become a reason for consumers to switch to premium cigars. This is essentially what occurred when Congress implemented a

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<sup>4</sup> Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,142, 23,150 (proposed Apr. 25, 2014) (to be codified at 21 C.F.R. pts. 1100, 1140, 1143) [hereinafter 2014 Proposed Deeming Rule].

<sup>5</sup> 2014 Attorneys General Comment, *supra* note 1.

<sup>6</sup> *Id.* at 26.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* (citing 2014 Proposed Deeming Rule, *supra* note 4, at 23,151) (giving the relevant rates as 2.5%, 1.2%, and 0.4%).

<sup>9</sup> *Id.* at 25, 26 (citing Melissa Vonder Haar, *The Natural Cigar Advantage: Swedish Match's Joe Teller Breaks Down the Growing Natural Leaf Business*, CONVENIENCE STORE NEWS (May 14, 2014), <http://www.cspdailynews.com/category-news/tobacco/articles/natural-cigar-advantage>; see also Angel Abcede, *Vape, Cigars Boost C-Store Tobacco Sales*, CONVENIENCE STORE NEWS, <http://www.cspdailynews.com/category-news/tobacco/articles/vape-cigars-boost-c-store-tobacco-sales> (last visited July 17, 2018) (noting an increase in cigar sales of 14.1% for convenience stores in 2017)).

<sup>10</sup> See, e.g., ACID Blue, EXPERIENCE ACID, <http://experienceacid.com/brands/acid-blue/> (last visited July 17, 2018) (describing a range of cigars from large, hand-wrapped cigars to machine-made cigarillos all under the same brand).

ban on flavored cigarettes.<sup>11</sup> Consumers who had no reason to smoke cigars gained one when cigars became the only method to obtain rolled, flavored tobacco (other than menthol). Cross-segment branding would almost certainly facilitate such switching beyond what otherwise would be expected.

## B. Public Health Considerations (83 Fed. Reg. 12,903–04)

We again reiterate the conclusion in our 2014 comment that the public health is best served by FDA not distinguishing between types of cigars. Regarding labeling, packaging, and warning statements mentioned in (C)(1) & (14), differential treatment between premium and non-premium cigars will likely create confusion, hamper enforcement efforts, and reduce the effectiveness of any such regulations for all cigars.<sup>12</sup>

Placing warning labels on some cigars but not others will likely give the false impression that premium cigars are inherently less dangerous than non-premium cigars, similar to the public's view of cigars and cigarettes. Cigars previously lacked health warnings, contributing to the perception that cigars were safe alternatives to cigarettes.<sup>13</sup> The current FDA cigar health warnings seek, among other things, to remedy that misconception—"WARNING: Cigars are not a safe alternative to cigarettes"<sup>14</sup> and "WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale."<sup>15</sup> It makes little sense to repeat the mistakes of the past and contribute to another false health distinction between tobacco products.

Such differentiation will also create enforcement difficulties. As described below, premium and non-premium cigars are not readily identified by sight, regardless of the characteristics used to define the distinction between them. And given the myriad sizes and shapes of cigars,<sup>16</sup> applying different rules to premium and non-premium cigars will make regulatory enforcement significantly more complex and health warnings less effective.

For example, current FDA regulations require all cigar packages to bear health warnings.<sup>17</sup> However, if cigars are sold individually, "the required warning statements must be posted at the retailer's point-of-sale."<sup>18</sup> Retailers and inspectors can fairly easily comply with and enforce these regulations—if a package contains cigars, it must bear a warning, and if a retailer sells

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<sup>11</sup> See, e.g., Charles J. Courtemanche et al., *Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use*, 52 AM. J. PREVENTATIVE MED. e139 (2017) (finding the 2009 cigarette flavor ban to be correlated with reductions in cigarette smoking, but increases in menthol cigarette, cigar, and pipe tobacco use).

<sup>12</sup> See 2014 Attorneys General Comment, *supra* note 1, at 27.

<sup>13</sup> See 2014 Proposed Deeming Rule, *supra* note 4, at 23,158 ("One study showed that adult cigar smokers . . . were three times as likely as non-cigar smokers to believe, mistakenly, that switching from cigarettes to cigars reduces a smoker's chance of illness . . . , with former cigarette smokers the most likely among cigar smokers to believe cigars are a safer alternative (47.9 percent)." (citation omitted)).

<sup>14</sup> *Id.* § 1143.5(a)(1)(iii).

<sup>15</sup> *Id.* § 1143.5(a)(1)(i).

<sup>16</sup> See, e.g., *Cigar Shapes, Sizes and Colors*, CIGAR AFICIONADO (Nov./Dec. 2000), <https://www.cigaraficionado.com/article/cigar-shapes-sizes-and-colors-8094> (last visited July 17, 2018).

<sup>17</sup> 21 C.F.R. § 1143.5(a)(1).

<sup>18</sup> *Id.* § 1143.5(a)(3).

cigars individually, there must be a warning posted at the retailer's point-of-sale. If premium cigars are exempted from FDA regulation, however, and a retailer's point-of-sale lacks a posted warning, an inspector would have to determine whether any of the retailer's individually sold cigars are non-premium before the inspector can assess compliance. Not only will enforcement become more difficult, but the required focus on exactly which cigars must bear warnings would only exacerbate the false perception that premium cigars have fewer negative health consequences than non-premium cigars.

Even assuming current premium cigar use results in fewer negative health consequences than non-premium cigar use, there is no reason to exempt premium cigars from warning requirements, which would imply that premium cigars themselves are less harmful. This perception would likely eventually skew premium cigar use, negating the very premise of exempting them from warning statement requirements.

### **C. Definition of Premium Cigars (83 Fed. Reg. 12,903)**

We repeat our 2014 comment that differentiation between types of cigars would "likely result in numerous enforcement difficulties."<sup>19</sup> Additionally, we address the specific characteristics FDA identifies as potentially useful in distinguishing premium cigars and their attendant enforcement difficulties. The potential differentiating factors FDA identifies could complicate or forestall enforcement, while others could result in product manipulation or invite challenge or confusion.

#### *Effective Enforcement*

State enforcement of tobacco regulations is most effective when carried out at multiple levels of the supply chain. For example, cigarette tax enforcement is effective, in part, for this reason. Cigarette manufacturers and distributors report their sales to the states, and distributors in most states indicate payment of state cigarette excise taxes by affixing a tax stamp to tax-paid cigarette packs. This allows for collection of the tax from the distributor when the tax stamp is applied, easily distinguishes—at both the wholesale and retail level—whether any particular pack of cigarettes is tax-compliant, and allows for an overall check between sales and taxes paid. Similarly, enforcement of retail-focused laws, such as retailer licensing or prohibitions on self-service displays and sales to minors, enables monitoring of other parts of the states' regulatory regimes.

Several of the characteristics identified by FDA in section (A)(2) as potentially indicative of a premium cigar are not easily observable throughout the supply chain, which would necessitate concentration of enforcement efforts at one step in that chain. Such concentration would likely both be inefficient and increase evasion since a non-compliant product would essentially be free from oversight once it has passed through the single point of regulation.

Characteristics suffering this problem are those concerning the composition of the tobacco product in question, specifically those numbered (A)(2)(b)–(e), (j)–(k). The tobacco filler type, fermentation type, wrapper and binder composition, the provenance of the tobacco used, and the

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<sup>19</sup> 2014 Attorneys General Comment, *supra* note 1, at 27.

presence or absence of flavors/additives are all not readily observable or verifiable in a final product once it leaves the factory.

Similarly, the production method of a particular product and its rate of production, identified at (A)(2)(h)–(i), are not readily observable or verifiable except at the point of manufacture. Accordingly, it might be unreasonable for a consumer, retailer, wholesaler, distributor, common carrier, or inspector to know these characteristics in any given cigar. Such regulation would therefore, as a practical matter, only be enforceable at the manufacturer level.

Weight is also identified as a potential characteristic at (A)(2)(a). On the surface, weight appears to be an easily observable characteristic. However, tobacco products are typically described by weight per thousand,<sup>20</sup> and “[i]t may not be reasonable for a retailer, distributor[,] or inspector . . . to have available one thousand of the same item to determine the weight.”<sup>21</sup>

FDA identifies nicotine content, tar delivery amounts, and carbon monoxide delivery amounts as potential characteristics at (A)(2)(l)–(n). Absent a field test capable of measuring these characteristics that is reliable, affordable, and convenient, these characteristics would be virtually unascertainable by retailers, wholesalers, distributors, common carriers, or inspectors in a final product.

Frequency of price changes at particular levels of the distribution chain is raised as a potential characteristic at (A)(2)(p). This information is clearly unobservable through inspection of a particular cigar, and would likely necessitate a centralized database, discussed below, to give regulators and all members of the supply chain the ability to determine the applicability of a price-change-frequency characteristic.

At the end of the supply chain, retail price, identified at (A)(2)(o) as a potential distinguishing characteristic, would be enforceable only at the retail level. The retail level is the most dispersed level of the supply chain, making the exclusive concentration of enforcement efforts there particularly challenging.

Because retail price could only be confirmed at the point-of-sale, regulators, manufacturers, wholesalers, distributors, and marketers would be unable to make definite or well-informed determinations about whether specific cigars are or are not exempt until those cigars are actually sold at retail. This could lead to the incongruous possibility that a cigar in a warehouse be misbranded if sent to one retailer, but not if sent to another, merely due to the retailer’s future pricing practices. This possibility becomes more acute if, as it should, retail price takes into consideration state excise taxes, which differ among the states. A cigar could be misbranded if sent to one state, but not to another, making it nearly impossible for authorities to determine compliance with FDA regulations or with any state regulation that flows from FDA regulation.

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<sup>20</sup> See, e.g., 2014 Proposed Deeming Rule, *supra* note 4, at 23,150 (prosing premium cigars be defined, among other things, as “weigh[ing] more than 6 pounds per 1000 units”).

<sup>21</sup> 2014 Attorneys General Comment, *supra* note 1, at 27.

FDA has authority to require reporting that would create a national system of track and trace for tobacco products meeting its product standards.<sup>22</sup> A national track and trace system would do much to mitigate the enforcement issues identified above, should FDA decide to treat premium cigars differently from other tobacco products. For example, as mentioned above, tax stamps are used by nearly all states on cigarettes. In many instances, field agents have scanners that can instantly determine whether a product is stamped or not and whether the stamp is counterfeit or legal. If the stamp is legal, it also provides the agent with additional information about the product. A national system of track and trace for tobacco products meeting FDA standards could provide similar functionality.

Relatedly, a national tobacco product brand directory could alleviate the burden of enforcement on retailers, distributors, inspectors, and consumers. Such directory would list only product brands in compliance with FDA standards, and indicate their appropriate category, allowing all interested parties the ability to perform a quick check on whether any given cigar brand is considered “premium” and thus subject to a separate regulatory regime. Almost all of the states have Tobacco Directories containing all of the brands of cigarettes and roll-your-own tobacco that are in compliance with state statutes that enforce the Tobacco Master Settlement Agreement. Accordingly, the state Attorneys General would be a resource if FDA considers the creation of a national tobacco product directory.

### *Product Manipulation*

When governmental agencies treat similar tobacco products differently, the market often responds by producing a modified product that will be less regulated. For example, in its April 25, 2014 proposed deeming rule that originally addressed whether premium cigars should be exempted from FDA regulation, FDA identified that such behavior occurred in the early 1970s when cigars were taxed at a lower rate than cigarettes and when advertisements were banned for cigarettes, but not for cigars.<sup>23</sup> Similarly, “[a] 2009 increase in the federal tax on small cigars prompted some cigar and cigarette makers to add just enough weight to their products to meet the federal tax definition of large cigars and avoid the higher tax on cigarettes and small cigars.”<sup>24</sup> Several of the characteristics proposed by FDA to distinguish premium cigars invite just such manipulation.

Size, identified at (A)(2)(a), is the characteristic most vulnerable to manipulation. As mentioned above, manufacturers have previously manipulated the sizes of their products to avoid regulation and can reasonably be expected to do so again. Similarly, strict numerical standards for filler and wrapper composition invite manipulation. Just as manufacturers previously created little cigars that approximated cigarettes from the consumer’s perspective, they would likely be able to create “premium cigars” that approximate non-premium cigars from the consumer’s perspective.

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<sup>22</sup> 21 U.S.C. § 387t(b)(1)–(2).

<sup>23</sup> 2014 Proposed Deeming Rule, *supra* note 4, at 23,147; see also generally Christine D. Delnevo & Mary Hrywna, “A Whole ‘Nother Smoke’ or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars, 97 AM. J. PUB. HEALTH, Aug. 2007, at 12 (charting the history of the manipulation of little cigars as a less-regulated cigarette).

<sup>24</sup> CAMPAIGN FOR TOBACCO-FREE KIDS, NOT YOUR GRANDFATHER’S CIGAR 4 (2013), [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/industry\\_watch/cigar\\_report/2013CigarReport\\_Full.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf).

Rate of production, identified at (A)(2)(i) is also highly manipulable. It is wholly in the control of the manufacturer, and slowing the rate of manufacture to comport with standards for premium cigars would have little to no effect on the end product or the consumer's experience with the product. This is also true of retail price, identified at (A)(2)(o). A minimum price for premium cigars could be "eviscerated by promotions, such as 2-for-1 offers, coupons[,] and/or gift cards."<sup>25</sup>

Finally, using the presence of a mouthpiece to indicate a non-premium cigar, identified at (A)(2)(g), is also subject to manipulation. Mouthpieces are not integrated into cigars, allowing a manufacturer to circumvent such rule by simply selling mouthpieces separately or relying on third parties to manufacture and sell them.<sup>26</sup> Therefore, it seems unlikely that using the presence or lack of a mouthpiece would be useful as part of the definitions distinguishing premium and non-premium cigars.

#### *Characteristics That Will Likely Invite Challenge or Confusion*

A third category of potential enforcement issues concerns characteristics that will likely invite challenge or confusion. Among these would be definitions of the different kinds of tobacco that would be necessary to implement standards based on tobacco filler type and percentages, as well as wrapper and binder composition. Terms commonly used to describe premium cigar composition such as "long filler tobacco," "leaf tobacco binder," and "whole tobacco" leaf are inherently imprecise.<sup>27</sup> Determinations of whether a cigar is premium or non-premium may be contested by manufacturers and others due to disputes over, for example, how one distinguishes "whole tobacco."<sup>28</sup>

The proposed use of actions "directed to consumers, by a retailer or manufacturer, such as through labeling, advertising, or marketing, which would reasonably be expected to result in consumers believing that the tobacco product is a premium cigar" to distinguish premium cigars at (A)(2)(r) also would similarly invite challenge due to their amorphous nature. Additionally, different entities or persons involved in the supply chain might take differing actions toward consumers, rendering it difficult to categorize a product as definitely premium or non-premium. Evaluation of such actions becomes even more fraught considering that a single brand name is sometimes used across many different types of cigars.<sup>29</sup> A manufacturer could position a brand as "premium" through marketing efforts and then market a cheaper product that by any other measure would be non-premium with the same brand, thereby evading regulatory requirement applicable to non-premium brands.

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<sup>25</sup> 2014 Attorneys General Comment, *supra* note 1, at 27.

<sup>26</sup> This is unlike the presence or absence of a filter, identified at (A)(2)(f), which is integrated into the product. A consumer can only readily remove a filter, not add one, rendering its presence a more apt characteristic for identifying a non-premium cigar.

<sup>27</sup> See 2014 Proposed Deeming Rule, *supra* note 4, at 23,150 (proposing a premium cigar definition to required being "wrapped in whole tobacco leaf," containing "a 100 percent leaf tobacco binder" and "primarily long filler tobacco").

<sup>28</sup> See 2014 Attorneys General Comment, *supra* note 1, at 27 (arguing that terms such as "long filler tobacco," "leaf tobacco binder," and "whole tobacco" leaf "invite challenge").

<sup>29</sup> See, e.g., ACID Blue, EXPERIENCE ACID, <http://experienceacid.com/brands/acid-blue/> (last visited July 17, 2018) (describing a range of cigars from large, hand-wrapped cigars to machine-made cigarillos all under the same brand).

Similar confusion could also arise with any definition relying on the presence or absence of flavor imparting compounds, flavor additives, or characterizing flavors other than tobacco, as suggested at (A)(2)(j). Flavors other than tobacco—such as chocolate, caramel, clove, or citrus—are often used to describe cigars that contain no flavor additives.<sup>30</sup> Regulators, distributors, retailers, and consumers could become confused between which cigars are “flavored” versus those that are merely “flavorful” and either sweep too broadly or too narrowly in evaluating which cigars are considered premium or non-premium.

## Conclusion

Exempting premium cigars from FDA’s regulatory regime provides no known public health benefit. At the same time, numerous enforcement difficulties are likely to flow from segregating premium cigars, which themselves will likely have ripple effects on the tobacco market as a whole and on the states’ regulatory regimes. We therefore urge FDA to avoid potentially skewing the tobacco product marketplace and disrupting the states’ regulatory regimes for no gain for public health.

In the twenty years since the execution of the Tobacco Master Settlement Agreement, the state Attorneys General have gained intimate experience enforcing tobacco statutes and regulations and first-hand knowledge of how the market and consumer use shifts in response to regulatory changes. We offer FDA the benefit of this experience in urging FDA to consider the enforcement challenges, likely effects in the marketplace, and public health effects that would result from exempting premium cigars from FDA regulation.

Respectfully submitted,



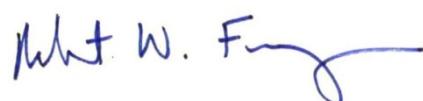
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<sup>30</sup> See, e.g., *Cigar Flavor Wheel: Main Cigar Flavor Components*, CIGAR INSPECTOR (last updated Jan. 18, 2014), <http://www.cigarinspector.com/cigars-101/cigar-flavor-components>.