

July 17, 2019

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Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA–2016-N-3818; Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports; Proposed Rule**

Dear Sir or Madam:

Davidoff of Geneva USA, Inc. (“Davidoff USA”), General Cigar Company (“General”), Nick’s Cigar Company d/b/a Tabacalera Perdomo (“Perdomo”), SWI-DE, LLC d/b/a Drew Estate (“Drew Estate”), Tabacalera Unidas, Inc. d/b/a C.L.E. Cigar Company (“CLE Cigars”) and Tabacalera USA Inc. (“TUSA”) (collectively “Premium Cigar Manufacturers”) are the six of the largest premium cigar companies in the United States and sell most of the iconic and acclaimed brands of premium cigars on the market today.

**I. Background on the Premium Cigar Manufacturers**

Davidoff USA is the exclusive U.S. importer and distributor of the portfolio of premium cigar products of the Swiss company, Oettinger Davidoff AG (“ODAG”) based in Basel, Switzerland. Davidoff USA is based in Pinellas Park, Florida and is a wholly-owned subsidiary of ODAG. Davidoff USA’s acclaimed premium cigar brands include Davidoff, AVO, Baccarat, Camacho, Cusano, The Griffin’s, La Fontana, Legendario, National Brands, Winston Churchill, Zino and Zino Platinum.

General Cigar Co. is one of the world’s foremost manufacturers and marketers of premium cigars. The company was started in 1907 by German immigrants and is now a subsidiary of

Scandinavian Tobacco Group. General Cigar is known primarily for producing brands like Macanudo, Cohiba, CAO, Hoyo de Monterrey, Punch, La Gloria Cubana and Partagas. General Cigar operates facilities in the United States, Honduras, the Dominican Republic and Nicaragua. General Cigar also operates the brick and mortar cigar lounge Club Macanudo in New York City, and its sister companies Meier & Dutch and Cigars International are respectively two of the largest wholesalers and online retailers of premium cigars in the country. General Cigar provides employment to approximately 125 people in the United States and 3000 people abroad.

Perdomo is a Miami, Florida based company with over 2,000 employees in Florida and Nicaragua. Perdomo is a family run business founded by third-generation cigar maker Nicholas Perdomo, Jr. Perdomo has its origins with Silvio Perdomo who was a leading cigar maker in Cuba prior to the Cuban revolution, and after years in a Cuban jail emigrated to the United States in 1974. Silvio taught his son Nicholas Perdomo Sr. his craft, and Nicholas Sr. also eventually emigrated to the United States with the assistance of close friends. Nicholas Jr. was determined to follow in the footsteps of his father and grandfather and founded Perdomo in his garage in Miami in 1992. Today, Perdomo runs an 88,000 sq. foot state of the art factory, which is one of the largest cigar factories in Nicaragua, and produces the Perdomo brand including the Perdomo 20<sup>th</sup> Anniversary, Perdomo Estate Seleccion Vintage, Perdomo Habano, Perdomo Reserve Champagne, Perdomo 12 Year Double Aged Vintage, Perdomo Lot 23, Perdomo Small Batch and Perdomo Factory Tour Blend, amongst other brands.

Drew Estate is a leading manufacturer of some of the most iconic brands in the premium cigar category, including ACID, Liga Privada, Tabak Especial, Undercrown, Herrera Esteli,

Larutan, Nica Rustica, Deadwood, La Vieja Habana and others. As the owner of one of the largest hand-rolled premium cigar factories in the world, Drew Estate employs more than 1,700 people at its manufacturing facility, La Gran Fabrica Drew Estate, in Esteli, Nicaragua, as well as more than 75 employees in its U.S. operations, based out of Miami, Florida. Drew Estate is also the exclusive U.S. distributor for Joya de Nicaragua, the original and oldest premium cigar company in Nicaragua. Guided by its stated mission, “The Rebirth of Cigars,” Drew Estate has always remained boutique at heart and committed to delivering a wide array of beautifully crafted handmade cigars that meet the diverse needs of the Mom & Pop specialty retail shops in which premium cigar brands are built. Drew Estate is renowned for its unparalleled ability to engage consumers, including through innovations such as Barn Smoker and Cigar Safari that educate adult smokers about the joyous artisanal traditions of handmade premium cigars.

CLE Cigars is based in Miami, Florida and employs over 700 people in Nicaragua, Honduras and the United States. CLE Cigars was founded in 2012 by third-generation premium cigar maker Christian Eiroa. Christian grew up in Honduras, but his cigar making roots trace to his grandfather Generoso Eiroa a Cuban cigar maker. The Eiroa Family Farm is one of the most technologically advanced tobacco farms in the world, and CLE cigars takes utmost pride in every aspect of creating each handmade, premium cigar from seed to smoke. CLE Cigars manufactures and distributes the brands CLE, Asylum, Eiroa, and Wynwood Hills.

TUSA, based in Ft. Lauderdale, Florida, is a wholly-owned subsidiary of Imperial Brands PLC, and is a leader in the United States premium cigar space. TUSA has three main businesses that operate within its portfolio: Altadis U.S.A. Inc., JR Cigar, and Casa de Montecristo. Altadis U.S.A. Inc. Premium Cigar Division (“AUSA PCD”) is a distributor of fine premium cigars; its

brands include Montecristo, Romeo y Julieta and H. Upmann. JR Cigar has a wholesale arm within its portfolio and is one of the premier cigar retailers in the United States, selling cigars to adult consumers through e-commerce and catalog retail mediums. Casa de Montecristo offers premier modern cigar stores, at 20 locations in eight states, featuring walk-in humidors and lounges for adults seeking an extraordinary and relaxing cigar smoking venue. In addition, TUSA works with various cigar manufacturers located outside the United States. TUSA companies are involved in every aspect of distributing and selling premium cigars.

## **II. Introduction**

The Premium Cigar Manufacturers are key stakeholders in the implementation of any regulation of cigars as these regulations significantly affect their ability to conduct business. The Premium Cigar Manufacturers submit this comment to FDA's Proposed Rule on the Format and Content of Substantial Equivalence Reports.<sup>1</sup> These comments will be organized into three main sections: (i) the scientific and legal reasons premium cigars should be exempt from regulation; (ii) the Proposed SE Rule as written is unworkable for premium cigars and does not account for the unique aspects of premium cigars; and (iii) the economic impact of the Proposed SE Rule would result in a ban on much of the premium cigar category.

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<sup>1</sup> Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports, 84 Fed. Reg. 12,740 (proposed Apr. 2, 2019) (to be codified at 21 C.F.R. pt. 16, 1107) [hereinafter Proposed SE Rule].

### III. Premium Cigars Should be Exempt from FDA Regulation

#### a. Definition of Premium Cigars

The Premium Cigar Manufacturers are all members of the Cigar Association of America, Inc. (“CAA”), and contributed extensively to comments submitted by CAA to FDA’s Advanced Notice of Proposed Rulemaking on the Regulation of Premium Cigars, which outlined the scientific and legal reasons why premium cigars should be exempt from FDA regulation.<sup>2</sup> The Premium Cigar ANPRM specifically asked for a proposed definition of Premium Cigar. The CAA Premium Cigar Comments proposed the following definition of premium cigar, which the Premium Cigar Manufacturers all adopt and endorse:

... a premium cigar (i) is wrapped in whole leaf tobacco; (ii) contains a 100% leaf tobacco binder; (iii) is made by manually combining the wrapper, filler, and binder; (iv) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; and (v) weighs more than 6 pounds per 1000 units.<sup>3</sup>

#### b. FDA’s History with Premium Cigars

##### i. *Proposed and Final Deeming Rule*

Since FDA first considered cigar regulation, it has recognized that premium cigars are unique, with construction, usage patterns, and potential health effects much different from any other tobacco product. The agency also understands that premium cigars are but a very small

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<sup>2</sup> Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (proposed Mar. 26, 2018) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) [hereinafter Premium Cigar ANPRM]. CAA’s comments on the Premium Cigar ANPRM are incorporated by reference and attached as Exhibit 1 [hereinafter CAA Premium Cigar Comments].

<sup>3</sup> Whenever the term “premium cigar” is used through this Comment, the Premium Cigar Manufacturers use this definition in reference to that term.

fraction of the overall tobacco space. These are, perhaps, among the reasons FDA has continually vacillated on the appropriate regulatory status of premium cigars.

First, in the Proposed Deeming Rule, FDA proposed “Option 1,” which did not distinguish among various types of cigars, and “Option 2,” which would have exempted premium cigars from regulation.<sup>4</sup> FDA proposed to define a “premium” cigar as one that:

(1) Is 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 (adjusted, as necessary, every 2 years, effective July 1st, to account for any increases in the price of tobacco products since the last price adjustment); (7) does not have a characterizing flavor other than tobacco; and (8) weighs more than 6 pounds per 1000 units.<sup>5</sup>

FDA explained it was considering Option 2 because:

...it has been suggested that different kinds of cigars (e.g., small cigars, cigarillos, large cigars, premium cigars) may have the potential for varying effects on public health, if there are differences in their effects on youth initiation, the frequency of their use by youth and young adults, and other factors. In addition, the proportion of cigar smokers showing clear signs of dependence remains unknown, and usage patterns indicate that cigar only use beginning in adulthood is less likely to produce addiction than the use of cigarettes.<sup>6</sup>

The Premium Cigar Manufacturers all submitted comments, whether independently or through CAA, outlining the legal, factual, and scientific reasons why FDA should adopt

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<sup>4</sup> Deeming Tobacco Products to be Subject to the Food, Drug and Cosmetic Act, as Amended by the Family Smoking and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,141, 23,150 (proposed April 25, 2014) [hereinafter Proposed Deeming Rule].

<sup>5</sup> *Id.*

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

proposed Option 2 (with a slightly revised definition).<sup>7</sup> Among other concerns, those comments outlined problems with the Substantial Equivalence (“SE”) process as a premarket pathway for premium cigars.<sup>8</sup>

FDA rejected the comments of these and other manufacturers and trade associations, as well as retailers and consumers, and instead chose Option 1 – to regulate all cigars under the Final Rule.<sup>9</sup> FDA stated:

After thorough review of the comments and the scientific evidence, FDA has concluded that deeming all cigars, rather than a subset, more completely protects the public health and therefore has adopted Option 1 in the final rule. FDA has concluded that: (1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults. The fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others.<sup>10</sup>

The data at the time belied these conclusions; however, the body of data submitted to FDA since, including research performed or sponsored by FDA itself, demonstrates unequivocally that

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<sup>7</sup> See CAA comments on Proposed Rule <https://www.regulations.gov/document?D=FDA-2014-N-0189-76530>; AUSA PCD comments on Proposed Rule <https://www.regulations.gov/document?D=FDA-2014-N-0189-76595> ; Davidoff USA comments on Proposed Rule <https://www.regulations.gov/document?D=FDA-2014-N-0189-75922> ; General Cigar Company comments on Proposed Rule <https://www.regulations.gov/document?D=FDA-2014-N-0189-76755> ; CLE Cigars comments on the Proposed Rule <https://www.regulations.gov/document?D=FDA-2014-N-0189-81752>

<sup>8</sup> The SE process, as currently proposed by FDA and as explained further throughout this comment, would, if applied to premium cigars, do little to benefit public health, but would come at enormous cost to industry, including countless small businesses.

<sup>9</sup> 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) [hereinafter Final Rule].

<sup>10</sup> *Id.* at 29,020.

regulating premium cigars in the same manner as other tobacco products is not based on sound science, and will impose enormous costs on industry without a discernable public health benefit.

ii. *FDA's Scientific Research on Premium Cigars Since the Final Rule*

Since promulgation of the Final Rule, FDA itself has undertaken scientific research on different categories of cigars. For a variety of reasons, including different usage patterns, premium cigars present much lower health risks than other products. Indeed, FDA's own research shows that (i) youth do not use premium cigars; (ii) adult premium cigar users represent less than 1% of the population; (iii) and the vast majority (over 95%) of premium cigar smokers face no increased health risk as compared to non-smokers.<sup>11</sup>

Two pieces of research are of particular importance. The first examined PATH<sup>12</sup> data regarding cigar use. The PATH study stratifies cigar use separately for filtered cigars, cigarillos, and "traditional cigars." Participants were asked about the categories of cigars, certain brands of cigars, and also to identify brands they smoke. These brands are recorded in the datasets available to researchers. "Traditional cigars" were defined as "...tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many others."<sup>13</sup> Corey, et al. (2017) ("Corey et al.") specifically

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<sup>11</sup> See *infra* notes 26, 32-46.

<sup>12</sup> The Population Assessment of Tobacco and Health (PATH) study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the country take part in this study. In October 2011, the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA) announced a new study called the Population Assessment of Tobacco and Health (PATH) study. The PATH study was one of the first projects that NIH and FDA have worked on together since Congress gave FDA authority to regulate tobacco products. The study will look at tobacco use and how it affects the health of Americans. About 49,000 people ages 12 years and older are participating in the PATH study. Some of them use tobacco; others do not. Interviewers meet with each person once a year or every other year. Each year the study will invite some participants to take part in additional study activities. See <https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx>

<sup>13</sup> Kasza, K. et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 276 N. Eng J. Med. 376:342-353 (Jan. 26, 2017) available at



examined the cigar data available in Wave 1 of the PATH study, examined all of the data available relating to “traditional” cigars, and segregated brands in that category into “premium” and “non-premium” cigars. The result was an FDA research paper on cigar use patterns, including premium cigar use patterns, based on FDA’s PATH data.<sup>14</sup>

In the adult population, Corey et al. found that the overall prevalence of premium cigar use was 0.7% and that the median age of first use of a premium cigar was 24.5 years old.<sup>15</sup> Additionally, Corey et al. confirmed what industry has long known -- that “...cigar smoking patterns and tobacco use behaviors varied by cigar type . . . .”<sup>16</sup> Finally, Corey et al. reported that the median consumer of premium cigars in Wave 1 of PATH smoked 1.7 days per month, dramatically less than consumers of other combustible products.<sup>17</sup>

In the second, Kasza et al. (2017) (“Kasza et al.”) reported on the categories exactly as listed in the PATH study, rather than doing a stratification of the traditional cigar group into “premium” and “non-premium” categories. Only 0.7% of youth reported using “traditional cigars” in the past 30 days.<sup>18</sup> Finally, the results show that for “traditional cigars,” (which

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[https://www.nejm.org/doi/10.1056/NEJMsa1607538?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%3dwww.ncbi.nlm.nih.gov](https://www.nejm.org/doi/10.1056/NEJMsa1607538?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov).

<sup>14</sup> Corey C, et al. *U.S. 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*; Nicotine and Tob. Res. (Nov. 15, 2018) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> Kasza, K. et al., *supra* note 13, at Table S18.

encompasses some non-premium cigars as well as premium cigars) there was so little data on “current use” of these products by youth that it could not be reliably measured.<sup>19</sup>

FDA’s own data and research confirm that premium cigars are not being used by youth and that the average premium cigar consumer is older and uses the product infrequently.

*iii. ANPRM on Regulation of Premium Cigars*

On July 28, 2017, then FDA Commissioner Gottlieb announced that FDA was undertaking a new Comprehensive Approach to Nicotine and Tobacco.<sup>20</sup> In that announcement, the agency took three actions relevant to these comments. The first was:

Among other things, we will advance rules that will lay out ... whether and how we would exempt premium cigars from regulation.... I’m also asking the Tobacco Center leadership to explore a process by which it could ask for new information related to the patterns of use and resulting public health impacts from so-called premium cigars. The final deeming rule covers all cigars. But I want the Center to consider opportunities it could provide to interested parties to develop and submit new information or data on this issue. This will take the form of a new Advance Notice of Proposed Rulemaking, to develop a new administrative record to explore these questions. We will explore any new and different questions raised, and seriously consider any additional data submitted relevant to the appropriate regulatory status of premium cigars.<sup>21</sup>

Second was: “...we will advance rules that will lay out what needs to be in applications for Substantial Equivalence . . . .”<sup>22</sup> Third was that FDA would reconsider the compliance deadlines for premarket review and the so-called “sunset policy” so “that existing products under review

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<sup>19</sup> Kasza, K. et al., *supra* note 13, at Table S4.

<sup>20</sup> Scott Gottlieb, M.D., Comm’r, U.S. Food & Drug Admin., *Remarks on Protecting American Families: Comprehensive Approach to Nicotine and Tobacco* (July 27, 2017) available at <https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017>

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

remain on the market” as opposed to “[t]he current policy [that] could have forced existing products off the market.”<sup>23</sup>

On March 26, 2018, FDA published the ANPRM on the Regulation of Premium Cigars.

FDA stated:

[T]he regulatory considerations with respect to premium cigars, their use, and related public health issues continue to be of significant interest to some stakeholders, as well as a topic of ongoing and emerging research. Given the ongoing interest from many parties and sectors, such as industry and Members of Congress, in the regulatory status of premium cigars, FDA is issuing this ANPRM to request relevant new and different information, data, and analysis not submitted in response to FDA’s proposed determining rule [] that could inform FDA’s regulation of premium cigars. . . .<sup>24</sup>

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<sup>23</sup> *Id.* In addition, after reviewing the Final Rule, the Premium Cigar Manufacturers, as well as CAA and others in the industry, sued FDA over many provisions of the Final Rule including the selection of Option 1 and the SE Pathway for cigars. (Complaint, *Cigar Association of America, Inc. et al. v. U.S. Food and Drug Admin. et al.*, (D.D.C. July 15, 2016) (No. 16-cv-1460 (APM)), ECF No. 1; Motion for Summary Judgment by Cigar Association of America, et al., *Cigar Association of America, Inc. et al. v. U.S. Food and Drug Admin. et al.*, (D.D.C. Feb. 13, 2017) (No. 16-cv-1460 (APM)), ECF No. 22.) Plaintiffs filed their Complaint in July 2016, and filed a first motion for summary judgment in February 2017. Due to the change in administration, FDA asked for extensions to respond to plaintiffs’ motion and correspondingly extended compliance deadlines. (Motion for Extension of Time to File Response/Reply, *Cigar Association of America, Inc. et al. v. U.S. Food and Drug Admin. et al.*, (D.D.C. Mar. 17, 2017) (No. 16-cv-1460 (APM)), ECF No. 26; Joint Motion to Amend/Correct Scheduling Order, *Cigar Association of America, Inc. et al. v. U.S. Food and Drug Admin. et al.*, (D.D.C. May 1, 2017) (No. 16-cv-1460 (APM)), ECF No. 34; Order granting parties’ Joint Motion to amend Scheduling Order, *Cigar Association of America, Inc. et al. v. U.S. Food and Drug Admin. et al.*, (D.D.C. May 2, 2017) (No. 16-cv-1460 (APM)), ECF No. 35; *see* U.S. FOOD & DRUG ADMIN., Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (May 2017), U.S. FOOD & DRUG ADMIN., Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (August 2017)). In light of FDA’s July 2017 announcement and August 2017 Guidance, the parties agreed to defer action on the parts of Plaintiffs’ Complaint relating to the regulation of premium cigars and the SE process. To date, those claims have not been litigated. The parties have agreed to stay those claims pending further FDA actions on policies relating to these issues.

In a case brought by certain public health groups, Judge Grimm of the District of Maryland vacated the August 2017 Guidance extending the premarket review deadline for newly deemed products. Judge Grimm issued an order requiring that all “new products” submit premarket review reports or applications within 10 months of his July 12, 2019 Order. (*American Academy of Pediatrics, et al. v. U.S. Food and Drug Admin., et al.*, (D.D.C. June 12, 2019) (18-cv-883 (PWG)), ECF No. 127). On July 2, 2019, CAA and the other trade associations filed a motion to amend the complaint, and a motion for partial summary judgement in the cigar industry litigation to seek a declaration from Judge Mehta that the August 2021 date for the filing of SE Reports is still in effect for cigars. (*Cigar Association of America, et al. v. U.S. Food and Drug Admin., et al.* (D.D.C. July 2, 2019) (No. 16-cv-1460 (APM)), ECF No. 135, 136.) The briefing on those motions is ongoing at the filing of this comment.

<sup>24</sup> Premium Cigar ANPRM, *supra* note 2, at 12,902.

It requested comments, data and information on (i) a definition of premium cigar; (ii) use patterns of premium cigars; and (iii) the public health considerations with premium cigars.<sup>25</sup> As noted above, CAA submitted extensive comments, accompanied by three expert reports, on usage patterns and public health consequences of premium cigars. These expert reports, as well as the independent research done by FDA, demonstrate unequivocally that the usage patterns of premium cigars are such that there are few to no adverse health consequences resulting from their use.<sup>26</sup> FDA received exactly what it requested – “...comments, evidence, information, data, and analysis that were not submitted in response to the proposed deeming rule...” in relation to premium cigars.<sup>27</sup> This evidence, along with the work done subsequently, contradicts every basis FDA relied upon in rejecting Option 2, and demonstrates clearly that due to absence

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<sup>25</sup> See Premium Cigar ANPRM, *supra* note 2.

<sup>26</sup> See Exhibit 1, Exs. A, B, and C. Since that work was done an additional independent scientific expert, Professor Brad Rodu, has reviewed the relevant literature and data available on premium cigars and has testified in a Congressional Hearing that

The following facts are indisputable with respect to cigars: (1) the prevalence of cigar use in the U.S. is extremely small, especially for premium cigars; (2) these products, especially premium category, are used infrequently and in small numbers; (3) they are puffed, rather than inhaled. The agency’s unsupported position has led to needlessly subjecting cigar and pipe smokers, and the manufacturers of those products, to the same onerous and burdensome regulatory regime as much more hazardous cigarettes. Low prevalence, infrequent use and reduced exposure translates into minimal harm at the population level. Epidemiologic analysis from FDA staff indicate that **consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.**

*Keeping Small, Premium Cigar Businesses Rolling*, 116th Cong. (Apr. 5, 2019) (statement of Brad Rodu, DDS professor, Dept. of Medicine Endowed Chair Endowed Chair, Tobacco Harm Reduction Research School of Medicine University of Louisville) (emphasis in original) [hereinafter Rodu Testimony]. Prof. Rodu’s testimony is attached as Exhibit 2.

<sup>27</sup> Premium Cigar ANPRM, *supra* note 2, at 12,902.

of youth usage or discernible public health impact premium cigars should be exempt from regulation under the TCA, and therefore not be subject to premarket review.

#### **IV. The Proposed SE Rule Cannot Work for Premium Cigars**

The Proposed SE Rule is based on FDA's experience with cigarettes, smokeless tobacco and roll-your-own tobacco. Those products, which are all manufactured using highly mechanized processes and are consumed differently, bear no relation to the construction or usage patterns of premium cigars. Therefore, with respect to premium cigars, the Proposed SE Rule clearly violates the TCA.<sup>28</sup>

The TCA grants FDA "flexible enforcement authority" and intends for FDA to regulate each tobacco product differently, in order to address the unique questions of public health raised by different classes and types of tobacco products.<sup>29</sup> The Proposed SE Rule entirely ignores this principle, and certainly ignores the established science regarding premium cigars (as well as the intent of the TCA and FDA's public health mission). The Proposed SE Rule does not distinguish between the information necessary for cigarettes, as opposed to cigars, and fails to recognize that premium cigars do not raise questions of public health as other tobacco products might.<sup>30</sup>

Premium cigars are unique among all tobacco products in that they have the widest scope of variability in terms of size, shape, tobaccos used and subtle distinctions inherent in a handmade

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<sup>28</sup> Family Smoking Prevention and Tobacco Control Act (2009) [hereinafter Tobacco Control Act or TCA].

<sup>29</sup> See Tobacco Control Act § 3(4). See also *e.g.* Tobacco Control Act §§ 906, 907, 909, 102.

<sup>30</sup> The Premium Cigar Manufacturers note there is but one reference to "premium" in the Proposed SE Rule: "The applicant would be required to include any additional properties needed to uniquely identify the tobacco product, if applicable (*e.g.* use of product descriptors such as "premium" would be required to be identified.)" Proposed SE Rule, *supra* note 1, at 12,755. It is not clear whether the Proposed SE Rule contemplates a different SE pathway for products designated as "premium," but this distinction does not appear anywhere else in the Proposed SE Rule.

process, while at the same time having the most limited patterns of use and potential health impacts.<sup>31</sup> The strain on Agency and industry resources to have premium cigars undergo premarket review is not warranted based on these indisputable differences, and also based on the scientific and economic considerations that differentiate this category.<sup>32</sup>

a. Premium Cigars Do Not Raise Questions of Public Health Similar to Other Tobacco Products

The extensive comments on the Premium Cigar ANPRM filed by CAA outlined in detail the usage patterns of premium cigar users. Among other things, the comments demonstrated: (i) youth do not use premium cigars; (ii) the population using premium cigars is older adults; and (iii) this population uses premium cigars infrequently.<sup>33</sup> The Premium Cigar Manufacturers refer FDA to those comments for a full analysis of the data, but present a few particularly relevant facts below.

- Across all three waves of the PATH study prevalence of usage of any premium cigar (including those that could be considered “flavored”) among ages 12-14 was 0.00%.<sup>34</sup>
- Youth usage of premium cigars (including those that could be considered “flavored”) continued to drop across waves of the PATH study from 0.08% to 0.04% to 0.02% in Wave 3.<sup>35</sup>

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<sup>31</sup> Further, as will be discussed below in in Section V, while there is great variety in the premium cigar market, many of these products have extremely low production volumes and would therefore be needlessly driven off the market by the unjustifiable economic burden of the Proposed SE Rule.

<sup>32</sup> CAA submitted a report of Econsult Solutions that analyzed sales of premium cigars carried by the largest internet retailers. This work showed that in 2017 there were 51,000 premium cigar SKUs, due to the huge variety of premium cigars. Exhibit 1, Ex. B. at 8, Table 3. There are thousands of additional SKUs not carried by these five retailers.

<sup>33</sup> The expert reports attached to the CAA Premium Cigar Comments relied on both the restricted and unrestricted use files from the first three Waves of the PATH Study.

<sup>34</sup> Exhibit 1, Ex. A. at Table 1.

<sup>35</sup> *Id.*

- Median age of first use of premium cigars (including those that could be considered “flavored”) is age 30.<sup>36</sup>
- The median age of premium cigar purchasers through internet retailers for all premium cigars is 57 years old, and for “flavored” premium cigars is 53 years old.<sup>37</sup>
- Approximately 96.1% of premium cigar users (including those that could be considered “flavored”) smoke premium cigars less than daily.<sup>38</sup>
- Median monthly use of premium cigars (including those that could be considered “flavored”) was 1.3 days in Wave 3 of the PATH study.<sup>39</sup>

The data is unequivocal – premium cigars are not used by youth, and usage patterns for adult cigar smokers are very different from those of other tobacco products. Further, two experts reviewed the available scientific literature and data on this subject and independently came to the same conclusion – use of premium cigars does not increase health risks. Dr. Geoffrey Kabat, a renowned epidemiologist, determined that “...there is no association between non-daily premium cigar smoking -- which applies to the overwhelming majority of premium cigar smokers – and increased health risks compared to non-smokers.”<sup>40</sup> Similarly, Dr. Brad Rodu, a noted tobacco harm reduction researcher, relying heavily on research sponsored or conducted by FDA, found:

The following facts are indisputable with respect to cigars: (1) the prevalence of cigar use in the U.S. is extremely small, especially for premium cigars; (2) these products, especially premium category, are used infrequently and in small numbers; (3) they are puffed, rather than inhaled. The agency’s unsupported position [regulating premium cigars] has led to needlessly subjecting cigar and pipe smokers, and the manufacturers of those products, to

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<sup>36</sup> Exhibit 1, Ex. A. at Table 5c.

<sup>37</sup> Exhibit 1, Ex. B. at 9.

<sup>38</sup> Exhibit 1, Ex. A. at Table 4c.

<sup>39</sup> *Id.*

<sup>40</sup> Exhibit 1, Ex. C. at 7.

the same onerous and burdensome regulatory regime as much more hazardous cigarettes. **Low prevalence, infrequent use and reduced exposure translates into minimal harm at the population level.** Epidemiologic analysis from FDA staff indicate that consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.<sup>41</sup>

Research published by FDA, or supported by FDA, confirms this. As discussed above in Section III.b, premium cigars are used infrequently by adults. Further, CTP researchers published a paper showing that non-daily users of cigars – which includes 96.1% of premium cigar smokers – have no statistically significant increase in mortality compared to non-smokers.<sup>42</sup> Christensen et al. examined results from the National Longitudinal Mortality Study, a longitudinal population-based, nationally representative health survey, with mortality follow-up with other information from the Current Population Survey and Tobacco Use Supplement, and mortality data from the National Death Index. The participants provided tobacco use information at baseline, in surveys beginning in 1985 and were followed for mortality through 2011. Tobacco use was categorized as “cigarettes,” “any cigar,” or “pipe tobacco.” Responses were analyzed for exclusive use of each product. Even without stratifying by type of cigar, there was no statistically significant increase in mortality for non-daily cigar smokers compared to non-smokers.<sup>43</sup>

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<sup>41</sup> Exhibit 2, Rodu Testimony, *supra* note 26, at 5-6 (emphasis added).

<sup>42</sup> Christensen C. et al., *Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population*, 178 JAMA Internal Medicine 14, 469-76, E-6 at table 3 (Apr. 2018) available at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2672576>.

<sup>43</sup> *Id.*



Finally, an FDA-funded study authored by CTP employees examined biomarkers of adult cigar smokers in Wave 1 of the PATH study.<sup>44</sup> This study found that “[d]ifferences in use patterns across different types of established cigar smokers ... were observed ... [and] traditional cigar smokers were less likely to be every day smokers of the product....”<sup>45</sup> In examining the biomarker data, the researchers found that exclusive “some day” traditional cigar smokers had biomarkers of exposure to certain HPHCs more similar to never tobacco users than any of the other studied types of tobacco users (exclusive cigarillo user, exclusive filtered cigar smoker, and exclusive cigarette smoker).<sup>46</sup> In this analysis “some day” smokers were those who had smoked a cigar or cigarette in the past 30 days, but were not everyday smokers. This study again demonstrates that use of premium cigars (included in the broader category of “traditional cigars”), due to their unique usage patterns, do not raise questions of public health.

The Proposed SE Rule should not be applied to premium cigars as they do not raise questions of public health similar to other tobacco products.

b. Characterization and Design Parameters

i. *Basic design parameters*

FDA suggests that, in order to “characterize” a “leaf wrapped cigar,” the “wrapper material” must be defined.<sup>47</sup> For premium cigars, however, the “wrapper material” is part of the definition. In order to be a “premium cigar” the cigar must be wrapped in “whole leaf tobacco.” As

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<sup>44</sup> Chang et al., *Biomarkers of Exposure among U.S. adult Cigar smokers: Population Assessment of Tobacco and Health Study Wave 1* (2013-2014) *Cancer Epidemiol Biomarkers Prev.*; 28(5), 943-953 (May 2019).

<sup>45</sup> *Id.* at 943.

<sup>46</sup> *Id.* at Table 4.

<sup>47</sup> Proposed SE Rule, *supra* note 1, at 12,754.

explained below, it is therefore inappropriate to require the wrapper material as part of FDA's mandatory "product properties information." By definition, a premium cigar is a roll of tobacco wrapped in whole leaf tobacco. It is this simple design that defines premium cigars.<sup>48</sup>

*ii. Packaging and Product Quantity are not relevant inquiries in any context, especially for premium cigars*

As discussed in depth in the CAA SE Comments, there are legal reasons why both packaging and product quantity changes are not relevant for cigars in general; for premium cigars, these concerns are even more compelling.<sup>49</sup> For one, there is no consistent standard for premium cigars in terms of product quantities or packaging. By comparison, cigarettes are sold in individual packs of either a hard pack or soft pack configuration each containing 20 or 25 cigarettes and/or in a carton containing 10 individual packs. These are generally the only two packaging and product quantities that exist for this product. In contrast, every premium cigar is intended to be sold as a single cigar, regardless of how it is originally packaged by the manufacturer. Tobacconists have been selling cigars this way for decades – having open boxes in a walk-in humidor for customers to select an individual cigar, or to have cigars on trays outside of boxes for customers to view and select a cigar. Premium cigars can be sold in their boxes (which come in a variety of product counts commonly including 10, 16, 20, 22, 24, and 25) and can be sold in countless other combinations.<sup>50</sup> There is no standard product quantity for premium cigars, and there is no basis to require premium cigars to file SE Reports for product

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<sup>48</sup> While premium cigars are sometimes rubbed or otherwise treated, this is done simply and solely for aesthetic or technical purposes, not to change the consumer experience.

<sup>49</sup> See CAA Comments on Proposed SE Rule at Section V.e., VI.a.[hereinafter CAA SE Comments].

<sup>50</sup> See Exhibit 1, Ex. B. at 15, Table 11 and 12.

quantity changes when at the most basic level consumers can always choose to buy one or multiple premium cigars at any given time. For premium cigars, “product quantity” is truly a misnomer. Moreover, inasmuch as premium cigars have been available for decades in essentially every count size, both large and small, it seems illogical to suggest that product quantity has any association with premium cigar usage, which has been shown as of Wave 3 of the PATH study to have a median monthly usage rate of 1.3 premium cigars *per month*. It is, therefore, no surprise that FDA itself has “determined that...changes in tobacco product quantity do not cause the new tobacco products to raise different questions of public health.”<sup>51</sup>

In addition to the wide variety of package quantities, premium cigars come in a wide variety of packaging options, for example, wooden boxes, acrylic boxes, cardboard boxes, jars, bags, foil packages and cellophane. As outlined in the CAA SE Comments, there are numerous legal reasons why neither packaging nor FDA’s self-defined term of “container closure system” should be part of any premarket review.<sup>52</sup> This especially holds true for premium cigars. Certain premium cigars are individually wrapped in food-grade cellophane, simply to preserve freshness

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<sup>51</sup> Memorandum from David B. Portnoy and Joanna C. Randazzo on Product Quantity Changes in Substantial Equivalence Reports for statutorily regulated products (Dec. 7, 2017), available at <https://www.fda.gov/media/124674/download>. [hereinafter FDA Memo on Product Quantity Change]. Further, even if FDA were to continue to argue that product quantity was in some manner a relevant consideration, recently published work by FDA shows that this is unfounded. (“...we found few associations between package quantity and cigar smoking behaviors.”) Persokie A., O’Brien EK, Donaldson EA, et al. *Cigar package quantity and smoking behavior*. BMC Public Health (2019) 19:868 at 6.

<sup>52</sup> See CAA SE Comments Section V.e. FDA proposes to define “container closure system” as any packaging materials that are a component or part of a tobacco product. Although the FD&C Act does not define “component” or “part,” FDA promulgated definitions for these terms in the Deeming final rule. According to [21 CFR 1100.3](#), “component or part” means any...assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory. FDA examples of a container closure system include the blister pack around a dissolvable tablet, the can containing a moist snuff product, and the plastic-wrapped hard pack or soft pack containing cigarettes. Proposed SE Rule, *supra* note 1 at 12,746.

and protect the cigar from damage. In addition, even for those premium cigars not individually wrapped in cellophane, the containers they are placed in -- be it, for instance, an acrylic box, a glass tube or a ceramic jar -- are not “container closure systems” as they do not “have the potential to alter or affect the performance, composition, constituents, or other physical characteristics of the product.”<sup>53</sup>

*iii. Comparative Testing would not produce any meaningful results because premium cigars are all handmade and subject to natural variation*

By the Premium Cigar Manufacturer’s proposed definition, a premium cigar is “handmade,” as it “is made by manually combining the wrapper, filler, and binder . . . .” Premium cigars, therefore, are going to be inherently variable – as no handmade process can produce exact replicas. There will always be the roller who rolls a premium cigar slightly tighter than another, or a cigar with a ring gauge slightly larger than the one next to it in the same box.<sup>54</sup> While all premium cigar manufacturers have quality controls to produce the most uniform product possible, with a handmade process there are simply limits to what can be controlled. Further, for premium cigars, “specifications” generally look and read more like recipe cards than any traditional technical specification document.<sup>55</sup>

The Proposed SE Rule states that FDA requires “comparative design testing” including “test protocols, quantitative acceptance criteria, and test results (including means and variances, data

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<sup>53</sup> Proposed SE Rule, *supra* note 1, at 12,746.

<sup>54</sup> Additionally, most premium cigars makers use “molds” to shape the bunch of tobacco before it is rolled. There is a great variety in these molds across manufacturers.

<sup>55</sup> Natural variance within the composition will require blenders to use different tobaccos to achieve the same flavor. Similar to the process with spirits, master blenders mixing various ages and barrels to get back to the original experience, not the same recipe. The goal of the blender will always be to achieve consistency through working with raw materials that are always variable due to nature.

sets, and a summary of the results).”<sup>56</sup> For premium cigars, none of this mechanized, routine testing is done. Instead, much as the process of making a premium cigar is manual, quality control is also manual. Any quality control generally consists of a manual physical inspection of the cigars to look for imperfections, and checks to determine if widths, lengths and weights are within a given range for the product. All of this is done by hand, and the procedures used (other than general measuring with a ruler) will vary from factory to factory. There is no “testing,” or “test protocols,” that can be used in this process. It is a manual process that has been performed this way for decades. Any comparative testing is simply meaningless for premium cigars.

Recent work published by CTP, and other researchers, confirms the variability in any testing, both within the cigar category as a whole and the premium cigar category in particular, and between cigars of like brands and sizes. This work did not attempt smoke testing; rather, it examined only product size, dry nicotine content, and tobacco pH (similar to the comparative testing FDA is attempting to mandate in the Proposed SE Rule), and found a “...wide variation in product size and nicotine content within the domestic cigar market.”<sup>57</sup> Further, the study found that “...cigar size does not necessarily correlate with nicotine or free nicotine content.”<sup>58</sup> Critically, the study found it was not possible to replicate results, noting “...in the two large cigar

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<sup>56</sup> Proposed SE Rule, *supra* note 1, at 12,757.

<sup>57</sup> Koszowski et al., *Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States*, *Nicotine and Tob. Res.* 20(3) 393-398 (Feb. 7, 2018) available at <https://www.ncbi.nlm.nih.gov/pubmed/28340022>.

<sup>58</sup> *Id.* This is yet another reason why “size” of the cigar should not be a component of the definition of premium cigars.

and cigarillo brands analyzed a second time, there was considerable within-brand variance in nicotine content and concentration between the first and second analyses.”<sup>59</sup>

*iv. Any premarket review requirements for co-packaged premium cigars are entirely unnecessary*

FDA has stated that “[c]o-packaging two or more legally marketed tobacco products, where there are no changes, including no change to the container closure system(s), does not result in a new tobacco product...[however,] co-packaging two or more tobacco products within the same container closure system results in a new tobacco product . . . .”<sup>60</sup> For premium cigars, this is completely illogical and unnecessary. Assuming for the sake of this example, a retailer places five cellophane wrapped cigars into a bag and sells these cigars as “sampler 1.” Under FDA’s analysis, no premarket review is needed. If, however, the retailer places three cellophane wrapped premium cigars and two premium cigars that are not wrapped in cellophane into a bag, this product would require premarket review.

There is no basis for FDA to require premarket review for co-packaged, finished tobacco products under the TCA. There has been no “modification” to the “physical elements” of the product. Further, for premium cigars, based on the usage patterns, and consequentially low health risk, there is no possible public health justification for pre-market review of co-packaged premium cigars.<sup>61</sup>

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<sup>59</sup> *Id.*

<sup>60</sup> Proposed SE Rule, *supra* note 1, at 12,744.

<sup>61</sup> Further, as discussed above, FDA has stated there “are not different questions of public health” raised by product quantity changes. *See* FDA Memo re Product Quantity Change, *supra* note 51. Additionally, every premium cigar may be sold individually at retail, making the idea of “co-packaged” premium cigars illogical.

c. Premium Cigar Tobacco

Premium cigars are made almost exclusively of “dark, air-cured tobacco.” CTP researchers who have studied “large cigars” stated that “...our data suggest there is wide variability in nicotine content and some physical properties in the domestic cigar market.”<sup>62</sup> These same researchers stated their study “...reveals some of the challenges to experimental cigar research . . .”<sup>63</sup> Premium cigars are constructed almost exclusively of tobacco, an agricultural product. Just as no two bottles of wine are identical, no matter where the grapes are grown, or in what year they are grown, neither can two premium cigars be identical. The quality of tobacco, and its chemical properties, are highly dependent on things such as rainfall, sun exposure, ambient temperature, and the availability of nutrients in the soil.<sup>64</sup> All of these things will be pre-determined at the time of harvest of the leaf. For instance, work has been done to examine premium cigar tobaccos of the exact same leaf (seed, country, area, farmer, texture and color) but from different crop years, and these results show very different levels of chemicals in the leaf itself.<sup>65</sup> Similar variety was shown when the same year of crop was examined and the only difference was the farm that grew the tobacco.<sup>66</sup> This shows that there is significant natural variation in the tobacco leaf itself.

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<sup>62</sup> Koszowski et al., *supra* note 57. The Premium Cigar Manufacturers note that not all of the large cigars used in this study would qualify as “premium cigars”, but since some would the study is still useful to see the variability in cigars.

<sup>63</sup> *Id.*

<sup>64</sup> While the vast majority of cigar tobacco is grown internationally, it is worth noting that FDA does not have authority over the “growing, cultivation, or curing of raw tobacco.” Tobacco Control Act § 4(b).

<sup>65</sup> Lindegaard, Thomas, Scandinavian Tobacco Group Lane, Ltd., Tobacco Science Research Conference, September 18, 2018.

<sup>66</sup> *Id.*

These are all natural variations due to the agricultural nature of the product. FDA has stated that it will not enforce premarket review provisions against manufacturers for “...tobacco blending changes to address the natural variation of tobacco (*e.g.* tobacco blending changes due to variation in growing conditions) . . . .”<sup>67</sup> As demonstrated above, nearly all blending in premium cigars is done to account for the natural variations in tobacco. The blending, however, is not done based on the chemical content of the leaf, but instead on the taste and flavor profile of the tobaccos in combination with one another. The Premium Cigar Manufacturers seek to maintain a consistent product so a consumer who enjoys a Montecristo No.1 can continue to purchase that cigar year after year and realize the same experience. This is the goal, even if the manufacturer has had to slightly change the blend to try to account for year-over-year differences, which may occur for a variety of reasons.<sup>68</sup>

In addition, FDA has stated that for the listing of ingredients in an SE Report, it wants information on “[t]he type of tobacco, including grade and variety.”<sup>69</sup> As noted above, premium cigars are constructed almost entirely of “dark, air-cured tobacco.” As most cigar tobacco is grown in foreign countries, using the USDA typing system would generally allow for three “types” of tobacco, which could be useful for classifying different tobacco in cigars – Type 81 (foreign grown cigar wrapper), Type 82 (foreign grown cigar filler) and Type 83 (foreign grown

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<sup>67</sup> Final Rule, *supra* note 9, at 28,996.

<sup>68</sup> As discussed in the CAA SE Comments, the February 15, 2007 grandfather date is unworkable for all cigars, but creates specific challenges for premium cigars. A grandfathered cigar, that blenders have meticulously maintained the consistency of, may have a very different blend profile in 2019 than it did in 2007. Yet, despite what on paper may look like a change, it will be the entirely same cigar, and any differences will be only to account for natural variation.

<sup>69</sup> Proposed SE Rule, *supra* note 1, at 12,763.



cigar binder).<sup>70</sup> While the USDA typing system may be useful for classification, the USDA grading system would not be useful as applied to premium cigar tobacco, as these grades are not uniformly used by premium cigar farmers and manufacturers. Instead, nearly every farmer and manufacturer use their own unique grading system for tobacco. For certain farmers and manufacturers there may not even be a written record of this system, it may just be passed down orally to each new generation. Requiring any grading system for premium cigars will not further any meaningful comparisons between products as there is no standard terminology or methodology used to grade cigar tobacco across the premium cigar industry.

d. HPHCs

The Proposed SE Rule as written requires Harmful and Potentially Harmful Constituent (“HPHC”) testing data to be submitted with all SE Reports, regardless of product category or type of SE Report.<sup>71</sup> For premium cigars this is unnecessary and unproductive, given the unique nature of cigar tobacco and each handmade premium cigar product. More importantly, at present, smoke testing methodologies for premium cigars do not exist that can yield reliable, reproducible, scientifically valid results for any HPHCs. Finally, and equally important, FDA has not yet stated which HPHCs will be required for reporting on any cigar, let alone a premium cigar.<sup>72</sup>

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<sup>70</sup> 7 C.F.R §30.43 (1991).

<sup>71</sup> Proposed SE Rule, *supra* note 1, at 12,763. The TCA itself does not state anywhere that HPHC testing must be part of any SE Report. *See* Tobacco Control Act §§ 905(j), 910(a)(3).

<sup>72</sup> The Premium Cigar Manufacturers note that FDA has stated that no HPHC testing will be required for any Newly Deemed Product until FDA releases Final Guidance on HPHC testing for these products. *See* U.S. FOOD & DRUG ADMIN., Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)\*, Guidance for Industry (Mar. 2019), at 12. As of the date of the filing of this comment, Draft Guidance on this issue had not yet been released. Further, if the decision by Judge Grimm referenced in footnote 23 stands,

First, there is no generally recognized and accepted methodology to perform smoke testing on premium cigars. While there is a working group within CORESTA dedicated to trying to understand the many complicating factors inherent in smoke testing for premium cigars,<sup>73</sup> there is no guarantee that any resulting smoke testing methodology will be able to overcome the inherent natural variations and challenges presented by premium cigars.<sup>74</sup> Unlike for cigarettes, where there are two internationally recognized methods that generate reproducible and repeatable smoke testing results both within and between laboratories, there is currently no method where repeatability and reproducibility has been established through collaborative studies of multiple laboratories for premium cigar smoke testing. This ensures that if FDA were to require premium cigars to submit any sort of HPHC testing the results would be inherently variable, not only due to the inherent variation in cigar tobacco and handmade cigar production as detailed above, but also due to the lack of smoke testing methodology.

Second, FDA has not yet established a list of HPHCs to be tested for in any cigar, let alone a premium cigar. Section 904 of the Tobacco Control Act requires a “...listing of all constituents, including smoke constituents as applicable...identified by the Secretary as harmful or potentially harmful to health in each tobacco product . . . .” (emphasis added).<sup>75</sup> FDA has only established

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there is again the possibility that premium cigars may have to submit SE Reports (i) prior to FDA determining whether they are to be exempt from regulation; and (ii) before FDA releases Final Guidance on HPHC reporting.

<sup>73</sup> CORESTA, Project No. 148, “Smoke Collection of Handmade Long Filler Cigars”, Cigar Smoking Methods (last visited on July 16, 2019), <https://www.coresta.org/study-groups/active-projects>

<sup>74</sup> The Premium Cigar Manufacturers are aware that certain independent laboratories state that they have methods to test premium cigars. Any such tests are not internationally recognized, validated methodologies and there is no way to know if they would be reproducible or repeatable in different laboratories.

<sup>75</sup> Tobacco Control Act. Sec. 904(a)(3).

lists for HPHC testing for originally regulated products.<sup>76</sup> Even if there were an established list of HPHCs for cigars, given the handmade nature of the product, and the inherent variability of cigar tobacco, there is a question whether test results, whether smoke testing results or dry leaf test results, would provide any meaningful data for FDA to make a comparison between a new and predicate product.<sup>77</sup>

It is inappropriate to subject any product to a testing requirement for which no guiding structure has been implemented, and for which no generally accepted scientific methodology yet exists. Even if basic methodologies did exist, the application by FDA of a testing requirement intended for cigarettes, which are an incredibly uniform product with an established testing protocol, to premium cigars, is fundamentally flawed given the inherent agricultural and production variations of these products. As a result of agricultural changes due to local growing conditions, the inherent natural variation present in cigar tobacco, and the unique nature of each hand-crafted cigar product, there is an almost infinite number of variables that impact the validity and usefulness of testing any set of HPHC's in premium cigars under any methodology.

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<sup>76</sup> U.S. FOOD & DRUG ADMIN., Draft Guidance for Industry, Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (March 2012).

<sup>77</sup> As noted, any test results would most likely show large, inconsistent variations between premium cigars. Therefore, while using HPHC test data as a standard for substantial equivalence for other products may be justified, for premium cigars it could have unintended consequences. For example, in the context of cigarettes, if there is one difference between a predicate and a new product, but the HPHC testing between the two products is substantially equivalent, then the products must be substantially equivalent. With premium cigars however, two "identical" cigars could be tested and yield different results, and yet a new and a predicate cigar could be tested and have similar results – all simply due to the variability in the leaf and the construction. This would undermine FDA's premise for basing SE decisions on HPHC levels. *See* CAA SE Comments at Section VI.c.ii.3. Further, as noted in note 55 above, to maintain a consistent product, master blenders adjust the blends as necessary, this could create products that although intended to replicate a 2007 product, will not be able to do so entirely and will therefore not yield meaningful comparisons through HPHC testing.

e. Stability Testing

The Proposed SE Rule “...would require stability information for smokeless tobacco products and any tobacco product that contains fermented tobacco.”<sup>78</sup> All premium cigars contain tobacco that could be considered fermented; however, as discussed below, stability is not an issue for premium cigars. Based on the general curing and fermentation processes for premium cigar tobacco set, stability testing is not relevant or appropriate for premium cigars and should not be required.

Nearly all cigar tobacco is hung post-harvest in a barn or other structure to naturally cure. At the start of the curing process, the tobacco leaves contain a high percentage of water; however, by the end of the curing process the water content is significantly reduced. The process can take from a few weeks to a few months depending on the conditions present both in the structure and the natural environments (e.g. amount of rainfall). Artificial heat may be added, and the windows or doors of the curing structure can be opened and closed as needed to adapt to changes in weather to control temperature and humidity during the curing process.

Additionally, while premium cigar tobacco generally has gone through a “fermentation” process, this process is entirely different from the one FDA is familiar with in the context of moist snuff.<sup>79</sup> “Fermentation,” can mean different things, both colloquially and in the tobacco industry. It is not the same for every product, or even every type of tobacco, or every farm or

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<sup>78</sup> Proposed SE Rule, *supra* note 1, at 12,764 (emphasis added).

<sup>79</sup> The Premium Cigar Manufacturers note that while FDA proposes stability testing is required for “any tobacco product that contains fermented tobacco” it does not define “fermented” or “fermentation.” Proposed SE Rule, *supra* note 1, at 12,764.

producer of cigar tobacco.<sup>80</sup> For cigar tobacco, the term “fermentation” refers generally to the aging, maturing, and preservation processes for cigar leaves. Cigar fermentation is generally accomplished by stacking whole tobacco leaves into bales and stacking the bales together. The pressure of the tobacco itself, along with added moisture, will generate heat that “ferments” the tobacco.

The stacks of tobacco bales are constantly monitored for heat and moisture and, generally, the tobacco bales are rotated within the stacks to ensure equal treatment. The process usually takes a few months with exact timing depending on the farm, type of tobacco, intended use of the tobacco (binder, wrapper, filler) and amount of tobacco in the bales and stacks. Ammonia and CO<sub>2</sub> are emitted during this process. This process results in cigar tobacco having lower pH values and lower content of natural sugar than existed at the beginning of the process; however,

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<sup>80</sup> The Premium Cigar Manufacturers have found at least three different definitions of “fermentation” none of which apply to the process used for cigar tobacco:

(i) Fermentation, chemical process by which molecules such as glucose are broken down anaerobically. More broadly, fermentation is the foaming that occurs during the manufacture of wine and beer, a process at least 10,000 years old. The frothing results from the evolution of carbon dioxide gas, though this was not recognized until the 17th century. French chemist and microbiologist Louis Pasteur in the 19th century used the term fermentation in a narrow sense to describe the changes brought about by yeasts and other microorganisms growing in the absence of air (anaerobically); he also recognized that ethyl alcohol and carbon dioxide are not the only products of fermentation. Encyclopedia Britannica, *Fermentation*, (published Dec. 28, 2017), <https://www.britannica.com/science/fermentation>;

(ii)1a : a chemical change with effervescence

b : an enzymatically controlled anaerobic breakdown of an energy-rich compound (such as a carbohydrate to carbon dioxide and alcohol or to an organic acid) broadly : an enzymatically controlled transformation of an organic compound Merriam-Webster, *fermentation* (last visited July 16, 2019), <https://www.merriam-webster.com/dictionary/fermentation>;

(iii)A chemical change induced in a complex organic compound by the action of an enzyme, whereby the substance is split into simpler compounds.

2. In bacteriology, the anaerobic dissimilation of substrates with the production of energy and reduced compounds; the mechanism of fermentation does not involve a respiratory chain or cytochrome, hence oxygen is not the final electron acceptor as it is in oxidation. Medical Dictionary for the Health Professions and Nursing, *fermentation* (2012), <https://medical-dictionary.thefreedictionary.com/fermentation>.

the chemical changes through this process are small compared to the chemical processes outlined above that occur during the actual growing and maturation of the plant. Further, certain cigar tobaccos (depending on type of cigar, producer of the tobacco, etc.) may then be aged in warehouses or barns for additional time post-fermentation. These fermentation processes have been in place for decades, if not hundreds of years.

Premium cigar tobacco is grown in countless farms all over the world all of which typically use slightly different curing and fermentation processes. FDA has stated that it will require stability testing for fermented tobacco products because

...the fermentation process can result in different degrees of change in the constituents of the tobacco ... and affect the microorganisms in the final product, thereby affecting the stability of the product, which could change the characteristics of the new tobacco product, which may cause the new tobacco product to raise different questions of public health.<sup>81</sup>

FDA misinterprets the TCA with this requirement, and shows a lack of understanding of product differences, especially in relation to premium cigars. Moist smokeless tobacco products contain a use-by date, and therefore shelf life may arguably be a consideration for these products. For premium cigars, however, requiring this testing is wholly inappropriate based on the characteristics of the product. In a high moisture product (such as moist snuff) concerns regarding shelf-life and micro-organisms may be applicable, again only depending on the nature of the change to the product; however, in a low-moisture product these concerns are not valid. Premium cigars, and cigar tobaccos, can be held in stable form for an extended period of time (e.g. many years) without risk of damage or change to the leaf. Further, there has been no

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<sup>81</sup> Proposed SE Rule, *supra* note 1.

indication that the fermentation process used for cigar tobaccos leads to any nitrite or nitrosamine formation. With premium cigars, the true concern is the opposite of that with smokeless tobacco: a premium cigar will only become stale if it sits on a shelf too long without any humidification. The tobacco will simply dry out and crumble. There is absolutely no scientific basis to require stability testing for premium cigars.

**V. The Proposed SE Rule Will Be an Economic Ban on Much of the Premium Cigar Category**

The Preliminary Regulatory Impact Analysis (“PRIA”) looks at the entire cigar category as a whole, but does not recognize that application of the Proposed SE Rule to premium cigars would impose an incredible cost on premium cigar manufacturers with very little, if any, benefit to the public health. The Premium Cigar Manufacturers submit the following analysis of the PRIA to demonstrate (i) FDA’s flawed reasoning in the PRIA; and (ii) the potential for the Proposed SE Rule to end up as a *de facto* ban on the premium cigar industry because of the onerous costs associated with it.

The PRIA examines the potential economic consequences of the Proposed SE Rule as required by Presidential Executive Orders 12,866 and 13,563, the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995. The provisions of those Executive Orders and Acts most relevant to the Proposed SE Rule require that FDA (i) conduct an assessment of the costs and benefits of the Proposed SE Rule and propose or adopt it only upon a “reasoned determination” that the benefits of the Proposed SE Rule justify its costs, and (ii) minimize any significant economic impact of the Proposed SE Rule on small entities. FDA has failed to meet both requirements with the Proposed SE Rule. FDA states that:

We believe that this [Proposed SE Rule] is not an economically significant regulatory action as defined by Executive Order 12866....Because we have determined that the compliance costs are less than 0.1 percent of revenues, we propose to certify that the rule would not have a significant economic impact on a substantial number of small entities.<sup>82</sup>

The Premium Cigar Manufacturers disagree with FDA's assessment because complying with the Proposed SE Rule will have a significant impact on numerous small entities.<sup>83</sup> Indeed, FDA has incorrectly speculated for years that premarket review would not be onerous to the cigar industry.<sup>84</sup>

a. FDA's Assumptions Regarding Costs for Each SE Report Are Flawed

FDA states that:

This [Proposed SE Rule] would impose compliance costs on affected entities to read and understand the rule, establish or revise internal procedures, and fill out a form for SE Reports....The costs range from around \$200 to around \$800 per affected entity per year, with a primary estimate of around \$500 per entity per year.<sup>85</sup>

This is, right from the start, a significant error. As drafted, the Proposed SE Rule does not simply require affected entities to "fill out a form for SE Reports." It also requires comparative

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<sup>82</sup> Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports, Preliminary Regulatory Impact Analysis, April 2019 [hereinafter PRIA]; Proposed SE Rule, *supra* note 1, at 12,773.

<sup>83</sup> According to the International Premium Cigar and Pipe Tobacco Retailers Association ("IPCPR") approximately 83% of their membership of retailers (or 2,900 businesses) are single store operations. *See* IPCPR, Comment on Modification to Compliance Policy for Certain Deemed Tobacco Products (Mar. 14, 2019), Dkt, No. 2019- D-0661.

<sup>84</sup> 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Regulatory Impact Analysis, May 2016; ("the costs of undergoing premarket review are expected to be relatively low for cigar products that seek marketing authorization through the substantial equivalence or exemption from substantial equivalence pathways.") *Id.* at 76.

<sup>85</sup> PRIA, *supra* note 82, at 4.



design testing, HPHC testing, and potentially stability testing.<sup>86</sup> Nowhere does the PRIA address the costs of these tests. While cigar manufacturers have only begun to estimate what these costs would be (assuming that an internationally recognized, validated method for them can be finalized), realistic estimates from companies who have done similar testing for cigarettes and smokeless tobacco estimate the testing costs alone to average \$80,000 - \$100,000 per product. This does not take into account additional costs of gathering information, purchase of scientific literature, analysis of test results, and required additional toxicological work, preparing an environmental assessment, or any consumer perception studies.<sup>87</sup> Some manufacturers estimate that the cost for a SE Report for one product could be between \$250,000 and \$2,000,000 depending on the testing and type of product.

FDA's statement that the sole requirement is to "fill out a form" becomes even more misleading when looking at FDA's estimates for the amount of hours it will take to prepare an SE Report. FDA estimates a low estimate of 87 hours and high estimate of 300 hours to complete a SE Report.<sup>88</sup> One CAA member company, who has submitted numerous SE Reports for other products, estimates that a SE Report for one product will take approximately 900 hours to prepare, based on the current experience with FDA.<sup>89</sup> A different CAA member company, which has also submitted numerous SE Reports, has estimated this in months instead, estimating

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<sup>86</sup> See Proposed SE Rule, *supra* note 1, at 12,757, 12,759, 12763-64.

<sup>87</sup> It is the position of the Premium Cigar Manufacturers that premium cigars should be exempt from FDA regulation. This list of costs is simply illustrating the greater flaws with the Proposed SE Rule as applied to premium cigars.

<sup>88</sup> PRIA, *supra* note 82, at 23.

<sup>89</sup> See CAA SE Comments *supra* note 49, at 66.

it can take 15-28 months to prepare a SE Report for one product depending on the scientific testing required.<sup>90</sup> FDA's estimate of 87-300 hours is rebutted by real world experience. This is especially true since FDA's estimate includes a range of 52-80 hours for the environmental assessment alone.

b. FDA's Estimates Regarding the Number of Affected Cigar Entities and Products Are Based on Incorrect Assumptions

Regarding cigars specifically, FDA's estimate of the number of affected products and entities lacks any reasonable method of accounting for the size of the industry. FDA has chosen to rely on the domestic establishment registration and product listing data to estimate the number of cigar products. While certain cigar manufacturers chose to register their establishments and list their products even though the products were manufactured primarily at foreign facilities, not all companies did so.<sup>91</sup> Given the fact that the vast majority of cigars are manufactured overseas, using this list as a baseline for this product category starts from a flawed premise. For premium cigars this analysis is even more flawed. First, many premium cigar manufacturers did not list their foreign manufactured products on FDA's product list. Second, there are hundreds, if not thousands, of premium cigars that will be grandfathered that have not submitted standalone grandfather requests. FDA's product counts for "cigars" are therefore inherently flawed.

FDA estimates there are 52,934 - 61,130 product-package label combinations of cigars at baseline. FDA then assumes a 67% proportion product-package combinations to product package label combinations, and comes to an estimate of 35,289 to 40,753 product-package

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<sup>90</sup> *Id.*

<sup>91</sup> FDA admits it does not have this information stating "we do not have enough information to count foreign manufacturers." *Id.*

combinations for cigars.<sup>92</sup> FDA then makes the astounding and unsupported statement, given the 2007 grandfather date, “we assume the majority of cigar products on the market as of the effective date for the Final Deeming Rule would be grandfathered.”<sup>93</sup>

In order to determine how many “initial SE Reports” there will be for the cigar category, FDA:

analyze[d] the relationship between SE Reports for originally regulated products...and the number of grandfathered products established through requests for standalone grandfathered determinations....We use this relationship, in addition to FDA’s past experience with SE Reports for originally regulated products and subject matter expertise on cigar manufacturing and the amount of variation in cigar products, and estimate that the number of SE Reports received for cigar products during the initial submission period will be an average of two to five times the number of cigar products that have been established as grandfathered through a standalone grandfather submission.<sup>94</sup>

This analysis led FDA to the assumption that a lower bound estimate would be that two SE Reports would be submitted for each established grandfathered product and an upper bound estimate of five SE Reports per established grandfathered product, for a total of 2,100 - 5,200 initial cigar SE Reports.<sup>95</sup> This estimate is already incorrect. FDA made this estimate based on information as of August 31, 2018 when there were 1,042 established grandfathered cigars. As of May 30, 2019, there are 1,442 established grandfathered cigars.<sup>96</sup> This alone shows the flaws

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<sup>92</sup> *Id.* at 17, Table 4. The Premium Cigar Manufacturers assume for this analysis FDA has included premium cigars in this “cigar” calculation.

<sup>93</sup> *Id.* at 18.

<sup>94</sup> *Id.* at 18.

<sup>95</sup> *Id.*

<sup>96</sup> U.S. FOOD & DRUG ADMIN., Standalone Grandfathered Determinations database, (last visited July 16, 2019) <https://www.accessdata.fda.gov/scripts/ctpgnd/> It is worth noting that many of the cigars in the established

in FDA's reasoning on this point. FDA looked to the established grandfather product database. This database, however, does not present a current or accurate picture of the number of grandfathered products. First, submitting a grandfather request outside of an SE Report is a voluntary process. While many cigar companies have chosen to make these submissions, many have not. Additionally, SE Reports for cigars on the market as of August 8, 2016 are not due to be filed until August 8, 2021.<sup>97</sup> Manufacturers may not have yet submitted grandfather requests for their products. Finally, the list may not be accurate as it can take FDA over a year at times to review a grandfather request.

c. The Premium Cigar Market – Large Variety with Low Volume

As was outlined in the CAA Premium Comment there is a huge variety in the premium cigar space – in fact, the largest online retailers report that in 2017, combined amongst these companies there were approximately 51,000 SKUs of premium cigars.<sup>98</sup> In line with the reasons for the great variety of premium cigar products on the market, Corey et al. showed that premium cigar smokers were much less likely to have a “regular tobacco brand” than other cigar smokers and cigarette smokers (49.7% v 77.1% v 93.1%).<sup>99</sup> The Econsult Report further demonstrates this. Econsult found that for premium cigar purchasers who purchased at least twice, 36% of the orders contained only one or two brands, meaning 64% contained three or more brands, and that

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grandfather database are premium cigars. As FDA is still evaluating “whether and how to exempt premium cigars from regulation” this PRIA is further flawed for not discussing this issue and the difference in cigar categories.

<sup>97</sup> See footnote 23 above regarding the date for submission of initial SE Reports.

<sup>98</sup> CAA Premium Cigar Comments, Ex. 1, Ex. B at Table 3.

<sup>99</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

for more frequent purchasers, only 13% of the orders contained one or two brands, meaning that 87% of the orders contained three brands or more.<sup>100</sup>

This data reflects both the artisanal nature of product category, and the customers desire for diverse product offerings. Unlike cigarettes where smokers are using the product frequently to receive nicotine, premium cigar users smoke premium cigars infrequently, and when they do they seek an “experience.” That experience is typically steeped in the nuance of each cigar, and the uniqueness of varying lengths, shapes, ring gauges, and other characteristics that define these truly “specialty” products. Unlike commodity products, the premium cigar consumer seeks out that which is different and rare, and thus limited editions, special editions, single production runs, and small runs of interesting sizes are a hallmark of the industry. This is exemplified by the product portfolio of one large premium cigar manufacturer for whom over half the SKUs sold in 2018 generated less than \$25,000 of annual sales per SKU. This typifies the boutique nature of the premium cigar industry. If the Proposed SE Rule was put into effect for premium cigars, this manufacturer would be forced to abandon upwards of 50% of the products it currently manufactures, without any seeming public health benefit.

The product portfolio referenced above is for a sizeable manufacturer. If FDA requires extensive testing and SE Reports for every new premium cigar, it will completely wipe out these smaller selling brands, and would potentially eliminate the entire product portfolio for smaller manufacturers – serving as a de facto ban on the category. As the Econsult report noted, premium cigar users are not brand loyal, and “frequent customers purchase a variety of cigars,

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<sup>100</sup> Ex. 1, Ex B, at 15-16, Figure 2.

more so than less frequent customers.”<sup>101</sup> In addition, CAA commissioned a report by Policy Navigation Group to examine the overall costs of the Final Rule itself.<sup>102</sup> In this Report, Policy Navigation Group concluded that:

The premium market, the last row in Table 12, shows a much more significant effect. There are assumed to be 6,000 SKUs in a market with sales of approximately \$175 million. On average, average prices must rise by 46 percent to offset the regulatory costs. This sharp price rise saps consumer demand; consumer demand is estimated to fall from \$175 million per year to around \$22 million per year. With this sharp fall in demand, very few existing firms could remain in business....The market impacts in the premium market are even more severe. Based on the reported elasticities, consumers would almost completely shift away from premium cigars to other cigars or other luxury goods.<sup>103</sup>

As discussed above, FDA’s analysis of the number of cigars that could be affected by the Proposed SE Rule is flawed in relation to all cigars, but is especially flawed in relation to premium cigars. Again, however, this pales in comparison to FDA’s incorrect assessment of the cost of SE Reports – an estimate that does not contemplate any testing as part of the SE Report. For the Premium Cigar Manufacturers, if these testing provisions were required, the costs would be astronomical. The sheer volume of product variety and offerings would require millions of dollars of testing, and testing that would have little benefit in FDA’s mission to protect the public health. FDA’s purpose in regulating tobacco products is to *regulate* them, not abolish product categories. In fact, Congress prohibited FDA from banning any category of tobacco products – FDA should not be able to undermine this provision by using its authority over premarket review

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<sup>101</sup> See Ex. 1, Ex. B, at 15-16, Figure 2.

<sup>102</sup> See Exhibit 3, Report of Policy Navigation Group (originally submitted under Docket 2017-N-5095).

<sup>103</sup> Ex. 3 at 32.

to eliminate a category of products from the market.<sup>104</sup> As has been demonstrated through sound scientific research, premium cigars (i) are not used by youth; (ii) are used by an older adult population; and (iii) are used infrequently by these adults. Based on their usage pattern they have little to no potential health risks. As applied to premium cigars, there is no public health benefit that would justify the extreme costs of the Proposed SE Rule, or that is worth putting countless companies out of business.<sup>105</sup> By insisting on applying the Proposed SE Rule, and regulation more broadly, to premium cigars, FDA is circumventing the provisions of the Tobacco Control Act and imposing an economic ban on premium cigars.

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<sup>104</sup> Tobacco Control Act, sec. 907 (c)(3)(A).

<sup>105</sup> This point was made succinctly by Charles Maresca, of the Office of Small Business Administration, at a field hearing conducted by Sen. Marco Rubio on April 5, 2019. Mr. Maresca noted that:

Advocacy believes that small businesses dominate the premium cigar industry. There are at least 50 manufacturers of premium cigars across 19 states or more, all small businesses. Indeed, over 20 of those manufacturers are in Florida alone. Additionally, there are over 3,000 retailers of premium cigars located in all 50 states, some of which also roll their own cigars and are considered manufacturers under FDA's Deeming Rule.

According to FDA's own estimates, the Deeming Rule's compliance costs will have significant impacts on small businesses. Specifically, FDA states that some "low-volume cigar" manufacturers may end their domestic operations entirely. Premium cigar manufacturers are the very definition of "low-volume" cigar manufacturers. Their cigars are handmade and labor intensive, manufactured by the hundreds per day as opposed to the thousands an hour for mass-marketed, machine-made cigars.

For a small business cigar manufacturer, FDA estimates compliance costs to be \$278,000 to \$397,000 in the first year, \$292,000 to \$411,000 in the second year, and \$235,000 to \$257,000 in the third year. Although many small businesses have argued that the costs will be much higher than FDA's estimates, the agency's own numbers will prove to be too much for most small businesses to pay to continue to manufacture premium cigars. Included in those costs would be applying for premarket approval or completing an SE Report.... For manufacturers who cannot afford the Deeming Rule's compliance costs and are forced to shutter their factories, there will be thousands of employees who will no longer be employed.

## **VI. Conclusion**

For the reasons set forth above, the Proposed SE Rule is wholly inappropriate as applied to premium cigars, and the Premium Cigar Manufacturers request FDA define “premium cigar” as outlined in Section II, and exempt premium cigars from regulation.

Respectfully Submitted,

*/s/ Dylan Austin*

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Dylan Austin, President  
Davidoff USA

*/s/ Glenn Wolfson*

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Glenn Wolfson, Chief Executive Officer  
Drew Estate

*/s/ Regis Broesrma*

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Regis Broesrma, President  
General Cigar Company

*/s/ Christian Eiroa*

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Christian Eiroa, President  
Tabacalera Unidas

*/s/ Nick Perdomo Jr.*

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Nick Perdomo, Jr., President  
Tabacalera Perdomo

*/s/ Javier Estades*

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Javier Estades, President and CEO  
Tabacalera USA



# Exhibit 1

# CIGAR ASSOCIATION OF AMERICA, INC.

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July 25, 2018

Submitted via [www.regulations.gov](http://www.regulations.gov)

Division of Dockets Management  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane Rm. 1061  
Rockville, MD 20852

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

Dear Sir or Madam:

Cigar Association of America, Inc. (“CAA”) is a leading national trade organization representing the interests of cigar manufacturers, importers, distributors, and major suppliers of the industry. CAA was founded in 1937 as a non-profit trade organization. Today, its 44 member companies come from all sectors of the industry, from major manufacturers of handmade premium cigars to producers of machine-made cigars. CAA members manufacture a significant share of the large, premium, little, and filtered cigars sold in the United States. Its members also include internet retailers of cigars, as well as leaf, and other suppliers to the cigar industry. CAA is a key stakeholder in the implementation of any regulation of cigars, as these regulations significantly affect its members’ ability to conduct business.

CAA submits the following in response to the request by the Food and Drug Administration (“FDA”) for Comment on the Advanced Notice of Proposed Rulemaking (“ANPRM”) entitled “Regulation of Premium Cigars.”<sup>1</sup>

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<sup>1</sup> Regulation of Premium Cigars, 83 Fed. Reg. 12,901 (Mar. 26, 2018) (“Premium Cigar ANPRM”).

## **I. Introduction**

On July 28, 2017, FDA Commissioner Dr. Scott Gottlieb announced that, as part of the “new comprehensive plan for tobacco and nicotine regulation,” FDA would examine “whether and how we would exempt premium cigars from regulation.”<sup>2</sup> Dr. Gottlieb stated:

I’m also asking the Tobacco Center leadership to explore a process by which it could ask for new information related to the patterns of use and resulting public health impacts from so-called premium cigars. The final deeming rule covers all cigars. But I want the Center to consider opportunities it could provide to interested parties to develop and submit new information or data on this issue. This will take the form of a new Advance Notice of Proposed Rulemaking, to develop a new administrative record to explore these questions. **We will explore any new and different questions raised, and seriously consider any additional data submitted relevant to the appropriate regulatory status of premium cigars** (emphasis added).<sup>3</sup>

The Premium Cigar ANPRM, released on March 26, 2018, seeks “comments, data, research results, or other information that may inform regulatory actions FDA might take with respect to premium cigars.”<sup>4</sup> Specifically, FDA has asked for comments in three broad areas: (i) the definition of premium cigars; (ii) use patterns of premium cigars; and (iii) public health considerations associated with premium cigars.

CAA has structured its Comment to the ANPRM in the following seven sections: (i) executive summary; (ii) background of the premium cigar industry; (iii) definition of “premium cigar”; (iv) use patterns of premium cigars; (v) public health considerations associated with premium cigars; (vi) why the existing regulations are fundamentally flawed as applied to premium cigars; and (vii) why premium cigars should be exempt from regulation.

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<sup>2</sup> Dr. Scott Gottlieb, *Protecting Families: Comprehensive Approach to Nicotine and Tobacco*, U.S. FOOD & DRUG ADMINISTRATION (July 28, 2017), <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>.

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

<sup>4</sup> 83 Fed. Reg. at 12,901.

This Comment is supported by three expert reports that analyze and discuss scientific and demographic issues confirming these indisputable conclusions. First, NERA Economic Consulting's report, *Consumption Patterns of Premium Cigars*, reviewed and analyzed cigar smoking data contained in all three currently released Waves of the PATH Study (cited in the ANPRM).<sup>5</sup> Second, Econsult Solutions's report, *Purchasing Patterns and Demographics of Online Premium Cigar Customers*, analyzed over 12 million orders from over 2.3 million customers who purchased premium cigars from five leading internet/catalogue retailers, whose sales comprise a significant portion of the premium cigars category, during the 2014-2018 time period.<sup>6</sup> Third, Dr. Geoffrey Kabat, a noted epidemiologist, analyzed recently-published scientific literature relating to cigar smoking and health.<sup>7</sup> These expert reports provide the type of "evidence, information, data, and analysis" requested in the ANPRM.<sup>8</sup>

## **II. Executive Summary**

Dr. Gottlieb's request, and the resulting ANPRM, seek new information to support a conclusion that premium cigars (as ultimately defined) should not be subject to the same regulatory treatment as other tobacco products, including non-premium cigars. To properly evaluate such new information, which establishes conclusively that premium cigars should not be subject to regulatory treatment, it is important to first go back to the stated reasoning upon which FDA initially concluded that premium cigars should be so regulated.

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<sup>5</sup> Exhibit A, Report of NERA Economic Consulting Group analyzing Waves I, II and III of the PATH data relating to Premium Cigar Use (hereinafter the "NERA Report").

<sup>6</sup> Exhibit B, Report of Econsult Solutions, Inc. (hereinafter the "Econsult Report"). This report was created using premium cigar purchasing data from 800-JR Cigar, Inc., Cigars International, Thompson & Co., Famous Smoke Shop and Best Cigar Prices.

<sup>7</sup> Exhibit C, Report of Dr. Geoffrey Kabat (hereinafter the "Kabat Report").

<sup>8</sup> See attached Appendix A for a chart summarizing the areas of concentration of each expert report.

In support of its determination not to exempt premium cigars from the Final Rule, FDA “concluded that deeming all cigars, rather than a subset, more completely protects the public health.”<sup>9</sup> FDA specifically based this conclusion on the following: “(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults.”<sup>10</sup>

Since FDA reviewed comments submitted in 2014 to the Proposed Deeming Rule, new research data has become available showing overwhelmingly that (1) “premium cigars” (as defined by Center for Tobacco Products (“CTP”) researchers) do not pose the same health risks as other tobacco products, including non-premium cigars, (2) patterns of premium cigar use differ substantially from patterns of other tobacco products, including non-premium cigars, in a manner that definitively reduces comparative health risks, and (3) use of premium cigars by youth is virtually non-existent.

The studies and the findings are discussed more fully in this Comment. FDA’s current request for comment in connection with its ANPRM is both proper and valuable, as the data made available since consideration of Option 2 in the Proposed Deeming Rule contradicts FDA’s conventional beliefs (shown in the summary table below) and as such the fundamental pillars upon which FDA’s original conclusions with respect to premium cigars were built.

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<sup>9</sup> Final Rule: 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81. Fed. Reg. 28,974 at 29,020 (May 10, 2016) (“Final Rule”).

<sup>10</sup> *Id.*

Division of Dockets Management

Docket No. FDA-2017-N-6107 – Regulation of Premium Cigars

July 25, 2018

<b>FDA Conventional Beliefs</b>	<b>The Facts</b>
<b>Youth Usage</b> Premium cigars are used by youth and young adults.	<b><i>Youth usage of premium cigars is virtually non-existent.</i></b> <ul style="list-style-type: none"> <li>• Youth premium cigar prevalence (aged 12-17) decreased from 0.08% in Wave 1 and 0.04% in Wave 2 to 0.02% in Wave 3 (NERA).</li> <li>• Across all three waves prevalence among ages 12-14 was 0.00% (NERA).</li> </ul>
<b>Initiation and Progression</b> Premium cigars are a pathway of tobacco initiation for youth.	<b><i>Premium cigars are not a pathway of initiation at an early age for use of other tobacco products.</i></b> <ul style="list-style-type: none"> <li>• Median age at first regular use of premium cigars is 24.8 years in Wave 1, 27.6 years in Wave 2, and 30.0 in Wave 3 (NERA).</li> <li>• Progression of premium cigar smokers to everyday cigarette smokers is statistically indistinguishable from non-smokers. (NERA)</li> </ul>
<b>Demographics</b> Tobacco products are used by those that are young, less educated, and less economically affluent and evidence does not support that premium cigar users are differently situated.	<b><i>Premium cigars are used by those who are older, better educated, and more economically affluent non-minorities (based on Wave 3 NERA data).</i></b> <ul style="list-style-type: none"> <li>• 67% were 35 years or older (NERA) (and 89% of internet/mail-order retail purchases of premium cigars were made by adults of the same age group (EConsult)).</li> <li>• 52.7% of premium cigar smokers had completed college (NERA).</li> <li>• 44% of premium cigar smokers had a household income of \$100,000 or more (NERA).</li> </ul>
<b>Usage Patterns and Frequency of Use</b> The available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion.	<b><i>Premium cigar smokers are unlikely to also use cigarettes and for those cigarette smokers who use premium cigars they do so no more frequently than non-cigarette smokers.</i></b> <ul style="list-style-type: none"> <li>• Percentage of premium cigar smokers, of any age, that progress from never smoking cigarettes or smoking cigarettes some days in Wave 1 to everyday cigarette smoking in Wave 3 is about 2.2% (NERA).</li> <li>• Wave 3 premium cigar smokers who are also current cigarette smokers do not smoke more premium cigars than those who are not current cigarette smokers (NERA).</li> </ul> <b><i>Patterns of premium cigar use materially reduce health risks in comparison to other tobacco products.</i></b> <ul style="list-style-type: none"> <li>• Wave 3 prevalence of premium cigar usage is 0.53% (NERA).</li> <li>• Median monthly use of premium cigars in Wave 3 was 1.3 days per month and this compares to 29.4 days per month for cigarette smokers (NERA).</li> <li>• About 96.1% of premium cigar smokers smoke premium cigars less than daily (NERA).</li> </ul>
<b>Health Impacts</b> Insufficient evidence that difference in use patterns for premium cigars substantially impact health analysis of premium cigar use.	<b><i>Difference in use patterns for premium cigars substantially impacts the health analysis of premium cigar use.</i></b> <ul style="list-style-type: none"> <li>• Cigar smokers (premium or otherwise) who smoke cigars less than daily (which includes 96.1% of premium cigar smokers) have no statistical difference in mortality rates as compared to non-smokers (Kabat).</li> <li>• Non-daily, exclusive smokers of cigars (of any kind) do not have an increased risk for smoking-related cancers, or an increased risk of death from all causes and certain specific causes (Kabat).</li> <li>• Non-daily premium cigar smokers have no increased health risks compared to non-smokers (Kabat).</li> </ul>

The data refutes the premises upon which FDA concluded that premium cigars should be subject to the Deeming Rule, and makes clear that the existing regulations cannot be rationally applied to premium cigars. As the above table demonstrates and is set forth more fully below, it is beyond dispute – scientific, factual, and legal – that premium cigars are a unique product. **Premium cigars are simply different.** Premium cigars are manufactured, marketed, sold, and consumed differently than any other tobacco product and, as a result, do not raise the same questions of public health as any other tobacco product. Furthermore, and as discussed in Section VII, central parts of the current regulatory structure – HPHC Testing, Pre-Market Review, and Health Warnings – are disproportionately burdensome and fundamentally flawed as applied to the premium cigar industry. Therefore, premium cigars should be exempt from FDA regulation.

### **III. Background of the Premium Cigar Industry**

As discussed in detail in this Comment, CAA believes it is important to appreciate that premium cigars are a unique product, particularly with respect to what they are made of, how they are made, and how they are consumed.

The premium cigar industry is a very small, niche industry within the overall cigar industry, and is but a fraction of the broader tobacco industry. It is defined by a hand-crafted, centuries-old product. The entire cigar industry is only about 11% the size of the cigarette industry,<sup>11</sup> and more cigarettes are sold in about two weeks than cigars are sold in a full year. The premium cigar industry

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<sup>11</sup> This percentage is based on the user fees paid by each category of products. *See Tobacco Product User Fee Assessment Formulation by Product Class*, U.S. FOOD & DRUG ADMINISTRATION, <https://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/manufacturing/ucm521052.htm> (last visited July 23, 2018).

is roughly 3% (by volume) of the overall cigar industry.<sup>12</sup> These percentages do not account for the declining percentage the cigar category occupies within the broader tobacco industry, now that e-cigarettes have entered the marketplace; percentages that are likely to decrease as the e-cigarette category continues to grow and represent a larger percentage of the tobacco space. One recent study stated that e-cigarette sales increased 16% between 2015 and 2016 (\$775 million to \$896 million) and 47% between 2016 and 2017 (\$896 million to \$1318 million).<sup>13</sup> It has been estimated that the e-cigarette industry will continue to grow and, by 2025, reach a total market value of \$50 billion.<sup>14</sup> The market share accounted for by cigars in total, as well as the premium cigar industry, will only decline with this rapid increase in sales of e-cigarettes.

Among the many reasons that the premium cigar category is so small is that premium cigars are truly a handmade, artisan product. Unlike the incredibly mechanized, high-speed cigarette manufacturing process, where machines can produce nearly 1,000,000 units an hour, a premium cigar is crafted, by hand, by skilled and highly trained artisans who spend a significant amount of time perfecting their craft. Premium cigar manufacturing is a manual and time-consuming process, with very low volume. In addition, there can be as many as 300 separate manual steps in the production of a premium cigar, and the entire premium cigar manufacturing process – covering the period from when the seeds are planted to when the cigar is packaged and ready to ship to customers

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<sup>12</sup> *Alcohol and Tobacco Tax Bureau, Statistical Report – Tobacco*, Report TTB S 5210-12-2017, DEPARTMENT OF TREASURY (July 20, 2018), <https://www.ttb.gov/statistics/2017/201712tobacco.pdf>.

<sup>13</sup> Huang J. et al., *Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market*. *Tob. Control*, 0: 1-6 (2018) available at <https://tobaccocontrol.bmj.com/content/early/2018/05/31/tobaccocontrol-2018-054382>

<sup>14</sup> *See Electronic Cigarettes and E-Vapor Market Research Reports*, BIS RESEARCH REPORT (2016), Abstract Available at <https://bisresearch.com/industry-report/electronic-cigarette-market-size-forecast.html>.



– can take over a year. Even for the few premium cigars that use a mechanized process, those cigars are generally produced at a rate of less than 25 per minute or 1500 per hour.

Variety of offerings is critically important in the premium cigar category. For this reason, the cigar category has a much greater variety of products than any other segment in the tobacco industry. In fact, the variety of products, as measured by Stock Keeping Units (“SKUs”), is greater for cigars than for other tobacco industry segments. For example, the four leading premium cigar manufacturers currently have over 6,000 active SKUs for their premium cigars. The data collected from the five online retailers shows that each retailer can, at times, have approximately 14,000 SKUs from the overall premium cigar category.<sup>15</sup> This stands in stark contrast to the cigarette industry, where – despite its enormous volume – approximately 100 brands comprise almost the entire category.<sup>16</sup>

Moreover, in contrast to the homogenous nature of cigarettes, the natural variation in cigar tobacco has historically required premium cigar manufacturers to procure tobacco from various regions. Doing so is necessary to maintain consistent products, and to develop new products by blending different types of tobacco, or to create new sizes or shapes of premium cigars. In contrast to other tobacco consumers, the data shows premium cigar smokers frequently try new cigars or cigar styles, and typically have less brand loyalty than consumers of other types of tobacco products.<sup>17</sup> In addition, the same cigar (i.e. Brand Family and Brand) may be offered in as many as ten different sizes (length and ring gauge), as many adult consumers will select a cigar size based on

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<sup>15</sup> Ex. B, Econsult Report at 8.

<sup>16</sup> See, e.g., Oregon Brand List, Directory of Cigarette Brands Approved for Stamping and Sale (last updated July 17, 2018) <https://www.doj.state.or.us/wp-content/uploads/2017/06/branddirectory.pdf>.

<sup>17</sup> See Ex. B, Econsult Report at 15-16, Figure 2 (demonstrating that purchasers of premium cigars exhibit little brand loyalty).

the circumstances, occasion, and time available to enjoy it. There are eight generic vitolas (sizes) for premium cigars,<sup>18</sup> but many brands come in vitolas outside of these generic staples. Each premium cigar has a unique length and a unique ring gauge allowing for an infinite variety of cigars, even for those with the exact same blend of tobaccos.

Further, each cigar size may be sold in a box, as a single, or broken down by a wholesaler or retailer into a five pack or ten pack configuration to be sold by retailers. Additionally, premium cigars come in many different shapes. For instance, cigars come in a generic cylindrical shape, box-pressed shape (square), torpedo shape (which possesses graduated thickness throughout the cigar), or even as two or more cigars twisted together into one, just to name a few. While the premium cigar industry actually represents only a tiny fraction of the tobacco industry by sales, as mentioned previously, it may be the largest segment in terms of SKU count (even though all the products are nearly identical).

The variety in the premium cigar market stems from the simplicity of the product. This simplicity allows for nuances in size, shape, and tobacco to make a variety of choices for premium cigar consumers. Premium cigars are generally composed of only three ingredients – tobacco leaves, water and a *de minimis* amount of vegetable-based adhesive. Therefore, all premium cigars are heavily dependent on the natural influence of the agricultural product from which they are made. Premium cigars typically use dark, air-cured tobacco, irrespective of seed type or the country in which the tobacco is grown. The tobaccos that comprise the different parts of a premium cigar – the wrapper, binder, and filler – determine the uniqueness of each “blend” of cigar. In this way, premium

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<sup>18</sup> Short Panatela (35-39 ring gauge; 4 ½” - 5 5/8” length); Robusto (50-56 ring gauge; 4 ½” - 5 ½” length); Corona (42-44 ring gauge; 5 1/16” – 5 ¾” length); Toro (48-56 ring gauge; 5 ¾” – 6 ½” length); Belicoso (50-54 ring gauge; 6” - 6 ¼” length); Pyramid (50-52 ring gauge; 6” – 6 1/8” length); Churchill (48-58 ring gauge; 6 5/8” – 8” length); and Gordo (58-80 ring gauge; 5 7/8” – 6” length).

cigars are similar to fine wines – each is a simply made product, yet with numerous offerings, reflecting the subtle variations that exist in agricultural products.

A significant portion of cigars sold in the U.S. are manufactured outside the U.S. and imported for sale, with a far lesser amount manufactured in the U.S. using imported tobacco. Growing and producing cigar tobacco is a lengthy and involved process, the success of which can be affected by a number of factors, including weather and local growing conditions that can result in natural variations in cigar tobacco. These crop and product variations present challenges for cigar manufacturers because they are often required to blend tobaccos to maintain the consistency of a cigar’s identity and taste from the prior year. Compared to cigarettes that have over 100 components, cigars have a limited number of components, amplifying the effect of each “natural variation” by making it significant and noticeable to the consumer. As a result, and as FDA has acknowledged in its guidance, blends often change from one year to the next to maintain consistent appearance and taste.<sup>19</sup>

Even with the subtle differences due to different tobaccos, the basic use of natural tobacco leaf as wrapper, binder, and filler has remained consistent over time. Because premium cigars are constructed so simply, a product that was on the market in 1990 is essentially the same as the one on the market in 2007, which from a public health perspective is essentially the same as the one on the market today. Therefore, as set forth below in greater detail, since the essential elements of premium cigars themselves, and the manner in which they are used, are consistent, various premium cigars with the same or very similar physical characteristics are unlikely to raise different questions of public health.

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<sup>19</sup> See 81 Fed. Reg. at 28,995 (“FDA generally expects that cigars with blending changes (*other than blending changes to address the natural variation of tobacco* . . .) will be able to successfully use the SE pathway. . . .”)

#### **IV. Definition of Premium Cigar**

The ANPRM requests comments on the “definition of premium cigar” and asks stakeholders to “[e]xplain what you believe to be the particular defining characteristics of premium cigars.”<sup>20</sup> CAA first outlines the “defining characteristics” that are appropriate to include in a definition of premium cigar, then addresses other “characteristics” suggested by FDA and details why these should not be part of any definition of premium cigar.

CAA proposes to define a “premium cigar” as a product that (i) is wrapped in whole leaf tobacco; (ii) contains a 100% leaf tobacco binder; (iii) is made by manually combining the wrapper, filler, and binder; (iv) has no filter, tip, or non-tobacco mouthpiece and is capped by hand; and (v) weighs more than 6 pounds per 1000 units.<sup>21</sup> This definition is objective and avoids other possible definitional components that are subjective and not relevant to an evaluation of premium cigars.

##### *A. Retail Price Should Not Be a Component of the Definition*

In both the Proposed Deeming Rule<sup>22</sup>, and in the Premium Cigar ANPRM, FDA has raised retail price as a possible criteria to consider as part of the definition of premium cigar.<sup>23</sup> While FDA may have suggested this because a hallmark of premium cigars is indeed that they are a higher-priced luxury item, retail price is simply and clearly not a relevant or reliable component to include

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<sup>20</sup> 83 Fed. Reg. at 12,903.

<sup>21</sup> Whenever the term “premium cigar” is used through this Comment, CAA uses this definition in reference to that term.

<sup>22</sup> Proposed Rule: Deeming Tobacco Products to be Subject to the Food, Drug and Cosmetic Act, as Amended by the Family Smoking and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements. (“Proposed Deeming Rule”), 79 Fed. Reg. 23141 at 23,150 (April 25, 2014); 83 Fed. Reg. at 12,903.

<sup>23</sup> 79 Fed. Reg. at 23,150.

in the definition of premium cigar. Further, the final retail price is always in the hands of the retailer.

There are many reasons why retail price should not be included in the definition of premium cigars.

- First, different retailers within a state apply state taxes differently. Specifically, some include it on the shelf (retail) price, while others add it with sales tax at checkout. The same cigar treated differently by retailers in a single state could end up being regulated differently.
- Second, state tax rates vary greatly from state to state and can result in a tax anywhere from zero to \$3.50 per cigar. For this reason, the same cigar in different states could be regulated differently. Further, certain localities now impose taxes on premium cigars. For instance, in New York City, as of June 1, 2018, premium cigars have an additional NYC tax. Therefore, even within the same state, prices can differ simply based on taxes and how they are imposed.
- Third, a single cigar brand may be offered in several different sizes (length and ring gauge), most often seven to ten, with larger ones being more expensive. Premium cigars that use the same combination of wrapper, binder, and filler tobaccos, but differ in length, ring gauge and/or weight (and thus price) should not be regulated differently.
- Fourth, retail price is impacted by geography. The same cigar is more expensive in high cost cities than in low cost cities. The same cigar should not be regulated differently based solely on geography.
- Fifth, retail price is impacted by channel of distribution. The same cigar is often priced very differently when sold by a retail tobacconist than when sold through mail order or e-commerce, which generally have lower overhead costs. The same cigar should not be regulated differently based solely on channel of distribution.
- Sixth, retail price is largely beyond the control of the manufacturers. A cigar intended by the manufacturer to be premium could end up outside the category based on the price set by the retailer. The reverse is true as well.
- Seventh, retail price could be dependent on the manufacturing year. For instance, if there is a drought, the price of tobacco could increase requiring manufacturers to increase price, this ultimately would affect the retail price of the cigars. Additionally, if a certain tobacco is not available for a manufacturer to make more cigars one year, retailers may raise the price of that cigar due to the decreased supply of the cigar. Regulatory decisions should not be made based on retail price, which is not always a stable, set price for any particular cigar year to year.

*B. Packaging Quantity and Size Should Not Be a Component of the Definition*

Premium cigars are luxury, artisan products, consumed occasionally, generally over a long period of time. They are not a high consumption product, such as cigarettes. Therefore, regardless of how a manufacturer packages the cigar, the intent is that all premium cigars can be sold individually. This way a consumer may choose to purchase just one premium cigar, five of the same cigar, or five different cigars. Nearly all retail tobacconists have walk-in humidors or trays of premium cigars so consumers can choose individual premium cigars. This known fact of cigar purchasing patterns was even referenced in the Final Rule:

[a]ffording adult consumers the opportunity to handle the product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period of the tobacco. It also will allow the users to capture the aroma of the cigar and the box (if the cigar is sold in a package).

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The same warning statement requirements will apply to cigars sold individually and not in product packages. However, instead of being required to place warnings directly on these product packages, retailers will be required to post signage at the point of sale....<sup>24</sup>

Premium cigars are sold in boxes of twenty-five, boxes of sixteen, jars of twenty, bundles of ten, packs of five, packs of two, and many other combinations. None of these variations, however, changes the indisputable fact that, ultimately, many premium cigars are both offered and purchased as single cigars.<sup>25</sup> Packaging quantity should not be part of the definition of a premium cigar, as there are no objective benchmarks for how these products are packaged or sold.

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<sup>24</sup> 81. Fed. Reg. 28,974 at 29,026, 29,061.

<sup>25</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res., ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423> (finding that 79% of in person premium cigar purchases were of single cigars).

Further, other than the objective weight criteria of more than six pounds per 1000, size of the cigar should also not be part of the definition of premium cigar. As noted above, there are eight generic vitolas for premium cigars. They are generic for a reason – there are many that differ from this. Using size as part of the definition of premium cigar would place limitations on the category without any showing that different sizes of cigars were likely to raise different questions of public health.

*C. Actions Directed Towards Consumers Should Not Be a Component of the Definition*

FDA has asked if “action[s] 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”, should be included in the definition of premium cigar.<sup>26</sup> CAA believes they should not. If a cigar meets the definitional requirements outlined above, CAA does not view otherwise permissible labeling, advertising, or marketing actions to be an appropriate or objective benchmark to include in the definition of premium cigar. Additionally, while manufacturers can control all advertising and marketing they create for their products, similar to retail price, they do not control the advertising that individual retailers or distributors may do for their products. It would be inappropriate, therefore, to incorporate into any definition of premium cigar a component that the manufacturers cannot fully control.

Regardless of who creates marketing materials, premium cigar marketing is only directed at adults. As set forth in greater detail below, however, youth usage of premium cigars is already below measurable levels. Indeed, CAA and its member companies are adamantly opposed to youth usage of cigars, or any other tobacco product, and actively discourage such usage where it exists, and any

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<sup>26</sup> 83 Fed. Reg. at 12,903.

advertising and marketing of premium cigars reflects this. It is CAA's strongly-held view that the consumption of cigars is, and should be, reserved for adults. CAA member companies direct their advertising to only target adult premium cigar consumers.

Further, CAA members include the largest online retailers of cigars in the United States. All of these companies use sophisticated third-party age-verification technology to ensure youth are not purchasing cigars. In fact, many members also voluntarily restrict access to their company and brand websites to people over the age of 21.<sup>27</sup> CAA and its member companies are steadfast in the position that cigars are only intended for adult consumers, and take seriously the obligation to prevent cigar use by youth.

CAA does not believe labeling, advertising, or marketing should be part of the definition of premium cigar because it is unnecessary; all premium cigar advertising is targeted at adults, and, much like retail price, there is no way for manufacturers to control all the advertising that may be done for their products by retailers.

*D. Other Considerations in the ANPRM that Should Not Be a Component of the Definition*

FDA has raised a number of other considerations as potential elements of a definition of a premium cigar. CAA does not believe that any of these are appropriate to include in the definition of premium cigar.

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<sup>27</sup> See, e.g., MONTECRISTO, <https://montecristo.com/age-gate> (last visited July 24, 2018); MACANUDO <http://www.macanudo.com/age-gate/> (last visited July 24, 2018); PERDOMO CIGARS, <https://perdomocigars.com/> (last visited July 24, 2018); DREW ESTATE, [www.drewestate.com](http://www.drewestate.com) (last visited July 24, 2018).



*First*, FDA has asked about whether flavor should be part of the definition of premium cigar.<sup>28</sup> CAA does not believe the presence or absence of a flavor should be a definitional characteristic of a “premium cigar.” Flavoring cigars is a centuries-old tradition and, now as then, many premium cigars may be considered to have a flavor.

As discussed above, and throughout this Comment, premium cigars are both a product different from other cigars and have usage patterns different from other cigars. These distinct usage patterns are there whether the premium cigar is flavored or unflavored. The NERA Report has shown that usage of premium cigars, flavored or unflavored, was zero percent (0.00%) by those aged 12-14 (all three Waves) and usage by those aged 15-17 was virtually non-existent – from 0.08% in Wave 1, down to 0.02% by Wave 3.<sup>29</sup> The relevant question is whether a cigar is premium, according to the criteria set forth above; accordingly, whether a cigar is flavored should not be a factor in defining what a premium cigar is. In this regard, CAA urges FDA to analyze the data, information, and comments submitted in response to the ANPRM regarding flavors in tobacco products.<sup>30</sup>

*Second*, FDA has asked whether the “(f)requency with which price changes are initiated by particular levels in the distribution chain” could be incorporated into any definition of premium cigar.<sup>31</sup> The premium cigar industry has no uniform distribution chain. Certain companies are vertically integrated and control nearly all processes of distribution. Other manufacturers rely on

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<sup>28</sup> FDA has issued a separate ANPRM to specifically address the use of flavors in cigars, and in response thereto CAA has submitted a more complete and specific response with respect to the use of flavors in cigars generally.

<sup>29</sup> Ex. A., NERA Report at ¶¶ 25, 26, Table 1. Further, regarding flavored premium cigar use NERA reports that “we do not report results for this flavored premium cigar smokers as there were too few flavored premium cigar smokers to produce reliable estimates.” *Id.* at ¶17.

<sup>30</sup> Regulation of Flavors in Tobacco Products, 83 Fed. Reg. 12,294 (Mar. 21, 2018).

<sup>31</sup> 83 Fed. Reg. at 12,903.

third party distributors who then sell to retailers. Yet others sell directly to retailers. Additionally, depending on tax levels in different states, state specific channels of distribution may be used. Accordingly, for many of the same reasons outlined above regarding retail prices, CAA fails to see how this is or could be relevant, or how any objective criteria could be created to incorporate it into a definition of a premium cigar.

*Third*, FDA inquires as to whether the country in which the tobacco used in the wrapper or filler is grown should be included in the definition, and whether growing practices in different areas could create different health impacts. CAA sees no relevance in country of origin of the tobacco from a definitional standpoint, or in analyzing whether one premium cigar is likely to raise questions of public health different from those raised by another premium cigar. A premium cigar is still generally made of its simple ingredients of tobacco and water and where the tobacco is grown does not impact the “blend.” A cigar should not be regulated based on whether Nicaragua had a rainy year or the Dominican Republic had a dry year. This is another area where premium cigars have many parallels with fine wine. Wine raises no different questions of public health whether it uses grapes from California, France, Spain, Italy or Canada. In fact, FDA acknowledged this in the Final Rule by stating that “FDA does not intend to enforce the premarket review requirements against cigar manufacturers that make tobacco blending changes to address the natural variation of tobacco (e.g. tobacco blending changes due to variation in growing conditions) in order to maintain a consistent product.”<sup>32</sup> Including the country of origin as a definitional element of a premium cigar undermines the reason FDA has articulated for enforcement discretion for natural variation in tobacco not creating a “new” cigar.

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<sup>32</sup> 81 Fed. Reg. at 29,026.

*Finally*, the Premium Cigar ANPRM raises the issue whether “nicotine content . . . [and] tar delivery amounts (and how this should be defined and measured) . . . [and] carbon monoxide delivery amounts (and how this should be defined and measured) should be included in any definition of premium cigar.”<sup>33</sup> CAA is encouraged by FDA’s apparent recognition that there is currently no available methodology or definitional structure for smoke testing of premium cigars. Currently, no methodology, or even machinery, exists to allow for the smoke testing of all premium cigars.<sup>34</sup> A CORESTA working group is currently seeking to create a methodology for testing premium cigars, but this work is not expected to be completed for as much as another 24 months. At this point, the preliminary findings of this group raise questions as to whether it will be possible to create a reliable, reproducible methodology for smoke testing of premium cigars. As discussed above, premium cigars are a simple product dependent on tobacco leaves, which vary greatly. Additionally, these are hand-made products, which are essentially unique in each creation, and therefore will vary slightly from cigar to cigar making reliable results of testing near impossible. Therefore, any testing suffers from both variability within labs on testing repetitions and variability between labs due to the undefined methodology and product variability.

Recent work published by CTP, as well as from other researchers, confirms the variability in any testing, both within the cigar category as a whole and the premium cigar category in particular, and between cigars of like brands and sizes themselves. This work did not attempt smoke testing; rather, it examined only product size, dry nicotine content, and tobacco pH, and found a “wide

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<sup>33</sup> 83 Fed. Reg. at 12,903.

<sup>34</sup> Machinery does exist that could potentially test cigars with a maximum diameter of 22.5 millimeters, however, many, if not most premium cigars are larger than this. Further, premium cigars come in “shapes” such as box pressed and torpedo which are challenging with current smoking machinery.

variation in product size and nicotine content within the domestic cigar market.”<sup>35</sup> Further, the study found that “cigar size does not necessarily correlate with nicotine or free nicotine content.”<sup>36</sup> In trying to replicate results, the study found this was not possible, noting “in the two large cigar and cigarillo brands analyzed a second time, there was considerable within-brand variance in nicotine content and concentration between the first and second analyses.”<sup>37</sup> This study underscores the importance of two critical issues – (i) that any testing or comparison of constituents of cigars will be highly variable due to the natural variation of tobacco, and (ii) that testing should not be required for premium cigars, or even more critically, be used to define premium cigars.

## **V. Use Patterns of Premium Cigars**

FDA has asked for information on the use patterns of premium cigars in the Premium Cigar ANPRM. In the Final Rule, FDA stated that “there [was] no data provided to support the premise that there are different patterns of use of premium cigars and that these patterns result in lower health risks.”<sup>38</sup> While CAA disagrees with FDA’s characterization of the data provided in connection with the Proposed Deeming Rule, the scientific evidence now available (some published by CTP personnel) makes clear both that premium cigar usage patterns differ from those of other cigars and that those usage patterns result in lower health risks. Among other critical points, there is virtually no youth usage of premium cigars, and dual usage of premium cigars and other tobacco products is much lower than is dual usage of two other tobacco products. Stated differently, premium cigar

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<sup>35</sup> Koszowski et al., *Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States*, *Nicotine and Tob. Res.* 20(3) 393-398 (2018) available at <https://www.ncbi.nlm.nih.gov/pubmed/28340022>.

<sup>36</sup> *Id.* This is yet another reason why “size” of the cigar should not be a component of the definition of premium cigars.

<sup>37</sup> *Id.*

<sup>38</sup> 81 Fed. Reg. at 29,020.

smokers are less likely than those who use other tobacco products to also smoke cigarettes. Additionally, as discussed above, CAA provides reports of three experts addressing these issues with this Comment.<sup>39</sup>

It has long been known that premium cigars are an adult product, used and enjoyed by adults. Youth usage of these products is so low as to be unquantifiable. Until recently, however, survey data was not targeted to track the differences in the use of premium cigars, as opposed to little cigars or cigarillos, by youth. The PATH<sup>40</sup> study, however, asked both youth and adults questions specifically regarding cigar use, which can be examined with reference to premium cigars specifically, and that data strongly and clearly demonstrates that premium cigars are used almost exclusively by adults.<sup>41</sup>

The PATH study stratified cigar use separately for filtered cigars, cigarillos, and “traditional cigars.” Participants were asked about the categories of cigars, certain brands of cigars, and also could identify brands they smoke. These brands are recorded in the datasets available to researchers. “Traditional cigars” were defined as “tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta, and Arturo Fuente, but there are many

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<sup>39</sup> See Ex. A, The NERA Report; Ex. B, Econsult Report; Ex. C, Kabat Report.

<sup>40</sup> The Population Assessment of Tobacco and Health (PATH) study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the country take part in this study. In October 2011, the [National Institutes of Health \(NIH\)](#) and the [U.S. Food and Drug Administration \(FDA\)](#) announced a new study called the Population Assessment of Tobacco and Health (PATH) study. The PATH study was one of the first projects that [NIH](#) and [FDA](#) have worked on together since Congress gave [FDA](#) authority to regulate tobacco products. The study will look at tobacco use and how it affects the health of Americans. About 49,000 people ages 12 years and older are participating in the PATH study. Some of them use tobacco; others do not. Interviewers meet with each person once a year or every other year. Each year the study will invite some participants to take part in additional study activities. See <https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx> (last visited July 24, 2018).

<sup>41</sup> See Ex. A, NERA Report at ¶¶ 4, 7.

others.”<sup>42</sup> Corey, et al. (2017) (“Corey et al.”) specifically examined the cigar data available in Wave 1 of the PATH study, examined all of the data available relating to “traditional” cigars, and segregated brands in that category into “premium” and “non-premium” cigars in order to author a paper on cigar use patterns, including premium cigar use patterns, based on the PATH data.<sup>43</sup> Using the designations from that paper of cigars as premium and non-premium, the NERA Report was able to both replicate Corey et al.’s analysis, and to perform a similar analysis on Waves 2 and 3 of the PATH data.<sup>44</sup> That data strongly and clearly demonstrates that premium cigars are used almost exclusively by adults.<sup>45</sup>

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<sup>42</sup> Kasza, K. et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 276 N. Eng J. Med. 376 (2017) available at [https://www.nejm.org/doi/10.1056/NEJMsa1607538?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%3dwww.ncbi.nlm.nih.gov](https://www.nejm.org/doi/10.1056/NEJMsa1607538?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%3dwww.ncbi.nlm.nih.gov).

<sup>43</sup> Corey C, et al. *U.S. 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*; Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>44</sup> The NERA Report outlines in detail the exact methodology used to classify cigars as “premium.” See NERA Report at ¶¶ 17-22. Corey et al. examined the data provided by respondents who responded they used “traditional cigars” and provided a brand of cigars they use. Corey et al. then analyzed those brands and created a group of “premium” and “non-premium brands.” The NERA Report used the Corey et al. criteria, with some adjustments to analyze the three Waves of PATH data. The Econsult Report also looked at how Corey et al. characterized brands as premium versus non-premium and used the same criteria to distinguish premium from non-premium brands in the sales data that report is based on. The PATH study is a representative survey of usage patterns of different types of tobacco products – it is by definition a sub-section of the entire population of premium cigar smokers, and therefore, premium cigar brands. The Econsult Report, on the other hand, collected transaction data from five of the largest online retailers of premium cigars, and recorded SKU level data regardless of the amount of times the individual SKUs were purchased. By definition, therefore, this data set contains a much larger number of brands than Corey et al. and NERA reviewed in the PATH data. The brand list and purchase data in the Econsult Report do not address prevalence of use of premium cigars. Similarly, the prevalence data in the NERA report does not address purchasing patterns of premium cigar consumers.

<sup>45</sup> Ex. A, NERA Report at Table 1. The NERA Report examines data from all three Waves of the PATH data and demonstrates that in Wave 1, only 8 observations were made of youth reporting use of a premium cigar, only 6 observations were made in Wave 2 and in Wave 3 only 1 observation was made.

In examining all cigar data, Kasza et al. reported that 7.5% of youths had “ever used cigars.”<sup>46</sup> Examining past thirty days, use shrinks to 2.5% of youths using any cigar and only 0.7% using “traditional cigars.”<sup>47</sup> Finally, the results show that for “traditional cigars,” there was so little data on “current use” of these products that it could not be reliably measured.<sup>48</sup> Even solely based on the results of Wave 1 of the PATH study, the available, published scientific evidence does not support FDA’s position that “premium cigars are used by youth and young adults,” as stated in the Final Rule.<sup>49</sup> While Corey et al. and Kasza et al. examined only Wave 1 PATH results, the NERA Report has examined data from all three Waves of the PATH study currently available and confirmed that there is nearly zero use of premium cigars by youth.<sup>50</sup> In fact, in Wave 3, prevalence of youth usage was at 0.02%, based on only one observation.<sup>51</sup> Youth usage of premium cigars is simply not occurring.

In the adult population, Corey et al. found that the overall prevalence of premium cigar use was 0.7%.<sup>52</sup> The NERA Report shows that in Wave 3 of the PATH study the overall prevalence of premium cigar use in the adult population is 0.53%.<sup>53</sup> For comparison, prevalence of adult cigarette

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<sup>46</sup> Kasza, K. et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 276 N. Eng J. Med. 376 (2017) available at [https://www.nejm.org/doi/10.1056/NEJMsa1607538?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%3dwww.ncbi.nlm.nih.gov](https://www.nejm.org/doi/10.1056/NEJMsa1607538?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%3dwww.ncbi.nlm.nih.gov).

<sup>47</sup> Supplement 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. Eng. J. Med. 376, 342-53 (2017). DOI: 10.1056/NEJMsa1607538; Table S18.

<sup>48</sup> *Id.* at Table S4.

<sup>49</sup> 81 Fed. Reg. 29,020.

<sup>50</sup> Ex. A, NERA Report at ¶¶ 25, 26, Table 1.

<sup>51</sup> *Id.*

<sup>52</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>

<sup>53</sup> Ex. A, NERA Report at ¶28, Table 2.

us is 18.7%. Premium cigars are used almost exclusively by adults, and even within the adult population, premium cigar smokers are in older cohorts. The NERA report shows that in Wave 3 of the PATH study, 67% of adults using premium cigars were over age 35.<sup>54</sup> Further, the Econsult Report shows that the average age of an online premium cigar purchaser is 55, the median age is 57, and that approximately 88% of purchasers are over age 35.<sup>55</sup> Additionally, the older adults using and purchasing premium cigars are better-educated and wealthier. The NERA Report shows that in Wave 3 of PATH over 52.7% of premium cigar smokers had completed college, and 44% had household incomes over \$100,000, as compared to 13% of non-premium traditional cigar, 10% of cigarillo, 4% of filtered cigar and 8% of cigarette smokers.<sup>56</sup> The Econsult Report shows that 15% of the online purchasers of premium cigars lived in census tracts with median household incomes over \$100,000 compared to 10% of the general population, and that 20% of online premium cigar purchasers live in census tracts where over 50% of the population has a bachelor's degree compared with 15% of the general population.<sup>57</sup>

As discussed above, the Corey et al. study, and the NERA report examined PATH data specifically for premium cigars. Further, Econsult examined data from five of the largest online retailers, relating exclusively to premium cigar purchasers. Corey et al. confirmed the well-known concept that “cigar smoking patterns and tobacco use behaviors varied by cigar type.”<sup>58</sup> The data

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<sup>54</sup> *Id.*

<sup>55</sup> Ex. B, Econsult Report at 9, Table 4.

<sup>56</sup> Ex. A, NERA Report at ¶¶ 37, 38, Table 3c.

<sup>57</sup> Ex. B, Econsult Report at 19-21, Table 14, Figures 4, 5.

<sup>58</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.



provided in Corey et al., the NERA Report, and the Econsult Report all strongly support this statement and, specifically, show that premium cigars have usage and purchase patterns distinct from other tobacco products.

*First*, Corey et al, reported that in Wave 1 of the PATH study, the median age of first use of a premium cigar was 24.5 years old.<sup>59</sup> The NERA Report shows that in Wave 3 of the PATH study, the median age of first use of a premium cigar was 30.0 years old.<sup>60</sup> In contrast, the median age of first use of cigarettes was 16.6 years in Wave 1 and 16.7 years in Wave 3.<sup>61</sup>

*Second*, in line with the reasons for the great variety of premium cigar products on the market, Corey et al. showed that premium cigar smokers were much less likely to have a “regular tobacco brand” than other cigar smokers and cigarette smokers (49.7% v 77.1% v 93.1%).<sup>62</sup> The Econsult Report further demonstrates this. Econsult found that for premium cigar purchasers who purchased at least twice, 36% of the orders contained only one or two brands, meaning 64% contained three or more brands, and that for more frequent purchasers, only 13% of the orders contained one or two brands, meaning that 87% of the orders contained three brands or more.<sup>63</sup>

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<sup>59</sup> *Id.*

<sup>60</sup> Ex. A, NERA Report at ¶49, Table 5c.

<sup>61</sup> *Id.* at ¶¶ 47, 49, Tables 5a and 5c.

<sup>62</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>63</sup> Ex. B, Econsult Report, at 15-16, Figure 2.

*Third*, according to the PATH study, approximately 25% of premium cigars were purchased online or by mail order.<sup>64</sup> According to government and industry estimates, however, there are approximately 300 million premium cigars sold in the US each year.<sup>65</sup> The Econsult Report encompassed approximately 125 million premium cigars sold in 2017.<sup>66</sup> For premium cigars purchased in person, 46.8% were purchased in specialty tobacco shops and 29.9% were purchased in cigar bars.<sup>67</sup> This stands in stark contrast with other cigar types and cigarettes, which were nearly all purchased in person (95.5-97.2%) and were mostly purchased at convenience stores/gas stations (75.4% - 86.8%).<sup>68</sup>

*Fourth*, Corey et al. reported that the median price paid was \$7.49 per premium cigar. In contrast, the median price was \$1.00 for non-premium cigars and cigarillos.<sup>69</sup>

*Fifth*, for people who purchased premium cigars in person, 79.1% purchased single premium cigars, as opposed to a box or pack.<sup>70</sup> This number is even more important when compared to the

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<sup>64</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>65</sup> TTB data shows that in 2017, approximately 351 million premium cigars were imported into the United States. See *Alcohol and Tobacco Tax Bureau, Statistical Report – Tobacco*, Report TTB S 5210-12-2017, DEPARTMENT OF TREASURY (July 20, 2018), <https://www.ttb.gov/statistics/2017/201712tobacco.pdf>. This number is not an accurate representation of the premium cigar market as (i) tariff classifications are solely based on price; and (ii) there are many cigars that would fall into these tariff categories that would be not considered premium under CAA's definition. Therefore industry puts estimates closer to 300 million.

<sup>66</sup> Ex. B, Econsult Report at 8.

<sup>67</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at Table 3.

1.8% of people who purchased single cigarettes and the 13.8% who purchased single filtered cigars.<sup>71</sup> The Econsult Report shows that for online premium cigar purchases, consumers purchase a variety of product quantities, but most often purchase five packs of cigars.<sup>72</sup>

*Sixth*, Corey et al. reported that the median consumer of premium cigars in Wave 1 of the PATH smokes 1.7 days per month, as opposed to cigarette smokers who smoke on a near daily basis.<sup>73</sup> The NERA Report shows that in Wave 3 of the PATH study this number has decreased to 1.3 days per month, and that on the days premium cigar smokers smoke, they smoke 0.6 cigars per day.<sup>74</sup> Further, Econsult shows that 86% of online premium cigar purchasers ordered premium cigars 10 or fewer times.<sup>75</sup>

*Finally*, 76.6% of respondents stated that “I like socializing while smoking them” applied to their premium cigar smoking experience. This again highlights that premium cigars are used in a very different manner from cigarettes, or even filtered cigars, where only 49.9% of respondents replied similarly to that question.<sup>76</sup> All of these factors illustrate that those who enjoy premium cigars are different from users of other tobacco products. They are older, they appreciate and enjoy

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<sup>71</sup> *Id.* It should be noted that there is a federal prohibition on the sale of single cigarettes.

<sup>72</sup> Ex. B, Econsult Report at 15, Table 12.

<sup>73</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>74</sup> Ex. A, NERA Report at ¶44, Table 4c.

<sup>75</sup> Ex. B, Econsult Report at 12, Table 7.

<sup>76</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017), Supplementary Table B available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

variety in their products, and they purchase premium cigars in patterns very different from consumers of other tobacco products.

The PATH study is not the only data available regarding adult use patterns of premium cigars. The Adult Tobacco Survey also analyzed adult premium cigar use patterns. The Adult Tobacco Survey asked questions regarding use of “little filtered cigars,” “cigarillos/other mass market cigars,” and “premium cigars.”<sup>77</sup> “Premium cigar smoker” was defined as “reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper.”<sup>78</sup> The survey found that among adults who smoke cigars, only 19.9% smoke premium cigars. For premium cigar smokers, only 3.3% reported “every day” use, 25.6% reported “some day” use, and 71.2% reported using premium cigars “rarely.”<sup>79</sup>

The ANPRM also asks about dual use of “premium cigars and other tobacco products.” Here again, it is clear that premium cigar users are different. Specifically, premium cigar smokers are less likely than other cigar smokers to also smoke cigarettes. The results from the Adult Tobacco Survey showed that premium cigar smokers had the lowest dual use of cigarettes among cigar smokers –

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<sup>77</sup> Corey C. et al., *Little Filtered Cigar, Cigarillo and Premium Cigar Smoking Among Adults – United States 2012-2013*, Morbidity and Mortality Weekly Report (Aug. 1, 2014) available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm>. (“It should be noted that nearly 47% of current cigar smokers could not be assigned a usual cigar type because of insufficient information about the cigar smoked.”).

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* While this study did not precisely define “rarely,” it would be reasonable to assume the amount of cigars smoked by the population would be similar to the “occasional” smokers detailed in NCI Monograph 9. In 1998, when Monograph 9 was published, it found “as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year.” National Cancer Institute. Monograph 9: Cigars: Health Effects and Trends. 1998 at iii.

35.1% of usual premium cigar smokers also smoked cigarettes, as opposed to 58.3% of usual cigarillos/machine made smokers and 75.2% of usual filtered little cigar smokers.<sup>80</sup>

Corey et al. reported that Wave 1 of the PATH study had similar results, showing that only 29.9% of premium cigar smokers reported cigarette smoking; in contrast, approximately twice as many smokers of non-premium cigars, cigarillos and filtered cigars (58.0%-66.0%) reported cigarette smoking.<sup>81</sup> By Wave 3 this dropped to 23.8% for premium cigar users reporting cigarette smoking.<sup>82</sup> Further, in Wave 3, for current premium cigar smokers, “the median number of cigarette smoking days and the number of cigarettes smoked per day on days when they smoked are zero.”<sup>83</sup> Additionally, NERA finds that in Wave 3 PATH data, among current premium cigar smokers, those who are also current cigarette smokers, smoke premium cigars 0.7 days per month, as compared to 1.5 days per month for those that are not current cigarette smokers.<sup>84</sup>

The NERA Report also examines whether premium cigar smokers progress to become cigarette smokers – they do not. NERA reports that the percentage of premium cigar smokers that progress from never smoking cigarettes or smoking cigarettes on some days in Wave 1 to everyday cigarette smoking in Wave 3 is about 2%.<sup>85</sup> NERA also reports that “[n]ot only was the everyday

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<sup>80</sup> Corey C. et al., *Little Filtered Cigar, Cigarillo and Premium Cigar Smoking Among Adults – United States 2012-2013*, Morbidity and Mortality Weekly Report (Aug. 1, 2014) available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm>.

<sup>81</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>

<sup>82</sup> Ex. A., NERA Report at ¶59, Table 9c.

<sup>83</sup> *Id.* at ¶7(iv)

<sup>84</sup> *Id.* at Table 10c.

<sup>85</sup> *Id.* at ¶51, Table 6.

cigarette smoking progression for current users of premium cigars significantly lower than those of non-premium cigars, it was also **statistically indistinguishable from the transition into everyday smoking for respondents who were not current users of any tobacco product as of Wave 1.**<sup>86</sup>

The usage and purchasing patterns of premium cigar smokers show unequivocally that premium cigar smokers are a unique population who use premium cigars in a distinct manner. They are older, more educated and wealthier than the rest of the population. They begin smoking premium cigars as adults. They are much less likely to be brand loyal than other tobacco consumers. They are less likely to smoke cigarettes than others, and even when they do smoke cigarettes they smoke much less than other tobacco consumers. Finally, use of premium cigars does not progress to use of cigarettes.

## **VI. Public Health Considerations Associated with Premium Cigars**

The Premium Cigar ANPRM asks for information, comments and data regarding “public health considerations” surrounding premium cigars. CAA refers FDA to the CAA Comment submitted in connection with the Proposed Deeming Rule for comments on relevant information and data published prior to August 2014. Since 2014, there has been limited work done looking at premium cigars as an individual category; however, the work that has been done further demonstrates that public health questions relating to premium cigars are not the same as those raised by cigarettes, or other tobacco products.

*First*, as detailed above, and contrary to the conclusion in the Final Rule, youth do not smoke premium cigars in numbers that are even measurable. The PATH data shows that there is such small

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<sup>86</sup> *Id.* at ¶51 (emphasis added).

current use of these products by youth that it cannot even be reliably measured.<sup>87</sup> The NERA Report has confirmed the virtually non-existent youth usage of these products.<sup>88</sup> The NERA Report also demonstrates that the average first regular use of a premium cigar is at 30.0 years old.<sup>89</sup> In contrast, the average first regular use of cigarettes is 16.7 years old.<sup>90</sup> Additionally, according to Wave 3 PATH data, 52.7% of users of premium cigars have completed college or more, as opposed 11% of cigarette users.<sup>91</sup> By definition, in order to have completed college or additional education, this population has to be older. The PATH study reliably demonstrates that youth and young adults are not using premium cigars in more than a *de minimis* way, and that premium cigar smokers are an older, more educated population, even at the youngest end of the spectrum.

*Second*, this older population smokes less than users of other categories of cigars and cigarettes. Corey et al. reported that premium cigar smokers smoke a premium cigar on average only 1.7 out of every thirty days.<sup>92</sup> The NERA Report shows that in Wave 3, this number drops to 1.3 days.<sup>93</sup> This is drastically different from smokers of cigarettes, or smokers of filtered cigars,

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<sup>87</sup> Kasza, K. et al, *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 276 N. Eng J. Med. 376, at Supplement Table 4 (2017) available at [https://www.nejm.org/doi/10.1056/NEJMsa1607538?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%3dwww.ncbi.nlm.nih.gov](https://www.nejm.org/doi/10.1056/NEJMsa1607538?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov).

<sup>88</sup> Ex. A, NERA Report at Table 1.

<sup>89</sup> *Id.* at ¶49, Table 5c.

<sup>90</sup> *Id.*

<sup>91</sup> Ex. A, NERA Report at ¶37, Table 3.

<sup>92</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>.

<sup>93</sup> Ex. A, NERA Report at ¶44, Table 4c.

where the median days smoked was 29.4 days, and 14 days out of 30 days respectively.<sup>94</sup> Additionally, premium cigar smokers on average smoke only 0.1 cigars per day, as opposed to cigarette smokers who smoke 10.1 cigarettes per day, or filtered cigar smokers who smoke 1.6 cigars per day.<sup>95</sup> In fact, Corey et al. (2014) demonstrate that 96.7% of premium cigar smokers smoke less than one cigar per day.<sup>96</sup> The NERA Report analyzing the PATH study data confirms this, showing that 96.1% of premium cigar smokers are non-daily smokers.<sup>97</sup> Again, the available data reliably demonstrate that premium cigar smokers do not smoke as often, or with the same intensity (i.e., smoking fewer cigars per day, and smoking fewer days per month), as users of other tobacco products.

*Third*, non-daily users of cigars – the overwhelming majority of premium cigar smokers – have no statistically significant increase in mortality.<sup>98</sup> Christensen et al. examined results from the National Longitudinal Mortality Study, a longitudinal population-based, nationally representative health survey, with mortality follow-up. with other information from the Current Population Survey and Tobacco Use Supplement, and mortality data from the National Death Index. The participants provided tobacco use information at baseline, in surveys beginning in 1985 and were followed for

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<sup>94</sup>Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) <https://www.ncbi.nlm.nih.gov/pubmed/29059423> at Table 2.

<sup>95</sup> *Id.*

<sup>96</sup> Corey C. et al., *Little Filtered Cigar, Cigarillo and Premium Cigar Smoking Among Adults – United States 2012-2013*, Morbidity and Mortality Weekly Report (Aug. 1, 2014) <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm> .

<sup>97</sup> Ex. A, NERA Report at ¶44, Table 4c.

<sup>98</sup> Christensen C. et al., *Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population*, 178 JAMA Internal Medicine 14, 469-76, E-6 at table 3 (2018) available at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2672576>.



mortality through 2011. Tobacco use was categorized as “cigarettes,” “any cigar,” or “pipe tobacco.” Participants were analyzed for exclusive use of each product. Even without stratifying by type of cigar, there was no statistically significant increase in mortality for non-daily cigar smokers. As stated in the introduction, Dr. Geoffrey Kabat, a noted epidemiologist, reviewed the published literature on premium cigar usage patterns, and the epidemiologic data published since 2014, including the Christensen et al. study.<sup>99</sup> Upon reviewing this data, Dr. Kabat concludes:

Taken together, the epidemiologic studies described above show that there is no association between non-daily, exclusive smoking of cigars and an increased risk for smoking-related cancers, or an increased risk of death from all causes and certain specific causes.<sup>100</sup>

In looking at the entirety of the published literature, Dr. Kabat concludes “that these studies lead to the conclusion that there is no association between non-daily cigar smoking – which applies to the overwhelming majority of premium cigar smokers – and increased health risks compared to non-smokers.”<sup>101</sup>

This directly contradicts the findings in the Final Rule that the patterns of use of premium cigars do not sufficiently reduce health risks. Dr. Kabat’s Report, relying on work performed in part by authors from CTP, conclusively shows that there are no increased health risks for non-daily cigar smokers (which includes nearly all premium cigar smokers).

In the Final Rule, FDA decided to regulate premium cigars in the same blunderbuss manner in which it regulated all other cigars, and all other tobacco products, based on the conclusion that:

(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use

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<sup>99</sup> See, Ex. C, Kabat Report.

<sup>100</sup> Ex. C, Kabat Report at 6.

<sup>101</sup> *Id.* at 7.

sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults.<sup>102</sup>

FDA's historical use of a one-size-fits-all approach to the regulation of tobacco products does not account for the diversity that exists between, and within, the various tobacco product categories. The above data shows that (i) premium cigars are not used by youth and young adults; and (ii) that patterns of premium cigar use among the overwhelming majority of those who enjoy premium cigars show no increased health risk. Accordingly, premium cigars should be exempt from regulation.

## **VII. The Existing Regulations are Fundamentally Flawed as Applied to Premium Cigars**

As set forth above, the scientific data now available belies the fundamental factual and scientific bases upon which FDA originally determined to include premium cigars within the current regulatory structure. In the section below, CAA highlights but a few provisions of the existing regulations that are most egregious with respect to premium cigars in light of the scientific data now available. CAA offers these examples in order to demonstrate the current regulatory structure is fundamentally flawed and untenable in its application to the artisan premium cigar industry. These examples further underscore why premium cigars should be exempt from FDA regulation.

### *A. HPHC Testing is Fundamentally Flawed as Applied to Premium Cigars*

Harmful and Potentially Harmful Constituent ("HPHC") testing for premium cigars is unnecessary and extraordinarily cost-prohibitive, given the unique nature of each hand made cigar product. More importantly, the application of existing HPHC testing requirements to premium cigars is fundamentally flawed because, at present, testing methodologies do not exist (let alone an

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<sup>102</sup> 81 Fed. Reg. at 29,020.

understood definition of HPHC's for any cigar product) that can yield reliable, scientifically valid results.

*First*, as discussed above in Section IV.D, there is no generally recognized and accepted methodology to perform smoke testing on premium cigars. Additionally, there is currently no smoking machine that can accommodate the vast array of premium cigars, whether due to ring gauge, length or shape of the cigar. There is a CORESTA working group dedicated to trying to understand the many complications inherent in testing premium cigars, but that work remains up to two or more years away from completion, with no guarantee that any resulting testing methodology will be able to overcome the inherent natural variations and challenges presented by premium cigars. Simply stated, the FDA opted to blindly apply a testing requirement that was intended for an entirely different category of highly processed, commoditized, machine-made goods, with complete disregard to the absence of any scientifically valid methodology to comply with such requirements in the context of premium cigars. This decision was arbitrary and capricious from its inception, and in view of the now available data regarding usage patterns of premium cigar smokers, cannot be justified.

*Second*, FDA has not yet established a list of HPHCs to be tested for in any cigar, let alone a premium cigar. Section 904 of the Tobacco Control Act requires a “listing of *all constituents, including smoke constituents as applicable*...identified by the Secretary as harmful and potentially harmful to health in each tobacco product” (emphasis added).<sup>103</sup> FDA, through Guidance, with little notice to industry, has only established lists for HPHC testing for originally regulated products.

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<sup>103</sup> Tobacco Control Act § 904.

*Third*, the Final Rule states that “FDA intends to issue a guidance regarding HPHC reporting, and later a testing and reporting regulation required by Section 915 **with enough time for manufacturers to report given the three year compliance period for HPHC reporting.**”<sup>104</sup> FDA has released neither for newly deemed products, and at the time of filing this Comment, the HPHC reporting deadline is just over fifteen months away. It is also worth noting that the testing rule required by Section 915 of the Tobacco Control Act was supposed to be promulgated “not later than 36 months” after the date of enactment of the Tobacco Control Act.<sup>105</sup>

*Fourth*, even if valid methodologies existed, as FDA has recognized, the primary components of all premium cigars – wrapper, binder, and filler – are simple agricultural products subject to the common vagaries of any naturally grown crop, which requires manufacturers to make adjustments to account for natural variations in tobacco in order to retain the character of any given cigar. Even if such adjustments are not made, the exact same crop will be different from year to year based on local growing conditions. As a result of agricultural changes due to local growing conditions, the inherent natural variation present in tobacco, and the unique nature of each hand-crafted cigar product, there is an almost infinite number of variables that impact the validity and usefulness of testing any set of HPHC’s under any methodology.

It is inappropriate to subject any product to a testing requirement for which no guiding structure has been implemented, and for which no generally accepted scientific methodology yet exists. Even if basic methodologies did exist, the application by FDA of a testing requirement intended for cigarettes, which are an incredibly uniform product with an established testing protocol,

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<sup>104</sup> 81 Fed. Reg. at 29,052(emphasis added).

<sup>105</sup> Tobacco Control Act § 915(a).

to premium cigars, is fundamentally flawed given the inherent agricultural and production variations of these products. The extraordinary burden and cost necessary to try to create a practical solution to these complex problems is shown to be categorically misplaced based on the usage patterns of premium cigar smokers. There is simply no basis upon which the HPHC testing requirements under the Deeming Regulations can be rationally applied to premium cigars.

*B. Pre-Market Review is Fundamentally Flawed as Applied to Premium Cigars*

The substantial equivalence process, as it is currently implemented, would neither efficiently utilize FDA resources, nor be appropriate to protect the public health as applied to premium cigars.

FDA has had authority to regulate cigarettes, smokeless tobacco and roll-your-own tobacco since 2009. CTP is only now beginning to grasp the breadth of resources necessary to regulate those tobacco products that were originally made subject to its jurisdiction in 2009, and it is certainly not prepared to take on the pre-market review challenges of the newly deemed products. It is still reviewing regular Substantial Equivalence (“SE”) reports submitted for those products, and still has approximately 1000 Provisional SE reports to review for products in those categories introduced into the market between February 15, 2007 and March 22, 2011.<sup>106</sup> For instance, for Pre-Market Tobacco Product Applications (“PMTA”), since inception, CTP has received 383 applications. Of these, it has issued only eight marketing orders, three have been withdrawn, five have been resolved by a “Refuse to file” and CTP has refused to accept 367 of these applications.<sup>107</sup> Come 2021 and

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<sup>106</sup> FDA Update on Provisional Substantiation Equivalence (SE) Process, U.S. FOOD & DRUG ADMINISTRATION (Apr. 5, 2018) <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm583226.htm>. Further, CTP has not yet imposed graphic warnings on cigarettes, and has been sued by the public health industry for delaying in such action.

<sup>107</sup> Tobacco Product Marketing Orders, U.S. FOOD & DRUG ADMINISTRATION <https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/ucm339928.htm> (last visited July 24, 2018).

2022, CTP will drown in the deluge of SE reports from cigar and pipe tobacco companies, and PMTA applications by the e-cigarette companies.<sup>108</sup>

To illustrate the strain on FDA resources that would result from subjecting premium cigars to the current pre-market review process, CAA notes that FDA recently made a major announcement with respect to Provisional SE Reports,<sup>109</sup> which were submitted by March 22, 2011, for products that had been on the market from February 15, 2007 until March 22, 2011.<sup>110</sup> FDA received nearly 3,600 provisional SE applications. Seven years later, however, in 2018, FDA still had not finished the review process for approximately 70% (2,500) of these applications. Therefore, FDA announced that “[t]he agency will continue to review the approximately 1,000 pending provisional SE Reports that were determined to have the greatest potential to raise different questions of public health and will remove from review the approximately 1,500 provisional SE Reports that were determined less likely to do so.”<sup>111</sup> In a speech later that month, the Director of the Office of Science, Dr. Matt Holman, stated that reasons a provisional SE Report would continue to be reviewed might be: (i) non-conventional new product; (ii) new or predicate product inadequately characterized, (iii) new product category different from predicate product category, (iv) less than 5% increase in total alkaloids or bases, (v) design changes that may increase HPHC quantities, (vi) increase in HPHCs,

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<sup>108</sup> See Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (November 2017).

<sup>109</sup> *FDA Update on the Provision Substantial Equivalence (SE) Report Review Process*, U.S. Food & Drug Administration (April 5, 2018), <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm583226.htm>.

<sup>110</sup> Tobacco Control Act § 910(a)(2)(B).

<sup>111</sup> *FDA Update on the Provision Substantial Equivalence (SE) Report Review Process*, U.S. Food & Drug Administration (April 5, 2018), <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm583226.htm>.

and (vii) >30% blend change.<sup>112</sup> He stated that removing provisional SE Reports from review “allows FDA to focus on provisional SE reports most likely to impact the public health.”<sup>113</sup> It is obvious that CTP needs to be “strategic” in how it uses its resources.

A primary failing of the current substantial equivalence process, and a major reason it cannot work for premium cigars, is that there are no unique requirements for each category of tobacco products. The Tobacco Control Act grants FDA “flexible enforcement authority” and intends for FDA to regulate each tobacco product differently, in order to address the unique questions of public health raised by different classes and types of tobacco products.<sup>114</sup> The current blunderbuss approach ignores the limited public health issues raised by premium cigars, as well as the intent of the Tobacco Control Act and FDA’s public health mission. FDA has refused to acknowledge that premium cigars raise questions of public health different than other tobacco products including, as outlined above in Sections V and VI, other types of cigars. Further, as the Econsult Report shows, there are currently approximately 10,000 SKUs per large, online retailer of premium cigars.<sup>115</sup> Premium cigars are unique among all tobacco products in that they have the widest scope of variability in terms of size, shape, tobacco blends and subtle distinctions inherent in a handmade process, while at the same time having the most limited patterns of use and health impacts. The strain on Agency resources to have premium cigars undergo premarket review is not warranted based on the different health effects of premium cigars.

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<sup>112</sup> Dr. Matt Holman, “TMA 2018 Annual Meeting,” slide 16, April 11, 2018. CAA understands Dr. Holman’s presentation was not an official statement by FDA, but uses this information simply as guidance and background for preparation of the positions outlined in this Comment.

<sup>113</sup> *Id.* at slide 17.

<sup>114</sup> See Tobacco Control Act § 3(4). See also *e.g.* Tobacco Control Act §§ 906, 907, 909, 102.

<sup>115</sup> Ex. B, Econsult Report, at 8, Table 3.

i. The SE Process is Fundamentally Flawed As To Premium Cigars

Premium cigars are not a new, novel product, and in fact, they are historically the most stable and consistent tobacco product due to their simplicity. Premium cigars are for the most part made of tobacco, water and a bit of vegetable-based adhesive; as such, premium cigars will rarely undergo changes that are likely to raise different questions of public health or otherwise substantially impact the public health. FDA failed to consider whether subtle distinctions in combinations of what is effectively a natural crop even merit such a review. In fact, the data shows that such an exercise is not warranted. First, almost the entire population of premium cigar smokers has no statistically significant increase in mortality rate versus non-smokers. Second, premium cigar smokers switch frequently between brands and vitolas. The endless combinations of tobacco leaves (including year to year natural variations in tobacco crops) used to make premium cigars, the usage patterns of premium cigar smokers, and the fact that premium cigars have no statistically significant impact on the health of most premium cigar smokers, raise the question of whether there is a justification to require premium cigars to go through such an extraordinarily burdensome process. The question has, in effect, already been answered in the negative.

Given the data on usage patterns and health outcomes, there is no need for an SE process for premium cigars, and under any circumstances the SE process as currently implemented by FDA is fundamentally flawed as applied to them. Given the great number of premium cigars typical at any time in the marketplace, the natural variations and agricultural vagaries that occur, and the inherent, subtle distinctions between cigars in a handmade, artisanal process, the SE process adopted by FDA is fundamentally untenable as applied to premium cigars. FDA's decision to simply apply a process created for highly processed, commoditized, machine-made products on premium cigars is not only arbitrary and capricious, but unjustifiable given FDA's history of implementation of more refined



systems in other circumstances. An example is the highly regarded medical device modification flowchart FDA promulgated as part of the 501(k) program, where FDA created logical categories of exempt changes for modifications that did not create “new” devices.

In this case, FDA could have employed a similar notice-based process, and could have considered the negligible impact of any host of changes to premium cigars. FDA could have recognized that a centuries-old history of tobacco blend changes and yearly agricultural variations do not result in a “new” premium cigar, and could have exempted blend changes from the SE process. FDA could have recognized that, given the endless variations of packaging that are ubiquitous in the premium cigar space, changes in packaging and ingredients used in premium cigar packaging and other components should not be subject to reporting under Section 905(j) and Section 910. FDA chose not to take any of these sensible steps.

Similarly, FDA could have looked at available data or simply walked into any cigar shop to recognize that, notwithstanding the quantity count of premium cigars in any finished goods packaging, premium cigars are primarily purchased and sold individually, rendering quantity counts essentially irrelevant. FDA could have looked to these and other characteristics that have little impact on how premium cigars are manufactured, purchased or consumed to develop a minor modification exemption system, rather than subject this artisanal niche industry to crushing governmental regulation, with no apparent benefit to the public health. Again, FDA chose not to.

These decisions, viewed even more clearly in light of the data now available, cannot be defined as anything less than arbitrary, capricious, and wholly unjustified. The data makes clear that an SE process is not necessary for premium cigars and that, under any circumstances, the SE process as currently implemented is fundamentally flawed as to premium cigars.

ii. Existing Product Quantity Change Regulations are Fundamentally Flawed as Applied to Premium Cigars

FDA has taken the position that changes to the product quantity in a tobacco product's package renders that product a "new tobacco product," even if all other product characteristics remain constant. As such, FDA's "current thinking" regarding product quantity changes requires a manufacturer to file a Product Quantity Change Substantial Equivalence Report ("Product Quantity Change SE") anytime there is a change from a February 15, 2007 configuration of that exact product.<sup>116</sup> FDA states this Product Quantity Change SE is necessary because:

[c]hanges in product quantity can affect initiation and cessation, such as by affecting consumer harm perceptions, use intentions and use behavior. The information in these Product Quantity Change SE Applications would allow for FDA to fully evaluate the potential of such changes in product quantity to determine whether the new product raises different questions of public health....

<sup>117</sup>

Previously available data on the public health impact of product quantity changes, without any corresponding change to a tobacco product itself, was inconclusive.<sup>118</sup> Newly available data, however, regarding purchasing and usage patterns demonstrates that such product quantity changes should not be subject to pre-market review for premium cigars.<sup>119</sup> As previously stated, the data presented in the expert reports accompanying this Comment demonstrate that package quantity of premium cigars is not relevant to usage patterns. Indeed, the hypothesis that product quantity affects

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<sup>116</sup> See Guidance for Industry: Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 3)\*, pp. 7, 8, 13 (December 2016).

<sup>117</sup> *Id.* at 7.

<sup>118</sup> See, e.g., Joachim Marti & Jody Sindelar, *Smaller Cigarette Pack as a Commitment to Smoke Less? Insights from Behavioral Economics*, Plos One, p. 11 (Sep. 10, 2015) available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0137520>. ("there is little to no empirical evidence to confirm or reject" the hypothesis that quantity changes in tobacco product packages impact consumer behavior).

<sup>119</sup> See Section V, above.

consumer behavior misses a fundamental point of the premium cigar category – premium cigars are never sold in “new” product quantities in the typical sense. In fact, regardless of how they may be packaged at any one moment in time, these cigars are always available for sale as single cigars.

Manufacturers may create luxury, beautiful boxes for distribution to retailers, generally containing twenty or twenty-five premium cigars in each box. Retailers purchase these boxes and sell some full boxes to consumers, but also offer single premium cigars from open boxes on trays, and from open boxes inside humidors, so consumers can buy only a few cigars of one brand, or one premium cigar of a few different brands. Online retailers mimic this experience by selling “five packs” of one premium cigar brand or “sampler packs” of different premium cigar brands that they create.<sup>120</sup> The underlying concept is that premium cigars are intended to be sold individually, as well as in boxes. Additionally, recent data has shown that 79% of premium cigars bought in person are purchased as single cigars.<sup>121</sup> Moreover, the available data conclusively establishes that despite the endless array of quantity counts available in the marketplace, over 96% of premium cigar smokers smoke premium cigars on a less than daily basis, and at the median at a rate of only 1.3 cigars per month.<sup>122</sup> The purchasing patterns and usage rates of premium cigar smokers illustrate that the notion of product quantity impacting premium cigar usage patterns is misplaced.

Further, subjecting so-called product quantity changes in the context of premium cigars to pre-market review, as called for under the existing regulations, would result in the unintended

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<sup>120</sup> See Ex. B, Econsult Report at 14-15, Tables 9, 10, 12. Sampler packs represent 25% of overall online premium cigar orders. Similarly 5-packs and a 10-packs are two of the most commonly purchased quantities by online premium cigar consumers.

<sup>121</sup> Corey C, et al., *U.S. 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*, Nicotine and Tob. Res. ntx209 (2017) available at <https://www.ncbi.nlm.nih.gov/pubmed/29059423>

<sup>122</sup> Ex. A, NERA Report at ¶44, Table 4c.

consequence of subjecting nearly all wholesalers and retailers to regulation as tobacco product manufacturers, as the definition of manufacturing includes repackaging. Not only does this approach subject nearly all wholesalers and retailers to the pre-market review process, and inundate FDA with Product Quantity Change SE Reports, but it will also subject these wholesalers and retailers to registration and listing requirements and other requirements only meant for true manufacturers. The vast majority of product quantity changes are those made by the wholesalers, most of whom have currently had to register as domestic manufacturers because they “repackage or relabel” cigars.

As an example of what can happen in the tobacco distribution chain, a cigar distributor buys boxes of twenty-five cigars from the foreign manufacturer. The distributor then distributes those boxes to other wholesalers and retailers across the country, some of whom will take the box of twenty-five cigar and break it down into smaller quantities such as into packs of ten or five. These wholesalers and retailers then sell to their customers both the box of twenty-five as received from the distributor, and the cigars repackaged into packs of ten and five. A consumer can then purchase either the box twenty-five, the packages of ten, the package of five, or a single cigar. The data from the online sellers of premium cigars demonstrates this exact point. Sales of samplers, five packs and ten packs represent a great percentage of all cigar sales.<sup>123</sup>

The basis for the conclusion that product quantity change SEs might be necessary for high consumption, standardized quantity products is based on the potential effect on the usage patterns of consumers of those products. For premium cigars smokers, however, all available data demonstrate conclusively that these products are used differently, and therefore the same conclusions are not

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<sup>123</sup> Ex. B, Econsult Report at 14-15, Tables, 9-12.

valid. Given the purchasing and use patterns of premium cigar smokers, pre-market review for product quantity changes is irrelevant in terms of consumer usage, safety and health, and the existing regulation is unjustifiable as applied to premium cigars.

iii. The Requirement of Environmental Impact Statements is Fundamentally Flawed as Applied to Premium Cigars

The existing regulations require Environmental Assessments (“EA”) or an Environmental Impact Statement (“EIS”) for SE Reports for all tobacco products, which as currently stands, includes premium cigars. In one circumstance, FDA appropriately created a categorical exception to this requirement – for Provisional SE Reports.<sup>124</sup> Categorical exceptions can be made for a “category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not normally require the preparation of an EA or EIS.”<sup>125</sup> FDA determined that “certain classes of tobacco products normally do not cause significant environmental effects” and “certain actions on tobacco-related applications do not result in significant environmental impacts to the quality of the human environment.”<sup>126</sup>

FDA justified providing a categorical exclusion for Provisional SE Reports because “[a]ctions on provisional SEs reports, by contrast will relate only to product already on the market.”<sup>127</sup> The current grandfather date for ALL tobacco products is February 15, 2007 and, as explained above, given their simple construction, premium cigars made in 2007, premium cigars made today, and premium cigars made at any time in between or before this period, are essentially

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<sup>124</sup> National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exceptions, 80 Fed. Reg. 57,531 (Sept. 24, 2015).

<sup>125</sup> 80 Fed. Reg. at 57,532

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

the same from a public health perspective. The requirement for an EIS or EA for any substantial equivalence application for a newly deemed product is misplaced, based on the reasoning for the categorical exception for Provisional SE Reports. This provision is egregious when considering premium cigars. Not only are there no “new” products coming to market, even if there were, they would be identical in their impact on the environment.

*C. The Health Warning Requirements are Unjustifiable*

The Final Rule requires that cigar packages and advertisements carry six rotating warning statements.<sup>128</sup> These warnings must occupy 30% of two principal display panels of all cigar packages, and 20% of the upper portion of all cigar advertisements.<sup>129</sup> As of the date of filing of this Comment, a federal district court in Washington, D.C. has issued an injunction prohibiting FDA from enforcing the health warning provisions of the Final Rule for all cigars and pipe tobacco pending resolution of the plaintiffs’ appeal in the case. Judge Mehta, in his ruling granting plaintiffs’ motion for an injunction pending appeal, stated with respect to plaintiffs’ First Amendment claims that:

The issues appealed by Plaintiffs present “serious legal questions” as to the constitutionality of FDA’s warnings regime, a conclusion only reinforced by the Supreme Court’s recent decision in *National Institute of Family and Life Advocates v. Becerra*, No. 16-1140, 2018 WL 3116336 (U.S. June 26, 2018). Additionally, Plaintiffs likely will suffer irreparable harm absent injunctive relief: they will have to communicate purely factual government speech in a form and size to which they object; will have their own commercial speech diminished; and will have to incur millions of dollars in compliance costs, which they will not be able to recover if the warnings regime is determined to be unconstitutional.

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<sup>128</sup> 21 C.F.R. §1143.5.

<sup>129</sup> FDA has declined to define the term “advertisement” but has stated that “it should be interpreted broadly.” 81 Fed. Reg. at 29062. FDA, however, has yet to release promised guidance on “how to comply with the health warning requirements on unique types of media.” 81 Fed. Reg. at 29064. Industry is simply left to conjecture as to what FDA will interpret as complying with the advertising requirements, and what FDA interprets as “unique media.”

Finally, both the balance of equities and the public interest favor an injunction pending appeal.

In the end, this court believes that Plaintiffs are entitled to a full hearing before an appellate court without the specter of a warnings regime going into effect that might ultimately be found to run afoul of the First Amendment.<sup>130</sup>

Even in the absence of the pending litigation, however, the data now available makes clear that the overbearing, extraordinarily expensive warning scheme imposed upon the premium cigar industry under the existing regulations is, and at all times has been, wholly unjustified. As with other portions of the Final Rule, the FDA provided no substantive evidence to support its actions related to cigars, stating, “reliable evidence on the impact of warning labels . . . on users of cigars . . . does not, to our knowledge, exist.”<sup>131</sup>

Similar to the SE Process, FDA could have easily looked to an existing example of a warning scheme, but, without any apparent justification FDA chose not to, once again choosing a one-size-fits-all approach without consideration of the individual product.

The seven largest cigar manufacturers have been putting five rotating warnings on their cigar packages and advertisements since signing the FTC Consent Decree in 2001.<sup>132</sup> The Consent Decree warning size flexed off the surface area of a package, requiring only a limited number of warning sizes for companies to apply to packages, and much like the system in the European Union, had a

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<sup>130</sup> See *Cigar Ass’n of America, et al. v. FDA et al*, Case No: 1:16-cv-1460(APM), Memorandum Opinion and Order of Judge Amit Mehta, Dkt. No. 106, 107 at 2.

<sup>131</sup> 81 Fed. Reg. at 29,026, 29061; Final Regulatory Impact Analysis at 62.

<sup>132</sup> See e.g., *In the Matter of Consolidated Cigar Corp.*, Docket No. C- 3966 (F.T.C. Aug. 18, 2000). The “FTC Consent Decree” was the resolution reached by the seven major cigar companies and the FTC that required the companies to place five rotating Surgeon General warnings on all cigar packages and advertisements.

maximum size for the warning.<sup>133</sup> This ensured that package warnings only had to be produced in a limited number of sizes, and that there were detailed instructions for the size of warnings on advertisements, including warnings on “unique media” such as video and radio ads. FDA, for reasons unknown, ignored all available information about how a warning scheme can be implemented, and the Final Rule has none of this specificity regarding the size of the warnings or applications in non-packaging contexts.

Additionally, premium cigars come in boxes, canisters, jars, cellophane wrapped bundles and other packaging types. Further complicating the matter for the premium cigar industry is the shape of the cigar box, perhaps the most frequently used type of cigar packaging, means that a package will typically require two different sized health warning in order to meet the FDA’s requirement of warnings on “*two* principal display panels.” Given the foregoing, premium cigars manufacturers are faced with the prospect of having to use hundreds of different sized warning labels to comply with the existing regulations. Further, this warning scheme requires adding a significant amount of complexity to the manufacturing process to ensure the right labels are placed on the right panel of the right packages; keeping in mind that placement of the labels is generally done by hand. The scientific data now available shows that the warning scheme called for by the FDA is unwarranted as applied to premium cigars.

In imposing the Final Rule, FDA did not make any scientific findings as to whether the FTC Consent Decree warnings were ineffective, thereby justifying the larger and less specifically-sized FDA warnings. In fact, FDA found the content of the FTC warnings completely acceptable,

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<sup>133</sup> This is similar to the system in place in the European Union for cigars. The regulation in the European Union outlines that if “the health warnings referred in 1 & 2 are to appear on a surface exceeding 150 cm<sup>2</sup>, the warnings shall cover an area of 45 cm<sup>2</sup>.” Directive 2014/40/EU, Art. 11(4).



adopting those warnings nearly wholesale.<sup>134</sup> Further, there has still not been any work done regarding this issue in relation to cigars generally, or premium cigars in particular.<sup>135</sup>

In addition, as noted above in Section V, premium cigars are used by an adult, educated population. For over seventeen years, the largest manufacturers of premium cigars have used the Consent Decree health warnings to provide consumers with the same information required under the Final Rule. The Federal Trade Commission determined these warnings were “clear and conspicuous” and FDA has not provided any evidence determining them not to be so.

As noted above, the question of whether FDA’s proposed cigar health warnings are constitutional is currently before a federal appellate court. CAA believes this court will find the FDA warnings violate the First Amendment rights of cigar manufacturers and retailers. FDA should withdraw its proposed warnings regulations for premium cigars.

#### **VIII. Premium Cigars Should be Exempt from Regulation**

Based on the available data on usage patterns and health effects of premium cigars, premium cigars should be exempt from regulation. As Dr. Gottlieb noted in his July 28, 2017 speech, CTP must use its resources “efficiently” and “must be strategic about how it uses its tobacco and drug

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<sup>134</sup> In fact, while FDA offered an optional reproductive harm warning that was cigar specific (WARNING: Cigar use while pregnant can harm you and your baby”) as opposed to the FTC reproductive harm warning, the California Attorney General has stated that the industry must use the FTC reproductive harm warning in order to satisfy California’s Proposition 65, thereby ensuring very few cigar companies, if any, will choose use the FDA drafted warning. See Letter from California Attorney General Xavier Becerra to James Jack dated April 11, 2018.

<sup>135</sup> See Jarman KL. Et al. *Are Some of the Cigar Warnings Mandated in the U.S. More Believable Than Others?* 14 Int’l J. of Res. And Envir. Health 1370, at 2 (2017) available at <http://www.mdpi.com/1660-4601/14/11/1370> (“To date no experimental studies have addressed the impact of cigar warnings among adults; the extant literature focuses on cigarette warnings or involves qualitative designs....This review found no relevant studies on cigar warnings, and called for more research on tobacco products other than cigarettes....Thus, we know little about effective messaging, including for warnings, for cigars.”).

authorities.”<sup>136</sup> Due to the different questions of public health raised by premium cigars, regulation of premium cigars is not an efficient or necessary use of CTP funds. President Trump has emphasized that it is the policy of the executive branch “to be prudent and financially responsible in the expenditure of funds, from both public and private resources” and “it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.”<sup>137</sup> Further, “it is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.”<sup>138</sup> To that end, in order to preserve precious government and industry resources, FDA must exempt premium cigars from regulation.

Moreover, as set forth in Section II, the stated reasons why FDA did not in the first instance exempt premium cigars were:

(1) All cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults.”<sup>139</sup>

In ordering this ANPRM, Dr. Gottlieb requested new information to re-evaluate FDA’s original conclusions in this regard. New data is available, and the new data categorically contradicts the premises upon which FDA based its initial determination to subject premium cigars to the Final Rule.

As noted above in Section III, premium cigars represent a small portion of the cigar industry and a tiny fraction of the tobacco industry as a whole. The premium cigar industry has the largest

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<sup>136</sup> Dr. Scott Gottlieb, *Protecting Families: Comprehensive Approach to Nicotine and Tobacco*, U.S. Food & Drug Administration (July 28, 2017), <https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm>.

<sup>137</sup> Executive Order 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

<sup>138</sup> Executive Order 13,777, 82 Fed. Reg. 12,285, sec. 1. (Feb. 24, 2017).


<sup>139</sup> 81 Fed. Reg. 29,020.

assortment of sizes, shapes, and tobacco blends in the tobacco industry. Estimates of the total SKU count vary, but seeing as how each of the online retailers currently have an average of 10,000 SKUs, the volume of products is enormous.<sup>140</sup> Neither CTP nor public health is served by devoting substantial resources to products that have usage patterns distinct from other tobacco products and that as a result present no increased health risks. Both because virtually all premium cigar smokers face no increased risk of mortality and agency resources are much better used elsewhere, premium cigars must be exempt.

**IX. Conclusion**

For the reasons set forth above, CAA requests FDA define “premium cigar” as outlined in Section IV, and exempt premium cigars from regulation.

Respectfully Submitted,

  
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Craig Williamson  
President  
Cigar Association of America, Inc.

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<sup>140</sup> Ex. B, Econsult Report at 8.

### **Appendix A**

<b>Expert Report</b>	<b>Topic</b>	<b>Major Findings</b>
<b>NERA Economic Consulting</b>	Prevalence of cigar usage	<ul style="list-style-type: none"> <li>• Prevalence of youth cigar usage</li> <li>• Prevalence of adult cigar usage</li> <li>• Demographic characteristics of cigar and cigarette users, Wave 1-Wave 3 of the PATH Study</li> </ul>
	Frequency and intensity of premium cigar use	<ul style="list-style-type: none"> <li>• Prevalence of smoking</li> <li>• Days smoked in past 30 days</li> <li>• Number of sticks per day in days smoked</li> <li>• Number of sticks smoked per day in past 30 days</li> </ul>
	Initiation of use and progression to use other tobacco products	<ul style="list-style-type: none"> <li>• Age at initiation</li> <li>• Progression from cigar smoking to cigarette smoking</li> <li>• Current cigar smokers transition to cigarette smoking</li> </ul>
	Dual usage of premium cigars and cigarettes	<ul style="list-style-type: none"> <li>• Cigarette smoking status – current, former, never</li> <li>• Prevalence of now smoke cigarettes every day</li> <li>• Number of cigarette smoking days in past 30 days</li> <li>• Number of cigarettes per day on days smoked</li> <li>• Number of cigarettes per day in past 30 days</li> </ul>
<b>EConsult Solutions</b>	Market size and share	<ul style="list-style-type: none"> <li>• Share of cigar market defined by Catherine Corey</li> <li>• Percent of premium cigar market defined by Corey</li> </ul>
	Total premium cigar transactions	<ul style="list-style-type: none"> <li>• Summary statistics of total premium cigar transactions – orders, unique customers, cigars sold, SKUs, cigar revenue</li> </ul>
	Customer age	<ul style="list-style-type: none"> <li>• Stratified age cohorts of online premium cigar purchasers</li> <li>• Comparison of premium cigar purchasers to overall US population by cohort</li> </ul>
	Purchasing patterns	<ul style="list-style-type: none"> <li>• Unique customers, orders, unique SKUs sold, number of cigars sold, total revenue, price per cigar, average spend</li> <li>• Cigar units and expenditures by month</li> <li>• Frequency of repeat purchasing over a four-year period</li> <li>• Average cigars per order and average spending per order</li> <li>• Order characteristics</li> </ul>
	Demographics	<ul style="list-style-type: none"> <li>• Percent of urban population purchasing premium cigars</li> <li>• Median household income of the census tract of premium cigar purchasers</li> <li>• Education level of premium cigar purchasers compared to US population</li> </ul>
<b>Dr. Geoffrey Kabat</b>	Epidemiology	<ul style="list-style-type: none"> <li>• Review of three studies examining prevalence data on the use of premium cigars – youth usage, age of initiation, frequency of smoking, number of days smoked in past 30 days</li> <li>• Review of three mortality studies plus a pooled analysis of five cohort studies examining the association of cigar use with health outcomes</li> <li>• Review of one study and one abstract which examined biomarkers of tobacco smoke exposure among cigar smokers</li> </ul>

Cigar Association of America, Inc.  
Comment to Docket No. FDA-2017-N-6107  
Regulation of Premium Cigars

**EXHIBIT A**

**RE: DOCKET NO. FDA-2017-N-6107 REGARDING THE REGULATION  
OF PREMIUM CIGARS**

**REPORT REGARDING CONSUMPTION PATTERNS OF PREMIUM  
CIGARS**

**FATEN SABRY, PH.D.  
IGNACIO FRANCESCHELLI, PH.D.  
DREW CLAXTON**

**July 25, 2018**

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## **I. INTRODUCTION**

### **A. Assignment**

1. The Food and Drug Administration (“Agency” or “FDA”) published a proposed rule in the Federal Register of April 25, 2014, seeking to deem additional products meeting the statutory definition of “tobacco product” to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). After considering the public comments on the rule, the Agency concluded that there was no appropriate public health justification to exclude premium traditional cigars (“premium cigars”) from regulation. The Agency stated that “comments against regulation provided little data to support the opinions expressed and, where studies were submitted, provided little information about the studies cited.” Consequently, premium cigars were included in the scope of the final deeming rule published on May 10, 2016.

2. On July 28, 2017, the FDA announced a “new comprehensive plan for tobacco and nicotine regulation,” and stated that it would seek additional comments and scientific data that were not submitted in response to the 2014 proposed deeming rule that could further inform the Agency’s thinking about the regulatory status of premium cigars.<sup>1</sup> The Agency is now seeking comments, data, research results, and other information related to the definition of premium cigars, the use patterns of premium cigars and the public health considerations associated with premium cigars. The Agency has requested comments on the use patterns of premium cigars, both generally and among youth and young adults, and as compared to and contrasted against that of non-premium traditional cigars, filtered cigars and cigarillos (together “non-premium cigars”).

3. I have been asked by Cigar Rights of America, the Cigar Association of America, and the International Premium Cigar and Pipe Retailers Association to provide a statistical analysis of four aspects of consumption behavior that is related to premium cigar usage: i) the prevalence of use and the demographic characteristics of premium cigar users as compared to users of non-premium cigars and cigarettes; ii) the frequency and intensity of premium cigar use as compared to that of non-premium cigars and cigarettes; iii) the initiation of premium cigar use and the progression from premium cigar use to cigarette use as compared to that of non-premium

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<sup>1</sup> Federal Register, Vol. 83, No. 58, p.12902. Monday, March 26, 2018 Proposed Rules.

cigar; and iv) the dual usage of premium cigars and cigarettes, as compared to that of non-premium cigars.

## **B. Population Assessment of Tobacco and Health Study**

4. The Population Assessment of Tobacco and Health Study (“PATH” or “Study”) is a large, nationally representative, longitudinal cohort study of adults and youth selected between September 2013 and December 2014. The Study’s design allows for the longitudinal assessment of tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes for individuals nine years old or older in the U.S.<sup>2</sup> The sampling rates were designed to achieve sufficiently large sample sizes for young adults, Black or African American adults and adult tobacco users of all ages. According to the Inter-University Consortium for Political and Social Research (ICPSR), the PATH data provide “an empirical evidence base for developing, implementing, and evaluating regulations governing tobacco products by measuring the behavioral and health effects associated with changes in such regulations.”<sup>3</sup> These data were not available during the public comment period for the proposed rule published on April 25, 2014.

5. The PATH data follows 45,971 respondents (32,320 adults, and 13,651 youth) over time and consists of repeated observations on the same cross section of individuals, so for example, one can determine whether an 18-year-old e-cigarette user at time 1 is still using the product at time 2. The first wave of data collection began in September 2013, was completed in December 2014 (“Wave 1”) and included an adult questionnaire with 2,011 variables and 32,320 cases in the database and a youth (and parent) questionnaire with 1,431 variables and 13,651 cases in the database. The second wave of data collection began in October 2014, was completed in October 2015 (“Wave 2”) and included a follow-up on individuals that had already completed the first wave questionnaire. Similarly, the third wave of data collection took place from October 2015 through October 2016 (“Wave 3”) and was released on May 1, 2018.

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<sup>2</sup> United States Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse, and United States Department of Health and Human Services. Food and Drug Administration. Center for Tobacco Products. Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2018-05-01. <https://doi.org/10.3886/ICPSR36231>, v14.

<sup>3</sup> PATH Restricted-Use Data User Guide, p. 2.

6. The target population for Wave 1 is the civilian household population 9 years of age or older in the United States.<sup>4</sup> The PATH data include information for adults, ages 18 and older, youth ages 12 to 17, and “shadow youth” ages 9 to 11. Shadow youth will “age-up” to the youth category and be interviewed as youth upon reaching 12 years of age.<sup>5</sup> Similarly, those classified as youth in Wave 1, will “age-up” to be classified and interviewed as adults if they become 18 years of age in subsequent waves.<sup>6</sup>

### **C. Summary of Opinions**

7. Based on my statistical analysis of the PATH data, my opinions are summarized as follows:

- i. The prevalence of premium cigar usage and the demographic characteristics of premium cigar consumers differ from that of non-premium cigar products and cigarette users. For example, in Waves 1, 2 and 3, among youth, the prevalence of non-premium cigar use is 16.5 to 25 times that of premium cigars. Similarly, among adults, the prevalence of non-premium cigar use is more than 3.7 to 4.5 times that of premium cigars. Prevalence is the estimated weighted percentage of respondents who are identified as current cigar or cigarette users.
  - a. Among the 11,814 respondents aged 12 to 17 in the recently released Wave 3, there is only one current premium cigar user, or a 0.02% prevalence. In Wave 3, the premium cigar prevalence for respondents aged 12 to 17 remains lower than that of any single non-premium cigar—in the 0.05% to 0.35% range—and cigarettes with a 1.77% rate. No respondents aged 12-14 reported using premium cigars. Similar results are obtained for the first and second waves of data collection. The prevalence of premium

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<sup>4</sup> PATH Restricted-Use Data User Guide, pp. 17 and 21. Wave 1 respondents continued to be eligible for interview in Wave 2 and Wave 3 as long as they continued to live in the U.S. and were not incarcerated.

<sup>5</sup> PATH Restricted-Use Data User Guide, p. 8.

<sup>6</sup> PATH Restricted-Use Data User Guide, p. 18.

cigar uses among youth respondents decreased from 0.08% in Wave 1 and 0.04% in Wave 2 to 0.02% in Wave 3. See Table 1.

- b. Among adults, the prevalence of premium cigar use is statistically significantly less than that of non-premium cigars and cigarettes across all three waves of PATH data. Overall, in Wave 1, the prevalence of premium cigar use is 0.56% as compared to 2.51% for non-premium cigars. In Wave 2, the prevalence of premium cigar use increased slightly to 0.58%, but remains statistically significantly less than the 2.16% for non-premium cigars. In Wave 3, the prevalence of premium cigar use drops to 0.53%, and again, is statistically significantly less than the 1.94% for non-premium cigars. As compared to the detailed non-premium cigar types, the prevalence of premium cigars is statistically significantly less than cigarillos and filtered cigars in all three Waves, and statistically significantly less than non-premium traditional cigars in Wave 1. See Table 2.
- c. Premium cigar users are typically white males, 35 years or older, who have higher levels of education and higher incomes than consumers of non-premium cigar or cigarettes. In Wave 3, 81% of adult premium cigar users were white, 98% were male, and 67% were 35 years or older. In addition, 83% of premium cigar users aged 25 and up have higher-level education, and 53% completed college. In comparison, 17% of non-premium cigar users, 11% of cigarillo smokers, 5% of filtered cigar smokers, and 12% of cigarette smokers age 25 and older completed college. Finally, 44% of premium cigar users have a household income of \$100,000 or more, as compared to 13% of non-premium traditional cigars, 10% of cigarillo, 4% of filtered cigar, and 8% of cigarette smokers. Similar results are obtained for the first and second waves of data collection. See Table 3a, Table 3b, and Table 3c.

- ii. Among adult current users, premium cigar consumers were less likely to use them daily, used them on fewer days and consumed fewer cigars per day than users of non-premium cigar or cigarette users. In Wave 3, the most current PATH data, about 3.9% of premium cigar consumers smoked them daily. Premium cigar users typically used them 1.3 days out of 30, as reported by the median and smoked 0.1 cigars per day in past 30 days. In comparison, 20.7% to 40.9% of non-premium cigar consumers smoked them every day, used them on 4.4 to 14.5 days out of 30 and smoked 0.2 to 0.9 non-premium cigars per day in past 30 days. For cigarette smokers, 77.0% smoked cigarettes every day. The median cigarette smoker smoked on 29.4 of the past 30 days, and smoked 9.9 cigarettes per day in past 30 days. Similar results are obtained for the first and second waves of data collection. See Table 4a, Table 4b, and Table 4c.
- iii. Most cigarette smokers experiment and progress to becoming established smokers between the ages of 12 and 24.<sup>7</sup> Using the most recent PATH data, we find that the median age at first regular use is 30.0 years for premium cigar users, older than that of cigarillo and cigarette users. We also find that premium cigar users are as likely to become cigarette users as those who do not use any tobacco product and are less likely than users of non-premium cigar.
  - a. In Wave 1, the median age at first regular use reported by premium cigar users is 24.8 years. In comparison, the median age at first regular use is 19.4 years for non-premium traditional cigars, 18.0 years for cigarillo users and 16.6 years for cigarette users. Filtered cigar users, like premium cigar users, were generally older at initiation, with a median age at first regular use of 26.8 years. In Wave 3, the median age at first regular use increased to 30.0 years for premium cigar users. The median age at first regular use for non-premium cigar ranged from 24.2 years for cigarillos to

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<sup>7</sup> Trinidad, D. R., Pierce, J. P., Sargent, J. D., et al. (2017), "Susceptibility to Tobacco Product Use Among Youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study", *Preventive Medicine*, 101, 8-14.

34.2 years for filtered cigars. The median age at first regular use remained unchanged at 16.7 years for cigarette smokers. See Table 5a, Table 5b, and Table 5c.

- b. The percentage of premium cigar users that progress from never smoking cigarettes or smoking cigarettes some days in Wave 1 to everyday cigarette smoking in Wave 3 is 2.2%. In comparison, 9.1% of non-premium traditional cigar users, 11.5% of cigarillo users, 26.4% of filtered cigar users and 1.1% of not tobacco users transition to smoking cigarettes everyday by Wave 3. The difference between the 2.2% transition rate for premium cigar users and the 1.1% for respondents that did not use tobacco products is not statistically significant. Similar results are obtained for transition into some day cigarette smoking. See Table 6 and Table 7.
  - c. Of adults who are current established premium cigar users and are also current established cigarette users, 78.8% smoked cigarettes first before they started smoking traditional cigars—premium or not-premium, 10.1% started smoking traditional cigars before they started to smoke cigarettes and 11.0% started smoking traditional cigars and cigarettes at the same age. See Table 8.
- iv. The prevalence and intensity of dual usage of cigars and cigarettes is less for premium cigar users than for non-premium cigar users.
- a. In Wave 3, for current premium cigar users, the median number of cigarette smoking days and the number of cigarettes smoked per day in past 30 days are zero (0). In comparison, the non-premium traditional cigar user typically smoked cigarettes on 1.6 days in past 30 days and smoked 0.1 cigarettes per day in past 30 days. The cigarillo smoker typically smoked cigarettes on 8.0 days in past 30 days and smoked 1.0 cigarettes per day in past 30 days. The filtered cigar smoker typically smoked cigarettes on 28.3 days in past 30 days and smoked 5.9 cigarettes per day in past 30 days. See Table 9c.

- b. Also in Wave 3, non-premium traditional cigar users were more than twice as likely to smoke cigarettes when compared to premium cigar users. These differences increase when compared to cigarillos and filtered cigars. For example, in Wave 3, 23.8% of premium cigar users also smoked cigarettes as compared to 51.3% of non-premium traditional cigar users, 56.3% of cigarillo users and 69.8% of filtered cigar users. Similar results are obtained for the first and second waves of data collection. See Table 9a, Table 9b, and Table 9c.
- c. Among current premium cigar users in Wave 3, those who are also current cigarette users do not use more premium cigars. They use premium cigars 0.7 days per month as compared to 1.5 days per month for those who are not current cigarette smokers. Premium cigars smoked, per day in past 30 days, among these two groups, is less than 0.1 cigars per day for current cigarette smokers and also for those who are not current cigarette smokers. Similar results are obtained for the first and second waves of data collection. See Table 10a, Table 10b, and Table 10c.

#### **D. Qualifications**

8. I am an economist and a Managing Director in the Securities Practice and the Product Liability and Mass Torts Practice of NERA Economic Consulting. I provide economic consulting services and testimony in cases involving product liability, mass torts, complex damages disputes and securities. This work includes both advisory consulting engagements and litigation support in cases that have culminated in trials, bankruptcy hearings, or regulatory proceedings. My case work includes: estimating the future personal injury claims likely to be brought against defendants involved in asbestos, silica, medical products, and construction products litigation; analyzing liabilities related to environmental contamination for the Met-Coil bankruptcy Trust and the future silica and asbestos liabilities for the Tyler Pipe/Swan Transportation bankruptcy Trust; assessing recall costs of automobile and construction products; analyzing insurance allocation; applying statistical and content analyses to examine product



identification; and analyzing class certification and allegations of diminution of value in consumer class actions, including actions related to automobile recalls.

9. I have testified at trial in state and federal courts and am the author of various articles on the econometric analysis of claiming behavior, impact of tort reforms and regulatory changes, and determinants of anti-dumping protection. I have testified before the U.S. Department of Labor on an economic and statistical analysis of the methodology used to quantify the expected benefits of the proposed rule regarding silica.<sup>8</sup> I have also recently submitted comments regarding the CFPB's request for changing the Bureau's public reporting practices of consumer complaint information. I have worked for opponents of tobacco companies on consulting and litigation projects, estimating tobacco-related liabilities and, consulted on the tobacco Master Settlement Agreement with a NERA team that worked with the Special Master. In addition, I have conducted a study for a municipality on the economic impact of smoking bans.<sup>9</sup> My research has been published in the *Journal of Investment Compliance*, *Journal of Alternative Investments*, *Business Economics*, *International Trade Journal* and others. I was a Post-Doctoral Fellow at the International Food Policy Research Institute and an assistant professor of economics at the American University in Cairo. I received my Ph.D. from Stanford University.

## **II. PATH DATA AND IDENTIFICATION OF PREMIUM CIGARS**

10. To identify relevant academic studies on patterns of premium cigar usage, we followed the procedures set out in Chang et al. (2015), and conducted a systematic literature review of tobacco studies published after the FDA's 2014 request for comments. We then excluded any study cited in the FDA's 2016 rule on the regulation of tobacco products.

11. To identify relevant academic studies, we specified search terms to search through three databases—PubMed, Embase, and ISI Web of Science—that record academic studies. We

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<sup>8</sup> See, "Re: Docket No. OSHA-2010-0034 Occupational Exposure to Respirable Crystalline Silica – Comments of Dr. Faten Sabry, Ph.D. of NERA Economic Consulting for the US Chamber of Commerce," January 27, 2014, available at: <https://www.regulations.gov/document?D=OSHA-2010-0034-2263>.

<sup>9</sup> See, "Re: Docket Number CFPB-2018-0006 Regarding the Consumer Financial Protection Bureau's ("CFPB") Reporting Practices of Consumer Complaint Information," April 19, 2018, available at: <https://www.regulations.gov/document?D=CFPB-2018-0006-0017>. See also, Faten Sabry and Robert Patton, "Village of Tinley Park - Study of Impact of Smoking Bans Final," *NERA Economic Consulting*, March 12, 2007.

used the terms “Cigar” or “Cigars” in combination with the terms “PATH” or “NATS” or “NYTS” to identify potentially relevant articles.<sup>10</sup> Appendix A provides a summary of the process used to identify and select relevant academic studies of tobacco usage. We identified only one study - “U.S. 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” by Corey et al.– that analyzed tobacco use in the U.S. by cigar type and distinguished between premium and non-premium traditional cigars.<sup>11</sup>

#### **A. Corey et al. (2017) Distinguishes between Premium and Non-Premium Traditional Cigars**

12. In 2017, Corey et al. published the results of their analysis of “U.S. 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” (the “Corey Study”) and noted that “despite the diversity in the cigar market place,” most tobacco studies treated cigars as a single product type. In their study, they distinguished between traditional cigars, cigarillos and filtered cigars, and further divided traditional cigars into premium and non-premium. They found that user characteristics, cigar smoking patterns and dual smoking with cigarettes varied by cigar type, and that sufficient descriptions of cigar types, as well as distinguishing between premium and non-premium traditional cigars, is important to “enhance tobacco regulatory science.”

13. In particular, Corey et al. found that, among adults ages 18 years and older, the prevalence of premium cigar smoking was 0.7% as compared to 0.8% for non-premium traditional cigars, 1.7% for cigarillos, 0.9% for filtered cigars and 18.1% for cigarettes.

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<sup>10</sup> NYTS is the acronym for the National Youth Tobacco Survey conducted by the U.S. Centers for Disease Control and Prevention (DCP). NATS is the acronym for the National Adult Tobacco Survey conducted by the U.S. Centers for Disease Control and Prevention (DCP).

<sup>11</sup> Corey, C. G., Holder-Hayes, E., Nguyen, A. B., et al. (2017), “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”, *Nicotine & Tobacco Research*.

Prevalence is the estimated weighted percentage of adult respondents who are identified as adults who are current cigar or cigarette smokers.<sup>12</sup>

14. They also found that the percentage of daily cigar smoking and the number of cigars smoked per day in past month were higher for filtered cigars than all non-premium cigars, daily smoking of cigars per day were similar for non-premium traditional cigars and cigarillos, and cigarette smoking was twice as common among users of non-premium traditional cigars, cigarillos and filtered cigars than among users of premium cigars.

15. In addition, they found that demographic characteristics of users varied by cigar type and cigarettes. Young adults (aged 18 to 34 years) accounted for 64.5% of cigarillo users, as compared to 34% to 47% of users of non-premium cigars. More than half of users of non-premium traditional cigars, cigarillos, filtered cigars and cigarettes had a high school diploma/GED or less, whereas 26% of premium cigar users had a high school diploma/GED or less. In addition, Corey et al. found that “those smoking premium cigars tended to differ from those smoking non-premium cigars, cigarillos, and [filtered cigars] including having users with higher socioeconomic status.” For example, they found that 41% to 47% of non-premium traditional cigar, cigarillo and filtered cigar users, as compared to 14% of premium cigar users, lived below the federal poverty level.

16. In the Advanced Notice of Proposed Rulemaking (“ANPRM”) published in the Federal Register in March 2018, the FDA cited the Corey Study as an example of the type of information that would be responsive to its request, noting that it “assessed use patterns and related behaviors of users of ‘premium’ and other cigar types.”<sup>13</sup> The Agency also notes that in its conclusion, the Corey Study “highlighted the importance of adequately describing the cigar type studied and, where appropriate, differentiating results by cigar type.”<sup>14</sup>

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<sup>12</sup> “Current smokers” are “current established smokers” defined in PATH. According to PATH, current established cigar smokers are defined as those who have ever smoked the cigar type, ever smoked the cigar type “fairly regularly,” and now smoke the cigar type every day or some days; current established cigarette smokers are defined as those who have smoked at least 100 cigarettes in their lifetime and now smoke cigarettes every day or some days.

<sup>13</sup> Federal Register, Vol. 83, No. 58, March 26, 2018. Proposed Rules, p. 12902.

<sup>14</sup> Federal Register, Vol. 83, No. 58, March 26, 2018. Proposed Rules, p. 12903.

## B. Identification of Premium Cigars

17. The PATH Study is a large, nationally representative, longitudinal cohort study of tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes for individuals 12 years old or older in the U.S.<sup>15</sup> The data collected also include detailed information on cigar characteristics such as cigar type (traditional cigars, cigarillos, or filtered cigars), brand and product name. With this level of detail, one can further distinguish traditional cigars as premium and non-premium. These data were not available during the public comment period for the proposed rule published on April 25, 2014.

18. To identify premium cigars, we used the definition of “premium cigar” adopted in the Corey Study, and made certain limited adjustments where necessary to correct the designation of a premium cigar type. Corey et al. acknowledged that “regulatory definitions of premium cigars do not exist.” Using information obtained through research about the brand’s tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade), they used the brand and product information collected by the PATH study to distinguish premium from non-premium traditional cigars. The Corey Study used the Restricted Use files for Wave 1 of the PATH Study in which respondents identified the usual brand of “traditional cigar” that they smoked. Using this list of brands, Corey et al. determined, through research, whether a brand qualified as “premium” based on three criteria: (1) tobacco blends, (2) components (e.g., long filler, whole leaf wrapper), and (3) manufacturing process (e.g., handmade).<sup>16</sup> For brands that could not be classified as premium or non-premium traditional cigars based on the above criteria, the study’s authors considered the usual price paid per cigar and set a cut-off of \$2 per cigar for premium brands. Corey et al. acknowledged that “[a]lthough the results illustrate clear distinctions between premium and nonpremium smoker characteristics,

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<sup>15</sup> United States Department of Health and Human Services. National Institutes of Health. National Institute on Drug Abuse, and United States Department of Health and Human Services. Food and Drug Administration. Center for Tobacco Products. Population Assessment of Tobacco and Health (PATH) Study [United States] Restricted-Use Files. Ann Arbor, MI: Inter-university Consortium for Political and Social Research [distributor], 2018-05-01. <https://doi.org/10.3886/ICPSR36231> v14. Sampling rates were designed to achieve sufficiently large sample sizes for young adults, Black or African American adults and adult tobacco users of all ages.

<sup>16</sup> The PATH survey asked respondents to provide information on each of the tobacco products that they used, including cigarettes, cigarillos, filtered cigars and traditional cigars. If a respondent answered that they used traditional cigars, they were provided a list of traditional cigar brands/products so that they could specify which brand/product they used. If the respondents did not find the brand/product of traditional cigar on the PATH list, they could select “Other” and write in the specific brand/product of traditional cigar that they used.

use patterns and purchasing behaviors, some traditional cigar smokers may have been misclassified using this approach.”<sup>17</sup> The full methodology used by Corey et al. to produce a list of premium and non-premium traditional cigars (the “Corey List”) is laid out in Supplemental Table A to the study.

19. We compiled traditional cigar brands and products specified by respondents and reported in the PATH Restricted Use data files for Waves 1. We then cross-referenced those brands/products with the Corey List of premium cigars. Having replicated the Corey List using the PATH data, we then replicated Corey et al.’s statistical results, as published. We replicated their results on the prevalence of smoking, demographic characteristics of smokers, age at first regular use, dual use of cigars and cigarettes, and the frequency and intensity of use by cigar types and cigarettes.

20. Next, we made certain limited adjustments where necessary to the Corey List. We reclassified certain brands using Corey et al.’s own study criteria (without any reference to usual retail price) and criteria provided by the Cigar Rights of America, the Cigar Association of America, and the International Premium Cigar and Pipe Retailers Association. Based on these criteria, we reclassified nine brands reported in Wave 1 that were identified as premium cigars in the Corey Study: (1) Optimo, which is a brand of cigarillos; (2) Ben-Bay, which makes only cigar accessories and little cigars; (3) Chubb, which makes “wooden stogie cigar pipes”; (4) Cuban, which is not a cigar brand; (5) Durango, which is a brand of cigars made with pipe tobacco; (6) El Pita, which is not a cigar brand; (7) El Verso, which is a brand of machine-made cigars and fails the handmade requirement; (8) Indio, which is not a cigar brand; and (9) Marsh Wheeling, which is a brand of machine-made cigars and fails the handmade requirement. Similarly, we reclassified two brands reported in the Wave 1 data and that were not identified as premium cigars in the Corey Study: (1) Thompson and (2) JR. Thus, where Corey et al. analyze 377 premium cigar users in Wave 1, we analyzed 315. We follow the same approach to identify premium cigars in Wave 2 and 3. For example, we added premium brands from the PATH

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<sup>17</sup> Corey et al. (2017), p. 8.

Restricted Use data set that were identified by respondents in Wave 2 and 3, but were not in Wave 1.<sup>18</sup>

21. A number of brands identified in the PATH Restricted Use data set produce cigars that meet the Corey Study’s criteria but contain non-tobacco flavoring. As one of the FDA’s questions addresses the use of flavors in premium cigars, we further divided the brands in the PATH Restricted Use data set into unflavored premium cigars and flavored premium cigars and conducted separate analyses for each category and for the overall premium cigar category.<sup>19</sup> In the narrative discussion in this report, we refer to the results for overall premium cigars, but we separately list the results for unflavored premium cigars in each of the tables. We do not report results for flavored premium cigar users as there were too few observations to produce reliable estimates.

22. Finally, we find no indication that the refinements made to the Corey List substantially change the findings of the Corey Study. As discussed in Section II-A above, Corey et al. found that, among adults, the prevalence of premium cigar use was 0.7% as compared to 0.8% for non-premium traditional cigars. Using the adjusted list of premium cigar brands, we find that, among adults, the prevalence of premium cigar use was 0.6% as compared to 0.8% for non-premium traditional cigars.

### **III. PREVALENCE AND USE PATTERNS OF CIGAR USAGE**

23. Using the PATH data (Wave 1, Wave 2 and Wave 3), we estimate the prevalence and patterns of cigar use by cigar type—premium cigars, non-premium traditional cigars, cigarillos and filtered cigars.

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<sup>18</sup> The added brands include Aldino, Asylum, Avo, Bohemia, Camacho, Carrillo, Cromagnon, DAS, Diesel, Don Diego, Don Lucas, Don Simon, Field of Gold, Gispert, Graycliff, Habanos, Illusione, Kauai Cigar, Liga Privada, Mr. B, Nostalgia, Omar Ortez, Pinar Del Rio (PDR), Penamil, Playboy, Por Larranaga, Quorum, Rancho Real, San Cristobal, Santiago, Sosa, Topstone.

<sup>19</sup> Based on information provided by the Cigar Rights of America, the Cigar Association of America, and the International Premium Cigar and Pipe Retailers Association, we identified unflavored premium cigar brands/products, as premium cigars brands that are not “Acid”, “Makers Mark”, “Java”, “Tabak” and Trader Jack”; and not CAO brand where the product is specified as “Bella Vanilla”, “Caramelo Joe”, “Cherry Bomb”, “Earth Nectar”, “Eileen’s Dream”, “Gold Honey” and “Moontrance”; and not “Cohiba” brand where the product is “Vanilla”, and not Don Tomas where the product is “Acid” or “Ambrosia”.

## **A. Prevalence of Cigar Usage**

24. Using the PATH data, we estimated the prevalence of cigar usage for youth and adults. Youth are persons ages 12 to 17. Adults include persons 18 years and older.

### **1. Prevalence of Youth Cigar Usage<sup>20</sup>**

25. As shown in Table 1, among youth aged 12-17, the prevalence of premium cigar use is close to zero and, overall, is statistically significantly lower than that of non-premium cigars, as well as that of cigarettes. The prevalence of youth premium cigar use is less than 0.1% and decreased over time—from 0.08% in Wave 1 to 0.04% in Wave 2, and to 0.02% in Wave 3. No respondents aged 12-14 reported using premium cigars. In Waves 1, 2 and 3, the prevalence of non-premium cigars use is 16.5 to 25 times that of premium cigars. Prevalence for cigarettes is 40.6 to 88.5 times that of premium cigars.

26. Among the 11,814 respondents aged 12-17 in the recently released Wave 3 there is only one current premium cigar user, or a 0.02% prevalence. The premium cigar prevalence in Wave 3 for respondents aged 12-17 remains lower than that of non-premium traditional cigars (0.05%), cigarillos (0.35%), filtered cigars (0.18%) and cigarettes (1.77%).

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<sup>20</sup> “Youth current smokers” of cigars or cigarettes are Past 30 Day “Not-Light” Cigar or Cigarette Smokers defined by PATH Study Youth/Parent Questionnaires. Past 30 Day “Not-Light” Cigar or Cigarette Smokers are youth respondents who have smoked more than 10 of the respective cigar or cigarette categories (traditional cigars, cigarillos, filtered cigars, or cigarettes) in their lifetime and smoked a product of the respective cigar or cigarette categories within the past 30 days. For example, Past 30 Day “Not-Light” cigarillo smokers are youth respondents who have smoked more than 10 cigarillos in their lifetimes and smoked a cigarillo within the past 30 days. “Not-Light” smokers are identified for this analysis because in PATH Study Restricted-Use Files for youth, only “Not-Light” smokers of traditional cigars are asked about the brand and product of traditional cigars they smoked. Brand and product variables are used to identify premium and non-premium traditional cigar smokers. Unlike the database for adults, there are no variables that identify “Current Established Smokers” of cigars or cigarettes in the youth database.

Table 1. *Prevalence of Cigar Usage Among Youth Aged 12-17, Wave 1 to Wave 3*

	Premium Cigars		Non-Premium Cigars				Cigarettes
	Overall	Unflavored	Overall <sup>1</sup>	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
<b>Wave 1 (13,651 youth respondents)</b>							
Overall youth prevalence <sup>2</sup>							
Percentage	0.08%	0.08%	1.38%	0.22%	1.17%	0.22%	3.25%
Confidence interval	(0.02-0.14%)	(0.02-0.14%)	(1.17-1.58%)	(0.12-0.32%)	(0.98-1.36%)	(0.12-0.33%)	(2.91-3.59%)
Number of users	8	8	195	29	165	30	450
<b>Wave 2 (12,172 youth respondents)</b>							
Overall youth prevalence <sup>2</sup>							
Percentage	0.04%	0.04%	0.66%	0.14%	0.44%	0.22%	2.73%
Confidence interval	(0.00-0.08%)	(0.00-0.08%)	(0.51-0.82%)	(0.08-0.20%)	(0.32-0.56%)	(0.12-0.33%)	(2.39-3.08%)
Number of users	4	4	82	18	54	26	333
<b>Wave 3 (11,814 youth respondents)</b>							
Overall youth prevalence <sup>2</sup>							
Percentage	0.02%	0.02%	0.50%	0.05%	0.35%	0.18%	1.77%
Confidence interval	(0.00-0.05%)	(0.00-0.05%)	(0.39-0.61%)	(0.01-0.10%)	(0.26-0.45%)	(0.10-0.26%)	(1.50-2.05%)
Number of users	1	1	61	7	42	20	198

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for youth.

<sup>1</sup> Respondents can be current smokers of multiple non-premium cigar types, including non-premium traditional cigars, cigarillos, and filtered cigars. The prevalence for each non-premium cigar type may not add up to the prevalence for overall non-premium cigars.

<sup>2</sup> Prevalence is the estimated weighted percentage of youth respondents who are identified as current users of cigars or cigarettes.

27. The youth population varies between waves. Youth in Wave 1 who become 18 in Wave 2 or Wave 3 age up and their responses are then captured in the adult PATH data. Similarly, “shadow youth”, who were ages 9-11 in Wave 1, also age up as they become 12 years of age in Wave 2 or Wave 3. The shadow youth who age up and are interviewed and their responses are newly included in the youth PATH data.<sup>21</sup>

## 2. Prevalence of Adult Cigar Usage<sup>22</sup>

28. As shown in Table 2, among adults ages 18 years and older, the prevalence of premium cigar use is statistically significantly less than that of non-premium cigar and cigarette

<sup>21</sup> PATH Restricted-Use Data User Guide, pp. 17 and 21. Youth who have relocated outside of the U.S. or have become incarcerated by Wave 2 or Wave 3 will not be interviewed and are not replaced in the sample data.

<sup>22</sup> Prevalence is the estimated weighted percentage of adult respondents who are identified as adults who are current cigar or cigarette smokers.



use across all three Waves of PATH data. Overall, in Wave 1, the prevalence of premium cigar use is 0.56% as compared to 2.51% for non-premium cigars. In Wave 2, the prevalence of premium cigar use increased slightly to 0.58%, but remains significantly less than the 2.16% for non-premium cigars. In Wave 3, the prevalence of premium cigar use drops to 0.53%, and again, is significantly less than the 1.94% for non-premium cigars. As compared to detailed non-premium cigar types, the prevalence of premium cigars is significantly less than cigarillos and filtered cigars in all three Waves, and significantly less than non-premium traditional cigars in Wave 1. Finally, as shown in Table 2, the prevalence of cigar use decreased from Wave 1 to Wave 3 for all cigar types. The prevalence of cigarette use increased, from 18.08% in Wave 1 to 18.27% in Wave 3.<sup>23</sup>

Table 2. *Prevalence of Cigar Usage among Adults, Aged 18 Years and Older, Wave 1 to Wave 3*

	Premium Cigars		Non-Premium Cigars				
	Overall	Unflavored	Overall <sup>1</sup>	Traditional Cigars	Cigarillos	Filtered Cigars	Cigarettes
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
<b>Wave 1 (32,320 adult respondents)</b>							
Overall adult prevalence <sup>2</sup>							
Percentage	0.56%	0.51%	2.51%	0.78%	1.59%	0.85%	18.08%
Confidence interval	(0.49-0.63%)	(0.45-0.58%)	(2.35-2.67%)	(0.70-0.85%)	(1.46-1.72%)	(0.77-0.94%)	(17.55-18.61%)
Number of users	315	289	1,760	506	1,186	551	11,402
<b>Wave 2 (28,362 adult respondents)</b>							
Overall adult prevalence <sup>2</sup>							
Percentage	0.58%	0.53%	2.16%	0.44%	1.32%	0.86%	18.60%
Confidence interval	(0.49-0.67%)	(0.45-0.61%)	(1.99-2.32%)	(0.38-0.51%)	(1.21-1.43%)	(0.74-0.98%)	(18.08-19.12%)
Number of users	270	248	1,237	243	790	473	9,694
<b>Wave 3 (28,148 adult respondents)</b>							
Overall adult prevalence <sup>2</sup>							
Percentage	0.53%	0.48%	1.94%	0.36%	1.20%	0.79%	18.27%
Confidence interval	(0.44-0.62%)	(0.39-0.56%)	(1.78-2.11%)	(0.30-0.42%)	(1.09-1.31%)	(0.67-0.91%)	(17.68-18.87%)
Number of users	215	193	1,055	179	682	424	9,013

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

<sup>1</sup> Respondents can be current users of multiple non-premium cigar types, including non-premium traditional cigars, cigarillos, and filtered cigars. The prevalence for each non-premium cigar type may not add up to the prevalence for overall non-premium cigars.

<sup>2</sup> Prevalence is the estimated weighted percentage of adult respondents who are identified as current users of cigars or cigarettes.

<sup>23</sup> As discussed above, Corey's list of premium cigars included 135 traditional cigar brands/products. After adjusting Corey's list of premium cigars, based on advice from counsel, we include 124 traditional cigar brands/products as premium cigars.

### **3. Demographic Characteristics of Cigar and Cigarette Users, Wave 1 – Wave 3**

29. Premium cigar users are typically white males, who are 35 years or older, and are relatively more educated and have higher incomes than non-premium traditional cigar, cigarillo, filtered cigar and cigarette smokers.

30. In Wave 1, of current premium cigar users 76% are white, 96% are male, and 57% are 35 years or older. In contrast, consumers of non-premium cigar products are 42-66% are white and 69-84% are male. Cigarillo users are generally younger, with only 36% being 35 years or older. See Table 3a.

31. Premium cigar users are also more educated than non-premium cigar or cigarette users. Similar to Corey et al., we report educational attainment data for respondents aged 18 and up, but we also compute statistics for those age 25 and older which allows for a better comparison to census data. We found that, in Wave 1, 78.1% of premium cigar users aged 25 and up had some higher-level education, and 44.9% had completed college. In contrast, among the same age group approximately 44.7% of non-premium traditional cigar users, 46.4% of cigarillo users, 40.0% of filtered cigar users and 45.0% of cigarette smokers respectively had at least some college experience. Of non-premium traditional cigar users age 25 and older, 9.4% had completed college, with a similar percentage observed for cigarillo users (10.6%), filtered cigar users (9.2%) and cigarette smokers (12.0%).

32. Finally, premium cigar users have higher incomes than non-premium cigar users or cigarette smokers. Of current users, 35.5% of premium cigar users had a household income of \$100,000 or more, as compared to 8.8% of non-premium traditional cigar, 5.8% of cigarillo, 4.8% of filtered cigar, and 7.5% of cigarette smokers.

Table 3a. *Demographic Characteristics of Adults, Aged 18 Years and Older, Current Smokers, Wave 1*

	Premium Cigars		Non-Premium Cigars			Cigarettes (6)
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	
Age group (%) <sup>1</sup>						
18-24	16.2%	16.0%	22.5%	35.9%	18.0%	14.1%
25-34	26.6	26.1	24.3	28.6	16.0	24.3
35-54	34.8	35.3	32.8	27.1	39.8	39.0
55+	22.4	22.6	20.5	8.5	26.3	22.7
Sex (%)						
Male	96.0%	96.5%	84.0%	72.7%	68.6%	55.3%
Female	4.0	3.5	16.0	27.3	31.4	44.7
Race/ethnicity (%)						
White, non-Hispanic	76.4%	75.1%	59.2%	41.7%	66.2%	69.8%
Black/AA, non-Hispanic	5.6	5.8	23.0	35.7	15.7	12.9
Other or multi-race, non-Hispanic	6.9	7.3	6.0	6.6	6.6	6.0
Hispanic	11.1	11.9	11.7	16.0	11.5	11.2
Education for adults aged 18+ (%)						
Less than high school diploma	4.7%	5.0%	14.4%	16.0%	17.7%	15.9%
GED	3.9	3.3	12.2	11.7	11.7	10.8
High school diploma	15.7	13.4	28.1	26.3	29.8	28.1
Some college/associate degree	36.2	37.4	37.7	38.2	33.0	33.8
Completed college or more	39.5	41.0	7.6	7.8	7.8	11.3
Education for adults aged 25+ (%)						
Less than high school diploma	3.7%	4.0%	13.4%	15.9%	18.3%	16.1%
GED	4.3	3.7	12.8	12.4	11.9	10.9
High school diploma	13.9	11.8	29.0	25.3	29.9	28.0
Some college/associate degree	33.2	34.1	35.3	35.8	30.8	33.0
Completed college or more	44.9	46.4	9.4	10.6	9.2	12.0
Household poverty (%) <sup>2</sup>						
<100% FPL	13.6%	12.7%	40.6%	47.1%	44.9%	34.2%
100-<200% FPL	14.7	13.7	22.5	23.6	27.4	25.1
>200% FPL	64.8	66.2	29.7	22.6	18.4	32.3
Missing FPL	6.9	7.4	7.2	6.8	9.2	8.5
Household income (%)						
Less than \$10,000	7.4%	7.4%	27.2%	30.4%	29.1%	21.0%
\$10,000-\$24,999	14.1	12.6	26.2	30.1	35.3	27.6
\$25,000-\$49,999	14.1	13.1	23.6	21.5	21.8	25.6
\$50,000-\$99,999	28.9	30	14.2	12.2	9.1	18.3
\$100,000-\$199,999	24.5	25.2	6.9	4.6	4.1	6.4
\$200,000 or more	11.0	11.7	1.9	1.2	0.7	1.1
Number of users	315	289	506	1,186	551	11,402

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

<sup>1</sup> When respondent age was missing, imputed values for age were used as described in the PATH Study Restricted Use Files 1 Guide (United States Department of Health and Human Services, 2017).

<sup>2</sup> Household poverty is from field "3 level poverty status based on annual household income and HHS poverty guidelines." TI field is only available in Wave 1, not Wave 2 or Wave 3.

33. In Wave 2, of current premium cigar users 85% are white, 98% are male, and 62% are 35 years or older. In contrast, consumers of non-premium cigar products are 47-62% white and 64-85% male. See Table 3b.

34. Again, premium cigar users are more educated than non-premium cigar or cigarette users. In Wave 2, 80.5% of premium cigar users aged 25 and up had some higher-level education. This percentage for premium cigar users is larger than the ones for non-traditional cigar users (48.3%), cigarillo users (49.5%), filtered cigar users (40.0%) and cigarette users (44.9%). The fraction of college completion of premium cigar users among those age 25 and older also compares favorably to non-premium cigar or cigarette users with percentages of 13.9% for non-premium traditional cigar users, 11.7% for cigarillo users, 8.8% for filtered cigar users and 12.3% for cigarette users.

35. Finally, in Wave 2, 35.6% of premium cigar users had a household income of \$100,000 or more, as compared to 10.8% of non-premium traditional cigar, 8.6% of cigarillo, 3.8% of filtered cigar, and 7.5% of cigarette smokers.

Table 3b. *Demographic Characteristics of Adults, Aged 18 Years and Older, Current Smokers, Wave 2.*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	
Age group (%)						
18-24	12.4%	11.4%	15.5%	27.5%	15.5%	12.5%
25-34	25.7	25.1	23.5	28.1	20.1	23.6
35-54	35.1	35.4	36.1	31.1	35.9	39.1
55+	26.8	28.1	25.0	13.3	28.4	24.7
Sex (%)						
Male	97.5%	97.7%	85.1%	75.0%	64.2%	54.8%
Female	2.5	2.3	14.9	25.0	35.8	45.2
Race/ethnicity (%)						
White, non-Hispanic	84.5%	84.1%	58.8%	47.4%	61.8%	68.4%
Black/AA, non-Hispanic	4.5	4.3	24.4	32.5	19.4	13.7
Other or multi-race, non-Hispanic	3.9	4.0	3.8	5.8	4.6	5.9
Hispanic	7.2	7.7	13.0	14.3	14.2	12.0
Education for adults aged 18+ (%)						
Less than high school diploma	3.5%	3.8%	15.7%	17.1%	21.3%	16.5%
GED	4.1	4.4	15.0	10.6	9.1	11.3
High school diploma	14.2	11.3	22.8	24.4	27.9	27.5
Some college/associate degree	33.0	33.5	34.4	38.0	33.7	33.2
Completed college or more	45.2	46.9	12.1	9.9	8.1	11.5
Education for adults aged 25+ (%)						
Less than high school diploma	3.1%	3.4%	15.1%	17.2%	22.2%	16.6%
GED	4.1	4.4	14.6	10.9	9.6	11.3
High school diploma	12.2	9.1	22.1	22.5	28.3	27.1
Some college/associate degree	31.4	32.3	34.4	37.8	31.2	32.6
Completed college or more	49.1	50.8	13.9	11.7	8.8	12.3
Household income (%)						
Less than \$10,000	4.4%	4.5%	27.5%	29.6%	39.6%	21.5%
\$10,000-\$24,999	9.3	7.6	25.5	27.0	28.3	27.4
\$25,000-\$49,999	18.8	18.1	22.0	17.5	17.4	24.2
\$50,000-\$99,999	32.0	32.1	14.2	17.2	10.8	19.4
\$100,000-\$199,999	25.4	27.0	9.8	7.1	2.8	6.3
\$200,000 or more	10.2	10.8	1.0	1.5	1.0	1.2
Number of users	270	248	243	790	473	9,694

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

36. In Wave 3, among adults, 81% of premium cigar users are white, as compared to 57% of non-premium traditional cigar smokers, 49% of cigarillo smokers and 57% of filtered cigar smokers. In addition, 98% of premium cigar users are male, as compared to 65%-83% for other cigar smokers and 54% of cigarette smokers. Premium cigar users are also older. Almost

no youth, aged 12-17, smoke premium cigars and, among adults, 67% of premium cigar users in Wave 3 were 35 years or older. See Table 3c.

37. Premium cigar smokers are also more educated and have higher incomes than those using non-premium cigar products or cigarette smokers. In Wave 3, 83.3% of premium cigar users aged 25 and up had some higher-level education, and 52.7% had completed college. In contrast, among the same age group approximately 43.6% of non-premium traditional cigar users, 51.5% of cigarillo users, 38.6% of filtered cigar users and 44.8% of cigarette smokers respectively had at least some college experience. Of non-premium traditional cigar users age 25 and older, 16.5% had completed college, with lower percentages observed for cigarillo users (11.1%), filtered cigar users (4.9%) and cigarette smokers (11.9%).

38. Finally, 44% of premium cigar users had a household income of \$100,000 or more, as compared to 13% of non-premium traditional cigar, 10% of cigarillo, 4% of filtered cigar, and 8% of cigarette smokers.

Table 3c. *Demographic Characteristics of Adults, Aged 18 Years and Older, Current Smokers, Wave 3.*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Age group (%)						
18-24	9.4%	9.1%	10.8%	23.9%	14.9%	11.2%
25-34	23.6	25.2	17.6	30.8	21.3	23.2
35-54	31.1	28.0	32.8	29.1	34.5	39.0
55+	35.9	37.8	38.9	16.2	29.3	26.6
Sex (%)						
Male	97.5%	98.5%	82.9%	73.2%	65.2%	53.7%
Female	2.5	1.5	17.1	26.8	34.8	46.3
Race/ethnicity (%)						
White, non-Hispanic	80.7%	80.5%	56.6%	49.4%	56.9%	68.5%
Black/AA, non-Hispanic	7.4	6.8	27.1	33.4	22.0	13.8
Other or multi-race, non-Hispanic	6.5	7.3	5.4	5.4	6.1	5.7
Hispanic	5.3	5.3	10.9	11.8	15.0	12.0
Education for adults aged 18+ (%)						
Less than high school diploma	3.2%	3.2%	13.7%	13.8%	23.0%	17.2%
GED	2.2	1.5	11.3	10.2	7.9	11.0
High school diploma	12.4	8.3	32.9	26.9	31.1	27.4
Some college/associate degree	32.1	33.8	26.9	39.7	32.9	33.1
Completed college or more	50.1	53.2	15.2	9.4	5.0	11.3
Education for adults aged 25+ (%)						
Less than high school diploma	3.4%	3.3%	13.2%	13.0%	24.0%	17.3%
GED	1.9	1.3	12.0	10.8	8.1	11.1
High school diploma	11.5	7.6	31.1	24.7	29.3	26.8
Some college/associate degree	30.6	31.8	27.1	40.4	33.7	32.9
Completed college or more	52.7	56.0	16.5	11.1	4.9	11.9
Household income (%)						
Less than \$10,000	6.0%	5.2%	29.4%	28.6%	39.1%	21.0%
\$10,000-\$24,999	9.2	8.9	22.3	24.6	30.6	27.1
\$25,000-\$49,999	12.0	10.4	22.4	20.5	15.7	24.6
\$50,000-\$99,999	28.9	30.2	12.5	16.7	10.3	19.7
\$100,000-\$199,999	28.9	29.5	11.5	8.6	3.1	6.7
\$200,000 or more	15.0	15.9	1.9	0.9	1.2	1.0
Number of users	215	193	179	682	424	9,013

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

## **B. Frequency and Intensity of Premium Cigar Use**

39. Using the PATH data, we analyzed the frequency and intensity of tobacco use by cigar type and cigarettes. We found that of current users, premium cigar users are far less likely to smoke every day, smoke on substantially fewer days, and smoke fewer numbers of cigars per day than non-premium cigar or cigarette users. Again, as the prevalence of premium cigar smoking among youth was 0.08% or less, we focused our analysis on persons aged 18 and older. See Table 4a-Table 4c.

40. Premium cigar users are less likely to smoke every day. Of current users in Wave 1, 6.5% of premium cigar consumers used them daily. In comparison, 24.0% of non-premium traditional cigar smokers, 22.0% of cigarillo smokers, 37.3% of filtered cigar smokers, and 79.5% of cigarette smokers smoke every day. See Table 4a.

41. Premium cigar users smoke on fewer days than non-premium cigar or cigarette users. The median number of days smoked in past 30 days ranged from 1.7 days for premium cigar users, to 8.1 for non-premium traditional cigar users, 7.5 for cigarillo users, 14.0 days for filtered cigar users, and 29.4 days for cigarette users, in Wave 1.

42. Premium cigar users also use fewer cigars on each day in past 30 days than those using non-premium cigars or cigarettes. The median number of cigars per day in past 30 days ranged from 0.1 cigars for premium cigar users to 0.3 for non-premium cigar users, 0.3 for cigarillo users and 1.6 for filtered cigar users.<sup>24</sup> Cigarette smokers smoked a median of 10.1 cigarettes per day in past 30 days, in Wave 1.

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<sup>24</sup> Using Corey et al.'s methodology, if a PATH respondent replied that they smoked less than one cigar per day, we coded them as having smoked 0.50 cigars per day.



Table 4a. *Frequency and Intensity of Tobacco Use by Cigar Type and Cigarettes, Wave 1*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Now smoke product every day						
Percentage	6.5%	6.9%	24.0%	22.0%	37.3%	79.5%
Confidence interval	(3.9-9.2%)	(4.1-9.6%)	(20.1-27.8%)	(19.7-24.2%)	(31.9-42.7%)	(78.5-80.6%)
Days smoked in past 30 days <sup>1</sup>						
Median	1.7	1.7	8.1	7.5	14.0	29.4
Interquartile range	(0.0-4.8)	(0.0-4.8)	(1.4-28.4)	(1.3-29.1)	(0.8-28.8)	(29.1-29.7)
Number of cigars or cigarettes per day on days smoked <sup>2</sup>						
Median	0.6	0.6	1.0	1.0	3.4	11.0
Interquartile range	(0.0-0.9)	(0.0-0.9)	(0.5-2.5)	(0.3-2.4)	(0.3-10.2)	(5.4-19.4)
Number of cigars or cigarettes per day in past 30 days <sup>2</sup>						
Median	0.1	0.1	0.3	0.3	1.6	10.1
Interquartile range	(0.0-0.2)	(0.0-0.2)	(0.1-1.9)	(0.1-2.0)	(0.1-9.5)	(5.0-19.6)
Number of users	315	289	506	1,186	551	11,402

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

43. In Wave 2, 7.5% of current premium cigar users smoke every day. In comparison, 14.4% of non-premium traditional cigar, 15.6% of cigarillo, 37.4% of filtered cigar, and 76.0% of cigarette users smoke every day. The median number of days smoked in the past 30 days was 1.4 days for premium cigar users and 2.6 days for non-premium traditional cigar users, 4.1 days for cigarillo users, 12.8 for filtered cigar users and 29.4 days for cigarette users. The median number of cigars per day smoked in past 30 days is 0.1 cigars for premium cigar users and 0.1 for non-premium traditional cigar users, 0.2 for cigarillo users and 0.9 for filtered cigar users.<sup>25</sup> Cigarette smokers smoked a median of 9.8 cigarettes per day in past 30 days, in Wave 2. See Table 4b.

<sup>25</sup> Using Corey et al.'s methodology, if a PATH respondent replied that they smoked less than one cigar per day on days smoked, we coded them as having smoked 0.50 cigars per day.

Table 4b. *Frequency and Intensity of Tobacco Use by Cigar Type and Cigarettes, Wave 2*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Now smoke product every day						
Percentage	7.5%	7.3%	14.4%	15.6%	37.4%	76.0%
Confidence interval	(3.5-11.4%)	(3.1-11.6%)	(9.5-19.3%)	(12.9-18.2%)	(32.8-42.0%)	(74.7-77.3%)
Days smoked in past 30 days <sup>1</sup>						
Median	1.4	1.4	2.6	4.1	12.8	29.4
Interquartile range	(0.0-4.0)	(0.0-4.1)	(0.3-11.4)	(0.8-16.5)	(1.5-29.4)	(29.0-29.7)
Number of cigars or cigarettes per day on days smoked <sup>2</sup>						
Median	0.6	0.6	0.6	0.8	2.6	9.7
Interquartile range	(0.0-0.8)	(0.0-0.8)	(0.1-1.4)	(0.2-1.7)	(0.5-9.1)	(4.6-19.3)
Number of cigars or cigarettes per day in past 30 days <sup>2</sup>						
Median	0.1	0.1	0.1	0.2	0.9	9.8
Interquartile range	(0.0-0.1)	(0.0-0.2)	(0.0-0.5)	(0.0-1.0)	(0.0-7.1)	(4.9-19.2)
Number of users	270	248	243	790	473	9,694

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

44. The frequency and intensity of smoking decreased between Wave 1 and Wave 3 for all cigar types except for filtered cigars. The daily use of premium cigars decreased from 6.5% in Wave 1 to 3.9% in Wave 3, and was lower than that of all non-premium cigars in Wave 3 —21.9% for non-premium traditional cigars, 20.7% for cigarillos, and 40.9% for filtered cigars. In Wave 3, the median number of days smoked in the past 30 days was a low of 1.3 days for premium cigars and 4.7 days for non-premium traditional cigars, 4.4 for cigarillos, 14.5 for filtered cigars and 29.4 days for cigarette smokers. The median number of cigars per day smoked in past 30 days is 0.1 cigars for premium cigar users and 0.2 for non-premium traditional cigar users, 0.2 for cigarillo users and 0.9 for filtered cigar users.<sup>26</sup> Cigarette smokers smoked a median of 9.9 cigarettes per day in past 30 days, in Wave 3. See Table 4c.

<sup>26</sup> Using Corey et al.'s methodology, if a PATH respondent replied that they smoked less than one cigar per day, we coded them as having smoked 0.50 cigars per day.

Table 4c. *Frequency and Intensity of Tobacco Use by Cigar Type and Cigarettes, Wave 3*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Now smoke product every day						
Percentage	3.9%	3.5%	21.9%	20.7%	40.9%	77.0%
Confidence interval	(1.4-6.3%)	(1.0-6.1%)	(13.8-29.9%)	(16.9-24.4%)	(33.8-47.9%)	(75.9-78.2%)
Days smoked in past 30 days <sup>1</sup>						
Median	1.3	1.3	4.7	4.4	14.5	29.4
Interquartile range	(0.0-4.2)	(0.0-4.3)	(0.8-24.3)	(0.7-22.6)	(1.6-29.4)	(29.0-29.7)
Number of cigars or cigarettes per day on days smoked <sup>2</sup>						
Median	0.6	0.6	0.8	0.8	2.7	9.7
Interquartile range	(0.0-0.8)	(0.0-0.8)	(0.2-1.8)	(0.2-1.8)	(0.5-9.3)	(4.5-19.3)
Number of cigars or cigarettes per day in past 30 days <sup>2</sup>						
Median	0.1	0.1	0.2	0.2	0.9	9.9
Interquartile range	(0.0-0.1)	(0.0-0.1)	(0.0-1.2)	(0.0-1.0)	(0.1-8.4)	(4.1-19.5)
Number of users	215	193	179	682	424	9,013

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

### C. Premium Cigars, Tobacco Initiation and Progression to Use of Other Tobacco Products.

45. Using the PATH data, we analyzed tobacco initiation and the progression from non-regular to regular cigarette use. We analyzed the age at first regular use, the transition of cigar users to cigarette smoking between Wave 1 and Wave 3, and the percent of dual users of premium cigar and cigarette who started smoking traditional cigars before they started smoking cigarettes.

## 1. Age at Initiation

46. Most cigarette smokers experiment and progress to becoming established users during an “initiation window” between the ages of 12 and 24.<sup>27</sup> Using the PATH data, we analyzed the age at first regular use by cigar type and cigarettes, for current smokers in Wave 1, Wave 2 and Wave 3. See Table 5a, Table 5b, and Table 5c.

47. In Wave 1, premium cigar users were typically older at first regular use as compared to non-premium traditional cigar users, cigarillo users and cigarette users. For premium cigars, the median age at first regular use was 24.8 years, as compared to 19.4 years for non-premium traditional cigar users, 18.0 years for cigarillo users and 16.6 years for cigarette users. Filtered cigar smokers were generally older at initiation, with a median age at first regular use of 26.8 years. See Table 5a.

Table 5a. *Initiation, Median Age at First Regular use by Cigar Type and Cigarettes, Wave 1*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Age at first regular use <sup>1</sup>						
Median	24.8	24.8	19.4	18.0	26.8	16.6
Interquartile range	(19.2-33.1)	(19.4-33.1)	(16.5-29.5)	(15.9-23.3)	(17.8-44.3)	(14.7-18.7)
Current age <sup>2</sup>						
Median	37.7	38.1	35.5	28.1	42.5	40.1
Interquartile range	(28.0-53.4)	(28.1-53.5)	(24.8-51.5)	(22.0-40.2)	(27.6-54.5)	(28.3-52.9)
Number of users	315	289	506	1,186	551	11,402

### Notes and Sources:

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

<sup>2</sup> When respondent age was missing, imputed values for age were used as described in the PATH Study Restricted Use Files User Guide (United States Department of Health and Human Services, 2017).

<sup>27</sup> Trinidad, D. R., Pierce, J. P., Sargent, J. D., et al. (2017), “Susceptibility to Tobacco Product Use Among Youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study”, *Preventive Medicine*, 101, 8-14.

48. In Wave 2, the median age at first regular use was more similar for premium and non-premium traditional cigars, 27.6 years and 27.3 years respectively. For cigarillos, the median age at first regular use is 21.7 and for cigarettes, is 16.6. Filtered cigar users were 35.1 years old at first regular use, as measured by the median. See Table 5b.

Table 5b. *Initiation, Median Age at First Regular use by Cigar Type and Cigarettes, Wave 2*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Age at first regular use <sup>1</sup>						
Median	27.6	27.8	27.3	21.7	35.1	16.6
Interquartile range	(20.6-39.1)	(21.4-39.4)	(17.9-43.6)	(17.5-34.0)	(20.6-49.7)	(14.7-18.9)
Current age						
Median	39.6	41.0	42.6	31.3	45.1	41.2
Interquartile range	(29.6-54.7)	(30.0-55.6)	(27.2-54.0)	(23.4-46.2)	(26.6-55.1)	(29.1-53.9)
Number of users	270	248	243	790	473	9,694

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

49. The median age at first regular use increased between Wave 1 and Wave 3 for each cigar type. In Wave 3, the median age at first regular use was 30.0 for premium cigars, 29.8 for non-premium traditional cigars, 24.2 for cigarillos, and 34.2 for filtered cigars. The median age at first regular use for cigarettes remained essentially unchanged at 16.7. See Table 5c.

Table 5c. *Initiation, Median Age at First Regular Use by Cigar Type and Cigarettes, Wave 3*

	Premium Cigars		Non-Premium Cigars			Cigarettes
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	(6)
Age at first regular use <sup>1</sup>						
Median	30.0	29.8	29.8	24.2	34.2	16.7
Interquartile range	(24.0-48.6)	(24.0-49.5)	(19.4-48.6)	(17.9-38.2)	(22.0-50.6)	(14.7-19.1)
Current age						
Median	44.5	46.0	49.0	31.9	43.3	42
Interquartile range	(30.7-58.2)	(30.5-58.6)	(31.8-62.1)	(24.2-47.1)	(27.4-56.3)	(29.6-54.8)
Number of users	215	193	179	682	424	9,013

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Respondents reporting age at first regular use <6 years old were assigned a value of 6 years old.

## 2. Progression to Everyday Cigarette Smoking

50. Using the PATH data, we analyzed the cigar users' progression from non-regular cigarette smoking to regular cigarette smoking in two ways. In the first case, we analyzed the number of adult current smokers, by cigar type, that did not smoke cigarettes regularly in Wave 1, but became regular cigarette smokers by Wave 3. In the second case, we took all respondents that were current cigar smokers and current cigarette smokers, and determined what percentage of this group reported an age of first use for cigars that was lower than that of cigarettes.

### a. Current Cigar Smokers Transition to Regular Cigarette Smoking

51. In Table 6, we report the number of survey respondents that are current cigar smokers and that are also not everyday cigarette smokers, in Wave 1. For example, in Wave 1, 173 survey respondents were current premium cigar users and did not smoke cigarettes every day. Next, we report the number of these respondents who become everyday cigarette smokers as of Wave 3. For example, 5 of the 173 premium cigar and not-everyday cigarette smokers in Wave 1 became everyday cigarette smokers by Wave 3. In the bottom panel of the table, we convert these counts to percentages. Our results show that 2% of premium cigar and not-

everyday-cigarette smokers in Wave 1 became everyday cigarette smokers between Wave 1 and Wave 3. The percentage for premium cigar users is lower than the 9% for non-premium traditional cigar users, the 12% for cigarillo users, and the 26% for filtered cigar users that became everyday cigarette smokers between Wave 1 and Wave 3. Not only was the everyday cigarette smoking progression for current users of premium cigars statistically significantly lower than those of non-premium cigars, it was also statistically indistinguishable from the transition into everyday smoking for respondents who were not current users of any tobacco product as of Wave 1.

Table 6. *Progression from Current Cigar Smoker to Everyday Cigarette Smoker, 2013-2016*

	Current Users of					Not Current Tobacco Users
	Premium Cigars		Non-Premium Cigars			
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	
Number of Respondents						
Not Everyday Cigarette Users as of Wave 1	173	161	170	469	148	12,584
Progress to Everyday Cigarette Users in Wave 3	5	5	20	56	38	302
Remain as Not Everyday Cigarette Users in Wave 3	168	156	150	413	110	12,282
Weighted Percentage						
Not Everyday Cigarette Users as of Wave 1	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Progress to Everyday Cigarette Users in Wave 3						
Percentage	2.2%	2.3%	9.1%	11.5%	26.4%	1.1%
Confidence Interval	(0.1-4.3%)	(0.1-4.6%)	(5.6-12.6%)	(8.3-14.8%)	(19.0-33.7%)	(1.0-1.3%)
Remain as Not Everyday Cigarette Users in Wave 3						
Percentage	97.8%	97.7%	90.9%	88.5%	73.6%	98.9%
Confidence Interval	(95.7-99.9%)	(95.4-99.9%)	(87.4-94.4%)	(85.2-91.7%)	(66.3-81.0%)	(98.7-99.0%)

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- Respondents who are defined as “Not Current Tobacco Users” are adult respondents who are not defined by PATH data as any of the following in Wave 1: Current Established Cigarette User, Current Established Dissolvable User, Current Established E-Cigarette user, Current Established Filtered Cigar User, Current Established Cigarillo User, Current Established Traditional Cigar User, Current Established Hookah User, Current Established Pipe User, Current Established Smokeless Tobacco User, or Current Established Snus User.
- Not Everyday Cigarette Users are respondents who chose “No” when asked “Have you ever smoked a cigarette, even one or two puffs?” or chose “Not at all” or “Some day” when asked “Do you now smoke cigarettes . . .” The respondents must be in both Wave 1 and Wave 3.
- Everyday Cigarette Users are respondents who chose “Every day” when asked “Do you now smoke cigarettes . . .” The respondents must be in both Wave 1 and Wave 3.

52. Similar results are obtained for transition into some day cigarette smoking. Our results show that 5.9% of premium cigar users who did not smoke cigarettes in Wave 1 became some day or everyday cigarette smokers in Wave 3. The percentage for premium cigar users is lower than the 13.2% for non-premium traditional cigar users, the 17.3% for cigarillo users, and the 29.5% for filtered cigar users that became cigarette smokers between Wave 1 and Wave 3.

Not only was the someday cigarette smoking progression for current users of premium cigars statistically significantly lower than those of non-premium cigars, it was also statistically indistinguishable from the transition into someday smoking for respondents who were not current users of any tobacco product as of Wave 1.

Table 7. *Progression from Current Cigar Smoker to Someday Cigarette Smoker, 2013-2016*

	Current Users of					Not Current Tobacco Users
	Premium Cigars		Non-Premium Cigars			
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars	
	(1)	(2)	(3)	(4)	(5)	
Number of Respondents						
Not Someday Cigarette Users as of Wave 1	149	138	101	252	77	11,993
Progress to Someday Cigarette Users in Wave 3	9	9	15	48	20	596
Remain as Not Someday Cigarette Users in Wave 3	140	129	86	204	57	11,397
Weighted Percentage						
Not Someday Cigarette Users as of Wave 1	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Progress to Someday Cigarette Users in Wave 3						
Percentage	5.9%	6.4%	13.2%	17.3%	29.5%	2.5%
Confidence Interval	(1.7-10.0%)	(1.8-10.9%)	(5.8-20.6%)	(13.1-21.4%)	(19.3-39.7%)	(2.2-2.8%)
Remain as Not Someday Cigarette Users in Wave 3						
Percentage	94.1%	93.6%	86.8%	82.7%	70.5%	97.5%
Confidence Interval	(90.0-98.3%)	(89.1-98.2%)	(79.4-94.2%)	(78.6-86.9%)	(60.3-80.7%)	(97.2-97.8%)

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- Respondents who are defined as “Not Current Tobacco Users” are adult respondents who are not defined by PATH data as any of the following in Wave 1: Current Established Cigarette User, Current Established Dissolvable User, Current Established E-Cigarette user, Current Established Filtered Cigar User, Current Established Cigarillo User, Current Established Traditional Cigar User, Current Established Hookah User, Current Established Pipe User, Current Established Smokeless Tobacco User, or Current Established Snus User.
- Not Someday Cigarette Users are respondents who chose “No” when asked “Have you ever smoked a cigarette, even one or two puffs?” or chose “Not at all” when asked “Do you now smoke cigarettes . . .” The respondent must be in both Wave 1 and Wave 3.
- Someday Cigarette Users are respondents who chose “Some day” or “Every day” when asked “Do you now smoke cigarettes . . .” The respondent must be in both Wave 1 and Wave 3.

**b. Which Tobacco Product Was Used First: Premium Cigars or Cigarettes?**

53. To determine whether premium cigar use progressed to cigarette use, we identified those respondents who currently used both premium cigars and cigarettes and determined the percentage of those who started smoking traditional cigars first. I relied on the following PATH study questions to conduct this analysis:

- How old were you the first time you smoked part or all of a traditional cigar, even one or two puffs?
- How old were you the first time you smoked part or all of a cigarette?



54. Note that the first question does not specify whether the traditional cigar was premium or not. In addition, no brand or product information was collected as a follow-up to this question. Hence we are not able to identify whether it was a premium or non-premium traditional cigar.

55. Table 8 shows that of adults who are current established premium cigar users and also current established cigarette smokers, 78.8% smoked cigarettes first before they started smoking traditional cigars—premium or non-premium, 10.1% started smoking traditional cigars before they started to smoke cigarettes and 11.0% started smoking traditional cigars and cigarettes at the same age.

Table 8. *First Traditional Cigar or Cigarette Use Among Current Premium Cigar and Cigarette Smokers*

	<b>Started Smoking (1)</b>
<b>Cigarette first</b>	
Percentage	78.8%
Confidence Interval	(71.1% - 86.5%)
<b>Traditional cigars first</b>	
Percentage	10.1%
Confidence Interval	(3.6% - 16.7%)
<b>Both at the same age</b>	
Percentage	11.0%
Confidence Interval	(4.7% - 17.3%)
Number of users	101

**Notes and Source:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adult.
- Age when started smoking is identified by the following questions: "How old were you the first time you smoked part or all of a traditional cigar, even one or two puffs?" "How old were you the first time you smoked part or all of a cigarette?" These questions are only available in Wave 1, not Wave 2 or Wave 3.

#### **D. Dual Use of Premium Cigars and Other Tobacco Products**

56. As the prevalence of premium cigar use among youth is close to zero, we focused our analysis of the dual use of cigars and cigarettes on PATH respondents age 18 years and older. We found that, in Wave 1, the dual use of cigarettes and premium cigars was substantially lower than that of non-premium cigar products. We also found that the current premium cigar smoker typically did not smoke any cigarettes on any day in the past 30 days. See Table 9a-Table 9c.

57. Of current smokers in Wave 1, non-premium cigar users were more than twice as likely to be dual users than premium cigar users. Of current users, 29.0% of premium cigar users were also current cigarette users, as compared to 58.3% of non-premium traditional cigar users, 58.0% of cigarillo users and 66.0% of filtered cigar users. The median premium cigar user had not smoked any cigarettes on any day in the past 30 days – the median number of cigarette smoking days and the number of cigarettes smoked per day in past 30 days are both zero (0). In contrast, the median non-premium traditional cigar user smoked cigarettes on 29.0 days of the past 30-day period, and typically smoked 4.7 cigarettes per day in the past 30 days. The median cigarillo smoker smoked cigarettes on 19.9 days of the past 30-day period and smoked 3.0 cigarettes per day in the past 30 days. The median filtered cigar smoker smoked cigarettes on 29.2 days of the past 30-day period and smoked 7.8 cigarettes per day in the past 30 days.

Table 9a. *Dual Use of Cigars and Cigarettes, Wave 1*

	Premium Cigars		Non-Premium Cigars		
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars
	(1)	(2)	(3)	(4)	(5)
Cigarette smoking status <sup>1</sup>					
Current smoker					
Percentage	29.0%	27.5%	58.3%	58.0%	66.0%
Confidence interval	(24.2-33.7%)	(22.5-32.6%)	(53.6-63.0%)	(54.4-61.6%)	(61.3-70.7%)
Former smoker					
Percentage	30.2%	32.0%	15.4%	10.6%	10.6%
Confidence interval	(24.3-36.1%)	(25.9-38.2%)	(11.8-19.0%)	(8.4-12.8%)	(7.5-13.8%)
Never smoker					
Percentage	40.9%	40.4%	26.3%	31.4%	23.4%
Confidence interval	(35.4-46.4%)	(34.5-46.3%)	(22.4-30.2%)	(28.2-34.6%)	(18.9-27.8%)
Now smoke cigarettes every day					
Percentage	24.8	23.5	54.5	50.3	65.2
Confidence interval	(20.3-29.3%)	(18.6-28.4%)	(49.1-59.9%)	(47.2-53.4%)	(60.6-69.9%)
Number of cigarette smoking days in past 30 days <sup>2</sup>					
Median	0.0	0.0	29.0	19.9	29.2
Interquartile range	(0.0-24.3)	(0.0-14.5)	(0.0-29.5)	(0.0-29.5)	(1.4-29.6)
Number of cigarettes per day on days smoked					
Median	0.0	0.0	5.1	4.2	9.2
Interquartile range	(0.0-3.2)	(0.0-2.6)	(0.0-18.6)	(0.0-14.7)	(0.0-18.9)
Number of cigarettes per day in past 30 days					
Median	0.0	0.0	4.7	3.0	7.8
Interquartile range	(0.0-1.4)	(0.0-1.2)	(0.0-18.5)	(0.0-14.8)	(0.0-18.8)
Number of users	315	289	506	1,186	551

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Former cigarette smokers are those who have smoked at least 100 cigarettes in their lifetime and do not smoke cigarettes now. Never cigarette smokers are those who have smoked less than 100 cigarettes in their lifetime.

<sup>2</sup> Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

58. Of current users in Wave 2, 31.6% of premium cigar users were also current cigarette users, as compared to 55.9% of non-premium traditional cigar users, 61.4% of cigarillo users and 73.2% of filtered cigar users. The median number of cigarette smoking days and the number of cigarettes smoked per day remain at zero (0). In contrast, the median non-premium traditional cigar user smoked cigarettes on 14.0 days of the past 30-day period, and typically smoked 1.0 cigarettes per day in past 30 days. The median cigarillo smoker smoked cigarettes on 14.7 days of the past 30-day period and smoked 1.4 cigarettes per day in the past 30 days. The

median filtered cigar smoker smoked cigarettes on 28.3 days of the past 30-day period and smoked 4.8 cigarettes per day in past 30 days. See Table 9b.

Table 9b. *Dual Use of Cigars and Cigarettes, Wave 2*

	Premium Cigars		Non-Premium Cigars		
	Overall (1)	Unflavored (2)	Traditional Cigars (3)	Cigarillos (4)	Filtered Cigars (5)
Cigarette smoking status <sup>1</sup>					
Current smoker					
Percentage	31.6%	30.1%	55.9%	61.4%	73.2%
Confidence interval	(25.2-38.0%)	(23.5-36.7%)	(48.6-63.3%)	(57.4-65.3%)	(68.9-77.5%)
Former smoker					
Percentage	30.5%	33.0%	18.1%	15.9%	9.4%
Confidence interval	(23.6-37.3%)	(25.6-40.4%)	(13.1-23.1%)	(13.1-18.7%)	(6.2-12.5%)
Never smoker					
Percentage	37.9%	36.9%	26.0%	22.8%	17.4%
Confidence interval	(31.5-44.3%)	(30.1-43.6%)	(19.2-32.7%)	(19.6-26.0%)	(13.5-21.3%)
Now smoke cigarettes every day					
Percentage	18.3	16.2	45.9	45.2	59.4
Confidence interval	(12.7-23.9%)	(10.8-21.7%)	(38.6-53.3%)	(41.0-49.3%)	(55.0-63.8%)
Number of cigarette smoking days in past 30 days <sup>2</sup>					
Median	0.0	0.0	14.0	14.7	28.3
Interquartile range	(0.0-6.8)	(0.0-3.6)	(0.0-28.9)	(0.0-28.9)	(2.7-29.1)
Number of cigarettes per day on days smoked					
Median	0.0	0.0	2.3	3.0	6.6
Interquartile range	(0.0-2.0)	(0.0-1.7)	(0.0-14.0)	(0.0-11.3)	(0.6-18.3)
Number of cigarettes per day in past 30 days					
Median	0.0	0.0	1.0	1.4	4.8
Interquartile range	(0.0-0.8)	(0.0-0.2)	(0.0-13.1)	(0.0-9.8)	(0.1-14.9)
Number of users	270	248	243	790	473

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Former cigarette smokers are those who have smoked at least 100 cigarettes in their lifetime and do not smoke cigarettes now. Never cigarette smokers are those who have smoked less than 100 cigarettes in their lifetime.

<sup>2</sup> Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

59. By Wave 3, the percentage of dual usage dropped to 23.8% for premium cigar users, still far below the 51.3% for non-premium traditional cigar users, 56.3% for cigarillos users, and 69.8% for filtered cigars. See Table 9c.

Table 9c. *Dual Use of Cigars and Cigarettes, Wave 3*

	Premium Cigars		Non-Premium Cigars		
	Overall	Unflavored	Traditional Cigars	Cigarillos	Filtered Cigars
	(1)	(2)	(3)	(4)	(5)
Cigarette smoking status <sup>1</sup>					
Current smoker					
Percentage	23.8%	24.0%	51.3%	56.3%	69.8%
Confidence interval	(17.1-30.5%)	(17.0-31.1%)	(41.5-61.1%)	(51.8-60.7%)	(64.4-75.3%)
Former smoker					
Percentage	40.1%	41.2%	28.6%	19.1%	11.0%
Confidence interval	(31.5-48.8%)	(31.7-50.8%)	(18.1-39.1%)	(15.7-22.5%)	(8.0-14.1%)
Never smoker					
Percentage	36.1%	34.7%	20.1%	24.6%	19.1%
Confidence interval	(27.4-44.8%)	(24.8-44.6%)	(11.4-28.8%)	(20.7-28.4%)	(13.2-25.0%)
Now smoke cigarettes every day					
Percentage	15.0	14.6	38.0	40.6	59.6
Confidence interval	(9.4-20.7%)	(8.7-20.4%)	(29.2-46.7%)	(36.1-45.0%)	(53.8-65.4%)
Number of cigarette smoking days in past 30 days <sup>2</sup>					
Median	0.0	0.0	1.6	8.0	28.3
Interquartile range	(0.0-0.5)	(0.0-0.6)	(0.0-28.6)	(0.0-27.5)	(2.2-29.2)
Number of cigarettes per day on days smoked					
Median	0.0	0.0	0.6	2.5	6.8
Interquartile range	(0.0-0.5)	(0.0-0.6)	(0.0-13.0)	(0.0-9.9)	(0.4-16.2)
Number of cigarettes per day in past 30 days					
Median	0.0	0.0	0.1	1.0	5.9
Interquartile range	(0.0-0.0)	(0.0-0.0)	(0.0-11.3)	(0.0-10.0)	(0.1-15.9)
Number of users	215	193	179	682	424

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.
- The median is the weighted middle value in a sequence of observations.

<sup>1</sup> Former cigarette smokers are those who have smoked at least 100 cigarettes in their lifetime and do not smoke cigarettes now. Never cigarette smokers are those who have smoked less than 100 cigarettes in their lifetime.

<sup>2</sup> Everyday smokers are assumed to smoke on all 30 days. Respondents who have never smoked are assumed to not have smoked on any days.

60. Among current premium cigar users in Wave 1, those who are also current cigarette smokers do not smoke more premium cigars. They smoke premium cigars 1.1 days per month as compared to 1.9 days per month for those who are not current cigarette smokers. The median number of premium cigars used a day in the past 30 days was 0 for current cigarette smokers and 0.1 for non-cigarette smokers.

Table 10a. *Premium Cigar Smoking by Cigarette Smoking Status, Wave 1.*

	<b>Current Cigarette Smokers?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
Now smoke premium cigars every day		
Percentage	4.5%	7.3%
Confidence interval	(0.2-8.7%)	(3.8-10.9%)
Days smoked premium cigars in past 30 days <sup>1</sup>		
Median	1.1	1.9
Interquartile range	(0.0-4.4)	(0.2-4.9)
Number of premium cigars per day on days smoked <sup>2</sup>		
Median	0.6	0.6
Interquartile range	(0.0-0.9)	(0.1-0.9)
Number of premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.1
Interquartile range	(0.0-0.2)	(0.0-0.2)
Number of users	101	214

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

61. In Wave 2, as in Wave 1, there is no statistically significant difference in premium cigar usage between those who currently smoke cigarettes and those who do not. See Table 10b.

Table 10b. *Premium Cigar Smoking by Cigarette Smoking Status, Wave 2.*

	<b>Current Cigarette Smokers?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
Now smoke premium cigars every day		
Percentage	5.8%	8.2%
Confidence interval	(1.5-10.1%)	(3.4-13.0%)
Days smoked premium cigars in past 30 days <sup>1</sup>		
Median	0.9	1.7
Interquartile range	(0.0-2.7)	(0.0-4.4)
Number of premium cigars per day on days smoked <sup>2</sup>		
Median	0.6	0.6
Interquartile range	(0.0-0.8)	(0.0-0.8)
Number of premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.1
Interquartile range	(0.0-0.1)	(0.0-0.2)
Number of users	84	186

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

62. As in Waves 1 and 2, in Wave 3, there is no statistically significant difference in smoking premium cigar every day between those who currently smoke cigarettes and those who do not. See Table 10c.

Table 10c. *Premium Cigar Smoking by Cigarette Smoking Status, Wave 3.*

	<b>Current Cigarette Smokers?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
Now smoke premium cigars every day		
Percentage	5.8%	3.3%
Confidence interval	(0.0-12.3%)	(0.7-5.9%)
Days smoked premium cigars in past 30 days <sup>1</sup>		
Median	0.7	1.5
Interquartile range	(0.0-2.7)	(0.2-5.4)
Number of premium cigars per day on days smoked <sup>2</sup>		
Median	0.5	0.7
Interquartile range	(0.0-0.8)	(0.1-0.9)
Number of premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.0
Interquartile range	(0.0-0.1)	(0.0-0.2)
Number of users	56	159

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day were assigned as smoking 0.5 cigars per day.

#### IV. MISCELLANEOUS

63. My work is ongoing and my opinions are subject to revision based on additional economic and statistical analyses.

July 25, 2018



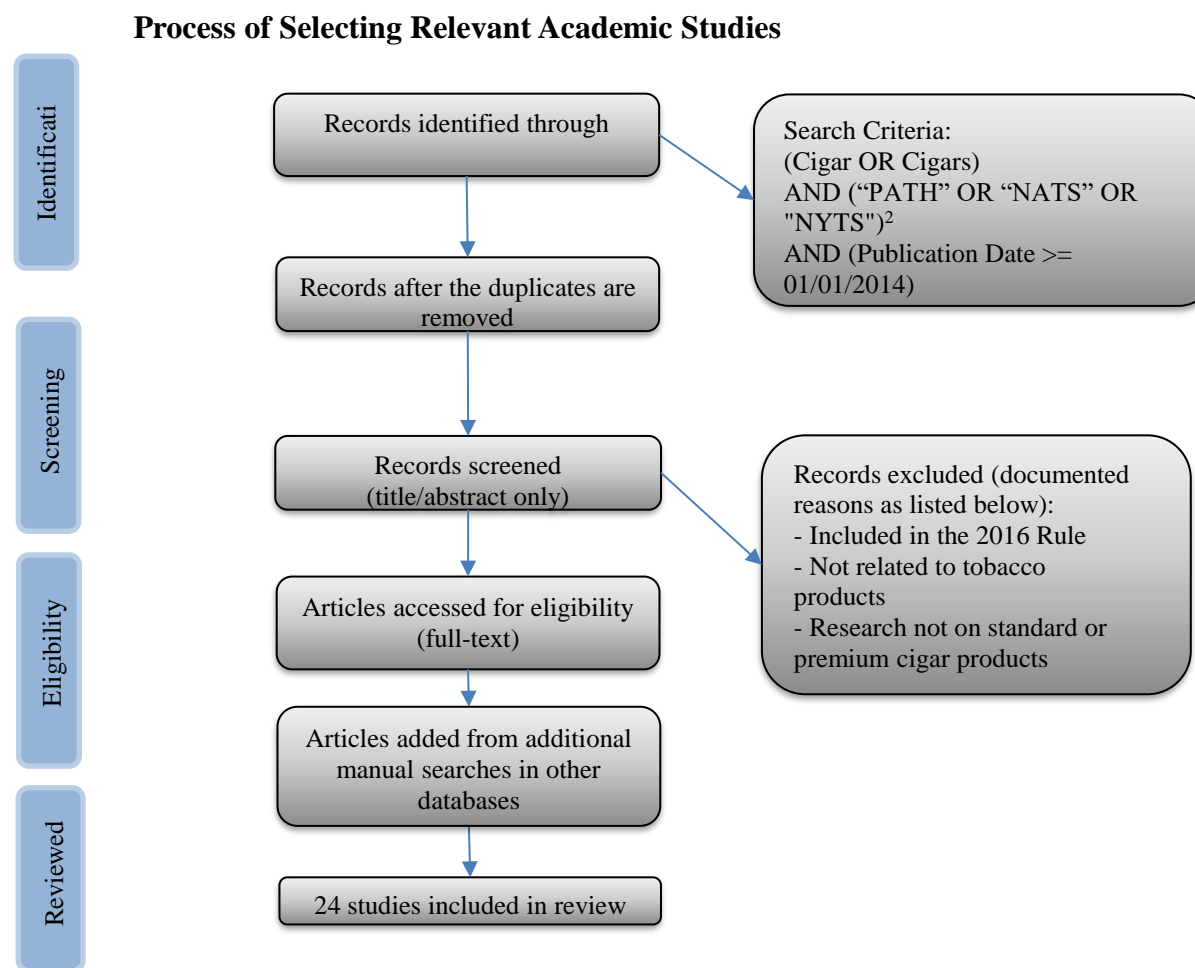

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## APPENDIX A

Table 11. *Literature Review*



### Notes and Sources:

<sup>1</sup> The databases searched are: PubMed, ISI Web of Science, and Embase.

<sup>2</sup> PATH: Population Assessment of Tobacco and Health; NATS: National Adult Tobacco Survey; NYTS: National Youth Tobacco Survey.

### Summary of Recent Studies on Traditional Cigar Smoking Patterns

No. (1)	Study Authors (2)	Title (3)	Types of Tobacco Products Analyzed (4)	Data Source (5)	Population (6)	Use Patterns of Tobacco Products Analyzed <sup>1</sup> (7)	Conclusion (8)
1.	Corey, et al. (2017)	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	Premium cigars, non-premium cigars, cigarillos, filtered cigars, and cigarettes. Premium cigars are defined by a brand's tobacco blends, components (e.g. long filler, whole leaf wrapper), and manufacturing process. Where brand information was unavailable, usual price paid per stick of ≥\$2 was applied to identify premium brands	PATH	Adult smokers and non-smokers (n = 32,320 participants aged 18 years and older; weighted response rate = 74.0%)	Initiation/Progression; Dual Use; Frequency of Use; Impact of Labelling/Advertising	Those smoking premium cigars tended to differ from those smoking non-premium cigars, cigarillos, and FCs (filtered cigars) including having users with higher socioeconomic status, lower smoking frequency, different purchasing behaviors (e.g., where and for how much cigars were bought) and reasons for use. Age at first regular use was higher for FCs (median: 26.8 years) and premium cigars (24.5 years) compared with non-premium cigars, cigarillos, and cigarettes (16.6–19.5 years; all p < .05). Currently smoking one or more of the other cigar products ranged from 64.0% for non-premium cigars to 16.8% for premium cigars. Prevalence of daily smoking was higher for FCs (37.3%), compared with all other cigar types (6.7%–25.3%; all p < .01); daily smoking was similar for non-premium cigars and cigarillos (p = 0.11). Endorsing advertising as a reason for smoking ranged from 9.7% for premium cigars to 15.1% for non-premium cigars. "That public figures smoke them" as a reason for smoking ranged from 12.1% for premium cigars to 21.0% for non-premium cigars. In terms of metrics - flavor, affordability, alternative to quitting tobacco altogether, similarity to the feeling of smoking a regular cigarette, tool to help quit/cut down cigarettes as reasons of smoking, premium cigars have the lowest percentage among all tobacco products listed in the analysis.
2.	Ambrose, et al. (2015)	Flavored Tobacco Product Use among US Youth Aged 12-17 Years, 2013-2014	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, snus pouches, and other smokeless tobacco	PATH	13,651 youths aged 12-17 years old	Initiation/Progression	The majority of youth ever-users reported that the first tobacco product they used was flavored, including 88.7% of hookah users, 81% of e-cigarette users, 65.4% of ever-users of any cigar type, and 50.1% of ever cigarette smokers. For past 30-day youth tobacco users, 71.7% of cigars used were flavored. In addition, youth consistently reported product flavoring as a reason for use across all product types, including e-cigarettes (81.5%), hookahs (78.9%), cigars (73.8%), smokeless tobacco (69.3%), and snus patches (67.2%).
3.	California Medical Association (CMA) White Paper (2016)	Flavored and Mentholated Tobacco Products: Enticing a New Generation of Users	Cigars (including traditional cigars, little cigars, and cigarillos), smokeless tobacco, hookah tobacco, liquid nicotine solution, and menthol cigarettes	N/A	N/A	Initiation/Progression; Dependence; Labelling/Advertising	Tobacco use remains the chief risk factor for the leading causes of death in the state, and evidence shows that the tobacco industry continues to engage in efforts to entice a new generation of users by adding specific flavors to mask the harsh taste of tobacco, which does not reduce the negative health impacts of tobacco use. Flavors and menthol tobacco products skew user preferences to the younger users. These products are usually the "starter" products that lead to dependence and addiction to tobacco products and even increase use of multiple tobacco products concurrently.

4.	Conway, et al. (2018)	Co-occurrence of Tobacco Product Use, Substance Use, and Mental Health Problems among Youth: Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study	Cigarettes, e-cigarettes, traditional cigars, cigarillos, filtered cigars, pipe tobacco, hookah, smokeless tobacco (i.e. loose snus, moist snuff, dip, spit, or chewing tobacco), snus pouches, kreteks, bidis, and dissolvable tobacco	PATH	13,617 youth, aged 12-17 years old, participants of PATH Wave 1	Association between tobacco use and substance use and mental health problems	In multivariable regression analyses, use of each tobacco product was associated with substance use, particularly cigarillos and marijuana. Cigarette and cigarillo use were strongly associated with substance use problems and tobacco users were more likely to report internalizing and externalizing problems. Female tobacco users were more likely to have internalizing problems than male tobacco users. Poly-tobacco users were more likely than exclusive users to use substances and have mental health and substance use problems. In terms of cigars, users of any cigar had relatively higher severity of substance use problems and a relatively high ever-substance use compared to other tobacco products analyzed.
5.	Conway, et al. (2017)	Co-occurrence of tobacco product use, substance use, and mental health problems among adults: Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study	Cigarettes, e-cigarettes, traditional cigars, cigarillos, filtered cigars, pipe tobacco, hookah, smokeless tobacco (i.e. loose snus, moist snuff, dip, spit, or chewing tobacco), snus pouches, kreteks, bidis, and dissolvable tobacco	PATH	32,202 Adult (18+ years) participants of PATH Wave 1	Association between tobacco use and substance use and mental health problems	In multivariable regression analyses, tobacco users were more likely to use substances and experience mental health problems. This result was more pronounced among female subjects. Cigarette users were found to be more likely to have problematic alcohol and other drug use, while cigarillo users had the highest likelihood of a combination of marijuana and alcohol use. Hookah use was strongly associated with the use of alcohol, marijuana, and Ritalin.
6.	Dickinson, et al. (2016)	The Language of Cigar Use: Focus Group Findings on Cigar Product Terminology	Traditional cigars, cigarillos, and little cigars	Self conducted research on 16 focus groups	123 participants who were current cigar users in the U.S.	Labelling/Advertising	Participants used a variety of terms for each product subtype. Brand names were often used, as well as slang terms, including terms describing cigars modified for marijuana use. Some subtypes were less likely than others to be considered “cigars.” Participants had mixed opinions about whether users of cigar products are “smokers.” In terms of cigars, participants saw little cigars and cigarillos as being more common, daily-use, products than large/traditional cigars, which were viewed as something to smoke during leisure time or special occasions. Participants were less likely to view users of large/ traditional cigars as “smokers.”
7.	Hinds, et al. (2018)	Flavored Cigars Appeal to Younger, Female, and Racial/Ethnic Minority College Students	Cigars (including traditional cigars, filtered cigars, and cigarillos)	Marketing and Promotions across Colleges in Texas project (M-PACT)	523 18-29 year old college students who reported current (past 30-day) cigar use	Prevalence and correlates of flavored and non-flavored cigar use	68.3% of those smoking flavored cigars smoked cigarillos, as compared to 20.4% who smoked traditional cigars. 64.5% of those who smoked non-flavored cigars smoked traditional cigars as compared to 25.5% that were cigarillo smokers. Younger participants (18-24) had 2.17 greater odds of choosing flavored cigars as compared to older participants (25-29). The number of days of cigar use in the past 30 days was not associated with flavored cigar use.

8.	Kasza, et al. (2017)	Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014	Traditional cigars, cigarillos, filtered cigars, pipe tobacco, hookah, snus pouches, other smokeless tobacco, dissolvable tobacco, bidis, kreteks, cigarettes, and e-cigarettes	PATH	32,320 adults (18+) and 13,651 youths (12-17)	Dual Use; Frequency of Use; Prevalence	The prevalence of tobacco use (%) for youth aged 12-17 who had "ever used" a tobacco product was 21.8 for any tobacco product as compared to 2.3 for traditional cigars. For youth who had used a tobacco product in the past 30 days, prevalence was 8.9 for any tobacco product as compared to 0.7 for traditional cigars. The prevalence for youth using a tobacco product daily was 1.6 for any tobacco product, and was unable to be reliably estimated for traditional cigars. The prevalence of tobacco use for adults age 18 or older who had used a tobacco product in the past 30 days was 29.7 for any tobacco product as compared to 3.6 for traditional cigars. The prevalence for adults using a tobacco product daily was 19.7 for any tobacco product as compared to 0.3 for traditional cigars. (Approximately 40% of tobacco users, adults and youths used multiple tobacco products, in which cigarettes+e-cigarettes was the most common combination.)
9.	Kong, et al. (2017)	Adolescent and Young Adult Perceptions on Cigar Packaging: A Qualitative Study	Traditional cigars and cigarillos	Focus groups conducted in Connecticut in 2016	Study participants were Connecticut Adolescent (up to 17 years old) and Adults (18-25 years old) in New Haven County who had ever used a cigar (N=47)	Labelling/Advertising	Findings showed that adolescents and young adults identified many features of cigar packaging as attractive, such as flavors, price promotions, branding, and marketing claims. Participants were shown packaging for cigars (mostly cigarillos, with a few traditional cigars) and asked to identify characteristics that they found appealing. The appealing components identified were flavors (46.8%), price promotions (28.8%), branding (21.2%), marketing claims (e.g., "natural", 17.2%), product features (e.g., the word "cigarillos", 15.2%), number of cigars (8.0%), color (4.4%), re-sealable features (2.8%), and other (6.0%).
10.	Kurti, et al. (2017)	Tobacco and Nicotine Delivery Product Use in a National Sample of Pregnant Women	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, snus pouches, other smokeless tobacco, and dissolvable tobacco	PATH	388 pregnant women 18 years or older	Prevalence and correlates of using tobacco products; Frequency of Use	13.8% maternal smoking prevalence among women whose average gestational age was 20.9 weeks (5-6 months) is consistent with an earlier study using 2002-2009 NSDUH data. Overall prevalence was highest for cigarettes (13.8%), followed by e-cigarettes (4.9%), hookah (2.5%) and cigars (2.3%), and below 1% for all other products. Prevalence of using other tobacco products is much higher among current smokers than the general population, with e-cigarettes (28.5%) most prevalent followed by cigars (14.0%), hookah (12.4%), smokeless (4.7%), snus (4.6%), and pipes (2.1%).

11.	Lopez, et al. (2018)	Tobacco and Nicotine Delivery Product Use in a U.S. National Sample of Women of Reproductive Age	Tobacco cigarettes, e-cigarettes, any cigar (traditional cigars, filtered cigars, and/or cigarillo), hookah, smokeless tobacco and snus, pipe tobacco, and dissolvable tobacco	PATH	12,848 women aged 15–44 who were not currently pregnant in the first wave of the PATH data, 2013–2014	Prevalence and correlates of using tobacco products; Dual Use	Cigarette smoking prevalence remains relatively high among women of reproductive age and strongly correlated with use of other tobacco products. Current cigarette smoking was the strongest correlate of current e-cigarette use (OR=65.7, 95% CI=44.8–96.5), cigar smoking (OR=19.2, 95% CI=14.1–26.1), and hookah use (OR=6.6, 95% CI=5.1–8.5). Use of other tobacco and nicotine delivery product was low among those who never smoked tobacco cigarettes. In terms of cigars, cigarette smoking was the strongest predictor of cigar smoking. Current and former cigarette smokers had 19.2 and 3.8 times greater odds of smoking cigars relative to never smokers, respectively. Those who were younger, non-White, had less than high school or some college education, or had used alcohol or illicit drugs in the past year were more likely to report any current cigar use.
12.	Miller, et al. (2015)	“You’re made to feel like a dirty filthy smoker when you’re not, cigar smoking is another thing all together.” Responses of Australian Cigar and Cigarillo Smokers to Plain Packaging	Premium cigars, premium cigarillos, non-premium cigarillos, and other cigars	Self conducted interviews and surveys in Australia	Interviewed premium cigar smokers (n=10); occasional premium cigar smokers and/or premium cigarillo smokers (n=14); non-premium cigarillo smokers (n=28); 268 respondents to the online survey of current cigar and cigarillo smokers in March 2014	Dual Use; Labelling/Advertising; Impact of Regulation	Premium cigar smokers had limited exposure to Plain Packaging (PP), with many purchasing fully branded cigars in boxes duty free or online, and singles in non-compliant packaging. Those who were exposed were concerned by the warnings, and felt more like “dirty smokers.” Premium cigar smokers perceived minimal changes in taste, harm, and value. Occasional premium cigar and premium cigarillo smokers with higher PP exposure perceived cigar/package appeal and value had declined and noticed the Graphic Health Warnings (GHW). Online survey participants reported increased noticeability of GHWs (33%), decreased appeal of packaging (53%), and reduced consumption of cigars (42%) and cigarillos (44%) since PP implementation.
13.	Neff, et al. (2015)	Frequency of Tobacco Use Among Middle and High School Students - United States, 2014	Cigars (including traditional cigars, filtered cigars, and cigarillos), cigarettes, e-cigarettes, and smokeless tobacco	NYTS	22,007 U.S. students from public and private schools, grade 6-12. A nationally representative sample (response rate = 73.3%)	Dual Use; Frequency of Use; Dependence	An estimated 480,000 middle school and high school students smoked cigarettes, 390,000 used smokeless tobacco, 340,000 used e-cigarettes, and 170,000 smoked cigars on 20 or more days of the preceding 30 days. Among high school students who were current users, cigar smokers were least likely to have smoked 20 or more days in the past 30 days -- 42.0% of smokeless tobacco users, 31.6% of cigarette smokers, 15.5% of e-cigarettes users, and 13.1% of cigar smokers were frequent users. In turn, of current users, cigar smokers were most likely to have only smoked 1-2 days in the past 30 days (52.0 % for cigar smokers as compared to 26.6% for smokeless tobacco users). Similarly, for middle school students, cigar smokers were less likely to be frequent smokers (20 or more days in the past 30 days), and more likely to be occasional smokers, smoking 1-2 days in the preceding 30 days.
14.	Pierce, et al. (2017)	Receptivity to Tobacco Advertising and Susceptibility to Tobacco Products	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, and smokeless tobacco	PATH	10,751 adolescents (12-17 years old) who had never used a tobacco product	Initiation/Progression; Labelling/Advertising	For youth aged 12-13 years old, 7.9% were receptive to ads for cigars as compared to 27.8% for e-cigarettes, 21.5% for cigarettes, and 14.8% for smokeless tobacco. For youth aged 16-17 years old, 12.6% were receptive to cigar ads as compared to 32.7% for e-cigarettes, 25% for cigarettes, and 20.5% for smokeless tobacco. 14-15 year olds had similar numbers as 16-17 year olds. In a multivariate logistic regression controlling for potential covariates, moderate to high receptivity to cigarettes, e-cigarettes, and smokeless tobacco was significantly associated with concurrent susceptibility to smoke cigarettes, which was not the case for moderate to high receptivity to cigar advertising.

15.	Pierce, et al. (2018)	Association Between Receptivity to Tobacco Advertising and Progression to Tobacco Use in Youth and Young Adults in the PATH Study	Cigars (including traditional cigars, cigarillos, and filtered cigars), electronic cigarettes, cigarettes, and smokeless tobacco products	PATH	10,989 respondents aged 12-24 who had no tobacco product use in Wave 1	Initiation/Progression; Labelling/Advertising	Receptivity to tobacco product advertising is substantial among US youth who are below the minimum required age to purchase tobacco products. Among young committed never users, receptivity is significantly associated with progression toward use within a 1-year period. In general, receptivity to cigar ads is lowest for all age groups, whereas receptivity to e-cigarette ads is highest.
16.	Protano, et al. (2017)	Second-hand Smoke Generated by Combustion and Electronic Smoking Devices Used in Real Scenarios: Ultrafine Particle Pollution and Age-Related Dose Assessment	Combustion (conventional and hand-rolled cigarettes, a cigar and tobacco pipe) and non-combustion (e-cigarette and IQOS®) devices	N/A	4 volunteer smokers (three male and one female of 60, 58, 53, and 37 years old), all of whom were employees of the Sapienza University of Rome	Characterization of smoke dispersal and second-hand smoke transmission	Aerosol measurements were carried out in a model room where both combustion and non-combustion devices were smoked. Regardless of the smoking device, the highest doses were received by infants, which reached $9.88 \times 10^8$ particles/kg bw during a cigar smoking session. Moreover, 60% to 80% of the particles deposited in the head region of a 3-month-old infant were smaller than 100nm and could be translocated to the brain via the olfactory bulb. The doses due to second-hand smoke from electronic devices were significantly lower, below $1.60 \times 10^8$ particles/kg bw, than those due to combustion devices. Dosimetry estimates were 50% to 110% higher for IQOS® than for e-cigarettes.
17.	Roberts, et al. (2017)	Rural versus Urban Use of Traditional and Emerging Tobacco Products in the United States, 2013-2014	Cigars, cigarillos, pipes, smokeless tobacco, e-cigarettes, cigarettes, and hookah	PATH	32,320 adults (18+)	Dual Use; Difference between Urban and Rural populations	No non-rural difference in the use of cigars, although the daily use of cigarettes and smokeless tobacco were higher in Rural populations, and the use of Cigarillos and Hookah were higher in Urban than Rural populations, at the $P < .001$ level.
18.	Rostron, et al. (2016)	Dependence Symptoms and Cessation Intentions among US Adult Daily Cigarette, Cigar, and E-cigarette Users, 2012-2013	Cigarettes, cigars (including large cigars, cigarillos, and little filtered cigars), and e-cigarettes	NATS	5,617 daily tobacco users that used a combination of cigars, cigarettes, and e-cigarettes (who either reported using a single product type every day or being a multi-product user and using at least one tobacco product every day)	Dual Use; Frequency of Use; Dependence	1) Among daily tobacco users, dual cigarette and cigar users show evidence of greater dependence symptoms -- they smoked more cigarettes per day (17.3 vs. 15.8), had shorter times to first tobacco use after waking (21.4 min vs. 25.9 min), and were more likely to report dependence symptoms (withdrawal and craving) than exclusive cigarette smokers. 2) Dual cigarette and e-cigarette users were more likely than exclusive cigarette smokers to report withdrawal and craving symptoms and cessation intentions. 3) Exclusive cigar and e-cigarette users were less likely to report dependence symptoms than users of other products, but more than a third of exclusive cigar users reported strong cravings for tobacco in the past 30 days.

19.	Singh, et al. (2016)	Tobacco Use Among Middle and High School Students--United States, 2011-2015	Cigarettes, cigars, smokeless tobacco, electronic cigarettes, hookahs, pipe tobacco, and bidis	NYTS	U.S. students in grades 6-12. Sample sizes and overall response rates were 2011: 18,866 (72.7%); 2012: 24,658 (73.6%); 2013: 18,406 (67.8%); 2014: 22,007 (73.3%); and 2015: 17,711 (63.4%)	Prevalence, Frequency of Use	In 2015, e-cigarettes were the most commonly used tobacco product among middle (5.3%) and high (16.0%) school students. During 2011-2015, current use of e-cigarettes and hookahs significantly increased for both middle school and high school students, whereas current use of conventional tobacco products, such as cigarettes and cigars decreased. During 2014-2015, current use of e-cigarettes increased among middle school students, whereas current use of hookahs decreased among high school students; in contrast, no change was observed in use of hookahs among middle school students, use of e-cigarettes among high school students, or use of cigarettes, cigars, smokeless tobacco, pipe tobacco, or bidis among middle and high school students. In 2015, an estimated 4.7 million middle and high school students were current tobacco product users.
20.	Soneji, et al. (2017)	Engagement with Online Tobacco Marketing and Associations with Tobacco Product Use among U.S. Youth	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, snus ouches, dissolvable tobacco, bidis, kreteks, and smokeless tobacco	PATH	13,651 youths aged 12-17 years old	Initiation/Progression; Labelling/Advertising	12% of youth engaged in one or more forms of online tobacco marketing. Compared to no engagement, the odds of susceptibility to the use of any tobacco product among never-tobacco users was independently associated with the level of online engagement. Similarly, higher levels of receptivity to tobacco marketing in traditional media venues were also associated with these tobacco-related outcomes, independent of on-line engagement. The prevalence of susceptibility was lower for cigars than for cigarettes, and e-cigarettes despite the level of online engagement for both ever smokers and smokers that have used tobacco for the past 30 days. For example, for those who have ever smoked tobacco, the prevalence of susceptibility for cigars ranged from 6.7 (no tobacco product online engagement) to 26.0 (two or more types of tobacco product online engagement) as compared to 12.5 to 39.2 for cigarettes.
21.	Strong, et al. (2017)	Indicators of Dependence for Different Types of Tobacco Product Users: Descriptive Findings from Wave 1 (2013-2014) of the Population Assessment of Tobacco and Health (PATH) Study	Cigars (including traditional cigars, filtered cigars, and cigarillos), cigarettes, e-cigarettes, hookah, and smokeless tobacco products	PATH	14,287 current established users of tobacco products	Nicotine Dependence	The PATH study questionnaire included 24 tobacco dependence ("TD") symptoms derived from four primary instruments used to represent multiple domains of TD. With levels of TD anchored at 0 (SD=1.0) for cigarette only users, the mean TD were more than a full standard deviation lower for cigar only users (mean= -1.92, SD=2.11). The lowest levels of TD relative to cigarette smokers were seen in e-cigarette users only, cigar only users (lowest, TD=-1.92), and hookah only users.
22.	Strong, et al. (2018)	Marijuana Use among US Tobacco Users: Findings from Wave 1 of the Population Assessment of Tobacco Health (PATH) Study	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, and smokeless tobacco	PATH	32,212 respondents from Wave 1 of the PATH Study	Correlation between tobacco use and marijuana use	1) When compared to non-current tobacco users, each tobacco user group except smokeless only users had higher odds of reporting current marijuana use. 2) Among current tobacco users, higher levels of tobacco dependence did not explain the relationship between tobacco use and marijuana use. 3) Concurrent marijuana use was associated with lower odds of attempts to quit tobacco (OR=0.86, 95% CI=0.79, 0.94, p < 0.001) and a higher probability (OR=1.35, 95% CI=1.21, 1.51, p < 0.001) of reporting a history of respiratory disease. 4) Marijuana use may represent an additive risk for respiratory harm among concurrent users of tobacco and marijuana. In terms of cigars, current cigar-only users had significantly higher odds of reporting current marijuana use than all other types of tobacco analyzed, but lower than the multiple product users.

23.	Trinidad, et al. (2017)	Susceptibility to Tobacco Product Use among Youth in Wave 1 of the Population Assessment of Tobacco and Health (PATH) Study	Cigars (including traditional cigars, cigarillos, and filtered cigars), cigarettes, e-cigarettes, pipe tobacco, hookah, smokeless tobacco, snus, dissolvable tobacco, bidis, and kreteks	PATH	13,651 adolescents, 13,589 parents, and 9,112 18-24 year old young adults	Initiation/Progression; Dual Use; Frequency of Use	The purpose of the study was to investigate susceptibility and ever use of tobacco products among adolescents and young adults in the U.S. Susceptibility is reflected by the number of "susceptible never users", which is defined by the authors who created a questionnaire and conducted a tobacco product uptake continuum from it. They found that susceptibility levels were lower for cigars (15.2%) as compared to cigarettes (28.6%). The reported ever use of cigars among adolescents ages 12-17 was approximately half that of cigarettes (7.4% for cigars as compared to 13.4% for cigarettes). The authors considered susceptible never users, non-current ever users and current users to be at risk for future established tobacco use in adulthood, and the proportion at risk for cigars is relatively low (22.9%) as compared to cigarettes (42.0%).
24.	Villanti, et al. (2017)	Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013-2014)	Traditional cigars, cigarillos, filtered cigars, pipe tobacco, hookah, snus pouches, other smokeless tobacco, dissolvable tobacco, cigarettes, e-cigarettes, kreteks, and bidis	PATH	32,320 adults (18+) and 13,651 youths (12-17)	Initiation/Progression	The prevalence of any current flavored cigar use among current tobacco users was higher in youth (20.6%) and young adults (18.4%) than adults (6.9%). Flavor was found to be a primary reason for using a given tobacco product, especially among youth.

#### Notes and Sources:

<sup>1</sup> Aspects of user patterns analyzed include initiation/progression, dual use, frequency of use, dependence, impact of labelling/advertising, impact of regulation, and other specific smoking patterns.



## APPENDIX B

Table 12a. *Unflavored Premium Cigar Smoking by Cigarette Smoking Status, Wave 1*

	<b>Current Cigarette Users?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
Now smoke unflavored premium cigars every day		
Percentage	5.1%	7.5%
Confidence interval	(0.2-10.0%)	(3.9-11.2%)
Days smoked unflavored premium cigars in past 30 days <sup>1</sup>		
Median	1.0	1.9
Interquartile range	(0.0-4.2)	(0.2-4.9)
Number of unflavored premium cigars per day on days smoked <sup>2</sup>		
Median	0.6	0.6
Interquartile range	(0.0-0.9)	(0.1-0.9)
Number of unflavored premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.1
Interquartile range	(0.0-0.2)	(0.0-0.2)
Number of users	90	199

### Notes and Sources:

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users. Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

Table 12b. *Unflavored Premium Cigar Smoking by Cigarette Smoking Status, Wave 2*

	<b>Current Cigarette Users?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
<hr/>		
Now smoke unflavored premium cigars every day		
Percentage	4.4%	8.5%
Confidence interval	(0.0-9.3%)	(3.4-13.7%)
<hr/>		
Days smoked unflavored premium cigars in past 30 days <sup>1</sup>		
Median	1.0	1.8
Interquartile range	(0.0-2.6)	(0.0-4.5)
<hr/>		
Number of unflavored premium cigars per day on days smoked <sup>2</sup>		
Median	0.6	0.6
Interquartile range	(0.0-0.9)	(0.0-0.8)
<hr/>		
Number of unflavored premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.1
Interquartile range	(0.0-0.1)	(0.0-0.2)
<hr/>		
Number of users	74	174

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users.

Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

Table 12c. *Unflavored Premium Cigar Smoking by Cigarette Smoking Status, Wave 3*

	<b>Current Cigarette Users?</b>	
	<b>Yes</b>	<b>No</b>
	<b>(1)</b>	<b>(2)</b>
Now smoke unflavored premium cigars every day		
Percentage	5.3%	3.0%
Confidence interval	(0.0-12.3%)	(0.4-5.5%)
Days smoked unflavored premium cigars in past 30 days <sup>1</sup>		
Median	0.5	1.5
Interquartile range	(0.0-2.4)	(0.1-5.8)
Number of unflavored premium cigars per day on days smoked <sup>2</sup>		
Median	0.5	0.6
Interquartile range	(0.0-0.8)	(0.1-0.8)
Number of unflavored premium cigars per day in past 30 days <sup>2</sup>		
Median	0.0	0.0
Interquartile range	(0.0-0.1)	(0.0-0.2)
Number of users	50	143

**Notes and Sources:**

- Data are from Population Assessment of Tobacco and Health (PATH) Study Restricted-Use Files for adults.

- The median is the weighted middle value in a sequence of observations. The interquartile range represents the weighted 25<sup>th</sup> and 75<sup>th</sup> percentiles.

<sup>1</sup> Number of days smoked in the past 30 days is available for someday users.

Everyday users are assumed to smoke on all 30 days.

<sup>2</sup> Respondents reporting smoking less than one cigar per day on days smoked were assigned as smoking 0.5 cigars per day.

Cigar Association of America, Inc.  
Comment to Docket No. FDA-2017-N-6107  
Regulation of Premium Cigars

## **EXHIBIT B**

**PURCHASING PATTERNS AND DEMOGRAPHICS OF ONLINE PREMIUM CIGAR  
CUSTOMERS**

**Expert Report Prepared For:**

Cigar Association of America, Inc.  
Cigar Rights of America  
International Premium Cigar and Pipe Retailers Association

**Prepared By:**

Richard P. Voith, Ph.D., CRE  
Peter Angelides, Ph.D., AICP  
Econsult Solutions, Inc.  
Philadelphia, Pennsylvania

July 25, 2018

## **1.0 Econsult Solutions, Inc.**

Econsult Solutions, Inc. is a Philadelphia-based economic consulting firm that provides businesses and public policy makers with economic consulting services in urban economics, real estate economics, transportation, public infrastructure, development, public policy and finance, community and neighborhood development, planning, as well as expert witness services for litigation support. Its principals are nationally recognized experts in urban development, real estate, government and public policy, planning, transportation, non-profit management, business strategy and administration, as well as litigation and commercial damages. Staff members have outstanding professional and academic credentials, including active positions at the university level, wide experience at the highest levels of the public policy process and extensive consulting experience.

President and Principal Dr. Richard Voith is a well-known expert in real estate economics, transportation, and applied microeconomics. Prior to joining Econsult Solutions, Dr. Voith held the position of Economic Advisor at the Federal Reserve Bank of Philadelphia. Dr. Voith has taught courses at the Wharton School of the University of Pennsylvania and continues as a Faculty Fellow at the University of Pennsylvania's Institute for Urban Research.

Dr. Peter Angelides, Senior Vice President and Principal, is an experienced economist concentrating in real estate, transportation, and economic development. Dr. Angelides also serves as a lecturer at the University of Pennsylvania, teaching courses in Urban Economics, Project Finance, and Infrastructure Investment in the Department of City and Regional Planning in the Fels School of Government. In addition to these positions, Dr. Angelides is a member of the American Economics Association, the American Institute of Certified Planners, and the Urban Land Institute.

Both Dr. Voith and Dr. Angelides have extensive experience providing analysis and testimony in support of litigation matters. The bios of Dr. Voith and Dr. Angelides are attached as Appendix A and B.

## **2.0 Scope of Work**

On March 26, 2018, the Food and Drug Administration ("FDA") issued an Advance Notice of Proposed Rulemaking ("ANPRM") regarding the regulatory status of Premium Cigars. In the ANPRM, FDA requested "comments, evidence, information, data, and analysis that were not submitted in response to the proposed deeming rule, or that may have become available since then, that could further inform FDA's thinking about the regulation of premium cigars." (83 Fed. Reg. at 12,902).

Data on the purchasing and use patterns of premium cigars has, up until now, been very limited. The dearth of information is in part a result of the fact that premium cigars are not defined as a class by the federal government, and are not routinely included in survey data or more general consumption data. Moreover, premium cigars are not sold in traditional mass-market channels. This stands in contrast to other types of cigars and cigarettes, where data is available from usage surveys and from scanner data as these products are sold in retail channels that are easily traceable. In order to examine purchasing patterns, therefore, it is necessary to conduct surveys of premium cigar consumers or to collect data from individual premium cigar retailers. To date, this has not been done using a verifiable analytical methodology. This analysis has taken data from five of the largest internet/mail-order retailers of premium cigars in order to analyze purchasing patterns of premium cigar consumers, and provides a new,

much more comprehensive window on the purchasing, and by implication, use patterns of premium cigars.

### **3.0 Executive Summary**

Using a definition of “premium” cigar developed by a researcher at FDA’s Center for Tobacco Products (CTP), this report analyzes sales data for approximately 125 million premium cigars in 2017. The data provided by the companies allows for analysis of premium cigar purchasing patterns that has never before been undertaken.

The data from these companies provide important demographic information about premium cigar purchasers. For example, it shows the average premium cigar purchaser is 55 years old, with a median age of 57, and that 89% of these consumers are over age 35. Further, premium cigar purchasers reside in communities with higher levels of education and higher incomes than the rest of the US population, and reside predominantly in urban environments. In addition, the data show no youth purchases, because all of these companies use third party age-verification to ensure that all consumers are of at least legal minimum age of purchase.

The data also shed light on the distinct purchasing patterns of premium cigar consumers. For the most part, these consumers purchase infrequently, and approximately 44% of the purchasers in this dataset made only a single purchase, and only 17% of premium cigar consumers average more than 2 purchases per year. In addition, premium cigar consumers do not display great brand loyalty, preferring instead to purchase a variety of brands. This differs from what is typically assumed of consumers of tobacco products. Additionally, and unlike purchases of other tobacco products, premium cigar purchases are not spread evenly throughout the year; rather they peak before the December holidays, around Father’s Day, and in the summer.

Regarding how premium cigars are sold, the data shows that in 2017, these retailers on average had approximately 10,000 individual Stock Keeping Units (“SKUs”), reflecting the great diversity of products in the premium cigar market. Reflecting the desire for variety among premium cigar consumers, nearly a quarter of orders for premium cigars contain “sample packs,” meaning different combinations of cigars, generally created by the retailers themselves. These sample packs are sold so that premium cigar consumers can (as the name implies) sample a variety of different cigars. Further, premium cigars are most often sold in package quantities of five, 10, 20 and 25.

Overall, the purchasing and sale patterns of premium cigars show that consumers (i) are older; (ii) seek variety in their products; and (iii) purchase only occasionally, in limited quantities, and in seasonal patterns.

### **4.0 Data Sources and Methodology**

#### **Approach**

The main purpose of this report is to analyze the purchasing patterns of premium cigar consumers and demographic information relating to the communities where premium cigar consumers live. This type of

analysis requires a data set that is broad and deep enough to generate reliable results. We have combined data from multiple online retailers to create a consistent, merged master data set. The data are linked to Census data to bring in information on demographics and the geographic pattern of purchasers.

## **Cigar Retailers**

We collected transaction level data from five major online retailers: Best Cigar Prices, Cigars International, Famous Smoke Shop, JR Cigar, and Thompson Cigar. Four of the retailers provided data for 2014-2016, inclusive, and all five provided data for 2017. In addition, two retailers provided partial year data for 2018.

## **SKUs**

Each retailer provided detailed information on sales. They reported each transaction, broken down by SKU. A record consists of a SKU, the quantity ordered, the customer number, the order number, the date of the order, date of birth, and geographic information about the customer. An order that consists of three SKUs would have three rows, each with the same order number and customer number. A customer who ordered twice in one year would have two order numbers, but one customer number. Each retailer also provided information on the SKU, including brand, brand family, and other identifying information on the product.

Some retailers identified SKUs as premium brands. Some identified which cigars were “hand rolled,” which were also identified as “premium” brands.

Each retailer uses a different system for identifying SKUs, so it is not possible to match a specific SKU from one retailer to a SKU from another retailer. Said another way, a specific package of cigars from one retailer that is exactly the same as a package from another retailer will not have the same SKU and cannot be matched from one retailer to another. Brands, on the other hand, are consistent from one retailer to another, except for house or retailer-specific brands.

We note that using manufacturer’s Universal Product Codes (UPC), or barcodes, to match cigars across retailers is not feasible because of two retailer practices. First, it is common for retailers to create new package combinations, for example by packaging smaller quantities, such as one to five cigars that are otherwise identical, or the creation of “sampler” packs that combine different types of cigars, either all from the same brand or from different brands, into a new package. None of these configurations has a manufacturer’s UPC code. Second, retailers have “house” brands of cigars that only they sell. These house brands also generally do not have UPC codes.

## **Customers**

Each retailer has a unique customer identification system, which allows us to analyze multiple transactions by a single customer. The identifiers are not common across retailers. It is therefore not possible to perfectly identify customers across retailers, so a customer who purchases from two retailers would be counted as two separate customers in this dataset.



To estimate the potential overlap in customers, we used a combination of location and age. The retailers provided zip codes, in most cases nine-digit zip codes, and date of birth (DOB) for most customers.<sup>1</sup> Using customers' nine-digit zip code and date of birth, we measured how many customers with identical dates of birth shared a nine-digit zip code. Because there are relatively few people in a given nine-digit zip code compared to the number of potential birthdays, this combination is likely to be unique, or close to unique, within a nine-digit zip code. Therefore, any overlap in a nine-digit zip code/DOB combination between retailers is likely to indicate the same customer. In our analysis, approximately 4% of nine-digit zip code/DOB combinations appear in more than one retailer's sales information. This percentage indicates that there is relatively little overlap between customers in the data.

## Basic Data Facts

The retailers sell premium and non-premium cigars. In total, the data contain information on more than 12 million orders from more than 2.3 million customers. Importantly, the data illustrate the breadth and depth of the cigar industry, containing over 74,000 SKUs, and an average of approximately 15,000 unique SKUs per retailer. In 2017, over 4 million orders were made by 1.2 million unique customers.

**Table 1 - Dataset Summary Statistics, All Years and 2017**

Item	Quantity (all years)	Quantity 2017
Total Orders	12,753,862	4,062,002
Total Unique Customers	2,312,552	1,223,926
Total number of SKUs	74,339	54,554
Average Unique SKUs per retailer	14,868	10,911

## 5.0 Premium Cigars

### 5.1 Definition of "Premium" Cigar

There are many types of cigars on the market, including both premium and non-premium. Our analysis focuses on premium cigars, which means we need to identify which cigars in the data are premium. As noted above, while there is no federal definition of "premium" cigars, CTP researcher Catherine Corey, in her analysis of data relating to cigar use as reported in Wave 1 of the Population Assessment and Tobacco and Health ("PATH") study, provided guidance on classifying premium cigars that can be adopted and

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<sup>1</sup> Because nine-digit zip codes are not required by the postal service, some addresses did not include full zip codes. We used the address verification service from SmartyStreets to standardize addresses to USPS specifications, including full nine-digit zip codes.

adapted to the analysis here.<sup>2</sup> Corey developed criteria for determining what constitutes a “premium” cigar and then applied it to brands included in her analysis. The criteria used is as follows:

“In general, premium cigars, also referred to as “stogies”, consist of more expensive tobacco varieties and components, such as whole tobacco leaf wrapper and binder, and may be assembled by hand.”<sup>3</sup>

and

“...information about the brand’s tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade), obtained through online searches (conducted fall/winter 2015), was used to distinguish premium cigar brands from non-premium brands.”<sup>4</sup>

In our analysis, brands that Corey identified as premium were treated as premium, and brands she considered non-premium were treated as non-premium.<sup>5</sup> Corey’s designation of premium versus non-premium cigars nearly perfectly matches industry designations in the data from the retailers who provided such information.

For brands sold by the retailers that Corey did not identify, we followed her approach, as described in the quotes above. For example, we designated hand-rolled cigars as premium. We also conducted internet research on brand descriptions to help determine which were premium.

In total, the brands analyzed by Corey accounted for 30,667 of the SKUs sold by the retailers, leaving 43,672 SKUs to be categorized as premium or non-premium. Of the 30,667 SKUs accounted for in Corey’s research, 28,883 SKUs were from brands categorized as premium by Corey, which translates to 149 million cigars. We deemed an additional 41,022 SKUs, out of the 43,672 not addressed by Corey, as premium using the Corey definition and, where necessary, additional research. The brands Corey categorized as non-premium encompassed 1,784 SKUs in our dataset, and we identified an additional

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<sup>2</sup> “The Population Assessment of Tobacco and Health (PATH) Study is a national longitudinal study of tobacco use and how it affects the health of people in the United States. People from all over the country take part in this study.” <https://pathstudyinfo.nih.gov/UI/HomeMobile.aspx>. The PATH study has over 40,000 participants in the youth and adult cohorts.

<sup>3</sup> Corey C, et al., *U.S. 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*; Nicotine and Tob. Res. ntx209 (2017).

<sup>4</sup> Corey C, et al., *U.S. 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*; Nicotine and Tob. Res. ntx209 (2017) Supplemental Table A.

<sup>5</sup> Two brands, Marsh Wheeling and Optimo, were treated as non-premium even though Corey designated them as premium because their characteristics, including being machine-made, are more similar to non-premium cigars.

2,650 SKUs as non-premium which Corey did not comment on. While the vast majority of SKUs sold by the retailers are premium, nearly half of the cigars sold are non-premium.<sup>6</sup>

**Table 2 – Share of Cigar Market Defined by Corey, All Years**

	Number of SKUs	Number of Cigars
<b>Premium</b>		
Identified by Corey	28,883	149,195,309
Not identified by Corey	41,022	239,780,128
Total Premium	69,905	388,975,437
<b>Non-Premium</b>		
Identified by Corey	1,784	172,909,021
Not identified by Corey	2,650	178,954,944
Total Non-Premium	4,434	351,863,965
<b>Total</b>		
Identified by Corey	30,667	322,104,330
Not identified by Corey	43,672	418,735,072
<b>Total</b>	<b>74,339</b>	<b>740,839,402</b>

Once the non-premium SKUs were identified, we excluded non-premium cigar purchases from the analysis. If a transaction contained premium and non-premium SKUs, the non-premium SKUs were dropped, leaving only the premium portion of the order. As such, customers who purchased non-premium cigars exclusively are not analyzed. After accounting for non-premium cigars, our dataset has 11.2 million premium cigar orders, including 3.6 million in 2017. The dataset includes 2.1 million customers, over half of whom made a purchase in 2017. In total, 389 million cigar purchases are represented and almost 70,000 SKUs. Premium cigar purchases for all data received from 2014-2018 totaled \$1.1 billion, including \$376.6 million in 2017.

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<sup>6</sup> Corey et al. classified the brands available in the PATH study, which is a survey, and by definition the brands included would represent only a subsection of premium cigars. The brand data from the five companies includes all brands sold, which is the entire market of brands sold, but with no reference to consumer use of these brands.

**Table 3 – Summary Statistics of Premium Cigar Transactions, All Years and 2017**

<b>Premium Cigars</b>	<b>All Years</b>	<b>2017</b>
Total Premium Cigar Orders	11,196,240	3,619,014
Total Unique Premium Cigar Customers <sup>7</sup>	2,129,018	1,123,994
Total Premium Cigars Sold	388,975,437	125,314,590
Total Number of Premium Cigar SKUs	69,905	51,123
Average Premium SKUs per Retailer	13,981	10,225
Total Premium Cigar Revenue	\$1,142,980,082	\$376,556,960

## **5.2 Share of the Premium Market**

As noted, there is no regulatory or other federal government definition of a “premium” cigar and, therefore, no precise way to determine the true size of the premium cigar market. There is, however, a way to approximate the size, by volume, of the premium cigar category. Premium cigars are nearly all imported. Premium cigars are taxed according to weight, and the harmonized tariff codes are assigned to cigars by price. Therefore, analyzing tax and tariff data can approximate the volume of premium cigars sold in the United States. According to this data, as compiled by the Alcohol Tobacco Tax and Trade Bureau, in 2017, there were 351,011,000 cigars imported into the United States that fall into the two highest Harmonized Tariff Categories (HTS) for large cigars.<sup>8</sup> This number is approximate both due to the imprecise nature of using the HTS classifications for premium cigars, and because this number represents premium cigars imported into the US in 2017, not necessarily premium cigars sold in 2017. The data provided by the five online retailers indicated that they sold 125,314,590 premium cigars in 2017.

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<sup>7</sup> This number includes customers who purchases both premium cigars and non-premium cigars in the same order, and only excludes those customers who **only** purchased non-premium cigars.

<sup>8</sup> Department of the Treasury, Alcohol and Tobacco Tax and Trade Bureau, Statistical Report Tobacco, TTB-S-5210-12-2017, Mar. 5, 2018. This number is most likely artificially inflated as a reference point for premium cigars, however, as the HTS classification is based on price at import and does not discriminate based on cigar characteristics. The 351,011,000 number includes cigars included in the highest two tariff classes, but would likely not be considered premium cigars. It follows that this number can be considered only an approximation of the premium cigar market, and the actual volume of the market is lower than this number.

## 6.0 Customer Age

Retailers record the birthdate of purchasers, allowing us to calculate the purchaser's age at the date of sale.<sup>9</sup> The data indicate that premium cigar customers of the online retailers are older than the general population. The average age of a cigar customer is 55.3 years and the median age is 57 years. A full 88% were over 35 years old, with almost 55% being over 55 years at the time of purchase, and over 34% being between 35 and 54 years old; approximately 11% were under 34. This distribution skews considerably older than the country as a whole.

**Table 4 – Age of Online Premium Cigar Purchasers, 2017<sup>10</sup>**

Age Cohort	Customers	Percent	US Population	Percent
18-20	3,928	0.4%	12,774,579	5%
21-24	16,120	1.8%	17,841,890	7%
25-34	84,127	9.4%	45,342,672	18%
35-54	305,443	34.3%	83,250,322	33%
>55	480,814	54.0%	92,854,337	37%
<b>Total</b>	<b>890,432</b>	<b>100.0%</b>	<b>252,063,800</b>	<b>100%</b>
Average Age	55.3			
Median Age	57.0		38.0	

A subset of the premium cigar market includes flavored premium cigars. We analyzed the average purchaser age of flavored premium cigars and found that the average age was 52 years old and the median is 53.<sup>11</sup>

## 7.0 Purchasing Patterns

The dataset of premium cigar transactions allowed for a rich analysis of purchasing patterns. These trends include overall market trends, such as seasonal purchasing patterns and the geographic dispersion of customers, as well as how often customers order and what they order when they purchase premium cigars.

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<sup>9</sup> Retailer data provided date of birth for 83% of the orders, and the age analysis performed here is based on these numbers. We understand that the retailers all now use independent third-party age verification software, ensuring there are no underage sales even if a date of birth is not currently recorded for the customer.

<sup>10</sup> While there were 883,779 premium cigar purchasers in 2017 with age information, there were slightly more, 890,432, ages recorded. This is because a single customer could make multiple purchases in a calendar year before and after their birthdate, resulting in two age entries for that individual.

<sup>11</sup> We undertook a limited study of flavored premium cigars in order to compare the average age of flavored premium cigar purchasers to the whole universe of premium cigar purchasers. In order to identify the flavored premium cigars we started with the brands analyzed in the PATH study and did additional keyword searches in the product name for flavors including “Java”, “Vanilla”, and “Rum.”

## 7.1 Basic Results

Our dataset captured 11.2 million orders by 2.1 million unique customers, who purchased 389 million cigars. The average price per premium cigar was \$2.94, and the average number of premium cigars sold per order was 34.7.

**Table 5 – Basic Premium Cigar Purchasing Results**

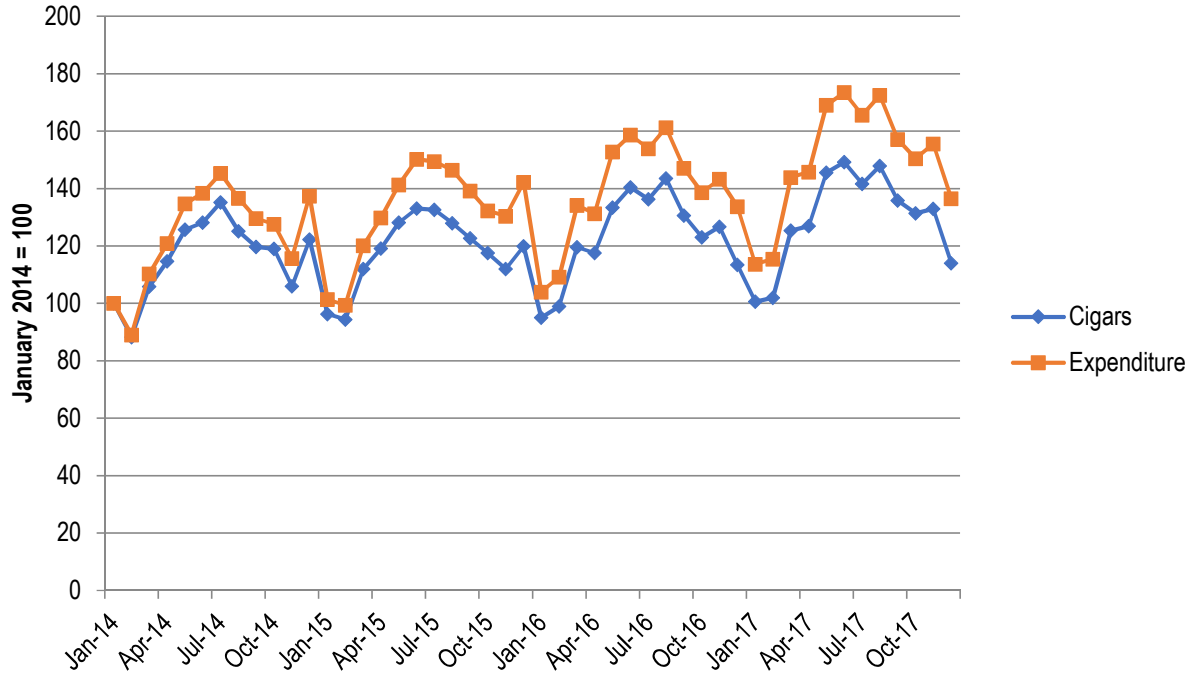
<b>Premium Cigars</b>	<b>All Years</b>	<b>2017</b>
Unique Customers	2,129,018	1,123,994
Orders	11,196,240	3,619,014
Total valid rows (Order-SKU)	18,172,016	6,146,470
Unique SKUs Sold	69,905	51,123
Number of Cigars Sold	388,975,437	125,314,590
Average Number of Cigars per Order	34.7	34.6
	18,172,016	
Avg Price per Cigar	\$2.94	\$3.00
Avg Amount Spend per Order-SKU Purchase	\$62.90	\$61.26

## 7.2 Market Purchasing Patterns

### Seasonality

Cigar purchases exhibit significant seasonality. Cigar purchases are lowest in January and February, increase through the spring as Father's Day approaches, and peak in the summer before declining throughout the fall. The only exception to this pattern is a sales surge in November/December in advance of the holiday season. In the peak month, the number of cigars purchased is between 41% and 53% greater than in the month of lowest purchases.

**Figure 1 - Cigar Units and Expenditures by Month, 2014-2017**



**Table 6 – Seasonality of the Number of Cigars Purchased**

Year	Peak month	Lowest Month	Ratio
2014	135.15	88.25	1.53
2015	132.99	94.42	1.41
2016	143.47	95.02	1.51
2017	149.17	100.60	1.48

### 7.3 Frequency

The data cover four full years (2014-2017) of sales for four of the retailers. We examined repeat purchasing patterns over these four years by summing how many times each customer placed an order in that period. A customer who ordered eight times would have eight order numbers in the data assigned to a single customer number. We also measured the number of cigars that each customer purchased. For this analysis we considered only customers who placed orders 240 or fewer times over the four year

period, or approximately once per week.<sup>12</sup> More frequent purchasers were viewed as more likely to be retail stores or other reseller restocking as opposed to end purchasers buying cigars.

For the four retailers over the four years, there were 1,469,334 unique customers and 304,119,528 cigars purchased. Approximately 44% (648,824 out of 1,469,334) customers purchased only once, and accounted for 5% of the cigars ordered. A significant majority of customers, 86 %, ordered 10 or fewer times, but account for only 29% of cigars. In contrast, the 14 % of customers who ordered at least 11 times account for 71% of cigars purchased.

**Table 7 – Frequency of Premium Cigar Purchases, All Years**

Number of Orders (2014-2017)	Number of Customers	% of Total Customers	Total Cigars Purchased	% of Total Cigars Purchased
1	648,824	44%	14,774,926	5%
2	216,525	15%	11,321,694	4%
3	119,620	8%	9,931,874	3%
4	79,295	5%	9,180,555	3%
5	56,932	4%	8,456,268	3%
6	43,265	3%	7,908,170	3%
7	34,254	2%	7,480,944	2%
8	27,676	2%	6,979,435	2%
9	22,844	2%	6,662,368	2%
10	19,304	1%	6,466,243	2%
Sub-Total – 10 or fewer orders	1,268,539	86%	89,162,477	29%
Tri-Monthly (11-20)	101,427	7%	52,468,590	17%
Bi-Monthly (21-36)	56,717	4%	61,263,292	20%
Monthly (37-60)	28,253	2%	54,970,487	18%
Bi-Weekly (61-120)	13,128	1%	39,736,035	13%
Weekly (121-240)	1,270	0%	6,518,647	2%
Sub-Total – 11-240 orders	200,795	14%	214,957,051	71%
<b>Total 1-240 orders</b>	<b>1,469,334</b>	<b>100%</b>	<b>304,119,528</b>	<b>100%</b>

We also analyzed the average order size based on frequency. In general, the more frequently a customer orders cigars, the more cigars, *per order*, the customer purchases. For example, customers who ordered only once in the data purchased 23 cigars on average. Customers who ordered ten times in the data ordered 33 cigars per order on average. The maximum average order size is for customers who purchase

<sup>12</sup> Customers who ordered more than 240 times over the period represent less than 1% of the customers and purchased 1.14% of the total cigars sold.



monthly, and customers who ordered bi-weekly or more frequently ordered fewer cigars, per order, than the monthly purchasers.

**Table 8 – Average Number of Premium Cigars Ordered and Order Amount by Order Frequency, All Years**

<b>Number of Orders (2014-2017)</b>	<b>Average Cigars per Order</b>	<b>Average Spending per Order</b>
1	23	\$75.42
2	26	\$85.27
3	28	\$89.47
4	29	\$92.62
5	30	\$94.16
6	30	\$96.22
7	31	\$97.44
8	32	\$99.15
9	32	\$100.00
10	33	\$101.17
Tri-Monthly (11-20)	35	\$105.08
Bi-Monthly (21-36)	40	\$111.43
Monthly (37-60)	42	\$116.39
Bi-Weekly (61-120)	39	\$108.95
Weekly (121-240)	34	\$98.63

### **Most Frequent Purchasers**

Approximately 1.1% of cigars were purchased by customers who placed more than 240 orders over four years. Forty-one customers placed a total of 12,144 orders in the period, or an average of 74 orders per customer per year.<sup>13</sup> The average number of cigars per order is 31.9 and the average amount spent per order is \$94.85. The average age of these purchasers is 60.9, and the median age is 60.0.

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<sup>13</sup> Five customer IDs were dropped from this analysis. Two IDs, “NA” and “00000” appear to include incomplete data entries and do not reflect actual customers. The remaining three IDs place orders with dramatically higher frequency and are removed as outliers. These IDs placed over 3,000 orders over the four years. These five IDs account for 1.02% of the total cigar purchases captured in this dataset.

## 7.4 Product Quantity

We have analyzed the product quantity of the cigars purchased. There are three main methods by which these retailers sell premium cigars: as single cigars, as sample packs, and as boxes.<sup>14</sup>

### Samplers

A sampler is a single SKU that contains more than one type of cigar, and in their product descriptions the retailers identified those SKUs that are samplers. Approximately 25% of orders include at least one sampler SKU. Samplers are a smaller portion of the overall sales, as approximately 13% of premium cigars sold are in samplers, and the other 87% are non-sampler cigars.

**Table 9 – Sampler and All Other Orders, All Years and 2017**

<b>Type</b>	<b>All Years</b>		<b>2017</b>	
	<b>Number</b>	<b>Percent</b>	<b>Number</b>	<b>Percent</b>
Orders Including Samplers	2,775,109	25%	816,016	23%
Orders Not Including Samplers	8,421,131	75%	2,802,998	77%
<b>Total</b>	<b>11,196,240</b>	<b>100%</b>	<b>3,619,014</b>	<b>100%</b>

**Table 10 – Premium Cigars Sold in Samplers, All Years and 2017**

<b>Type</b>	<b>All Years</b>		<b>2017</b>	
	<b>Number</b>	<b>Percent</b>	<b>Number</b>	<b>Percent</b>
Cigars Sold In Samplers	50,424,486	13%	16,043,731	13%
Cigars Not Sold In Samplers	338,550,951	87%	109,270,859	87%
<b>Total</b>	<b>388,975,437</b>	<b>100%</b>	<b>125,314,590</b>	<b>100%</b>

### Single Cigars or Boxes

We analyzed the sales with respect to product quantity. Cigars are often thought of as coming in “boxes” of 20 or 25, though box sizes vary widely. For our purposes, a single cigar is a SKU with a single cigar, and multi-pack is a SKU with a quantity of 2 - 4 cigars, and a box is a SKU of 5 or more cigars.

Most orders are focused on boxes as opposed to individual cigars or multi-packs. More than 90% of orders consist only of boxes, as we have defined them. Relatively few orders contain single cigars or multi-packs.<sup>15</sup>

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<sup>14</sup> In this report “box” will refer to any product quantity above 5 cigars. A “multipack” refers to packages of 2-4 cigars.

**Table 11 – Orders by Mix of Individual Cigars and Boxes, All Years**

	# Orders	% Orders of Total	# Cigars	% Cigars of Total
Single Cigar Only	130,275	1.2%	766,671	0.2%
Multit-Packs and Single Cigar Only	82,545	0.7%	519,107	0.1%
One Box Only, No Single or Multi	7,416,110	66.2%	211,836,839	54.5%
Multiple Boxes, No Single or Multi	3,193,946	28.5%	157,932,618	40.6%
Mix of 1+ Boxes and 1+ Single or Multi	373,364	3.3%	17,920,202	4.6%
<b>Total</b>	<b>11,196,240</b>	<b>100%</b>	<b>388,975,437</b>	<b>100%</b>

**Table 12 – Order Characteristics by Box Size, All Years**

Box Size	Number of Boxes Ordered	Total Number of Cigars	Number of Sampler Cigars	Sampler Cigars as % of Box Size	Total Spent	Avg Price per Box	Avg Price per Cigar
5	6,372,667	31,863,335	5,286,950	16.6%	\$141,537,070	\$22.21	\$4.44
6-9	783,321	5,673,414	2,904,611	51.2%	\$23,700,473	\$30.26	\$4.18
10	2,482,261	24,822,610	6,651,520	26.8%	\$108,548,916	\$43.73	\$4.37
11-19	1,491,336	21,339,045	8,395,120	39.3%	\$75,593,806	\$50.69	\$3.54
20	5,950,477	119,009,540	8,975,660	7.5%	\$321,021,901	\$53.95	\$2.70
21-24	601,098	14,135,911	1,529,362	10.8%	\$75,255,014	\$125.20	\$5.32
25	2,301,634	57,540,850	668,725	1.2%	\$201,609,329	\$87.59	\$3.50

## 7.5 Brand Variety

We investigated the variety of brands purchased by customers by summing the total number of brands an individual customer purchased. For all customers, more than 60% purchase one or two brands. However, this statistic disguises the behavior of more frequent cigar purchasers. For customers who order at least twice, approximately 36% order one or two brands. For customers who order at least 10 times, only 13% order one or two brands. As indicated in Figure 2, the more frequently a customer purchases, the more brands the customer purchases in total. Put another way, frequent customers purchase a variety of cigars, more so than less frequent customers.

<sup>15</sup> The most popular product quantity configurations, based on number boxes ordered, are (i) a five cigar “box,” (ii) a twenty cigar box, (iii) a 10 cigar “box,” and (iv) a twenty-five cigar “box.” We understand that many of the five and ten cigar configurations contained in the data are actually “packs” of five or ten that generally have been created by the retailers from the original boxes of 20 or 25. For ease of analysis we have included these “packs” in the “box” category.

The majority of the time, sampler packs are created by the retailer and listed in our dataset under a single SKU. As such, they are considered one “brand” in this chart, even though the SKU contains multiple brands of premium cigars.

**Figure 2 – Number of Brands Ordered by Order Frequency**



## 8.0 Geocoding and Geographic Information

### 8.1 Geographic Data from Retailers

The retailers provided geographic information on the shipping address for each order. The type of information provided varied by retailer. Some retailers provided a mailing address, while others disclosed the nine-digit zip code associated with the order.

Where address data was available, the addresses were geocoded to give the precise longitude and latitude (XY coordinates) of the location. In order to geocode the data, we tested a sample set of addresses using two geocoding services, and observed the accuracy scores of each.

There are many providers that offer geocoding services. To find the best service for our analysis, we selected two providers, Geocodio and Texas A&M GeoServices (an affiliate of Texas A&M University Department of Geography), to geocode sample datasets. When the sample data set was analyzed, Geocodio located 93% of the addresses with an accuracy score above 90%, whereas Texas A&M GeoServices matched 86% of addresses with an accuracy score above 90%. On the basis of this analysis, we used Geocodio to geocode all the addresses in our dataset, of which 90% were geolocated with an accuracy score above 90%.

In instances where nine-digit zip code data was provided, we matched zip codes to geographic coordinates using a database purchased from GreatData.com.<sup>16</sup> With this database, we were able to assign coordinates to the provided nine-digit zip codes.

The full data set of all premium cigar purchases includes 2,234,584 customer addresses and nine-digit zip codes, which includes instances where multiple addresses and/or nine-digit zip codes are associated with a single customer ID. Of these, 85% are valid addresses or nine-digit zip codes, and 95% of the valid addresses or nine-digit zip codes were successfully geocoded to a Census Tract.

**Table 13 –Premium Cigar Customers Successfully Matched to Census Tracts**

Total Addresses or 9-Digit Zip Codes Associated with Premium Purchases	2,234,584
Valid Addresses or 9-Digit Zip Codes	1,899,527
Valid Addresses or 9-Digit Zip Codes as Percent of Total	85%
Addresses or 9-Digit Zip Codes Geocoded to a Census Tract	1,796,341
Percent of Valid Addresses or 9-Digit Zip Codes Geocoded	95%

## Linking to Community Data

We used the geographic data provided by the retailers to understand the geographic distribution of cigar purchasers and to identify the community characteristics of the Census Tract of the purchaser. This geographic information provides insight into the distribution of cigar purchasers throughout the country, including the weighting of purchasers by state and in rural or urban areas. Further, by geocoding the addresses, we were able to identify the Census Tract of the purchaser. With the Census Tract, we were able to link a purchaser to community data, such as median household income and education.

With the geographic coordinates of consumers, we were able to identify the Census Tract of the location, providing demographic information from the US Census about the socioeconomic status of their community.

## 8.2 Geography

Cigar purchases are correlated with geography as well. More urbanized states have more cigar purchasers, relative to population, than more rural states. Figure 3 plots penetration of cigar purchasers against the urban population. Each dot is a state. States in which most of the population lives in urban

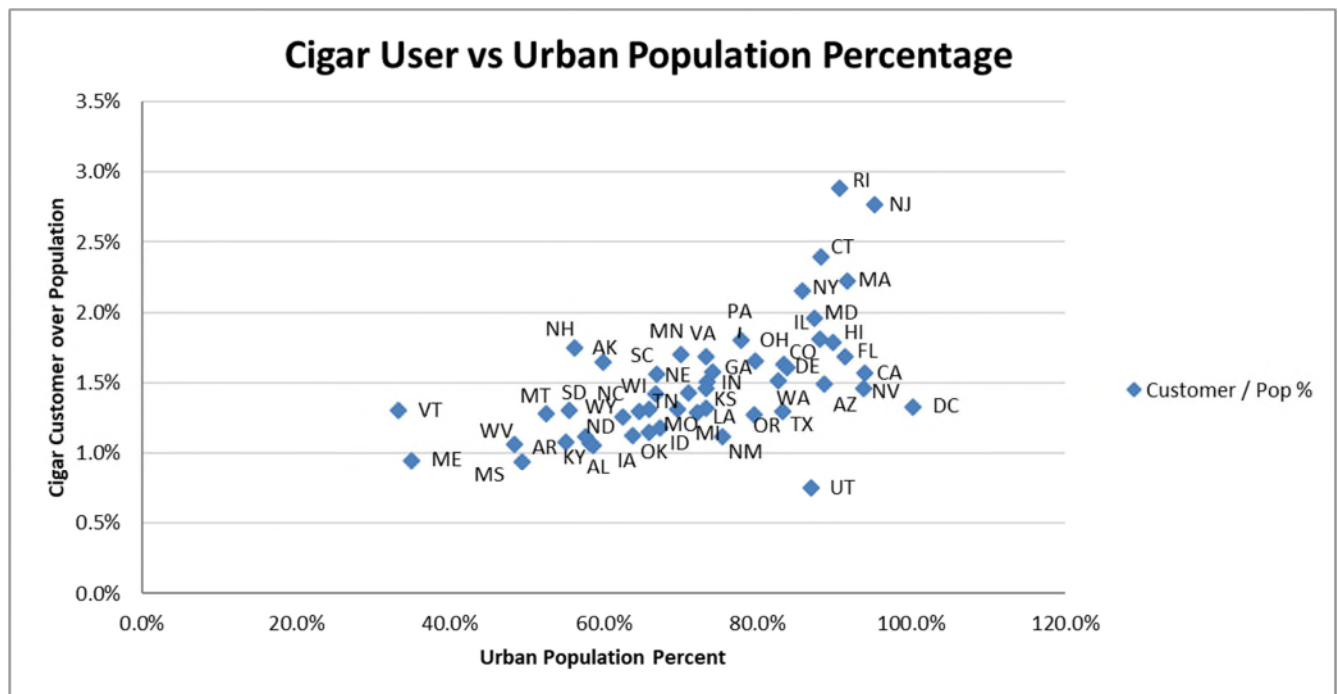
<sup>16</sup> GreatData.com uses the latest United States Postal Service database to match nine-digit zip codes to their latitude and longitude coordinates. A nine-digit zip code usually refers to a segment of one side of a street and can contain multiple addresses, but it can also be assigned to a single building or cluster of buildings. As such, they cannot be used to find an exact location, but they do provide a good approximation of an address's location.

<https://greatdata.com/product/51/zip4-geo>

areas, as defined by the Census, are on the right side of the figure, and more rural states are on the left side of the figure. States with many cigar purchasers relative to population are on the top of the figure, and states with few purchasers relative to population are lower on the figure. For example, Washington DC is 100% urban, so it is on the far right side of the figure.<sup>17</sup>

The dots in the figure generally slope up, which means that the more urban states, in general, have higher percentages of cigar purchasers than states that are less urban. The one obvious outlier is Utah, which is nearly 90% urban but has relatively few cigar purchasers. The skew towards urban sales is somewhat unexpected, given the fact that urban customers have access to competing bricks and mortar cigar retailers. However, as is seen in the next section, premium cigar purchasers tend to live in higher income communities, which also skew urban.

**Figure 3 – Percent of Population Purchasing Premium Cigars by State’s Urban Population**



<sup>17</sup> The customer list includes all customers. There may be some overlap, as an individual who orders from multiple retailers will be included in the calculation twice. Because this overlap can occur in any state, and is relatively minor to begin with, the overall pattern will be the same had it been possible to de-duplicate the customer list. As discussed above in Section 4, there is only an approximate 4% overlap of customers between the retailers.

### 8.3 Demographics

Retailers do not collect personal data about customers, preventing us from commenting directly on characteristics of purchasers beyond age and geographic location. By identifying the Census Tract in which a consumer resides, however, we can analyze the community they live in. By design, Census Tracts contain a small number of people, with an optimum population of 4,000.<sup>18</sup> As such, Census Tracts serve as a useful measure of the characteristics of premium cigar purchasers. In this section we look at the median income and education attainment in the Census Tracts of premium cigar purchasers.

### 8.4 Income

Overall, the Census Tracts of premium cigar purchasers have higher incomes than the general population. The median household income in the Census Tracts of premium cigar purchasers is \$65,573. By comparison, nationally, median household income is \$57,617. Over 15% of customers live in tracts with median household income above \$100,000, whereas 10% of households nationally are in that bracket.

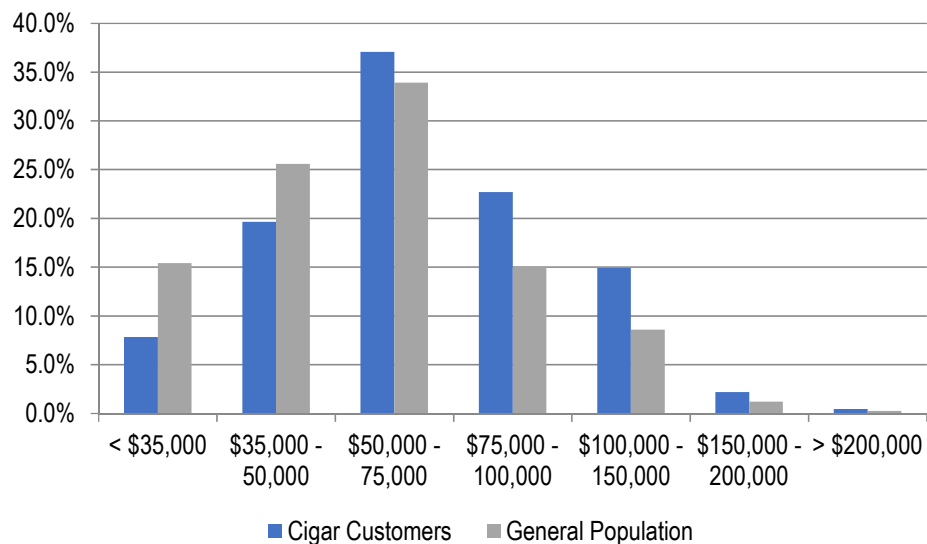
**Table 14 – Median Household Income of the Census Tract of Premium Cigar Purchasers**

Income Category	# Customers	Percentage	Total Population in these CT	% of US Pop Census Tracts
< 35,000	140,443	7.8%	38,154,387	15.4%
35,000 - 50,000	352,466	19.6%	63,370,525	25.6%
50,000 - 75,000	665,660	37.1%	83,951,957	33.9%
75,000 - 100,000	407,767	22.7%	37,317,707	15.1%
100,000 - 150,000	267,903	14.9%	21,300,987	8.6%
150,000 - 200,000	39,382	2.2%	2,993,843	1.2%
> 200,000	7,832	0.4%	618,297	0.2%
Median HH Income	\$65,573			
Mean HH Income	\$71,633			
US Median HH Income	\$57,617			

*Source: US Census Bureau, American Community Survey 2016 5-year Estimates*

<sup>18</sup> US Census Bureau, 2010 Geographic Terms and Concepts, [https://www.census.gov/geo/reference/gtc/gtc\\_ct.html](https://www.census.gov/geo/reference/gtc/gtc_ct.html)

**Figure 4 –Distribution of Median Income of the Census Tracts of Premium Cigar Purchasers and the US Population**



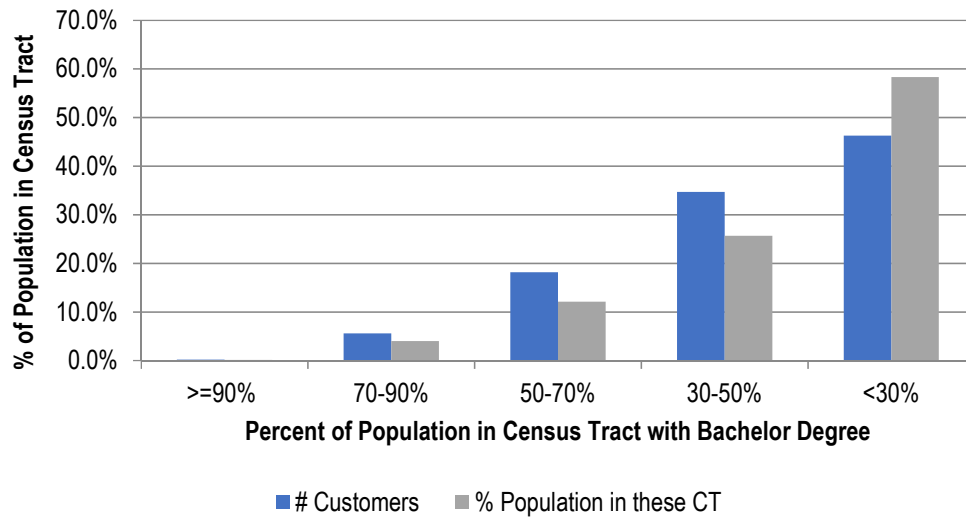
*Source: US Census Bureau, American Community Survey 2016 5-year Estimates*

## **8.5 Education**

Premium cigar purchasers live in more educated Census Tracts than the general population. Nearly 60% of the general population lives in Census Tracts where less than 30% of the population has a bachelor degree. In contrast, approximately 45% of premium cigar purchasers live in similar tracts. Over 20% of premium cigar purchasers live in tracts where over 50% of the population has a bachelor degree, compared to approximately 15% of the general population.



**Figure 5 - Percent of Population 25 and Above with a Bachelor Degree, Census Tracts of Premium Cigar Purchasers and the US Population**



*Source: US Census Bureau, American Community Survey 2016 5-year Estimates*

## 9.0 Conclusion

The data from these five retailers show consistent trends and data about both premium cigar purchasers themselves, and their purchasing patterns.

- First, premium cigar purchasers are an older population, with an average age of 55 and a median age of 57.
- Second, premium cigar purchasers reside in areas with higher levels of education and higher incomes than the rest of the US population.
- Third, premium cigar purchasers are, for the most part, infrequent purchasers of premium cigars. Only 17% of purchasers place more than, on average, two orders per year.
- Fourth, premium cigar purchasers reliably purchase orders containing sample packs or five packs of cigars.
- Fifth, repeat purchasers of premium cigars show little brand loyalty.
- Sixth, premium cigars purchases spike at certain times of the year, rather than being spread evenly over the year.
- Finally, the premium cigar market has incredible diversity, with a current average of approximately 10,000 SKUs per retailer.

Overall, premium cigar purchasers are older, live in communities that are wealthier and better educated than the average population, and are not purchasing premium cigars on a regular and consistent basis.

## Appendix A



## Richard P. Voith, Ph.D.

### President and Principal

Dr. Voith is a well-known expert in real estate economics, transportation, and applied microeconomics. As president and founding principal of Econsult Solutions, Dr. Richard Voith oversees a wide variety of projects in the realm of housing, labor markets, transportation, and economic development. Just as importantly, Dr. Voith is involved in setting the strategic direction of organizations both large and small. Also, he regularly provides analysis and testimony in support of litigation in real estate and transportation matters.

## Areas of Expertise

Real Estate Economics

Transportation

Applied  
Microeconomics

Funding for Transit  
Systems

Energy

Metropolitan  
Development

## Experience

Prior to joining Econsult Solutions, Dr. Voith held the position of Economic Advisor at the Federal Reserve Bank of Philadelphia.

Dr. Voith has worked frequently in the public policy arena. In 2013, he was a principal author of *Understanding SEPTA's Statewide Economic Value* which demonstrated the importance of transportation investment for the state. In 2006, Dr. Voith was appointed by Governor Rendell to the newly created Transportation Funding and Reform Commission charged with recommending appropriate levels of funding for transit systems, roads and bridges. Dr. Voith is also a member of the SEPTA Board of Directors, serving as Vice Chairman of SEPTA from 1996 to 1998.

## Professional, Corporate, Civic Leadership

Dr. Voith is a founding board member of Pentrans, an organization dedicated to balanced, multimodal transportation and mobility alternatives in Pennsylvania. Dr. Voith is active in Philadelphia area organizations, including Philadelphia Youth Basketball, an organization which is focused on the holistic development of Philadelphia youth.

## Additional Experience

Dr. Voith has taught *Cost Benefit Analysis* at the Wharton School's Business and Public Policy Department, and *Urban Real Estate Economics* through the Wharton's Real Estate Department. Dr. Voith continues as a Faculty Fellow at the University of Pennsylvania's Institute for Urban Research.

Over the last 15 years, Dr. Voith has served on several National Academy of Science Foundation Advisory Panels addressing topics such as the interrelationships between highway and transit investment and land use, valuing the costs and benefits of transit investments, and the relationships between land use and public health. He has been a guest speaker at numerous forums, including those sponsored by the Lincoln Land Institute, the Brookings Institution, Urban Land Institute, and the Department of Housing and Urban Development. Until 2007, Dr. Voith served on the editorial board of Real Estate Economics.

## Education

PhD in Economics  
University of  
Pennsylvania

MS in Energy  
Management and  
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BS in Economics  
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## Appendix B

**Peter A. Angelides, Ph.D., AICP****Principal**

Dr. Peter Angelides is principal of Econsult Solutions, Inc. (ESI) and a member of the teaching faculty at the University of Pennsylvania. Dr. Angelides has high-level expertise in both economics and city planning, applying critical economic thinking to projects in real estate, economic development, transportation, tax policy, valuation and litigation. He assists clients in many industries, including real estate development, transportation, local and regional government, affordable housing, gaming, utilities, health care, and insurance.

**Areas of Expertise**

Real Estate

Transportation

Economic  
Development

Tax Policy

Gaming

Litigation

**Experience**

When he joined ESI, Dr. Angelides brought a wealth of experience in both economics and planning. Prior to joining ESI, he practiced economics in the private sector having worked for large and small firms including:

- Econsult Corporation, Vice President and Director;
- PricewaterhouseCoopers, Philadelphia PA, Director;
- Charles River Associates, Washington, DC, Economist;
- Putnam Hayes & Bartlett, Washington, DC, Economist.

In these roles he evaluated market competitiveness in merger and rate-setting proceedings before several federal regulatory agencies, estimated the economic impacts from private investment, set prices for intellectual property, evaluated the impact of technology licensing agreements and calculated damages in numerous commercial disputes.

Dr. Angelides practiced planning in the public and private sectors having worked for:

- Wallace Roberts and Todd;
- The Central Philadelphia Development Corporation;
- Philadelphia City Planning Commission.

**Professional, Corporate, Civic Leadership**

Dr. Angelides serves as a board member or in other contributing roles for several civic and professional organizations, including:

- Design Advocacy Group;
- Philadelphia Historic Preservation Task Force;
- PenTrans;
- Urban Land Institute;
- The Transportation Research Board;
- American Institute of Certified Planners (AICP);
- Racquet Club of Philadelphia.

**Additional Experience**

Dr. Angelides teaches courses in the areas of urban economics, public finance, and infrastructure investment at the University of Pennsylvania in both the Department of City and Regional Planning, and at the Fels Institute of Government.

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Cigar Association of America, Inc.  
Comment to Docket No. FDA-2017-N-6107  
Regulation of Premium Cigars

**EXHIBIT C**

July 24, 2018

## **Premium Cigars:**

### **What is known about patterns of use and about health effects?**

Geoffrey Kabat, Ph.D. M.S.<sup>1</sup>

#### **Introduction**

On March 26, 2018, the Food and Drug Administration (“FDA”) issued an Advance Notice of Proposed Rulemaking (“ANPRM”) regarding the regulatory status of premium cigars. In the ANPRM, FDA requested data regarding the “use patterns of premium cigars” and data and information regarding “public health considerations associated with premium cigars.” (83 Fed. Reg. at 12,903).

The purpose of this review is two-fold: (i) to describe what is known about prevalence of use of premium cigars, and (ii) to describe what is known about the health effects of cigar smoking generally and, particularly, of premium cigars.

#### **Prevalence of Use of Premium Cigars**

Little work has been done to specifically study users of premium cigars. There are, however, three recent studies analyzing recent tobacco usage data that contain relevant information regarding premium cigar usage prevalence (1-3). These three studies are analyzed below.

The most recent data analyzing use patterns of tobacco products is the Population Assessment of Tobacco and Health (PATH) study, a national longitudinal study of tobacco use and health. Started in 2013, the PATH study is the first large research effort undertaken by the National Institutes of Health and the Food and Drug Administration. As such, it uses data acquired by the government.

Kasza, Ambrose, Conway et al. looked at Wave 1 of the PATH study to examine tobacco product use by youth and young adults (1). While “premium cigar” itself was not defined in the PATH dataset, the survey collected data and information regarding “traditional cigars.” “Traditional cigars” were defined as “contain[ing] tightly rolled tobacco that is wrapped in a tobacco leaf. Some common brands of cigars include Macanudo, Romeo y Julieta and Arturo Fuente, but there are many others.” All of the brands specified are premium cigars. Thus, the “traditional cigar” category in this survey has a large degree of overlap with premium cigars. **This**

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<sup>1</sup> My CV is attached as Exhibit A.

**study showed that only 0.4% of the adult population used traditional cigars “frequently”** (Supp. Table S4). “Frequent use” was defined as “at least 20 of the past 30 days.” For youth, no frequent use of traditional cigars could be reliably reported (Supp. Table S4). This indicates that youth are not using premium cigars.

One of the first studies to report data on usage of premium cigars in particular was the National Adult Tobacco Survey (NATS) in 2012-2013 (2). In this study, premium cigar smokers were defined as “those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder or wrapper” (2). Among usual premium cigar smokers, 3.3% reported “every day” use, 25.6% reported “some day” use, and 71.2% reported “rarely.” **This means that 96.7% of premium cigar smokers smoke premium cigars on less than a daily basis.** Regarding dual use of cigars with cigarettes, 75.2% of little filtered cigar smokers also smoked cigarettes, 58.3% of usual cigarillo/mass market cigar smokers also smoked cigarettes, whereas only 35.1% of premium cigar smokers also smoked cigarettes. Overall, premium cigar smokers were much less likely to smoke cigarettes compared to smokers of other types of cigars. Finally, it is clear that premium cigar smokers are older -- only 15.1% of cigar smokers aged 18 to 29 years old smoked premium cigars.

Corey, Holder-Hayes, Nyugen, et al. (3) also presented information from Wave I of the PATH study on smoking patterns among adult current established smokers of different cigar types and cigarettes. In addition to cigarillos and filtered cigars, “traditional cigars” were divided into “premium” and non-premium” cigars. Since there are no regulatory definitions of premium cigars, the authors used information about the brand’s tobacco blends, components (e.g., long filler, whole leaf wrapper), and manufacturing process (e.g., handmade) to identify premium cigars. Premium cigar smokers were substantially older at first regular use of a tobacco product than other smokers (24.5 years compared to 16.6 -19.5 years for cigarettes, cigarillos and non-premium cigars). **Overall, 0.7% of adults smoked premium cigars.** Although smokers of premium cigars had comparable lifetime consumption compared to smokers of other tobacco products (Table 2), they differed markedly from smokers of other products on four important smoking parameters: (i) whether they smoked every day, (ii) median number of days smoked in the past 30 days, (iii) number of cigars smoked per day, and (iv) whether they currently smoked cigarettes. These differences were all in the direction of lower consumption. For example, **only 6.7% of premium cigar smokers reported smoking every day**, compared to 25.3% of non-premium cigar smokers, 22.0% of cigarillo smokers, 37.3% of filtered cigar smokers, and 79.5% of cigarette smokers. **The median number of days smoked in the past 30 days was 1.7 among premium cigar smokers**, 9.2 among non-premium cigar smokers, 7.5 among cigarillo smokers, 14.0 among filtered cigar smokers, and 29.4 among cigarette smokers. **The median number of premium cigars smoked per day was 0.1**, compared to 0.4 for non-premium cigars, 0.3 for cigarillos, 1.6 for filtered cigars, and 10.0 cigarettes per day for cigarette smokers. **Dual use of cigarettes was markedly lower among**



### **premium cigar smokers compared to smokers of other types of cigars and other non-cigarette tobacco products (Table 4).**

The three papers that present prevalence data on the use of premium cigars are consistent in indicating that:

- there is no measurable use of premium cigars by youth;
- users of premium cigars tend to be older at first regular use;
- the overwhelming majority of premium cigar smokers do so on a non-daily basis -- 93.3% according to PATH, and 96.7% according to NATS;
- frequency of use is extremely low – the median number of days smoked in past 30 days is 1.7, and the median amount smoked is 0.1 cigars per day.

### **Association of cigar smoking with disease mortality and incidence.**

Four studies since 2014 have examined the association of cigar use with health outcomes (4-7). These studies differ in the level of detail regarding smoking behavior. For example, none of these studies differentiate between types of cigars. Further, most studies do not provide information regarding specific frequency of cigar smoking, or the amount smoked per day on days smoked. Three of the studies examined the association of cigar use and mortality (4-6), and one examined the association of cigar use with cancer incidence (7).

Christensen et al. (4) is the most probative of this group of studies due to its examination of cigar only users, and its division of this population into non-daily and daily smokers. Christensen et al. used data from the National Longitudinal Mortality Study to examine the mortality risk associated with cigarette, cigar, and pipe smoking among 357,420 participants who reported exclusively using cigars, pipes, or cigarettes or reported never using any type of tobacco product. Participants provided tobacco use information at baseline in surveys beginning in 1985 and were followed for mortality through the end of 2011. A total of 51,150 deaths were recorded during follow-up. **Among non-daily cigar users there were no increased risks for mortality from tobacco-related cancers (tobacco related cancers HR 1.08, 95% CI 0.45-2.61) and there was no increased risk for lung cancer (HR 0.74, 95% CI 0.08-7.26). Further, for non-daily cigar smoking, no increased health risks were reported for oral cancer, cerebrovascular disease, respiratory or COPD. Additionally, no deaths were reported for any cigar smoking, daily or non-daily, for oral cancer (Table 3).** Compared to never users of tobacco, exclusive, daily cigar smokers as a group had higher total mortality (HR 1.20, 95% CI 1.03-1.38) and higher mortality from tobacco-related cancers (including oral cavity, esophagus, larynx, lung, bladder, and pancreas). Among daily cigar users, mortality risks (hazard ratios [HR]) from tobacco-related cancer (HR 1.80, 95% CI 1.20-2.69), lung cancer (HR 4.18, 95% CI 2.34-7.46), and COPD (HR 3.29, 95% CI 1.33-8.17) were elevated and statistically significant (Table 3).

As mentioned, limitations of this study include: lack of detailed information on specific frequency of cigar use (only daily/non-daily and exclusive/non-exclusive), no information on amount smoked per day, no inhalation information, and the fact that the type of cigar smoked was not distinguished. The age range of the study population was 35-80. The main strength of this study is that it provides information on the mortality risk associated with both daily and non-daily exclusive cigar smoking. As nearly all premium cigar smokers are non-daily smokers, this study is of particular relevance.

Chang et al. (5) conducted a systematic review of studies of cigar smoking and all-cause and smoking-related mortality. They included 22 studies from prospective cohorts. These cohort studies were initiated in the twentieth century, when smoking habits were very different from what they are today. The study populations included in this systematic review were mainly white middle-aged men in North America and Europe who smoked cigars in the 1960s or earlier. At that time, the predominant cigar type studied was the “large cigar,” whereas today the U.S. cigar market consists of products manufactured with various shapes, sizes, tips, filters and packaging. The focus was on current cigar smoking at baseline. “Primary cigar” smokers (i.e., current exclusive cigar smokers with no previous history of cigarette or pipe smoking) were distinguished from “secondary cigar” smokers (i.e., current exclusive cigar smokers with a previous history of cigarette or pipe smoking).

Although the systematic review included data from 22 studies, only two studies provided information on mortality risks by amount smoked and by inhalation. In the Dorn study, the lowest level of cigar use listed was less than five cigars per day. At this level of cigar smoking, there was no suggestion of increased risk of all-cause mortality 1.04 (95% CI 0.98-1.11) (Table 3). In CPS-I, the lowest level of cigar smoking was 1-2 cigars per day. The hazard ratio for this category was 1.02 (95% CI 0.97- 1.07), again showing no increased risk. The CPS-1 study also presented data on risk estimates for inhalation levels in relation to all-cause mortality in primary cigar smokers. For the “no inhalation” category among daily primary cigar smokers, the risk estimate was 1.04 (95% CI 1.00-1.08) suggesting little increased risk. While these two studies did report on mortality risks by amount smoked and by inhalation, they did not present any data for cigar smokers smoking less than one cigar per day. The other 20 studies similarly did not provide this data.

A large number of results are reported in this paper for the different studies, the different outcomes, and exclusive cigar smoking versus non-exclusive cigar smoking. Owing to different categories of exposure reported in the 22 studies, it was not possible to perform a meta-analysis by level of exposure, which would have provided more precise estimates of the risk associated with different usage patterns. As noted above, the review did not present any results regarding “occasional” or “rare” cigar smoking, or smoking less than one cigar per day.

Nonnemaker et al. (6) estimated mortality from regular cigar use, using data from that National Adult Tobacco Survey, relative risks from the American Cancer Society's Cancer Prevention Studies I and II, and annual U.S. deaths from the National Vital Statistics System. They estimated that regular cigar smoking was responsible for approximately 9,000 premature deaths among U.S. adults aged 35 years or older in 2010. The goal of this analysis was to estimate the impact of cigar smoking on mortality and economic costs (years of potential life lost, etc.). The main analysis focused on current cigar smokers who reported smoking cigars on at least 15 of the past 30 days. The rationale for using this figure given by Nonnemaker et al. is that this is the level of smoking that corresponds to the RRs [relative risks] used in their analysis. Importantly, however, no breakdowns were provided by type of cigar or specific frequency of use, and the threshold used by the authors – smoking cigars on at least 15 of the past 30 days -- is not applicable to use of premium cigars, since, as noted above, premium cigar smokers are overwhelmingly non-daily smokers; in the PATH study, premium cigar smokers smoked on average 1.7 days out of 30. **Thus, the mortality estimates derived in the Nonnemaker et al. paper are not pertinent to the use of premium cigars.**

In addition to the three mortality studies described above, Malhotra et al. (7) carried out a pooled analysis of five cohort studies (one from the Netherlands, one from Australia, and three from the U.S.) to examine the association of exclusive cigar use and predominant lifetime cigar use with risk of smoking-related cancers. Participants enrolled in the five cohort studies were in their late fifties and early sixties. "Ever cigar smokers only" (i.e., smoked cigars currently or in the past, but not cigarettes) had increased risks for all smoking-related cancer (HR 1.47, 95% CI 1.34-1.61), head and neck cancer (HR 1.40, 95% CI 0.98-2.00), and lung cancer (2.73, 95% CI 2.06-3.60), as well as for all cancers (HR 1.07, 95% CI 1.02-1.16). Both exclusive and predominant cigar smokers had increased risks of head and neck cancer, lung cancer, gastric cancer, and kidney cancer, as well as all cancers. These results as reported, however, cannot – for several reasons -- be applied to premium cigars. First, none of the five underlying studies had data on frequency of cigar smoking, therefore the pooled analysis could not present data stratified by frequency of cigar smoking. Second, this analysis does not include any information on the type of cigar smoked. Third, it does not provide any data on the number of cigars smoked per day. Fourth, it provides no age breakdown of the subjects, including age at initiation and (if applicable) cessation. Given these limitations, the Malhotra et al. paper is of questionable use in assessing the risks associated with premium cigars.

There has been one study, and one abstract, published regarding biomarkers of tobacco smoke exposure among cigar smokers. Chen et al. (8) looked at biomarker data in participants in the National Health and Nutrition Examination Survey (NHANES) 1999-2012. They examined biomarkers of tobacco smoke exposure among cigar smokers, smokers of other tobacco products and non-tobacco users in over 25,000 participants. Cigar smokers were classified as either primary cigar smokers or cigar-only smokers, and were further classified as daily or non-daily

cigar smokers. Among both non-daily and daily smokers, both primary cigar smokers and cigar-only smokers had elevated concentrations of serum cotinine and urinary NNAL compared to non-tobacco users. The concentrations were lower, however, than those seen in secondary cigar smokers (i.e. those also using cigarettes) and cigarette smokers. Studies on biomarker data are subject to limitations including that a biomarker measurement obtained at one point in time cannot necessarily be used to characterize a person's habitual level. Further, biomarker data tell us nothing about long-term exposure. Additionally, this study had no information on the type of cigar smoked or on levels of inhalation, which further limits its usefulness. The abstract by Chang et al. (9) reported on biomarkers of urinary metabolites and tobacco-specific nitrosamines in adult cigar smokers in the PATH study (all cigars, and separately for traditional cigars, cigarillos, filtered cigars, cigarettes and non-smokers). This study had very small number of smokers of different types of cigars.

**Taken together, the epidemiologic studies described above show that there is no association between non-daily, exclusive smoking of cigars and an increased risk for smoking-related cancers, or an increased risk of death from all causes and certain specific causes. The results from different studies show a fair degree of consistency.**

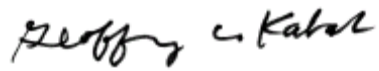
### **Conclusion**

In 1998, NCI Monograph 9 (10) concluded that in relation to all cigars “as many as three-quarters of cigar smokers smoke only occasionally, and some may only smoke a few cigars per year. This difference in frequency of exposure translates into lower disease risks.” (p. iii). The present report has addressed new literature both on use patterns and health risks specific to premium cigars, and comes to similar conclusions based on better and more recent data.

The pattern of use of premium cigars is distinct from that of other types of cigars and far removed from use patterns of cigarettes. Adult prevalence of premium cigar use is extremely low (0.7% in the PATH study), and users are overwhelmingly non-daily users (93% in PATH and 97% in NATS). In addition, compared to other tobacco users, premium cigar smokers smoked fewer days in the past 30 days (1.7 days), smoked few cigars per day on the few days they smoke (0.1 cigars), and were less likely to be current cigarette smokers. Furthermore, these cigars tend to be used by an older population. All of these features point to the risk from premium cigar use being substantially lower than that associated with other types of cigars.

No information is available bearing directly on the health risks of smoking premium cigars. When we examine the most informative prospective studies providing information on current cigar use and mortality (4,5), we see that there is no indication of an increased risk for daily smokers of all types of cigars combined in the lowest category of amount smoked (1-2 cigars per day or less than five cigars per day)(5). Furthermore, in the study by Christensen et al. (4), there is no

indication of an increased risk among non-daily cigar smokers for tobacco related cancer or lung cancer (Table 3). **Taken together, these studies lead to the conclusion that there is no association between non-daily premium cigar smoking -- which applies to the overwhelming majority of premium cigar smokers -- and increased health risks compared to non-smokers.**

A handwritten signature in black ink that reads "Geoffrey C. Kabat". The signature is written in a cursive, flowing style.

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Geoffrey Kabat, Ph.D., M.S.

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10. National Cancer Institute. Monograph 9: Cigars: Health Effects and Trends. 1998.

# **EXHIBIT A**

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**PROFESSIONAL AND RESEARCH EXPERIENCE:**

7/2018-present	Independent scientist; author.
2006 – 6/2018	Senior Epidemiologist, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY 10461-1602.
2001 - 2006	Independent consultant in epidemiology; consultant to UCLA School of Public Health.
1996 - 2001	Associate Professor, Department of Preventive Medicine, School of Medicine, State University of New York at Stony Brook, Stony Brook, NY 11794-8036.
1993 - 1996	Cancer Investigator, Cancer Research Center, Albert Einstein College of Medicine, Bronx, NY.
1992 - 1996	Associate Professor, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, New York, 10461-1602.
1982 - 1992	Senior Epidemiologist, American Health Foundation, New York, New York 10017.
1984 - 1986	Senior Staff Associate, Division of Epidemiology, School of Public Health, Columbia University, New York.
1982 - 1984	Senior Staff Associate, Comprehensive Cancer Center, Columbia University, New York.
1978 - 1981	Associate Epidemiologist, American Health Foundation.
1977 - 1978	Technical Writer, American Health Foundation.

**EDUCATION:**

1984   Columbia University, New York, NY   M.S.   Epidemiology



1976 Columbia University, New York, NY Ph.D. Slavic Languages and Literatures

1970 Columbia University, New York, NY M.A. Slavic Languages and Literatures

1967 Haverford College, Haverford, PA B.A. French, Classics

### **HONORS AND FELLOWSHIPS:**

2009 *Choice* Outstanding Academic Title (*Hyping Health Risks*)  
1971 - 1972 International Research and Exchange (IREX) Graduate Fellowship for study in the Soviet Union (Leningrad).  
1968 - 1971 Faculty Fellowship, Columbia University  
1967 - 1968 Woodrow Wilson Fellow, Stanford University  
1967 Phi Beta Kappa, High Honors in French, Haverford College

### **CONSULTANTSHIPS:**

Consultant to distilled alcoholic beverages trade association group, DISCUS. Prepared report titled "Assessment of the carcinogenicity of alcoholic beverages under two sets of guidelines: OSHA and American Council of Industrial Hygienists (ACIH)," 1979.

Consultant to Bristol-Myers on cancer statistics, 1982.

Extensive discussions with statisticians at Warner-Lambert concerning results of American Health Foundation epidemiologic studies of the association of mouthwash use and oral cavity cancer (1982-83).

Independent consultant to Weinberg Group, Inc., Washington, D.C. Researched and wrote report entitled: "A Critical Appraisal of Epidemiologic Studies of Alcohol Use in Relation to Cancer Risk" (1991-92).

Served as consultant to the Environmental Protection Agency's Science Advisory Board Committee on the Health Effects of Environmental Tobacco Smoke (December 4-5, 1990 and July 21-22, 1992).

Senior Consulting Investigator to "Environmental Tobacco Smoke and Mortality among CPS I," P.I. Dr. James Enstrom, UCLA, 1997-2006.

Consultant in nutritional epidemiology on "Pubertal development in a multi-ethnic population of nine-year-old girls," Dr. Mary S. Wolff, Mount Sinai School of Medicine, NY, 2001-2002.

Consultant in nutritional epidemiology on "Intake of folate and other B-vitamins and risk of breast cancer," Dr. Jia Chen, Mount Sinai School of Medicine, NY, 2002.

## REVIEWER FOR JOURNALS:

*American Journal Epidemiology*

*Annals of Epidemiology*

*BMJ*

*BMC Cancer*

*Cancer*

*Cancer Causes and Control*

*Cancer Epidemiology*

*Cancer Epidemiology Biomarkers Prevention*

*Cancer Research*

*Epidemiology*

*European Journal of Cancer and Clinical Oncology*

*International Journal of Cancer*

*International Journal of Epidemiology*

*International Journal of Environmental Research and Public Health*

*Journal of the American Medical Association*

*Journal of the National Cancer Institute*

*Journal of the South Carolina Medical Association*

*Lung Cancer*

*New England Journal of Medicine*

*Nicotine and Tobacco Research*

*Nutrition and Cancer*

*Preventive Medicine*

*Regulatory Toxicology and Pharmacology*

## LANGUAGES:

Fluent in French and Russian; working knowledge of Japanese and German.

## PUBLICATIONS:

**Total publications: >150; total citations: 8,879; H-index: 54.**

### Peer-Reviewed Feature Length Articles:

1. Wynder EL, **Kabat GC**. Opportunities for prevention of cancer in blacks. *Prog Clin Biol Res* 1981;53:237-252.
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### **BOOKS:**

*Ideology and Imagination: The Image of Society in Dostoevsky*. Columbia University Press, 1978.

*Hyping Health Risks: Environmental Hazards in Daily Life and the Science of Epidemiology*. Columbia University Press, 2008; Portuguese edition: *Riscos ambientais à saúde: mitos e verdades*. Rio de Janeiro: Guanabara-Koogan, 2010.

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*Getting Risk Right: Understanding the Science of Elusive Health Risks*, Columbia University Press, 2016.

### **JOURNALISTIC ARTICLES:**

Since 2011, I have written approximately 80 articles for the general reader. These focus on the frequent misperception of risks in everyday life and what the science has to say. Other pieces include book and film reviews and commentaries on politics and health-related issues. Many of these articles have appeared in Forbes and Slate.

<https://www.forbes.com/sites/geoffreykabat/#e36e4036d80b>

[http://www.slate.com/authors/geoffrey\\_kabat.html](http://www.slate.com/authors/geoffrey_kabat.html)

### **HIGHLIGHTS/INTERVIEWS:**

Interview with *Epidemiology Monitor*, Nov., 2009

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### **Advisory Role:**

Genetic Literacy Project – Board of Directors

<https://www.geneticliteracyproject.org/our-team/>

American Council on Science and Health – Advisor <http://www.acsh.org/our-team>

### **Peer-Reviewed Short Articles and Letters:**

1. Stellman J, **Kabat G**. Arsenical air pollution and lung cancer. *Lancet* I: 211, 1978.
2. Wynder EL, **Kabat GC**. Oral cancer and mouthwash use. *J Natl Cancer Inst* 71:1105, 1983.
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14. **Kabat GC,** Enstrom JE. Interpreting the epidemiologic evidence concerning environmental tobacco smoke and coronary heart disease. *bmj.com* (5 March, 2004).
15. **Kabat GC.** When results look too good to be true, they probably are. *BMJ* 5 June 2004.
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#### **Technical Publications, Book Chapters, and Proceedings:**

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4. Wynder EL, **Kabat G**. Opportunities for prevention of cancer in Blacks, In: C. Mettlin and G. Murphy (eds.), *Cancer in Black Populations*, Alan R. Liss, New York, 1980.
5. O'Day J, **Kabat G**. "Traffic Accidents" chapter, In: Wynder EL (ed.), *The Book of Health*, Franklin Watts, 1981.
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## PRESENTATIONS:

Bladder cancer in non-smoking males. Am Publ Health Assn meeting, Anaheim, CA, Nov. 13, 1984.

Patterns of exposure to environmental tobacco smoke in a group of hospitalized patients (invited paper). Air Pollution Control Assn, Minneapolis, MN, June 22, 1986.

A prospective surveillance system for reproductive hazards: Preliminary results of a pilot study. Am Publ Health Assn meeting, Las Vegas, NV, Sept. 30, 1986.

Beer consumption and rectal cancer. Am Publ Health Assn meeting, Las Vegas, Oct. 1, 1986.

Smoking and adult leukemia. Int Epidemiol Assn meeting, Helsinki, Aug. 12, 1987.

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Comparison of smoking habits in blacks and whites. Int Epidemiol Assn, Los Angeles, Aug. 9, 1990.

Risk factors for lung cancer in lifetime nonsmokers. Epidemiology Seminar, Memorial Sloan-Kettering Cancer Center, May 21, 1991.

Body mass index and lung cancer risk. Society for Epidemiologic Research, Buffalo, NY, June 12, 1991.

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Can differences in tobacco and alcohol use explain excess incidence of tobacco-related cancers in black Americans? President's Cancer Panel, New York, June 8, 1992.

Case-control study of adenocarcinoma of the gastro-esophageal junction. Society for Epidemiologic Research, Minneapolis, June 11, 1992.

Previous reproductive cancer as a risk factor for lung cancer in lifetime nonsmoking women. Society for Epidemiologic Research, Keystone, Colorado, June 17, 1993.

Adenocarcinoma of the esophagus and gastric cardia. Epidemiology Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY, September 27, 1993.

The epidemiology of breast cancer. 11th Annual Advances in Cancer Treatment Research, New York, March 23, 1994.

Aspects of the Epidemiology of Lung Cancer in Smokers and Nonsmokers in the United States. Keynote speech delivered at the International Symposium on Lifestyle Factors and Human Lung Cancer. Guangzhou, China, December 12-16, 1994.

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Environmental Tobacco Smoke and Coronary Heart Disease Mortality in the United States. Arnold School of Public Health, University of South Carolina, Columbia, SC, April 13, 2005.

Environmental Tobacco Smoke and Coronary Heart Disease Mortality in the United States. Mailman School of Public Health, Columbia University, New York City, October 7, 2005.

Environmental Tobacco Smoke and Coronary Heart Disease Mortality in the United States. Center for Environmental Health and Susceptibility, University of North Carolina, Chapel Hill, NC, March 3, 2006.

Reassessment of the Long-term Mortality Risks of Passive Smoking, Albert Einstein College of Medicine, Department of Epidemiology and Population Health, Bronx, NY, June 7, 2006.

Reassessment of the Long-term Mortality Risks of Active and Passive Smoking, Invited Symposium, Second North American Congress of Epidemiology, Seattle, June 24, 2006.

The Role of Epidemiology in Controversies over Low-Level Environmental Exposures, Dept. of Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY. May 13, 2008.

Body Mass Index and Waist Circumference in Relation to Lung Cancer Risk in the Women's Health Initiative, Society for Epidemiologic Research (SER), Chicago, Ill, June 25, 2008.

The Role of Epidemiology in Characterizing High-Profile, but Low-Level, Environmental Hazards, Society for Epidemiologic Research (SER), Chicago, Ill. June 26, 2008.

Controversies over Low-Level Environmental Exposures: An Epidemiologist's Perspective, Health Economics Seminar, Rand Corporation, Santa Monica, CA, Sept. 24, 2008.

Controversies over Low-Level Environmental Exposures, Department of Epidemiology. School of Public Health, UCLA, Los Angeles, CA, Sept. 26, 2008.

Electromagnetic Fields and Cancer: A 30-Year Retrospective, Molecular Epidemiology Training Program Seminar, Mailman School of Public Health, Columbia University, April 3, 2009.

A Longitudinal Study of Serum Carotenoid, Retinol, and Tocopherol Concentrations in Relation to Breast Cancer Risk among Postmenopausal Women, Society for Epidemiologic Research, Anaheim, CA, June 23, 2009.

Power Lines, Cell Phones, and the Science of Fear. New York City Skeptics Society: Symposium on Hyped Health Risks. Pace University, New York City, Nov. 14, 2009.

The Controversy over Passive Smoking. "Epidemiology and Global Health," Haverford College, April 6, 2010.

How Dangerous Are Electromagnetic Fields? A Case Study in the Sociology of Health Hazards. Haverford College, Distinguished Visitors Program, April 6, 2010.

Environmental Risks to Health: Myths versus Facts. Escola Superiora da Magistratura, Porto Alegre, Brazil, May 17, 2010.

Environmental Risks to Health: Myths versus Facts. AGE+, Sao Paulo, Brazil, May 19, 2010.

Environmental Risks to Health: Myths versus Facts. Casa do Saber, Rio de Janeiro, Brazil, May 20, 2010.

Environmental Risks to Health: Myths versus Facts. Academy of Medicine of Amazonas, Manaus, Brazil, May 21, 2010.

Cell Phones, Science, and Fear: How Our Society Manufactures Hazards (keynote address), Symposium on Mixed Messages in Public Health, UCONN Storrs, CT, October 22, 2010.

Association of Food Intake Patterns with Breast Cancer Risk: A Cohort Study. Society of Epidemiologic Research/North American Congress of Epidemiology, Montreal, CA, June 21, 2011.



The Metabolic Syndrome and Risk of Breast Cancer in Postmenopausal Women: Insights from the Women's Health Initiative (keynote address). Symposium on the Metabolic Syndrome, Karmanos Cancer Institute, Wayne State University Medical Center, Detroit, MI, May 9, 2012.

Science vs. "Consensus" in Epidemiology, International Epidemiological Institute, Rockville, MD, Jan. 23, 2013.

Adult stature and risk of cancer at different anatomic sites. Society for Epidemiologic Research, Boston MA, June 18<sup>th</sup>, 2013.

The "environment" and breast cancer: Is there a relationship? Gradient Corporation, Cambridge MA, June 20, 2013.

Do Cell Phones Cause Brain Cancer? A Tale of Two Sciences. 2015 Lorne Trottier Public Science Symposium, Sept. 28-29, McGill University, Montreal, Canada.

Book presentation and discussion of *Getting Risk Right.*, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, Jan. 11, 2017.

Countering distrust of science, Department of Family, Population, and Preventive Medicine, Stony Brook University, Stony Brook NY, Nov. 28, 2017.

Assessing Health Risks: A View from the Front Lines Atlantic Legal Foundation, Metropolitan Club, New York, June 21, 2018.

7/19/2018

# Exhibit 2

**U.S. SENATE  
COMMITTEE ON SMALL BUSINESS &  
ENTREPRENEURSHIP**

Friday April 5, 2019

1:00 p.m.

Performing Arts Building  
Ybor City Campus, Hillsborough Community College  
Tampa, FL

Hearing: Keeping Small Premium Cigar Businesses Rolling

**Prepared Testimony By:  
Brad Rodu, DDS  
Professor, Department of Medicine  
Endowed Chair, Tobacco Harm Reduction  
Research  
School of Medicine  
University of Louisville**

## Summary

- Cigarette smoking is associated with high risks for cancers, circulatory diseases and emphysema. Every year, nearly 500,000 adults die from smoking-related diseases. For the past 50 years, the American cancer “epidemic” has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.
- Compared with cigarette smoking, prevalence of cigar use is much lower; in 2014 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made products.
- Compared with cigarettes, other tobacco products are associated with considerably lower health risks. Smoke-free tobacco products are vastly less hazardous than combustible products. Among combustible products, epidemiologic studies document that cigar smoking is much less hazardous than cigarette smoking.
- A recent FDA study found that consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, smoking-related cancers, coronary heart disease, stroke, or emphysema.
- With low prevalence and minimal to no adverse health effects, regulation of cigars will have negligible impact on public health.
- FDA’s unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. This posture wastes government resources, undermines public health and does nothing to address the deaths caused by cigarette smoking.

I was trained as an oral and maxillofacial pathologist 40 years ago. By the early 1990's, I had been on the staff of the Comprehensive Cancer Center at the University of Alabama at Birmingham for 10 years. At this large academic medical center, I watched countless patients succumb to cancers and other diseases caused by cigarette smoking. I had been educated to believe that all tobacco products were equally hazardous. However, my experience providing pathologic diagnoses for hundreds of mouth cancers did not sync with what I had been taught. The vast majority of the patients I diagnosed were cigarette smokers and/or heavy drinkers. Virtually none of them had used moist snuff or chewing tobacco, despite the fact that these products were commonly used in the deep South.

I resolved the discrepancy by conducting research, resulting in the publication of 70 articles in peer-reviewed medical journals (1). I documented that, compared with cigarette smoking, smokeless tobacco use is 98% less hazardous, even for mouth cancer. In fact, a large recent study from federal and federally-funded investigators found that men who dipped or chewed tobacco had no excess risk for that disease (2). In addition, an American Cancer Society report on the top causes of 660,000 cases of cancer in the U.S. (3) ranked cigarette smoking #1, while smokeless tobacco did not even make the list.

The principal takeaway here is that all tobacco products do not have the same health risks. This also applies to combustible products like cigars, according to research from FDA officials (4).

### Cigar Smokers

The cigar category encompasses a diverse spectrum of products. On one end are premium cigars that are hand-rolled by craftsmen; the rest of the category consists of machine-made, mass-produced cigarillos, little cigars and filtered cigars, sold in packs of various quantities.

Using nationally representative survey data, FDA investigators have distinguished between premium cigar smokers and those smoking mass-produced products (5,6). They estimated that 0.7% of Americans smoked premium cigars and 3.4% smoked machine-made cigars in 2014 (5). Smokers of premium products make up only 14-20% of all cigar users (5,6). Furthermore, only 7% of premium cigar smokers are daily users, compared with daily use by 22-37% of smokers of mass-produced products. Premium cigar smokers light up less than 2 days per month, and only 30% also smoke cigarettes. In contrast, mass-produced cigar smokers light up 1-2 weeks each month, and 58-66% smoke cigarettes. (5)

In another study FDA staff differentiated primary cigar smokers, who never smoked cigarettes, from two other groups: secondary cigar smokers who are former smokers, and dual users of both cigars and cigarettes (7). In that study, primary cigar smokers made up just over 40% of the 462 cigar smokers, while the other two groups comprised almost 60%. This is important because extensive cigarette use by the latter two groups, compounded by the likelihood that they smoke more and inhale more, likely raises their

health risks. Although this FDA study did not precisely describe smoking patterns, primary cigar smokers use fewer products (average 1.5 cigars on days smoked) and smoked fewer days, compared with secondary and dual users.

### Health Effects of Cigar Smoking

The vast majority of cigar smokers are men (5), so it is best to focus only on men when discussing epidemiologic studies.

Usage patterns are important as we look at the health effects of cigar smoking. First, some basic principles. When you burn tobacco and inhale smoke, you consume nicotine and about 7,000 other chemicals. A 20- to 30-year career involving 10 deep puffs per cigarette and 20 to 40 cigarettes per day builds high risks for cancers, circulatory diseases and emphysema. The risks of cigarette smoking are proportional to the amount of smoke inhaled and the duration (years, decades) of exposure, and the death toll from cigarette smoking is high. Every year, 440,000 adults die from smoking-related diseases. For the past 50 years, the American cancer “epidemic” has primarily consisted of one disease, cancer of the lung, owing to one dominant lifestyle factor – cigarette smoking.

While cigar use involves burning tobacco, puffing on one or two cigars occasionally or even daily is not the same as deeply inhaling smoke from 20 or 30 cigarettes per day. One would therefore expect that cigar smokers, especially the primary group, would have lower health risks than cigarette smokers. That is in fact documented in a 2015 study authored by FDA staff (4).

For that report, FDA staff reviewed 22 epidemiologic studies on cigars and health outcomes, and they documented all causes of death and many smoking-related diseases. I will focus on the results for **men who are primary cigar smokers, that is, cigar smokers who had no history of cigarette use**. I will use the term relative risk (RR), which you can view as a multiplier. If a group of men who are cigar smokers has an  $RR=2$  for a particular disease, it means they have twice the risk as the referent group of nonusers. An  $RR=1$  is no risk at all. All RRs are accompanied by a 95% confidence interval, which is the generally accepted measure of statistical significance for epidemiologic results. If that range includes 1.0, the result is considered not statistically significant.

To start, let’s look at mortality for all causes of death. The first column of Table 1 shows that cigar smokers generally have elevated risks. While most studies do not report the number of daily cigars consumed, two studies (Kahn and Shanks) do. Those results are seen in the second column. Smoking one to two cigars per day had minimal to no risks.

Similar results are seen in the FDA study for various diseases related to smoking, including cancers, heart and circulatory diseases and emphysema. Table 2 shows risks for cancer among smokers of one to two daily cigars. For stomach, pancreas and bladder, elevated risks are minimal and/or based on very limited data. While some risk estimates are elevated, especially for parts of the body in contact with smoke, such as mouth/throat,

esophagus, larynx and lung, none are statistically significant. The risks for larynx cancer are based on only two deaths in the Shanks study and one death in the Shapiro study, which is why the confidence interval indicates that they are not reliable.

Table 3 contains the FDA results regarding cigar-related circulatory disease and emphysema for men who smoke one or two cigars a day. **There were no significantly elevated risks for death from coronary heart disease, stroke or emphysema, which are three big killers of cigarette smokers.** Aortic aneurysm – a bulge in the heart's main artery – was the only disease that was elevated in men who smoke 1-2 daily cigars. It is a serious disorder but a distinctly uncommon cause of death; the mortality rate due to aortic aneurysm among those 45 and older dropped precipitously from 16 deaths per 100,000 in 2000 to 7.4 in 2014.

A follow-up mortality study of 1,139 current cigar smokers, as well as 1,177 pipe smokers, identified in U.S. Census Bureau surveys in 1985 and 1992-2011 was published by FDA staff last year (8). They divided cigar and pipe smokers into daily and non-daily groups. The results, summarized in Table 4, show that some diseases were elevated in daily cigar smokers. However, the Census Bureau surveys did not collect information on number of cigars smoked, so it is likely that the higher risks were among secondary cigar smokers and dual users who are more likely to smoke little cigars and cigarettes in higher quantities. Importantly, nondaily cigar users, who are more likely to smoke premium cigars, had no elevated risks.

### **The Takeaway Message for Cigar Smokers**

Puffing or inhaling the smoke of burning tobacco is not without risk.

The FDA, which now regulates tobacco products, seems inclined to treat cigars the same as cigarettes. FDA staff wrote in their cigar study that "...cigar smoking carries many of the same health risks as cigarette smoking...We have observed that some risks associated with cigar smoking can be as high or higher than those associated with cigarette smoking, especially at the highest doses and levels of inhalation for cigar smoking."

All tobacco consumers in the U.S. deserve truthful information and guidance. The sweeping FDA indictment ignores scientific evidence and misleads cigar smokers. It also ignores the important epidemiology principle that the level of risk is related to the level of exposure. In other words, harm is based on (1) how many people smoke; (2) how frequently and how many products are smoked; (3) the degree to which smoke is puffed and/or deeply inhaled. The following facts are indisputable with respect to cigars: (1) the prevalence of cigar use in the U.S. is extremely small, especially for premium cigars; (2) these products, especially premium category, are used infrequently and in small numbers; (3) they are puffed, rather than inhaled.

The agency's unsupported position has led to needlessly subjecting cigar and pipe smokers, and the manufacturers of those products, to the same onerous and burdensome regulatory regime as much more hazardous cigarettes. Low prevalence, infrequent use

and reduced exposure translates into minimal harm at the population level. Epidemiologic analysis from FDA staff indicate that **consumption of up to two cigars per day, while not completely safe, is neither associated with significantly increased risks for death from all causes, nor smoking-related cancers.**

When Congress gave the FDA regulatory authority over tobacco products in 2009, it did not require that the agency treat all tobacco products as equally hazardous. Unfortunately, the FDA's regulatory actions have done just that, despite numerous scientific studies demonstrating that the risks from smoke-free tobacco (smokeless tobacco and e-cigarettes) are a tiny fraction of the risks of cigarette smoking, and despite the FDA's own study demonstrating that the risks of moderate cigar smoking are significantly lower than cigarette smoking.

The FDA's unscientific conflation of cigarette smoking with smokeless tobacco use, vaping, cigar and pipe smoking falsely informs consumers that all tobacco products are equally deadly. For all products other than cigarettes, the number of users is low, the adverse health effects are uncommon, rare or nonexistent. Thus, the impact of strict FDA regulation of these products will be inconsequential. The FDA's current posture wastes government resources, undermines public health and does nothing to address the 500,000 annual deaths caused by cigarette smoking.



**Table 1. Relative Risk, RR (95% Confidence Interval) For All-Cause Mortality Among Men Primary Cigar Smokers**

Study, year	All Cigar Smokers	Cigars per day	
Best, 1966	1.06 (0.92 – 1.22)		
Kahn, 1966	<b>1.10 (1.05 – 1.16)</b>	<5	1.04 (0.98 – 1.11)
		5-8	<b>1.17 (1.06 – 1.29)</b>
		8+	<b>1.49 (1.24 – 1.77)</b>
Cole, 1974	1.15 (0.70 – 1.90)		
Carstensen, 1987	<b>1.39 (1.16 – 1.65)</b>		
Lange, 1992	<b>1.60 (1.30 – 2.00)</b>		
Ben-Schlomo, 1994	0.48 (0.25 – 0.93)		
Shanks, 1998	<b>1.08 (1.05 – 1.12)</b>	1-2	1.02 (0.97 – 1.07)
		3-4	<b>1.08 (1.02 – 1.15)</b>
		5+	<b>1.17 (1.10 – 1.24)</b>

**Bold** indicates statistically significant elevation compared to never smokers.

**Table 2. Relative Risks (95% CI) for Mortality From Cancers Among Men Smoking 1 or 2 Cigars Per Day**

Cancer	Shanks, 1998	Shapiro, 2000	Other Studies
Mouth/throat	2.12 (0.43 – 6.18)	0	
Esophagus	2.28 (0.74 – 5.33)	1.80 (0.60 – 5.00)	
Stomach			1.68 (0.95 – 2.97) <sup>1</sup>
Pancreas	1.18 (0.69 – 1.89)	0.60 (0.30 – 1.40)	
Larynx	6.45 (0.72 – 23.3)	6.00 (0.70 – 53.5)	
Lung	0.90 (0.54 – 1.66)	1.30 (0.70 – 2.40)	1.14 (0.59 – 2.00) <sup>2</sup>
Bladder	0.78 (0.29 – 1.71)	0	

<sup>1</sup> Jacobs 1999, 1 cigar per day.

<sup>2</sup> Kahn 1966, fewer than 5 cigars per day.

**Table 3. Relative Risks for Mortality From Circulatory Diseases and Emphysema Among Men Who Smoke 1 or 2 Cigars Per Day**

Disease	Shanks, 1998	Other Studies
Coronary heart disease	0.98 (0.91 – 1.07)	1.00 (0.90 – 1.10) <sup>1</sup> 1.18 (0.76 – 1.82) <sup>2</sup>
Stroke	1.01 (0.88 – 1.17)	
Aortic aneurysm	<b>1.82 (1.11 – 2.81)</b>	
Emphysema	1.39 (0.74 – 2.38)	

<sup>1</sup>Kahn 1966, fewer than 5 cigars per day.

<sup>2</sup>Jacobs 1999, 1 cigar per day.

**Bold** indicates statistically significant elevation compared to never smokers.

**Table 4. Relative Risks for Mortality Among Daily and Nondaily Exclusive Cigar Smokers<sup>1</sup>**

Disease	Daily	Nondaily
All Causes	<b>1.22 (1.04 – 1.44)</b>	1.12 (0.82 – 1.53)
Smoking-related cancers	<b>1.80 (1.20 – 2.69)</b>	1.08 (0.45 – 2.61)
Lung cancer	<b>4.18 (2.34 – 7.46)</b>	0.74 (0.08 – 7.26)
Cardiovascular diseases	1.12 (0.83 – 1.52)	1.20 (0.67 – 2.15)*
Respiratory diseases	1.86 (0.94 – 3.68)*	0
Emphysema	<b>3.29 (1.33 – 8.17)*</b>	0

<sup>1</sup> Christensen, 2018.

\* Based in fewer than 10 deaths.

**Bold** indicates statistically significant elevation compared to never smokers.

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# Exhibit 3

# Exhibit A

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# **Evaluation of the Burden Reduction Opportunities In the Food and Drug Administration's Final Rule: Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act**

Prepared on Behalf of the  
Cigar Association of America

Submitted by:



January 2018





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# Evaluation of the Burden Reduction Opportunities In the Food and Drug Administration's Final Deeming Rule

## 1. EXECUTIVE SUMMARY

Policy Navigation Group (PNG) prepared this review of the final Regulatory Impact Analysis (RIA) for U.S. Food and Drug Administration (FDA) rule entitled *Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act*.<sup>1</sup> We evaluate the RIA to evaluate the impact on the cigar industry and to identify available opportunities to reduce the burden of the rulemaking.

Since FDA promulgated the rule, the Administration has issued two Executive orders that have launched new regulatory review processes under Executive Orders (E.O.) 13771 and 13777.<sup>2,3</sup> Through E.O. 13771, the Administration established a regulatory budget and required that regulatory agencies submit a proposed regulatory budget for along with its fiscal budget proposals to the Office of Management and Budget (OMB). For Fiscal Year 2017, E.O. 13771 established a regulatory budget of zero, meaning that the regulatory burden caused by new final rules had to be offset by changes that at least offset this new regulatory cost.

To implement E.O. 13771, Executive Order 13777 charges FDA with identifying existing regulations that:

- (i) Eliminate jobs, or inhibit job creation;
- (ii) Are outdated, unnecessary or ineffective;
- (iii) Impose costs that exceed benefits;
- (iv) Create serious inconsistencies or otherwise interfere with regulatory reform initiatives and policies;
- (v) Rely in whole or in part on data, information or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or,
- (vi) Derive from or implement Executive Orders of other Presidential directives that have been subsequently rescinded or substantially modified.

The rules FDA identifies using these criteria under E.O. 13777 are required to be considered for repeal or modification under the agency's regulatory budget (allocation) under E.O. 13771. FDA has

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<sup>1</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

<sup>2</sup> 82 FR 9339

<sup>3</sup> 82 FR 12285

issued a notice requesting ideas from the public for candidate regulations and guidance documents for regulatory revaluation and burden reduction.

In addition, in December 2017, OMB released each agency's regulatory allocation for Fiscal Year 2018. The Department of Human Health Services (HHS) is required to reduce annualized net burden by \$28.7 million by September 30<sup>th</sup>, leading to a present value reduction in regulatory compliance costs of \$410 million. To meet its allocation, HHS, and its component agencies like FDA, must identify opportunities for regulatory burden reduction over this year.

To determine whether the Deeming Rule offers such opportunities, we examine FDA's RIA and to evaluate whether it meets the E.O. 13777 criteria. We limit our review to the provisions of the rule that have not yet gone into force and therefore present opportunities for avoid pending regulatory burden. First, we find that the RIA substantially underestimated the likely regulatory burden on the cigar industry and on consumers. Second, the RIA has deficiencies that preclude accounting for the full regulatory burden. The principal deficiencies include the following:

- FDA's description of the future market structure and future products is based largely on assumptions. Inconsistent with HHS and OMB guidance, the RIA fails to consider important consumer costs from likely post-regulation market adjustments.<sup>4</sup>
- The substantial cost on certain segments of the cigar market is likely to lead to substantial reduction in the variety of products on the market. FDA underestimated the consumers' loss from the reduction in variety.
- Although the rule prompts a mandatory duty to report harmful and potentially harmful constituents, the RIA excludes the cost of composition testing. FDA's refusal to estimate costs when promulgating a standard - even when the final form of the requirement is uncertain - is inconsistent with federal economic analysis requirements and the practice of other agencies.<sup>5</sup>
- In assuming all new products will automatically qualify for Substantial Equivalence Demonstration, FDA likely underestimates the cigar industry's compliance cost by not providing adequate justification or breakdown for its burden estimates.

The RIA provided by FDA quantifies only cigar producers' compliance costs, omitting the additional social costs affecting consumers as well as small businesses via market adjustments.

This report discusses the major issues with the RIA in more detail, proposes some alternative approaches for the rule's social costs, and recommends approaches to more accurately characterize the regulatory burden. A partial re-estimate of the regulatory burden is presented in Table ES-1.

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<sup>4</sup>See White House, Office of Management and Budget, "Circular A-4: Regulatory Analysis"; Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, "Guidelines for Regulatory Impact Analyses."

<sup>5</sup> White House, Office of Management and Budget, "Circular A-4: Regulatory Analysis"; U.S. Environmental Protection Agency, "Guidelines for Preparing Economic Analyses."

The regulatory compliance costs for the non-premium market is about \$50-\$100 million for this initial compliance period. This value underestimates the full costs for this market since the ongoing costs are omitted as well as the loss of consumer surplus.

The regulatory costs for the premium market depend on the market choices of firms and of consumers. If firms reduce product offerings from 6,000 to 1,000, the combined consumer surplus loss is between \$3.5 million (see Table 16) and 2,300 million per year (see Table 1). The initial compliance costs are \$25 million (See Table 15).

**Table 1: Summary of the Rule's Initial Compliance Costs and Consumer Surplus Loss**

Cigar Category	Initial Regulatory Compliance Costs (million)	Consumer Surplus Loss
Non-Premium	\$50-\$100	Not estimated
Premium	\$150-\$300	\$3.5 to \$2,300 million per year <sup>6</sup>

With well over \$100 million in likely costs on the premium cigar industry and its consumers alone the rulemaking imposes an economically significant burden. The rulemaking has a significant effect many businesses, likely lead to substantial employment impacts. It also has a significant effect on a substantial number of small businesses. Since the rulemaking's effect meet some of the E.O. 13777's criteria, the rulemaking provides a substantial opportunity for FDA to reduce regulatory burden.

<sup>6</sup> Assuming a reduction of 5,000 SKUs



## 2. INTRODUCTION

Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the Food and Drug Administration (FDA) is granted authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.<sup>7</sup> The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, allows FDA to “deem” other tobacco products subject to the FD&C Act. Consequentially, the final rule, promulgated on May 10, 2016, deems cigars as meeting the statutory definition of “tobacco product” and now subject to the FD&C Act and its implementing regulations.

Requirements that now apply to the cigar industry include establishment registration and product listing, ingredient listing, labeling requirements, prohibition of free samples, product testing and warning statements for packages and advertisements.<sup>8</sup> FDA quantifies the total costs over 20 years for all new deemed products at approximately \$988 million at a three percent discount rate and \$817 million at a seven percent discount rate. However, FDA admits to excluding unquantified costs attributable to the final rule, including the following: consumer costs due to loss of product variety or potentially higher prices; costs for testing for harmful and potentially harmful constituents; costs for clinical testing to support substantial equivalence reports; market adjustment and exit; and more.<sup>9</sup>

The following table summarizes FDA’s estimated costs for cigars for the major provisions:

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<sup>7</sup> Food and Drug Administration, “21 CFR Parts 1100, 1140, and 1143 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule.”

<sup>8</sup> Food and Drug Administration, “Certain Tobacco Product Compliance; Deadlines Related to the Final Deeming Rule; Guidance for Industry.”

<sup>9</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., “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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis.”

**Table 2: Present Value of Quantified (Private Sector and Government) Costs**

Provision	Upper Bound (3%) 2016 \$	Average Costs per Cigar SKU 2016 \$
New Product Submission Requirements	\$93,100,000	\$12,000
Label Changes	\$176,400,000	\$22,000
Subtotal	\$269,500,000	\$34,000
Other Costs	\$30,200,000	\$4,000
<b>Total Costs</b>	<b>\$299,700,000</b>	<b>\$37,000</b>

For each item in Table 2, we then divide the cost by the 8,000 cigar SKUs that are estimated to have been on the market in a typical pre-regulatory year.<sup>10</sup> Table 3 shows FDA's estimated compliance costs for cigars by the major provisions during the initial compliance period and, thereafter, annually:

- Premarket requirements reflect the cost of obtaining marketing authorizations based on FDA's count of 2,625 newly deemed cigar products applying for marketing authorization (of the 7,500 cigar products at baseline, 60 percent are expected to be grandfathered) and a weighted average cost per product of \$6,560 for cigars.<sup>11</sup>
- Annual registration and product listing includes the estimated costs - first for years one through two, then for years three through twenty - incurred by owners and operators of establishments to register their establishments and submit product listings.
- Ingredient listing reflects the cost for tobacco product manufacturers and importers required to submit listings of all product ingredients by brand and by quantity for each brand and sub-brand.
- Labeling presents the estimated cost of changing cigar labels to six versions of every new label are required and warning statement provisions: the first year includes major labeling changes such as printing plates and prepress activities for adding or enlarging warning statements; after the first year, continued operation of equal random point-of-display will result in incremental ongoing yearly administrative and recordkeeping costs.

<sup>10</sup> Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: 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; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911." The CAA estimate was made in 2014, however, in 2016, after the Final Rule was enacted a large number of SKUs entered the market, which increased the total cumulative number of SKUs well above 8,000. In 2016, prior to the regulation, companies placed an additional number of SKUs on to the marketplace. This marketing positioning increased the total cumulative number of SKUs well above FDA's estimate of 8,000.

<sup>11</sup> In 2016, in FDA's RIA, the baseline number of cigar products (SKUs) was estimated in 7,500.

**Table 3: Total Initial Compliance Costs by Provision for Cigars Market Segment**

Provision	Total Cost during Initial Compliance Period	Annual Cost After Initial Compliance cost
Premarket Requirements	\$17,220,000	\$4,420,000 - \$5,907,000
Annual Registration and Product Listing	\$22,000 - \$65,000	\$4,000 - \$13,000
Ingredient Listing	\$1,139,000	\$47,000- \$94,000
Labeling	\$30,202,000- \$101,400,000 <sup>12</sup>	\$520,000 - \$3,600,000 <sup>13</sup>

*Values may not sum due to rounding*

### ***Project Scope***

This report systematically reviews FDA’s final Regulatory Impact Analysis (RIA) and documents the principal ways in which the analysis falls short of White House’s Office of Management and Budget (OMB), U.S. Department of Health and Human Services (HHS), and other regulatory analysis guidance. As part of this process, each flaw is reviewed and compared with the best practice recommended by these authoritative guidance documents.

In addition to identifying the flaws, two quantitative analyses are conducted. First, for some of the major methodological flaws or omissions, we develop more accurate values to estimate the regulatory costs for the cigar industry. We identify the key issues that can be revised quantitatively and develop partial re-estimates for them. The partial re-estimate demonstrates that the final RIA substantially underestimates the rulemaking’s cost for the cigar industry and for consumers.

Second, we gather publicly-available revenue data for small business in the cigar manufacturing and distribution system. We use both the FDA compliance cost estimate and PNG’s partial re-estimate to calculate the economic impact using the metrics in HHS’s guidance and metrics commonly used by other federal agencies. Presenting the economic impact of the rule in comparable terms will more clearly demonstrate the rule’s substantial impact on small businesses.

### ***Structure of This Analysis***

The data, assumptions, and conclusions presented in this report are those of Policy Navigation Group and do not necessarily reflect the opinions of the Cigar Association of America (CAA). The purpose of this report is to evaluate whether FDA’s economic assessment reflects the best available principles for economic analysis. Our estimates do not evaluate the social benefits of the regulation, do not offer commentary on the medical evidence concerning tobacco use, or do not comment upon potential health impacts associated with cigar smoking.

The report is structured as follows:

<sup>12</sup> Cost of changing cigar labels when six versions of every new label are needed.

<sup>13</sup> Incremental annual costs of equal random display.

1. We provide an overview of the rule's universe and the key baseline assumptions for the analysis.
2. We discuss FDA's failure to quantify how the future post-regulation market structures will be impacted by product withdrawals and likely consumer surplus loss.
3. We highlight how FDA assumes no cost imposed by the requirement of companies to conduct testing in compliance with harmful and potentially harmful constituents (HPHC) reporting.
4. We examine how FDA's cost estimates for new products to complete Substantial Equivalence (SE) Demonstration reports is based on assumptions that lack justification and clarity. Namely, we look at FDA's assumptions that most new products will qualify under SE and that companies will not have to conduct laboratory testing to fulfill SE demonstration requirements.
5. We offer an analysis of the market adjustment, the lost consumer surplus, and the economic impact resulting from the regulation.

### 3. THE PRE-REGULATION CIGAR MARKET AND GENERAL BASELINE ASSUMPTIONS

We rely on the estimates provided by the FDA in its RIA for the following data and assumptions about the pre-regulation cigar market:<sup>14</sup>

- Number of cigar brands;
- Number of cigar manufacturers;
- Number of cigar importers;
- Typical number of products per brand; and,
- Typical number of packaging variations by brand.

To estimate the size of the cigar industry in terms of revenue and how revenue is subdivided into premium and non-premium products, we use Cigar Association of America (CAA) and MarketLine data and model different scenarios.<sup>15</sup> For the number of cigar products (Stock Keeping Units, or, SKUs), including how they are broken down into premium and non-premium cigars, we use publicly available estimates provided by the CAA.

New SKUs are regularly created by cigar brands to be used in future products. It is customary in the cigar industry to have multiple product presentations and formulations for one single brand. The number of this type of SKUs can exceed over 1,000 units (SKUs) per brand.<sup>16</sup> In addition, there are dormant SKUs, such as those related to limited editions of cigars that are no longer being produced, that are still in the market. In response to this rulemaking, cigar producers introduced a significant number of SKUs in 2016. As a result, there is substantial uncertainty as to the number of SKUs that companies will bring to compliance with the regulation. For this analysis, we will assume a range of 8,000 to 16,000 SKUs in the cigar marketplace.

To calculate the number of product combinations per brand, we use FDA's estimate that each brand has 4.4 products and each product has 1.5 packaging variations.<sup>17</sup> Thus, on the assumption that there are 8,000 -16,000 cigar SKUs in the market and 1,100 brands, each brand will have on average 7.3-14.6 product combinations (e.g., 8,000/1,100).

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<sup>14</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

<sup>15</sup> MarketLine, "Tobacco in the United States"; Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: 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; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

<sup>16</sup> Minato, "Six Things: What FDA's 2021 Delay Means for Cigars."

<sup>17</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

The cigar market is segmented, broadly speaking, into premium and non-premium segments. In terms of products, we assume that there are 8,000 -16,000 SKUs in the market prior to regulation.<sup>18</sup> As discussed in Section 8, to obtain a better estimate of the regulatory cost by including the consumers' lost benefits, we examine in more detail the premium cigar market. We therefore require an estimate of the number of premium cigars sold and the number of premium cigar SKUs.

From a revenue perspective, the total size of the cigar industry in the United States represents approximately \$7 billion in 2016.<sup>19</sup> From this total, approximately 2.5 percent of the market is premium (\$175 million) and the remainder 97.5 percent is non-premium (\$6.8 billion).<sup>20</sup>

Since cigars have different price points, we divide cigars sold into four price categories: \$2-\$4, \$4-\$6, \$6-\$10, over \$10. These price categories are based on data from the International Premium Cigar and Pipe Retailers Association (IPCPR).<sup>21</sup> For each of these categories, IPCPR provides percentages of the best-selling range (i.e. \$2-\$4=5 percent, \$4-\$6=78 percent, \$6-\$10=15 percent, over \$10=2 percent), based on information reported by its members.

The next step is to estimate the number of cigars sold in each price category. The U.S. Treasury collects data on cigar domestic and production and imports. Cigar imports are further subdivided into categories based on their declared value. Specifically, there are five trade codes for large cigars (USTSA2402.10.3030 to USTSA 2402.10.8080). The U.S. Treasury groups these five categories of large cigars into two values reported each month. One category is almost 15-20 times larger than the other category. We assume that the smaller category contains the premium cigar imports.

The smaller Treasury category constitutes imports of large cigars in trade categories USTSA 2402.10.8050 and USTSA 2402.10.8080. Trade category USTSA 2402.10.8050 is defined as large cigars with an import price of between \$0.23 and \$0.76; category USTSA 2402.10.8080 are cigars with imported value greater than \$0.76. We obtained monthly declared imported value in each trade category for December 2016-December 2017.

We assume that all cigars in these trade codes have a more expensive retail price. We then can estimate the retail price of premium cigars imported that have a value greater than \$0.76. We first subtract the number of estimated for the \$6-\$10 category from the total imports in the Treasury category. Using the two price ranges, to bring the annual total to \$175 million, the mean retail prices for these two categories is assumed to be \$6 and \$10.

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<sup>18</sup> Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: 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; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

<sup>19</sup> MarketLine, "Tobacco in the United States."

<sup>20</sup> Cigar Association of America, Inc., "Comment on the Food and Drug Administration (FDA) Proposed Rule: 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; Extension of Comment Period. Docket No. FDA-2014-N-0189-75911."

<sup>21</sup> International Premium Cigar & Pipe Retailers Association, "Premium Tobacconist Member Profile."

Table 3 provides an overview of the main pre-regulation values we use in this analysis:

**Table 4: Major Pre-Regulation Market Values**

Pre-Regulation Market Description	Estimate
Number of Cigar Brands	1,100
Number of Cigar Manufacturers	113
Number of Cigar Importers	216
Number of Cigar Products (SKUs)	8,000 - 16,000
Number of Products by Brand	4.4
Number of Product Combinations (SKUs) per Brand	7.3 - 14.6
Total Revenue of the Cigar Industry	\$7 billion
New Product Rate	15%
Number of New Products by Brand	1.10

For the number of new cigar products that would have been introduced without FDA's regulation, we employ data from Rueda Media.<sup>22</sup> From this publicly available database we extract the total number of cigar brands that were released, planned to be released, or scheduled to be released in the market during 2016. The total number of new products was 800, which corresponds to 1,200 product variations or SKUs ( $800 * 1.5$ ). The baseline new product rate is estimated to be 15 percent ( $1,200/8,000$ ).

In addition, we calculate the number of new cigars by brand by multiplying the range of current SKUs (8,000 - 16,000), multiplying it by the new product rate (15 percent), and dividing the result by the current number of brands (1,100). Table 4 presents the number of new cigars by brand:

<sup>22</sup> Rueda Media, LLC, "2016 Cigar Release List - Halfwheel."

Table 5: Estimate of New Cigar Products

Post-Regulation Market Description	Estimate
New Product Rate	15%
Number of New Products by Brand	1.1 -2.2



## **4. FUTURE MARKET STRUCTURE AND PRODUCT AVAILABILITY**

### **a. SUMMARY OF FDA APPROACH**

The FDA deeming rule changes the market for cigars, causing shifts in cigar supply and demand. FDA simply posits the future market structure. FDA assumes that five percent of existing products will cease being sold eventually due to regulation. With regard to the rate of new tobacco products, in the final RIA, FDA estimated that new products seeking authorization annually will be approximately five to ten percent of the number of products estimated to remain on the market.

### **b. ERRORS WITH FDA APPROACH**

FDA makes the flawed assumption that market exit is exogenous to the regulation's cost. In the RIA, FDA assumes that five percent of products will be withdrawn from the market. FDA should instead note a regulated market in the baseline generally meets adjusted consumer preference. The current market is not "free" due to state regulation, federal and state taxes, and other constraints on product use. However, current purchasing patterns are the most readily-available measures of consumer willingness-to-pay for cigars. The diversity of products, rates of new product introduction, and consumer experience have arisen to meet consumer demand.

FDA's regulation will raise cigar manufacturers' operating costs. In a competitive market, firms then try to raise their prices to offset some of these increased production costs. Consumers, in turn, react to the price increases and reduce their purchases of cigars according to the price elasticity of demand. Lower consumer purchases then in turn reduce producers' revenue, causing them to either stop selling money-losing products or cease operations. Once producers decide on their compliance strategy, the social costs and economic impact of the rule are known. This dynamic response to regulation predicts producer/product exit.

FDA does not consider that, as companies ultimately change their products, consumers will no longer see their preferred options, and many will likely switch. As a result, consumers overall will suffer from no longer seeing their preferred brands. Thus, product withdrawal causes consumer welfare loss. FDA should compute the cost per product or cost per company to compare it to actual companies' revenues in order to quantify the impact of company closure, brand consolidation, and product withdrawals from the market.

### **c. ALTERNATIVE APPROACH**

We adopt dynamic modeling of consumer and producer response to regulation in this analysis. To do so, we calculate the costs of complying with each individual requirement of the rule, simulate consumer response to price increases, and the combined effect of lower demand and of higher operating costs on cigar manufacturers. See Section 8.

## 5. HARMFUL AND POTENTIALLY HARMFUL CONSTITUENTS

### a. SUMMARY OF FDA APPROACH

Under the FD&C Act, manufacturers or importers are required to submit a listing of constituents in each tobacco product, and the smoke if possible, that are identified by the FDA as harmful or potentially harmful (HPHC) by brand and quantity. FDA intends to enforce the required HPHC testing and reporting requirements three years after the effective date of the final rule for cigars and other newly-deemed products.

FDA states that it plans to issue additional guidance on HPHC reporting, as well as a separate testing and reporting regulation, but does not provide details on how they will approach HPHC reporting.<sup>23</sup> The final RIA does not estimate any costs for this regulatory requirement. The effective date of compliance for this provision is November 8, 2019 or, for products entering the market after November 8, 2019, 90 days prior to marketing.<sup>24</sup>

### b. ERRORS WITH FDA APPROACH

FDA's rule sets the requirement for companies to submit listings of HPHC imposes the costs of conducting product constituent and smoke tests. While future FDA actions will shape the magnitude and timing of these costs, social costs are triggered by the final rule.

FDA's approach of ignoring these costs is inconsistent with other agencies. For example, the U.S. Environmental Protection Agency (EPA) under the Clean Air Act sets National Ambient Air Quality Standards (NAAQS). These NAAQS air quality concentrations are not direct regulatory standards; states develop state implemental plans that contain the state's strategy of emission limits on specific industries, transportation projects, and other programs to meet the NAAQS in their area. EPA estimates the potential social costs when it sets NAAQS standards, even though the specific requirements are set later by states.<sup>25</sup> EPA does so because the NAAQS establishes a regulatory obligation; it is inconsistent with OMB guidance and other agency practice for FDA to ignore the regulatory costs simply because they are uncertain.

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<sup>23</sup> Food and Drug Administration, "21 CFR Parts 1100, 1140, and 1143 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule."

<sup>24</sup> Food and Drug Administration, "Certain Tobacco Product Compliance; Deadlines Related to the Final Deeming Rule; Guidance for Industry."

<sup>25</sup> U.S. Environmental Protection Agency, Office of Air and Radiation, "The Benefits and Costs of the Clean Air Act from 1990 to 2020."

In addition, the rule does not include organization costs to respond to FDA inquiries about the HPHC submission. FDA does not present any evidence that this extreme assumption is the most likely outcome. Given that an international standard and testing protocol for large cigar testing has not been developed, development of data may need to wait until this protocol is approved. Since the method will be very new, it is likely that problems could arise. There may be limited number of laboratories ready to conduct the test. Laboratory personnel may need training, leading to greater risk of error. Reproducibility concerns may arise as different laboratories conduct the tests. Finally, FDA staff must evaluate and understand the new testing protocol, the minimal quality standards, the limits of detection, and other testing parameters.

All of these factors increase the probability that FDA may at least initially require multiple resubmissions and testing to fulfill this requirement. A more reasonable assumption is that FDA requires more information on a certain percentage of submissions. The RIA should have included these costs.

### c. ALTERNATIVE APPROACH

It is difficult to adequately quantify the costs to industry of cigar testing. This is for two specific reasons. First, there are not established International Organization for Standardization (ISO) methods for cigar smoke testing, nor are there established third party methods for cigar smoke testing for all cigar products. Second, FDA has yet to identify what HPHCs will be required for cigar testing.

While there are established methods and ISO standards for testing cigarette smoke, no such methods or standards exist for cigar smoke. The two products are very different both in composition, shape and size and use, and therefore any methodologies or standards available for cigarette smoke testing cannot be used for cigar smoke testing. CORESTA (Cooperation Center for Scientific Research Relative to Tobacco) is the leading scientific body relating to tobacco science issues. CORESTA has various working groups that work on establishing testing protocols for tobacco products. While there are CORESTA methodologies relating to some cigar products, even these are currently undergoing review and update by CORESTA working groups.<sup>26</sup> Further, CORESTA has three other ongoing projects, in addition to this review and update, to try to establish protocols and testing methodologies for larger, and especially premium cigar, products.<sup>27</sup> None of these methodologies has been completed, none have received ISO certification, and none have been accepted by FDA.

FDA originally published a list of 93 HPHCs.<sup>28</sup> It then published a Guidance document which outlined the required HPHC testing for cigarettes, smokeless tobacco, and roll-your-own tobacco. Table 5 below lists the different HPHC testing required for the three different products.

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<sup>26</sup> Cooperation Centre for Scientific Research Relative to Tobacco, “Active Projects | CORESTA.”

<sup>27</sup> Ibid .

<sup>28</sup> U.S. Food and Drug Administration, “Compliance, Enforcement & Training > Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List.”

Table 6: Potentially Required Tests Under the Rule's HPHC Provision<sup>29</sup>

Cigarette Smoke	Smokeless Tobacco	Roll-your-own Tobacco and Cigarette Filler
Acetaldehyde	Acetaldehyde	Ammonia
Acrolein	Arsenic	Arsenic
Acrylonitrile	Benzo[a]pyrene	Cadmium
4-Aminobiphenyl	Cadmium	Nicotine (total)
1-Aminonaphthalene	Crotonaldehyde	NNK
2-Aminonaphthalene	Formaldehyde	NNN
Ammonia	Nicotine (total and free)	
Benzene	NNK	
Benzo[a]pyrene	NNN	
1,3 Butadiene		
Carbon Monoxide		
Crotonaldehyde		
Formaldehyde		
Isoprene		
Nicotine (total)		
NNK		

<sup>29</sup> U.S. Food and Drug Administration, "Compliance, Enforcement & Training > Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List."

<b>NNN</b>		
<b>Toluene</b>		

FDA creates product specific lists for HPHC testing. To date, no list has been provided for cigars, so it is impossible to determine which HPHCs will be required to be tested in cigars. Companies have received costs estimates from independent testing laboratories of \$5,000- \$20,000 per product for HPHC testing, depending on the protocols required and the number of HPHCs to be tested.

With regard to HPHC testing costs, given the uncertainty in the potential requirements, it is only possible to use a hypothetical value to assess the potential costs of this provision. For this analysis, we hypothetically assume that HPHC testing costs will be \$9,700. However, actual testing costs are likely to be significantly higher.

To estimate the other potential costs of HPHC, one can calculate the technical, management and clerical staff time to prepare, review and submit HPHC reports. For the purposes of this analysis, we assume that HPHC reports will require 50 percent less time than the modified costs for a substantial equivalence (SE). FDA assumed 220 hours for the SE application.

For the preparation and review of the submission, FDA's analysis fails to consider that multiple company staff will be involved in the application process, not only to prepare the submission, but also to review and record the submission. For our alternative analysis, we assume that three different labor categories are needed, one technical, one managerial, and one administrative/legal assistant. The unloaded rates we use are based on data from the Bureau of Labor Statistics for tobacco manufacturing.<sup>30</sup> To account for overhead, general and administrative costs, we multiply each unloaded rate by two, the same approach FDA uses.

For the HPHC report, we allocate our estimate of 110 hours between two staff members (55 hours each). Companies must contract for laboratory services, verify laboratory performance, review the results, and assemble the report. We assume that other members of the company require an additional 20 percent of the 110 hours to prepare the draft submission. Also, we assume that an administrative/legal assistant will be needed to assist in the preparation, review and recordkeeping of the submission (10 percent of the time spent by the technical staff).

The following table (Table 6) presents the rates and categories we use to estimate the labor costs of the HPHC provision:

<sup>30</sup> U.S. Department of Labor, Bureau of Labor Statistics, "Tobacco Manufacturing - National Industry-Specific Occupational Employment and Wage Estimates; NAICS 312200 - Tobacco Manufacturing."

**Table 7: HPHC Labor Costs**

Labor Category	Unloaded Hourly Rate	Fully Loaded Rate	Number of Hours
Industrial Production Manager	\$53.26	\$106.52	55
Chemists and Materials Manager	\$30.21	\$60.42	55
Administrative/Legal Assistant	\$19.92	\$39.84	11

To estimate the costs of this provision, we multiply the number of tests required by its unit cost. Then, we sum the corresponding labor costs by multiplying the number of hours in each category by the fully loaded rates.

Furthermore, our estimate assumes that 10 percent of applications submitted to FDA will need to be resubmitted due to rejection. Firms have a strong financial incentive to submit complete applications to sell their products. Application reconsideration would require 10 percent of the initial application labor and testing costs in case the initial application is rejected by the FDA. These assumptions may understate or overstate the actual costs. This estimate assumes that tests and harmful and potentially harmful constituents substance reports are conducted by brand and that multiple packaging combinations with the same product composition are covered in the same report.

## 6. PREMARKET AUTHORIZATION

### a. SUMMARY OF FDA APPROACH

Deemed products must provide justification to remain on the market after the FD&C and the deeming regulation occurred. Companies may only sell grandfathered products or products that have FDA premarket authorization. To obtain premarket authorization, firms may demonstrate that their new or existing, non-grandfathered product is substantially equivalent (SE) to an authorized product. If there is not an equivalent product, companies must submit premarket authorization (PMA) application.<sup>31</sup>

In the RIA, FDA asserts that 60 percent of cigar products will be grandfathered and thus will not require market authorization. FDA also states that all other existing cigar products are eligible to make a SE demonstration. Manufacturers must provide information that allows FDA to determine whether a new tobacco product is substantially equivalent to that of a predicate product or an existing product on which to base comparisons. There must be a comparison of all ingredients, materials, heating sources, design feature compositions, constituents, and other features that are identified with the predicate product. Changing the number of cigars sold in a package or changing an ingredient requires to SE demonstration.<sup>32</sup>

FDA estimates that, on average, it will take 220 hours to complete the task of preparing and submitting a complete substantial equivalence report. The time estimated to complete the Initial Quantity Change SE Report is 185 hours and the Bundled Quantity Change SE Report is 210 hours.

### b. ERRORS WITH FDA APPROACH

The RIA contains assumptions with little verifiable justification. FDA does not provide any justification that 60 percent of products qualify as grandfathered and thus do not require premarket authorization. FDA's burden estimate for an SE application does not include a breakdown of the component cost or does not have citations for its SE cost estimates.

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<sup>31</sup> Food and Drug Administration, "21 CFR Parts 1100, 1140, and 1143 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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule."

<sup>32</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

It also appears FDA assumes no costs for physical testing and laboratory analyses, which it appears companies are likely to be required to conduct to demonstrate a candidate product has the characteristics of predicate products. Many situations could lead to physical testing, but do not need to. For example, FDA may reasonably inquire as to whether different ingredients contain, or form when combusted, potentially hazardous constituents.

FDA's assumption is that no new cigar products will require premarket approval and will qualify under SE. However, FDA does not provide justification for this assumption. The rise of vapor technologies and non-combustion delivery systems are examples of innovation in the broader industry. By assuming that no similar innovation will occur in cigar markets, FDA likely underestimates the cigar industry's future compliance costs.

It is also unclear whether the total hours per application incorporate the time involved in communicating back-and-forth with FDA. FDA may have questions or require additional data after a company submits an SE application. Since the requirements for an SE are not known and may change over time, some fraction of SE applications will likely require multiple submissions before receiving a final FDA decision.

As previously shown in other parts of the RIA, FDA assumes that five percent of existing products drop out of the market and do not submit an SE application. As stated earlier, we use market data to estimate this percentage in this report. FDA also repeats its assumption that only one person is required to complete a submission; FDA should assume and account for more than one person, including legal and managerial staff, to write, review, and approve each submission. Lastly, FDA does not clarify what the environmental assessment entails or on what basis it estimates that it will require 80 hours per product.

### **c. ALTERNATIVE APPROACH**

We estimate the SE application cost by assuming it has three components per application. First, companies may conduct physical product and use testing to demonstrate that a non-grandfathered product is chemically similar to authorized products. Second, the physical data is supplemented by literature reviews and other analyses. Third, managerial and legal staff review a company's draft SE submission package prior to sending it to FDA.

As discussed in the last section, firms must test every cigar product - even grandfathered products - for HPHCs. Some of this physical testing can be used to support a SE application. Therefore, companies may try to conduct just one set of constituent characterization to satisfy both requirements. In addition, some SE applications will be required when companies change package quantity. These SE applications are not likely to change the constituent composition. For these reasons, not all SE applications will require physical testing.

On the other hand, the scope of the SE application is potentially greater than the HPHC reporting. While the HPHC reporting is based on a discrete list, FDA requires companies to demonstrate that non-grandfathered products have multiple attributes equivalent to existing product. Since FDA has not issued guidance, the number of points of comparison are unknown.



We assume that 10 percent of non-grandfathered products will require the same battery of tests required for the HPHC demonstration. Firms have a strong financial incentive to develop products for which they can develop a relatively straightforward SE demonstration. The 10 percent assumption may understate or overstate the actual costs.

For the preparation and review of the submission and for the preparation of the environmental assessment (220 hours for SE application and 80 hours for environmental assessment and), FDA's analysis fails to justify the fact that various staff members will need to be involved in the application process, not only to prepare the submission, but also for review and recordkeeping purposes.

For our alternative analysis, we assume that three different labor categories are needed, one technical, one managerial, and one administrative/legal assistant. The fully-loaded labor rates for these categories is extracted from BLS data.<sup>33</sup>

For the environmental assessment, FDA arbitrarily indicates that 80 hours of labor time would be required to complete that process. However, FDA's analysis does not mention how this estimate is derived and does not discuss specifics on the information that needs to be provided in the assessment. Since we cannot evaluate FDA's assumptions, we allocate the 80 hours stated by the FDA into managerial and technical staff time.

For the SE application, we allocate FDA's estimate of 220 hours between two staff members (110 hours each). In its estimate, FDA does not include any time to review the submission. We assume that other members of the company require an additional time equal to 20 percent of the 220 hours to review the submission. Also, we assume that an administrative/legal assistant will be needed to assist in the preparation, review and recordkeeping of the submission (10 percent of the time spent by the technical staff).

Table 7 presents the labor categories and rates and categories used to quantify the labor-related costs of the SE provision of the rule:

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<sup>33</sup> U.S. Department of Labor, Bureau of Labor Statistics, "Tobacco Manufacturing - National Industry-Specific Occupational Employment and Wage Estimates; NAICS 312200 - Tobacco Manufacturing."

Table 8: Estimated Labor Costs for SE Applications

Labor Category	Unloaded Hourly Rate	Fully Loaded Rate	Total Hours Needed	Environmental Assessment	SE Application Category		
					Preparation	Review	Recordkeeping
Industrial Production Manager	\$53.26	\$106.52	172	40	110	22	
Chemists and Materials Manager	\$30.21	\$60.42	172	40	110	22	
Administrative / Legal Assistant	\$19.92	\$39.84	17		12	4	1

To estimate the costs of this provision, we multiply the number of tests required by its unit cost. Then, we sum the corresponding labor costs by multiplying the number of hours in each category by the fully loaded rates.

Furthermore, our estimate assumes that 10 percent of applications submitted to FDA will need to be resubmitted due to rejection. Firms have a strong financial incentive to submit complete applications to sell their products. Application reconsideration would require 10 percent of the initial application labor and testing costs in case the initial application is rejected by the FDA. These assumptions may understate or overstate the actual costs. This estimate assumes that tests and reports are conducted by brand and that multiple packaging combinations with the same product composition are covered in the same report.

## 7. CONSUMER SURPLUS ESTIMATE

### a. WHITE PAPER METHODOLOGY

In the previous sections, we have examined the increased costs to cigar producers to comply with the regulation to stay in the market. However, the social cost of the rulemaking is not only the additional costs paid by producers, but the combination of the lost producer and lost consumer surplus when market prices rise to cover the regulatory compliance costs. This fundamental principle of economics is described in more detail in both OMB's Circular A-4 and HHS Guidance on conducting a regulatory impact analysis.<sup>34</sup> In particular, consumers have a surplus if their value - their willingness to pay (WTP) - is greater than the market price. When prices rise due to regulation, the new price will exceed some consumers' WTP. These consumers that are not willing to pay the higher prices and instead turn to other substitute goods that they value less. This lost consumer surplus is part of the social cost of the rulemaking.

The final RIA ignores lost consumer surplus and instead estimates the size of producer costs to comply with the regulatory requirements. While many federal economic analyses also do not estimate lost consumer surplus, lost consumer surplus is more important in this rulemaking than in others for several reasons. First, the rule restricts widely-used consumer goods that have established markets, prices, and consumer demand. Lost consumer demand is much more easily measured when regulated goods are bought and sold in transparent, relatively unrestricted markets. Second, certain parts of the cigar market are comparable to markets for luxury goods. For luxury goods, the consumer's WTP can far exceed the real resource cost to make the product.<sup>35</sup> Using the additional cost of real resources needed for regulatory compliance will underestimate a regulation's social costs when consumers value intangibles such as the experience, the emotion, and other, non-tangible product attributes. Third, since the regulation applies to all domestic and all imported products sold in the United States, market prices must rise. Consumers cannot easily turn to unregulated imports. When regulation raises all prices in a market, lost consumer surplus becomes more important.

By estimating only the additional cost to producers, FDA's RIA underestimates social cost. In the proposed RIA, FDA deserves credit for confronting this issue and considering lost consumer surplus.<sup>36</sup> FDA did not carry that analysis forward in the final RIA. In the Final RIA, FDA responded the following, with regard to estimating lost consumer surplus:

*FDA agrees that application of the concept of lost utility is complicated for products that are addictive or habitually consumed, and accepts that the approach taken in the PRIA*

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<sup>34</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Guidelines for Regulatory Impact Analysis" See Appendix B.

<sup>35</sup> Hennigs et al., "Consumer Desire for Luxury Brands."

<sup>36</sup> 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 Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis. Docket No. FDA-2014-N-0189."

*warrants reconsideration...FDA disagrees with the view that lost utility is not an appropriate concept for analyzing regulations addressing addictive goods. Consumer surplus is central to the welfare economics framework that FDA and numerous outside experts (including many commenters) believe serves as a useful guide to assessing efficiency of policy. The Office of Management and Budget's Circular A - 4 on regulatory impact analysis includes gains and losses in consumer surplus among the issues that agencies should evaluate when relevant...In the case of the deeming rule, lack of data on usage patterns and health risks for deemed products means the empirical approach used in the White Paper cannot be used to quantify utility offsets that may be associated with the deeming rule...<sup>37</sup>*

In summary, FDA's response is cursory and, even if accurate, lumps all deemed products together. FDA's arguments rest upon the assumption that rule would not have to save many quality-adjusted life-years (QALYs) to break even from a public health perspective. However, if FDA's regulation could lead to a severe contraction of the cigar market, the breakeven analysis is less favorable. More fundamentally, however, FDA's approach masks the variations in lost consumer surplus across different market segments. FDA's sweeping dismissal of utility concerns precludes the opportunity to examine if less burdensome approaches would be more cost-effective for different deemed products and product segments.

FDA has sufficient information to estimate the potential loss of consumer surplus due to the regulation of cigars. The HHS put forth a methodology in its 2015 White Paper on *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*.<sup>38</sup> The White Paper gives an overview of the issue and starts by affirming certain economic principles. First, not all consumers using an addictive good are irrational, in the economic sense. Some consumers are fully informed of the potential risks and addictive qualities of a good or service and decide that the benefit to them exceed the costs. Second, FDA regulations that increase production costs and restrict access to tobacco product effectively raise the price of the good to the consumer.

From these principles, the White Paper divides consumers into two categories and considers their response to a regulation that creates an effective price increase:

Figure 1 shows a graphical version of this model that underlies the framework for valuing benefits and costs of regulations. As is the norm, we include the monetary price and health and longevity costs as costs, and the consumption benefits net of withdrawal as the value to the individual, though no practical difference in results depends on whether a health harm is termed a cost or a negative benefit. The demand curve thus reflects the first two terms on the left-hand side of equation (2), and the remaining two terms are built into the cost. Because withdrawal costs vary with past consumption, so too will the value of current

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<sup>37</sup> U.S. Department of Health and Human Services, Food and Drug Administration, Office of Policy, Planning, Legislation and Analysis, Office of the Commissioner., "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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products and Advertisements. Final Regulatory Impact Analysis."

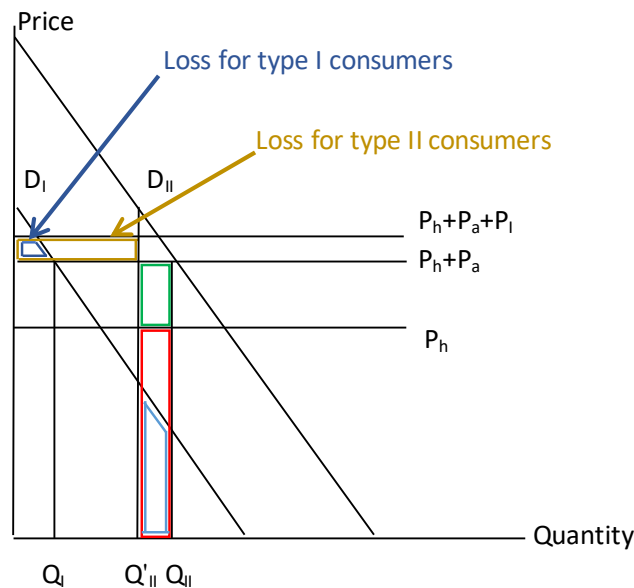
<sup>38</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Policy and Evaluation, *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*, August 3, 2015.

consumption. We start by assuming the individual has some addictive stock and draw the demand curve corresponding to that addictive stock. We return to the dynamics below.

The model can be applied for both existing users of the good and for potential initiators, although the implementation differs between the two cases. Considering existing users first, we delineate two types of individuals with otherwise similar characteristics (age, gender, etc.): type I consumers who make smoking decisions in a way that is fully rational and fully informed ...; and type II consumers who have time inconsistent preferences ... or misperceive how their current actions will affect their future choices and health risks ....<sup>39</sup>

For non-addicted consumers who are knowledgeable of the health risks and potential consequences, HHS found that conventional economic theory applied.<sup>40</sup> These consumers' purchases can be assumed to be rational decisions about trade-offs. In other words, agencies can estimate the social cost of a regulation in the same manner as other goods. In Figure 1, regulation increases the direct and indirect price consumers pay, rising from  $P_h + P_3$  to  $P_h + P_3 + P_l$ . Type I consumers respond along demand curve  $D_I$  and reduce their consumption to below  $Q_I$ . The consumer surplus loss is shown in Figure 1.

**Figure 1. Consumer Surplus Losses for Type I and Type II Consumers Due to Regulation**



Source: Cutler et al.<sup>41</sup>

<sup>39</sup> U.S. Department of Health and Human Services, Office of the Assistant Secretary for Policy and Evaluation, *Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods*, August 3, 2015, pg. 17.

<sup>40</sup> Cutler, Kenkel, and Starr, "Valuing Utility Offsets to Regulations Affecting Addictive or Habitual Goods."

<sup>41</sup> Cutler, Kenkel, and Starr.

To sort consumers into the Type I or Type II category, the White Paper applies several tests. By dividing cigarette smokers by whether they smoked within the first 30 min of being awake, HHS found that 56 percent of current smokers do not and are thus defined as Type I consumers. These Type I consumers are younger, have more educational achievement, and greater family annual income than Type II consumers.

The premium segment of the cigar market has consumers that are comparable to the Type I HHS criteria for cigarette smokers. Using the 2012 National Adult Tobacco Survey data, only 3.3 percent of premium cigar smokers smoked cigars daily; over 70 percent smoked these cigars only “rarely.” More than 40 percent of regular premium cigar smokers report having never smoked cigarettes.<sup>42,43</sup> In terms of educational attainment, more than 50 percent of premium cigar smokers have a college degree or a higher degree. Approximately only nine percent of cigarette smokers have the same level of educational attainment. Sixty-seven percent of cigar smokers have annual family income of \$50,000 per year (2012\$); more than 40 percent have family income of \$100,000 per year or greater.

The NATS data indicates that there is a consumer segment of the premium cigars that fits the characteristics of Type I consumers according to the HHS classification. They do not smoke cigars or tobacco products frequently enough to exhibit addictive behaviors. Their educational and income achievements suggest that they are capable of rational decisions concerning health risks and that they have sufficient disposable income to choose among available discretionary, luxury products that maximize their utility.

In this analysis, we create a quantified estimate of the lost consumer surplus for these Type I consumers -- occasional smokers who purchase premium cigars. The principle -- and FDA’s obligation under Circular A-4 -- to estimate lost consumer surplus extends to every component of the cigar market. In fact, the HHS 2014 approach provides a clear methodology that FDA should use for all Type I and Type II cigar consumers. In this analysis, we consider the Type I consumer in the premium market to illustrate the importance of lost consumer surplus to show how much FDA underestimated the social cost of its rulemaking.

## **b. PREMIUM CIGAR WILLINGNESS-TO-PAY ESTIMATE**

Available information about how most consumers acquire and consume premium cigars suggest that consumers’ willingness-to-pay is far greater than the cigar’s price. The attributes of premium cigar marketing are like other luxury goods. A multinational study of luxury good marketing and consumer preferences found consistent consumer values for luxury goods:

*Vigneron and Johnson (2004) proposed that a consumer’s decision-making process can be explained by five main factors: personal perceptions in terms of the perceived extended self,*

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<sup>42</sup> Corey et al., “Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults – United States, 2012-2013.”

<sup>43</sup> While no data is presented in the survey for cigarette smoking history for cigar smokers who only smoke “rarely,” it is reasonable to assume that this proportion is greater than 40 percent.

*perceived hedonism and nonpersonal perceptions referring to perceived conspicuousness, perceived uniqueness, and perceived quality. To acquire information regarding consumer motives and value perceptions, Wiedmann, Hennigs, and Siebels (2007) developed a four-dimensional model that explains luxury consumption through consumer perceptions of the social, individual, functional, and financial value dimensions of luxury and thus draws on and extends Bourdieu's capital theory (1986) and existing luxury research literature (Vigneron & Johnson, 2004).*<sup>44</sup>

A consumer assesses the value of a luxury good by combining the financial, use, individual, and social value of the product and experience to the individual. The premium cigar market is structured to offer these values to consumers. Companies appeal to a consumer's financial values through price. Cigar shops, on-line resources, and public health campaigns offer functional values through information about the smoking experience and its hazards. Cigar firms, trade magazines, cigar shops and cigar bars appeal to individual values through the education process of the cigar's quality and uniqueness, via its origins and fabrication. Since premium cigars are often smoked with others, the marketing appeals to social values through opportunities to interact with others at cigar shops or cigar bars and to fulfil values of perceived conspicuousness. It is these individual and social values that are the most intangible and require the consumer to gather information about the cigar to select the one that has the best attributes for the consumer.

Consumer pay to obtain these values separately from the price of the premium cigar. To have the social experience, they pay the travel and admission costs to attend cigar events. To gain the education about the quality and unique features, they spend time and resources to be educated, whether at a cigar shop, on-line, or in discussions with others. The costs to obtain these values are part of the consumers' willingness to pay for the premium cigar luxury experience. The same behavior and WTP attributes are found for certain liquors, wines, handbags, scarves, jewelry, automobiles, and other items.<sup>45</sup>

Therefore, when consumers drop out of the premium cigar market due to the direct and indirect price increase due to the regulation, the consumer will shift the value of all time and resources spend on the premium cigar experience to other items or luxury goods. The lost consumer surplus likely includes the following components:

- *Value of Time to Travel to a Store.* In a small marketing survey, most infrequent consumers purchased their premium cigars at a physical location such as a tobacco store, cigar club, or other location.<sup>46</sup> Like other goods whose attributes are not known until they are consumed, a significant proportion of cigars are sold in traditional retail shops. As with books or wines, consumers seek out information on the different options so that they can maximize the utility of their budget. The internet has created the opportunity for consumers to gain this information and to order products with less transaction costs. However, consumers still frequent retail cigar stores to learn from other consumers and from proprietors. They spend time and funds to travel to these locations. For this estimate, we assume consumers spend ½

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<sup>44</sup> Strehlau et al., "Consumer Value Perception of Luxury Goods."

<sup>45</sup> See for example, Silverstein, M.J., Fiske, N. *Luxury for the Masses*, Harvard Business Review, April 2003.

<sup>46</sup> Response Marketing, "Insights into Cigar Smokers and What That Means for Cigar Brand Marketers."

hour and travel a total of 15 miles per trip per cigar purchase. For the travel cost, we use the 2017 Internal Revenue Service allowable cost for business travel.<sup>47</sup>

- *Value of Time to Acquire Knowledge of a Preferred Cigar.* The retail and online purchasing experience is designed to give consumers knowledge of the flavor, the brand, the production history, and other elements. The analogy is to consumers' approaches to wine choices and to restaurant meal choices. Consumers will spend some time gathering information before spending that money and time. For this estimate, we assume that infrequent consumers spend one hour per purchase to gather information, to discuss options with others, and other educational activities.
- *Value of Relaxation.* From surveys, consumers smoke premium cigars alone roughly 43 percent of the time.<sup>48</sup> Otherwise, consumers report smoking together with friends. We assume that preparing the cigar to smoke and preparing the location at home requires ½ hour. The cigar smoking experience lasts one hour, leading to a total leisure activity of 1 ½ hours for smoking alone.
- *Value of Smoking with Others.* In the survey, respondents reported smoking with friends on golf courses, in cigar bars, at cigar shops, and in other social events. We assume that consumers must travel 15 miles to a specific event, pay an admission fee of \$100, and spend on average four hours at the event. We recognize that consumers would still gain utility from these events (e.g., golf) even if they did not smoke a cigar. However, consumers have these choices today; if the quality of these activities is reduced due to the regulation, this loss of value is a cost of the rule.
- *Value of Leisure Time.* For the value of leisure time, we use the U.S. Department of Transportation (DOT)'s value for leisure time.<sup>49</sup> US DOT establishes a value so that it can estimate the value of transportation projects that reduce congestion and travel times. In general, for many years, DOT has found that ½ hour of a person's hourly cash wage equivalent is its best estimate for the value of leisure time. Based on a majority of occasional premium cigar consumers having household income of \$50,000 per year or greater, we use a value of \$25 per hour as the value of leisure time. We calculate this value as ½ of an hourly cash wage of \$50 per hour, equivalent to a household income of \$100,000 per year.

### c. SUBSTITUTES TO CIGAR CONSUMPTION

If consumers chose not to pay the increased price for the premium cigar experience after the regulation, they will turn to substitutes. They may join whisky clubs, join fantasy sports organizations, or engage in yoga or exercise to relax at home. In particular, the regulation does not take away the consumer's time; it just shifts that time to a less-valued activity for that consumer. The loss in consumer surplus is the difference in WTP between the cigar experience and the closest substitute activity. We assume that consumers suffer a \$2 loss per hour when they shift to a lower-valued activity due the regulatory-induced price increase.

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<sup>47</sup> Internal Revenue Service, "2017 Standard Mileage Rates for Business and Medical and Moving Announced."

<sup>48</sup> Response Marketing, "Insights into Cigar Smokers and What That Means for Cigar Brand Marketers."

<sup>49</sup> U.S. Department of Transportation, Office of the Secretary of Transportation, "2016 Value of Travel Time Guidance."



#### **d. SUBSTITUTES IN THE CIGAR MARKET**

One of FDA's arguments in the RIA is that consumers will not miss the predicted loss of current market variety due to FDA's claim that different cigar products are close substitutes for each other. FDA's claim does not fully capture consumers' value calculation for luxury goods. The social values - e.g., conspicuous consumption - and the individual values - e.g., of uniqueness -- are diminished when the consumer has less products to match to their values. The market today has many, many varieties of wine and handbags with similar prices and functional value; however, consumers support product diversity and multiple vendors in these markets because of their differences in other consumer values - individual and social. Therefore, the loss of diversity is an implicit price increase that will cause additional current customers to drop out of the premium cigar market.

#### **e. ANALYTICAL APPROACH**

Using the assumptions above, we derive a representative estimate of an infrequent, Type I premium cigar smoker's WTP for the experience. We say "representative" because the purpose is to explore the magnitude of FDA's underestimation. The consumer smokes 57 percent of the time alone for the stated benefits of relaxation. The other 43 percent of the time the cigar consumer travels to smoke the cigar socially at an event that has a \$100 admission fee. In each scenario, consumers spend some time learning about their cigar choices. Table 8 gives the detailed information of the two scenarios. Weighting these two scenarios by their frequency, this consumer's WTP is approximately \$180 per cigar.

However, if this consumer drops out of this premium cigar market due to the regulation increasing the cigar's direct cost or the indirect cost of finding an alternative cigar that meets the consumers' values, the consumer will shift to a substitute activity. Using the assumption above that the consumer values the substitute activity \$2 per hour less than cigar smoking, the net loss of consumer surplus per cigar is \$70.

**Table 9: Willingness-to-Pay (WTP) of Infrequent Cigar Consumers**

Characteristics of Infrequent Cigar Consumers	Value and Unit
Number of Cigars Purchased Annually	4 cigars per year
Value of Leisure time	\$25.00 per hour
Weighted WTP	\$181.3 per cigar
Value of Leisure Time of Substitutes	\$23.00 per hour
Weighted WTP of Substitutes	\$110.29
Net WTP Loss	\$70 per cigar
<b>Cigar Smoking as Relaxation</b>	
Pre-Regulation Price of Cigar	\$10 per cigar
Time Spent Searching for Cigar	1 hour per cigar
Travel Cost to Obtain Cigar	\$21 per cigar
Miles to Cigar Store	15 miles per trip
Travel Cost per Mile	\$0.54 per mile
Internet Shipment Cost	\$10 per cigar
Cigar Smoking Preparation	0.5 hours
Smoking Cigar	1 hour
<b>Total</b>	<b>\$70</b>
<b>Total Time</b>	<b>4 hours</b>
<b>Cigar Smoking During Social Event</b>	
Pre-Regulation Price of Cigar	\$10 per cigar
Time Spent Searching for Cigar	1 hour per cigar
Travel Cost to Event	\$16.2 per cigar
Miles Traveled to Event	30 miles per trip
Travel Cost per Mile	\$0.54 miles per trip
Admission fee to Event	\$100 per event
Event Duration	4 hours per event
<b>Total</b>	<b>\$280</b>
<b>Total Time</b>	<b>5.5 hours</b>

## 8. RESULTS

### a. FUTURE MARKET ESTIMATE

In Section 3, we give our description of the pre-regulatory baseline market conditions. In Table 9, we summarize the cigar market segments and their estimated revenue. We use the sale percentages provided by IPCPR.<sup>50</sup> We multiply these percentages by the total size of the cigar industry (\$7 billion). Since sales data is proprietary, our assumptions may not reflect actual sales volumes in these price categories.

**Table 10: Cigar Industry Revenue Allocation Across Different Price Segments**

Price Range	Price (\$)	Sales Percentage	Equivalent Revenue (billions)
\$2-\$4	\$3	5	\$0.35
\$4-\$6	\$5	78	\$5.46
\$6-\$10	\$6	15	\$1.05
Over \$10	\$10	2	\$0.14

To estimate the total number of SKUs for non-premium cigars for each price segment, we multiply the corresponding sales percentage by 2,000 to 4,000. For premium cigars, we assume that the total number of SKUs is 6,000 - 12,000, based on CAA comments.

To be able to understand how price increases due to the regulation will lower cigar demand, we compile reported price elasticity values from the literature. An elasticity of -1.42 means that for a 10 percent price increase, the demand for that cigar will fall in 14 percent. For \$2 to \$4 cigars, we use the elasticity for small cigars (-1.42). For \$4-\$6 and \$6-\$10 cigars we assume that the elasticity corresponds to those of large cigars (-1.50). Both values are based on the estimates quantified by Zheng et al.<sup>51</sup> For premium cigars, we use the elasticity for Cuban cigars (-1.90), estimated by Fetzer.<sup>52</sup>

<sup>50</sup> International Premium Cigar & Pipe Retailers Association, “Premium Tobacconist Member Profile.”

<sup>51</sup> Zheng et al., “U.S. Demand for Tobacco Products in a System Framework.”

<sup>52</sup> Fetzer, “Partial Equilibrium Modeling of Trade Zeros.”

Table 10 summarizes the estimated number of SKUs and price elasticity values for these price ranges:

**Table 11: SKU Allocation and Corresponding Price Elasticity Values of Different Cigar Price Ranges**

Price Range	Price (\$)	SKU Allocation	Elasticity
\$2-\$4	\$3	102 - 204	-1.42
\$4-\$6	\$5	1,592 - 3,184	-1.50
\$6-\$10	\$6	306 - 712	-1.50
Over \$10	\$10	6,000 - 12,000	-1.90

Using the regulatory cost per SKU, we quantify the total regulatory cost of the rule for each price segment by multiplying the per product cost by the number of SKUs in each category. We then estimate how much the total costs for each category represent in terms of revenue (i.e. divide the total regulatory cost by equivalent revenue).

We compute the total revenue needed in each price segment by adding the total regulatory cost to the equivalent revenue. Then, we divide total revenue needed by the number of SKUs in the price segment to obtain the revenue needed per SKU. We assume that cigar prices will increase to cover the total regulatory cost. We divide both values to obtain the potential price increase (in percentage).

To calculate the decrease in demand, we use the elasticity values and the price increases to quantify the percentage of demand decrease for each price category. Then, we multiply this percentage by the equivalent revenue. Next, we calculate the lost revenue per SKU by dividing the decreased demand value by the number of SKUs in the price category.

Table 11 summarizes the current cost per product and per brand for the rule provisions for which we provided alternative quantified cost estimates:

**Table 12: Per-Product and Per-Brand Re-Estimated Costs of Key Rule Provisions**

Rule Provision	Current Cost by Brand	Current Cost per Product
Harmful and Potentially Harmful Constituents	\$31,352	\$4,311
Substantial Equivalence Demonstration	\$1,720	\$237
Labeling Costs	\$139,631	\$19,199
Total	\$172,703	\$23,747

We combine FDA's and the alternative cost estimates for the different requirements for the cigar industry to develop the total compliance cost. These costs are nearly \$24,000 per SKU. In a competitive market, firm then try to raise their prices to offset some of these increased production costs. Consumers, in turn, reduce their purchases of the higher-priced cigars according to the price elasticity of demand. Lower consumer purchases then in turn reduced producers' revenue, causing them to either stop selling money-losing products or cease operations. Once producers decide on their compliance strategy, the social costs and economic impact of the rule are known.

Table 12 shows the results of this market dynamic assuming 8,000 SKUs on the market. The lowest-priced cigar market segment has approximately five percent of total sales, or \$350 million per year. On average, each of the estimated 100 products would need a price increase of 0.7 percent or \$0.02 to adsorb the initial regulatory costs. Consumer demand falls slightly due to this price increase.

The premium market, the last row in Table 12, shows a much more significant effect. There are assumed to be 6,000 SKUs in a market with sales of approximately \$175 million. On average, average prices must rise by 46 percent to offset the regulatory costs. This sharp price rise saps consumer demand; consumer demand is estimated to fall from \$175 million per year to around \$22 million per year. With this sharp fall in demand, very few existing firms could remain in business.

Table 13 presents the same market analysis assuming a market with 16,000 SKUs. Overall compliance costs roughly double. The market impacts in the premium market are even more severe. Based on the reported elasticities, consumers would almost completely shift away from premium cigars to other cigars or other luxury goods.

Therefore, in the premium market, companies would reduce products offered to reduce the compliance costs to identify HPHCs and to seek SE approvals. Table 14 maps out possible scenarios that correspond to different decisions by cigar manufacturers.

The first row in Table 14 gives an important scenario. In this scenario, producers sharply limit the number of cigar products to limit their average revenue losses to three percent. This three percent threshold is the one federal agencies use as a guide to determine if a rulemaking will have a significant effect on small businesses. Federal agencies generally assume that if a regulation costs more than three percent of a small business' revenue, the firm is at high risk of failure. Many cigar

firms meet the U.S. Small Business Administration's classifications as small businesses. Therefore, if premium cigar firms sought to limit their revenue losses to three percent, they would have to lower the number of potential premium cigar products from 6,000 to 130.

If cigar firms maintain a product range of 1,000 SKUs, consumers would decrease purchases so that firms would receive 24 percent less revenue than prior to the regulation. This loss would likely lead to many smaller cigar firms leaving the market and consolidation of the remaining market in a few producers able to manage regulatory costs more efficiently. This type of market consolidation in heavily-regulated industries is apparent in nuclear power plant operators, pharmaceutical firms, and other sectors.

As producers withdraw products from the market, the apparent regulatory compliance costs go down. For example, in the scenario when firms limit their revenue loss on average to three percent, this regulatory compliance strategy reduces the apparent regulatory costs of the rule for premium cigars substantially -- from \$149 million in Table 13 to \$2 million in Table 14. However, the rulemaking costs only appear to be reduced because the lost consumer surplus is omitted.

**Table 13: Total Regulatory Cost for Cigar Market Assuming 8,000 SKUs**

Price Range	Mid-Point Price (Range values/2)	Sales Percentage	Equivalent Revenue (From 7 Billion) in million	SKU Allocation (Number of Products)	Adjusted Elasticity Based on Actual Price Increase	Regulatory Cost Per Product (i.e. SKU)	Total Regulatory Cost - in million	Total Revenue Needed to Cover Additional Regulatory Costs - in million	Revenue Needed Per SKU - in million	Cigar Price Increase (%)	Revenue Decrease Due to Lower Demand - in millions	New (Reduced) Demand - in millions	New Producer Revenue - in millions	New Price per SKU
\$2-\$4	3	5%	\$350	102	-0.01	\$24,768	\$2	\$352	\$3.52	1%	\$3	\$350	\$350	\$3.02
\$4-\$6	5	78%	\$5,432	1,592	-0.01	\$24,768	\$38	\$5,470	\$3.52	1%	\$57	\$5,380	\$5,431	\$5.04
\$6-\$8	6	15%	\$1,043	306	-0.01	\$24,768	\$7	\$1,050	\$3.52	1%	\$11	\$1,030	\$1,043	\$6.04
Over \$10 (Premium)	10	3%	\$175	6,000	-0.87	\$24,768	\$149	\$324	\$0.05	46%	\$153	\$22	\$42	\$14.60
						<b>Total Regulatory Cost</b>	<b>\$197</b>			<b>Total Revenue Decrease</b>	<b>\$224</b>			

Table 14: Total Regulatory Cost for Cigar Market Assuming 16,000 SKUs

Price Range	Mid-Point Price (Range values/2)	Sales Percentage	Equivalent Revenue (From 7 Billion) in million	SKU Allocation (Number of Products)	Adjusted Elasticity Based on Actual Price Increase	Regulatory Cost Per Product (i.e. SKU)	Total Regulatory Cost - in million	Total Revenue Needed to Cover Additional Regulatory Costs - in million	Revenue Needed Per SKU - in million	Cigar Price Increase (%)	Revenue Decrease Due to Lower Demand - in millions	New (Reduced) Demand - in millions	New Producer Revenue - in millions	New Price per SKU
\$2-\$4	3	5%	\$350	204	-0.01	\$24,768	\$5	\$355	\$1.7	1%	\$5	\$340	\$350	\$3.04
\$4-\$6	5	78%	\$5,432	3,184	-0.01	\$24,768	\$79	\$5,510	\$1.7	1%	\$79	\$5,320	\$5,430	\$5.07
\$6-\$8	6	15%	\$1,043	612	-0.01	\$24,768	\$15	\$1,060	\$1.7	1%	\$15	\$1,020	\$1,043	\$6.09
Over \$10 (Premium)	10	3%	\$175	12,000	-0.87	\$24,768	\$300	\$470	\$0.04	63%	\$300	\$0	\$0	\$16.30
						Total Regulatory Cost	\$400			Total Revenue Decrease	\$400			



Table 15: Potential Future Market Size for Premium Cigars

SKUs	Initial Price	Initial Revenue (million)	Regulatory Costs per SKU	Total Regulatory Costs (million)	New Total Revenue Needed (million)	New Revenue Needed per SKU	Price Increase	New Price per Cigar	Reduced Demand Elasticity	New Reduced Demand (million)	Decreased Revenue (million)	Revenue Decrease
130	\$10	\$175	\$24,768	\$3	\$180	\$1,370,000	2%	\$10.18	-0.008	\$174	-\$6.0	-3%
1,000	\$10	\$175	\$24,768	\$25	\$200	\$200,000	12%	\$11.24	-0.024	\$171	-\$41	-24%
2,000	\$10	\$175	\$24,768	\$50	\$220	\$110,000	22%	\$12.21	-0.042	\$168	-\$73	-42%
3,000	\$10	\$175	\$24,768	\$74	\$250	\$80,000	30%	\$12.98	-0.057	\$165	-\$99	-57%
4,000	\$10	\$175	\$24,768	\$99	\$270	\$70,000	36%	\$13.61	-0.069	\$163	-\$120	-69%
5,000	\$10	\$175	\$24,768	\$120	\$300	\$60,000	41%	\$14.14	-0.079	\$161	-\$140	-79%
6,000	\$10	\$175	\$24,768	\$150	\$320	\$54,000	46%	\$14.59	-0.087	\$160	-\$150	-87%

## b. ESTIMATES OF CONSUMER WELFARE LOSSES

The possible future markets described in Table 12-13 offer the consumer very different choices than the pre-regulatory market. If producers limit their compliance costs, consumers have much fewer choices of actual and potential products. Based on the pre-regulatory market, consumers value a variety of products and enjoy gaining and sharing information about these products. They will lose a great deal of variety and thus their enjoyment if producers dramatically cut back the number of SKUs. On other hand, if producers raise prices substantially to support more products, our best price elasticity estimate suggests many consumers will turn to non-cigar products. Cigar consumption will fall substantially.

In each of these cases, the social cost of the rule includes consumer utility not directly traded in the cigar market. As discussed above, the price consumers are willing to pay for the experience is much larger than the price of the cigar itself. When prices rise in a relatively free market due to regulation, the social cost is both the real resources necessary for compliance as well as the deadweight loss, the loss in consumer utility as they drop out of the market in response to the price increase.

We could estimate how much consumers value variety by estimating the cross-elasticities of price and of substitutions between different premium cigar products. We did not find readily-available estimates of product cross-elasticities in the publicly-available literature. Estimating these elasticities from market sales data is beyond the scope of this analysis.

In the absence of market data, we consider several approaches to estimate consumer welfare loss that will arise once the regulation is fully effective. First, we consider the traditional scenario where the cigar's market price fully includes all of the consumer's utility for the product. In free markets, the market's supply and price reflect the maximization of consumer utility subject to the production costs to produce it. Consumers will pay more for the product if the production cost is less than the cost of the physical resources needed to make the product; the cigar market is a good example where retail prices are substantially above production costs. However, if consumers bundle spending together as part of the cigar experience, just using the cigar price will underestimate the consumer's welfare to overcome this limitation, we also use the estimated consumer surplus loss of \$70 per cigar from Section 7.

Second, we will assume that consumers' utility is spread equally across all of the pre-regulation SKUs. This scenario represents a situation where consumers put a high value on the discovery of different products as a key part of their cigar experience. If actual or potential products are removed from the market, consumer lose utility each time a product is withdrawn. As with wine markets, some consumers enjoy exploring the thousands and thousands of different vintages, bottlers, and regions. However, some consumers value the social interaction as part of the cigar experience; they may value that more than the specific cigar they consume.

For the traditional scenario, we first estimate the change in the number of cigars sold under some of the future market descriptions given above. In Table 15, we estimate the number of cigars sold based on different product offering decisions by cigar firms. If firms only seek FDA approval to offer 3,000 of the current number of varieties of premium cigars, consumer demand falls to \$76 million per year. Using the average, post-regulation premium cigar price of \$12.98, the number of cigars sold

each year is more than 5.8 million. If producers curtail product choice more dramatically to 1,000 SKUs, nearly 12 million cigars will be sold.<sup>53</sup>

**Table 16: Assumed Number of Premium Cigar SKUs Remaining in the Market**

Category	Assumed Number of Premium Cigar SKUs Remaining in Market		
	3,000 SKUs	2,000 SKUs	1,000 SKUs
Regulatory Compliance Costs (million)	\$74	\$50	\$25
Price Increase	\$2.98	\$3.53	\$1.98
New Cigar Price	\$12.98	\$12.21	\$11.24
New Reduced Demand (million)	\$76	\$102	\$134
Number of Cigars Sold	5,800,000	8,300,000	11,900,000

Assuming the demand curve is linear, we can estimate the deadweight loss from the increases in price and decrease in quantity of cigars sold from the regulation. Table 16 gives this estimate for three post-regulation scenarios of 1,000, 2,000, and 3,000 SKUs remaining on the market.

**Table 17: Social Cost from Consumer Welfare Losses in Premium Cigar Market**

**Assuming Welfare Loss in Price**

Consumer Welfare Loss (\$ millions)	Assumed Number of Premium Cigar SKUs Remaining in Market		
	3,000 SKUs	2,000 SKUs	1,000 SKUs
Cigar Price Only	17	10	3.5
WTP Estimate	410	320	200

<sup>53</sup> In the 1,000 SKU scenario, the regulatory compliance costs are \$25 million. Since FDA approval is only sought for 1,000 SKUs, lower compliance costs lead to lower price increases. As a result, the demand in this scenario (\$134 million) and the number of cigars sold (\$11.9 million) are higher than for other scenarios shown in Table 15.

These social costs likely underestimate the actual social costs for the reasons discussed above. The linear demand curve assumption also likely underestimates the social cost. The demand curve may not be linear for such a substantial increase in price and reduction in quantity. If it has a traditional convex shape to the origin, the consumer welfare loss would be greater than this linear estimate.

For the second scenario, we estimate the total consumer welfare for premium cigars. It is the average willingness to pay (\$158) multiplied by the number of cigars sold (assumed to be 17.5 million per year) in the pre-regulation market. We then divide this total welfare by the assumed number of premium cigar SKUs in the pre-regulation market, 6,000 or 12,000. We then have the average welfare value consumers gain from each unique product in the marketplace.

In Table 17, the estimated lost consumer surplus for each post-market product volume is shown. If producers sharply curtail the number of products to minimize their compliance cost to three percent of revenue, almost all consumer welfare is eliminated. With only 130 products, the premium market would more resemble the other mass market segments of the market. It would be much harder to distinguish the remaining products as premium, luxury brands that can satisfy consumers' values for luxury goods. Consumers who gain enjoyment from exploring new products may quickly become bored with only 130 varieties. Due to this significant loss, consumers costs for having 130 cigar varieties in the market would be \$2,700 million. This consumer loss exceeds significantly the size of the \$175 million premium cigar market. At the other end of the spectrum, if producer pay the compliance costs to maintain 6,000 SKUs, consumers suffer no welfare loss due to the regulation.

The second scenario (Table 17 - Lost WTP for market of 12,000 premium SKUs) --- where consumers value product diversity - gives much higher estimates of consumer welfare loss. We expect that the likely loss in consumer welfare will be in between these estimates but is likely greater than \$100 million per year.

**Table 18: Consumer Costs of the Rule**

SKUs	Lost WTP	
	For Market of 6,000 Premium SKUs	For Market of 12,000 Premium SKUs
	(\$ million)	(\$ million)
130	2,700	2,700
1,000	2,300	2,500
2,000	1,800	2,300
3,000	1,400	2,100
4,000	900	1,800
5,000	500	1,600

SKUs	Lost WTP	
	For Market of 6,000 Premium SKUs	For Market of 12,000 Premium SKUs
	(\$ million)	(\$ million)
6,000	0 <sup>54</sup>	1,400

<sup>54</sup> Lost WTP for 6,000 SKUs in this scenario is zero, as producers pay the compliance costs to maintain the 6,000 SKUs in the market. In this scenario, consumers are unaffected.

## 9. CONCLUSION

The regulatory compliance costs for the non-premium market is about \$50-\$100 million for this initial compliance period. This value underestimates the full costs for this market since the ongoing costs are omitted as well as the loss of consumer surplus.

The regulatory costs for the premium market depend on the market choices of firms and of consumers. If firms reduce product offerings from 6,000 to 1,000, the combined consumer surplus loss is between \$3.5 million (see Table 16) and 2,300 million per year (see Table 17). The initial compliance costs are \$25 million (See Table 15).

**Table 19: Summary of the Rule’s Initial Compliance Costs and Consumer Surplus Loss**

Cigar Category	Initial Regulatory Compliance Costs (million)	Consumer Surplus Loss
Non-Premium	\$50-\$100	Not estimated
Premium	\$150-\$300	\$3.5 to \$2,300 million per year <sup>55</sup>

These values are not directly comparable to FDA’s cost estimates. FDA presented its values as present value estimates at different discount rates over a 20-year time horizon. The estimates presented in this analysis have different time periods. The direct regulatory compliance costs producers must spend over the next few years up to the final compliance deadlines. Some costs such as the registration, substantial equivalence, and other product-related requirements are on-going. The lost consumer surplus is an annual loss. As described in the HHS guidance, there is some evidence that this consumer loss will decline over time as other substitutes become available and consumers “forget” their past enjoyment of the experience.

Therefore, to convert these estimates to present value numbers equivalent to FDA’s metrics, we would need to make additional assumptions. However, it is clear that for the range of likely future market scenarios for the premium cigar market and given the estimated consumer welfare loss in the other cigar market segments, the likely social costs of this rulemaking are much larger than FDA’s estimate. In addition, the likely scenarios for the future premium cigar market all are likely to have a significant effect on a substantial number of small entities.

<sup>55</sup> Assuming a reduction of 5,000 SKUs

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