



Testimony of Drew Newman

General Counsel and Great-Grandson of the Founder

J.C. Newman Cigar Co.

April 5, 2019

Good afternoon Mr. Chairman and Members of Congress.

In 1895, my great-grandfather, J.C. Newman, founded our family business. Four generations and 124 years later, we are the oldest, family-owned, premium cigar company in America.

Here in Tampa, we proudly roll premium cigars the same way that my great-grandfather did a century ago – both by hand and by hand-operated, antique machines from the 1930s. We have 136 hard working and dedicated employees.

Premium cigars are all natural, handcrafted products that are just like fine wines. Just as the soil, sunlight, wind, and rain cause a grape grown in California to taste differently than the same grape grown in Oregon, the same is true of premium cigar tobacco. As with wines, certain vintages or years are better than others. And aging both wines and cigars enhances their taste. Many winemakers blend different grapes to create unique tasting wines; we do the same with premium cigar tobacco. We harness natural variation to make interesting blends for low-volume, limited edition cigars. None of this is standardized, written down, or formulaic. It is not a science. It is an art, and the tradition has been passed down from generation to generation.

Premium cigars are just 3% of the cigar industry and just one half of one percent of the tobacco industry as a whole. We are a tiny sliver of the tobacco world.



We are deeply concerned that FDA is regulating our small industry out of business by treating our handcrafted, premium cigars like a scientific product and creating standards that are impossible for us to meet.

In 2016, FDA adopted a “one size fits all” policy for tobacco and applied the massive and costly regulatory scheme developed for cigarettes to handcrafted, premium cigars. This approach simply does not work for several reasons:

- To create a new cigar, FDA requires it to be “substantially equivalent” to one sold in 12 years ago in 2007. This process is so exhaustive that it is expected to cost \$250,000 for a single new cigar. Moreover, the concept of “substantial equivalency” does not work because no two premium cigars are alike, and they change over time. A cigar rolled in 2007 tastes different today than it did a decade ago.
- FDA is requiring that we redesign our packaging to apply massive new warning labels.
- FDA is requiring us to test every type of cigar. Not only are there are no standards for testing premium cigars, but costs (\$18,000 per size) are enormous. This is particularly a problem since premium cigars are often made in small batches like craft beer.
- We are paying thousands of dollars in user fees per day so that FDA can regulate us.

According to current estimates, it will cost approximately \$30 million for our historic Tampa cigar factory to comply with FDA regulation. This is why FDA estimated that regulation would force as much as 50% of the cigar industry out of business.

Unlike “Big Tobacco,” the premium cigar industry is made up almost entirely of small, family businesses like ours. We sell our premium cigars to 3,000 specialty retailers across the country. These are mom-and-pop, small family businesses with just a handful of employees. Our boutique premium cigar industry simply cannot absorb these massive regulatory costs.



In 2009, Congress gave FDA authority to regulate tobacco products to address (a) youth usage and (b) addictiveness. However, FDA's own research has shown that (a) children do not smoke premium cigars and (b) the typical consumer smokes 1.7 premium cigars per month, a frequency that is not consistent with addiction. Premium cigars are an old-world, handmade craft enjoyed by adults infrequently for relaxation and celebration.

We respect FDA's mission and the important work that it does to protect public health. However, there is no scientific basis for FDA to regulate premium cigars.

We are extremely grateful to Chairman Rubio and Congresswoman Castor for reintroducing bipartisan legislation to exempt premium cigars from FDA regulation. The entire premium cigar industry, including the Cigar Association of America, Cigar Rights of America, and the International Premium Cigar and Pipe Retailers Association, supports exemption.

Our one goal as a family business is to continue my great-grandfather's legacy and hand roll premium cigars in America for another four generations and 124 years.

Thank you very much.

Comments of
**J.C. Newman
Cigar Company**

Regulation of
Premium Cigars

Docket No.
FDA-2017-N-6107

July 25, 2018

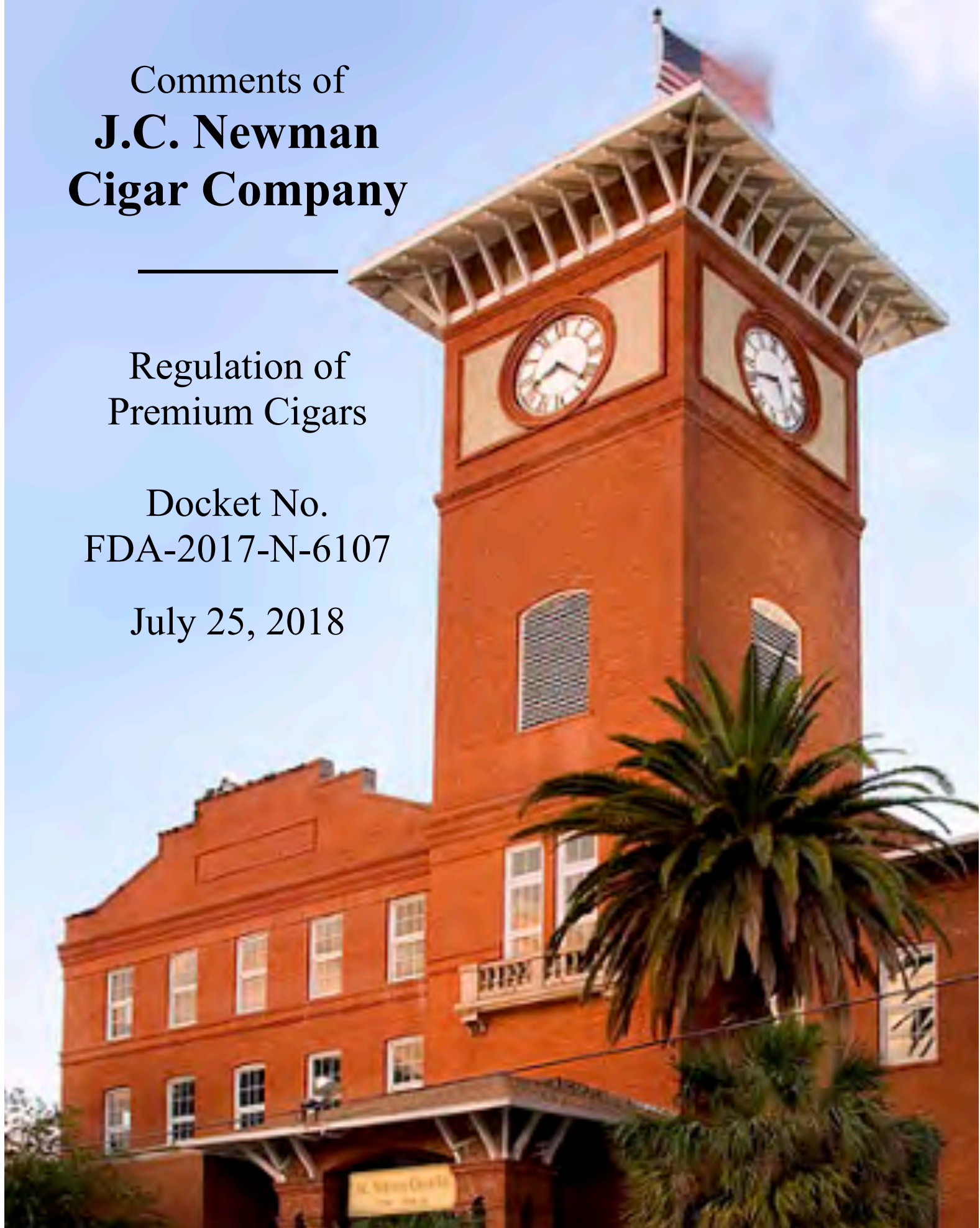




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Part I. Introduction.

J.C. Newman Cigar Company is the oldest, family-owned premium cigar company in America. We have been rolling premium cigars for four generations and 123 years. In addition to importing handmade cigars from the Caribbean and Central America, we operate the very last cigar factory in Tampa, Florida where 135 employees use antique, hand-operated cigar machines built in the 1930s to roll cigars that consumers perceive to be the same as handmade cigars.

In this Advance Notice of Public Rulemaking (“ANPRM”), the U.S. Food and Drug Administration (“FDA”) stated that it is seeking information “that may inform regulatory actions FDA might take with respect to premium cigars.”¹ In particular, the agency has requested “comments, data, research results, and other information related to the following topics:

- “• Definition of premium cigars
- “• Use patterns of premium cigars
- “• Public health considerations associated with premium cigars.”²

We sincerely appreciate the opportunity to address these questions and provide supporting information and data. First, we will provide an overview of our family history and explain how we roll cigars in our historic Tampa factory. Second, we will explain why FDA should adopt the definition of “premium cigar” in H.R. 564 / S. 294 or, alternatively, include our historic Tampa factory in the “Option 2” framework. Third, we will explain how premium cigars are not used by children and are instead enjoyed by adults in moderation. Lastly, we will discuss how smoking premium cigars does not significantly increase the risk of mortality.

As FDA staff have noted, premium cigars are distinct from other tobacco products.³ Because premium cigars are smoked by adults infrequently, are not used by children, and have limited health effects, we believe that there is an insufficient scientific basis for FDA to regulate premium cigars. Accordingly, we respectfully requests FDA to please:

1. Exempt premium cigars from regulation, and
2. Include J.C. Newman’s historic American cigar factory in the definition of “premium cigar”

¹ 83 Fed. Reg. 12,901 (Mar. 26, 2018).

² *Id.* at 12,903.

³ Corey, C. et al., “US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014,” *NICOTINE & TOBACCO RESEARCH*, at 7 (Sep. 15, 2017) (“[T]he results illustrate clear distinctions between premium and non-premium [cigar] smoker characteristics, use patterns and purchasing behaviors.”).



Part II. About J.C. Newman Cigar Company.

- A. *J.C. Newman is America's oldest family-owned premium cigar maker.*

In 1888, our grandfather/great-grandfather, Julius Newman, sailed across the Atlantic Ocean with his family and immigrated to America. While his brothers became tailors and bankers, Julius wanted to make cigars, so his mother paid \$3.00 per month for him to become a cigar maker's apprentice. During the recession of 1895, Julius was laid off and decided to go into business for himself. With \$50 borrowed from his family, Julius bought two bales of tobacco, built a rolling table, and rolled his first 500 cigars in the family barn for the family grocer.

The J.C. Newman Cigar Company ("J.C. Newman") was born.



Julius Caesar Newman



Stanford, Eric, Bobby, and Drew Newman

Four generations later and 123 years later, J.C. Newman is still family-owned and operated by Julius's grandchildren and great-grandchildren. Our family business has persevered through two world wars, the Great Depression, the Cuban Embargo, competition from low-wage Caribbean countries, massive federal excise tax increases, and more. When J.C. founded his company in 1895, there were 42,000 federally licensed cigar manufacturers in America. More than a century later, we are the only one of those that is still owned and operated by the founding family. As such, J.C. Newman is the oldest family-owned premium cigar company in America.

- B. *J.C. Newman rolls cigars in a 108-year-old historic factory in Tampa, Florida using antique hand-operated cigar machines from the 1930s.*

In 1885, Vicente Martinez Ybor traveled from Key West to Tampa to move his cigar factory to the area now known as Ybor City. Soon, many other cigar makers followed, transforming Tampa from a village with fewer than 1,000 residents into the city that it is today and making Tampa world famous as the "Cigar Capital of the World."

In its heyday, Tampa had over 150 cigar factories, employing tens of thousands of cigar rollers who made millions of cigars per year. Today, the J.C. Newman cigar factory in Ybor City is the lone survivor. Built in 1910, our historic red brick cigar factory is nicknamed "El Reloj" ("the watch") for its distinctive clock tower. **As a contributing building to the Ybor City National Historic Landmark District, our factory is in the National Register of Historic Places.** We have 135 hard-working, dedicated employees who are like family. Many have worked at our factory for decades. Their average age is 50 years old.



Visiting our famous Ybor City cigar factory is like walking back in time. Inside, we have been rolling cigars the same way for more than 80 years, using antique, hand-operated cigar machines that were built in the 1930s. These antique machines can roll, at most, 14 cigars per minute or 840 per hour. Each machine has more than 10,000 moving parts and is individually controlled by a cigar maker who hand applies the 100% natural tobacco leaf wrapper for each cigar. A skilled cigar maker is required to operate these machines and it takes four months to train a new cigar roller.⁴ To view a video of our antique, hand-operated cigar machines in action, please visit: <http://www.savecigarcity.com>. A delegation of FDA scientists also toured our factory on March 3, 2014.



The J.C. Newman Cigar Factory in Tampa, Florida

The only difference in components between the cigars rolled by our antique, hand-operated cigar machines and handmade cigars is that our cigars use a tobacco sheet binder and cap reinforcement made by Nu-Way Tobacco Company of Connecticut instead of a natural tobacco leaf binder. All of the other components are the same as handmade cigars. As explained below, this difference is imperceptible to consumers who perceive them to be the same as handmade cigars.

J.C. Newman’s Antique, Hand-Operated Cigar Machines from the 1930s:



⁴ For more information about our historic factory, see Alvarez, L., “After 128 Years of Rolling Them, Tampa Is Close to No Cigars,” *NEW YORK TIMES* (Jul. 22, 2014); Allen, G., “Fate Of Decades-Old Cigar Factory Dangles By A Phrase,” *National Public Radio’s ALL THINGS CONSIDERED* (Jul. 15, 2014).

- C. J.C. Newman's antique hand-operated machine cigars are just like handmade cigars.
1. They have the same look, feel, smell, and taste.

When compared side-by-side, our antique, hand-operated machine cigars look, feel, smell, and taste the same as handmade cigars. When consumers pick up, hold, smell, and taste a J.C. Newman antique, hand-operated machine cigar, they cannot readily tell the difference between it and a handmade cigar.



A Brick House Cigar,
 Handmade in
 Nicaragua



An El Reloj Cigar,
 Rolled by J.C.
 Newman's Antique,
 Hand Operated
 Machines in Tampa



A Box of El
 Reloj Cigars,
 Rolled by J.C.
 Newman's
 Antique, Hand-
 Operated
 Machines in
 Tampa



A Box of Brick
 House Cigars,
 Handmade in
 Nicaragua



2. *They use the exact same components, except for binder tobacco.*

The reason why our antique, hand-operated machine cigars appear the same as handmade cigars is because they are almost identical. Both use the same premium cigar wrapper and filler tobaccos. The only differences are that our antique, hand-operated machine cigars use a tobacco sheet binder from Nu-Way Tobacco Company and are rolled using an antique, hand-operated cigar machine.



For example, the tobacco wrapper leaf used on the El Reloj cigars that we roll on our antique, hand-operated cigar machines is a Havana-seed sun-grown leaf grown by Oliva Tobacco Company in Ecuador. This leaf is **the exact same tobacco wrappers** that Oliva sells to the handmade cigar factories in Nicaragua and the Dominican Republic that make our Brick House and Diamond Crown Maximus cigars, respectively. Similarly, the filler tobaccos that we use are the leftovers of the expensive, high quality tobacco wrappers that Tabacalera A. Fuente uses to make its handmade cigars in the Dominican Republic.

3. *They have the same packaging and appearance.*

Our antique, hand-operated machine cigars are packaged just like handmade cigars – wrapped with cigar bands, placed in individual cellophane tubes to protect the fragile wrapper leaves, and packaged in bundles and fancy boxes. The style of packaging is the same. In the eyes of a consumer, they are indistinguishable from any other handmade cigar brand – including the handmade cigars that J.C. Newman imports from the Dominican Republic and Nicaragua.

4. *They are sold on the same shelves in specialty cigar retailers.*

Cigars made by our antique, hand-operated machines are sold on the same shelves, in the same humidors, and in the same way as handmade cigars. Retailers display these cigars together with handmade cigars. The photo to the right was taken at Tampa Humidor, a specialty cigar retailer in Tampa. It shows El Reloj cigars, made by our antique, hand-operated cigar machines, on the same shelf next to handmade cigars imported from the Dominican Republic and Nicaragua.





5. *They are priced the same.*

It is important to note that our antique, hand-operated machine cigars are priced the same as many handmade cigars. For example, a single El Reloj cigar (made by our antique, hand-operated cigar machines in Tampa) sells for \$5.60 in California, while a similar single Quorum cigar (handmade in Nicaragua) sells for \$4.50 in California.

6. *They both have a slow, labor-intensive process.*

Our antique cigar machines are hand-operated. They only roll a cigar after the cigar maker places a 100% natural wrapper tobacco leaf on the machine and activates the machine. Because of this manual, labor-intensive process, our antique, hand-operated machines can roll no more than 14 cigars per minute, compared with high-speed mass-market cigar machines (225,000 cigars per hour) and cigarette machines (1 million cigarettes per hour). It takes four months to train a cigar maker to roll cigars on our antique, hand-operated cigar machines, which is similar to the amount of time it takes to train a hand cigar maker.

7. *They are marketed only to adults.*

Like handmade cigars, our antique, hand-operated, machine cigars are marketed only to adults. All product packaging, advertising, marketing, and promotions are directed only at adults. This has been a core principle of J.C. Newman since our family company was founded in 1895.

8. *They have the same health and youth access issues.*

Parts IV and V of these comments discuss the unique patterns of use and public health considerations of premium cigars, specifically how they are different from all other tobacco products. Importantly, the studies concluding that premium cigars are smoked infrequently, are not used by youth, and do not significantly increase the risk of mortality *all* treat our antique, hand-operated machine cigars just like handmade cigars. As such, **the cigars that we roll by antique, hand-operated machines in our historic Tampa factory have the same health and youth access issues as handmade cigars, which is yet another reason why they should be treated just like handmade cigars.**

9. *In sum, consumers perceive them to be the same as handmade cigars.*

As the Supreme Court explained, the FDA was created “primarily to protect consumers from dangerous products.” *United States v. Sullivan*, 332 U.S. 689, 696 (1948). Therefore, the FDA should view products like cigars from the perspective of a consumer and understand that consumers perceive our antique, hand-operated machine cigars to be the same as handmade cigars. They have the same look, feel, smell, and taste. All but one of the components are identical. They are sold on the same shelves and in the same way as handmade cigars. They have the same style of packaging and appearance as handmade cigars. Both have a slow, labor-intensive manufacturing process. And, they are both marketed only to adults. In support of this point, 6,700 individuals submitted comments to the FDA in 2014 stating:



J.C. Newman's vintage machine-made cigars are sold in the same specialty stores as handmade cigars, positioned on the same shelves as handmade cigars, marketed to adults the same as handmade cigars, smoked in moderation just like handmade cigars, and made and packaged so much like handmade cigars that **consumers cannot readily distinguish between them and handmade cigars.**⁵

Further emphasizing this point, Charles E. Bailes, III, the Chairman and CEO of ABC Fine Wine and Spirits, “the fourth largest retailer of cigars in the country,” stated in his 2014 comments:

As CEO of ABC Fine Wine & Spirits, founded in 1936, I’m personally aware of the 100 year old history at JC Newman in Tampa, Florida. I’m also very familiar with the safety and efficiency of the hand operated Depression era cigar machines that are used in their production of premium cigars. **The process by which they make these premium cigars is so close to that of any other hand-rolled premium cigar producer that the changes are not noticeable, even to the trained eye.** I might add that the quality of the cigars produced by JC Newman in Tampa is as high or higher than any company producing hand-rolled cigars today.⁶

Comments submitted by the New York City Department of Health and Mental Hygiene underscore this point. The agency wrote that, “for an exemption to work, without undermining FDA regulation of non-premium cigars, **the distinction should be obvious.**”⁷ When comparing them side-by-side, it is “obvious” that handmade cigars and our antique, hand-operated machine cigars appear to be the same. As noted above, distributors, retailers, and consumers perceive our antique, hand-operated, machine cigars to be just like handmade cigars. Therefore, treating them differently would make it very difficult to administer the exemption.

D. J.C. Newman’s antique hand-operated machine cigars are completely unlike mass-market, machine-made cigars.

In contrast, our antique, hand-operated machine cigars **are completely unlike** modern, high-speed, mass-market machine-made cigars.

1. Modern, high-speed mass-market cigar machines are fully automated and are 250 times faster.

⁵ Memorandum from FDA CTP regarding Summary of Write In Campaigns to Docket FDA 2014 N 0189 (Aug. 3, 2015) (emphasis added), <https://www.regulations.gov/document?D=FDA-2014-N-0189-82900>.

⁶ Comments from Charles E. Bailes III (Aug. 11, 2014) (emphasis added), <https://www.regulations.gov/document?D=FDA-2014-N-0189-63196>.

⁷ Comments from the New York City Department of Health and Mental Hygiene (Jul. 12, 2018) (emphasis added), <https://www.regulations.gov/document?D=FDA-2017-N-6107-6476> at 2.



Modern, high-speed, mass-market cigar machines are not individually operated and controlled by cigar rollers, like J.C. Newman's antique, hand-operated cigar machines. They are fully automated and make 225,000 cigars per hour, unlike J.C. Newman's machines, which roll a maximum of 14 per minute or 840 per hour. Modern, high-speed mass-market cigar machines are operated by turning on a switch while J.C. Newman's antique, hand-operated machines are operated by a highly skilled cigar roller who lays the natural tobacco wrapper for each cigar by hand, individually, on the machine. With J.C. Newman's antique machines, a skilled roller rolls each cigar, one by one.



- Because mass-market cigars do not have natural tobacco leaf wrappers, they look, feel, smell, and taste very different.*

The most critical difference between our antique, hand-operated machine cigars and mass-market cigars is the outer wrapper. We use 100% natural tobacco leaves – **the exact same tobacco wrappers used on handmade cigars**. In contrast, mass-market, machine-made cigars have a homogenized tobacco paper wrapper, which is much cheaper and inferior. This distinction is important because it changes how the product visually appears and a consumer's perception of it. With our antique, hand-operated machine cigars, a consumer sees, feels, and smells a 100% natural tobacco leaf wrapper – the same as a handmade cigar. With a mass-market cigar, however, the consumer instead sees, feels, and smells a tobacco paper wrapper instead.

- Mass-market cigars are packaged and marketed differently.*

As discussed above, our antique, hand-operated machine cigars have the same style of cigar bands, fancy boxes, and bundles as handmade cigars. Typically, there are 20-25 cigars in each box or bundle, and a specialty cigar retailer also sells them individually from the store's humidor. In contrast, mass-market, machine-made cigars are sold in packs of 3 to 5 cigars that are cheaper and tend to emphasize flavor over quality.

4. *Mass-market cigars are sold in gas stations and convenience stores.*

While our antique, hand-operated machine cigars are sold in specialty cigar retailers frequented by adults, just like handmade cigars, the vast majority of mass-market machine-made cigars are sold in gas stations and convenience stores. Accordingly, they have a very different market than our antique, hand-operated machine cigars and handmade cigars.



5. *Mass-market cigars are much cheaper.*

While our antique, hand-operated machine cigars, like handmade cigars, sell for several dollars each, mass-market cigars have a much lower price. Because of their cheaper components, lower quality, inexpensive packaging, convenience store market, and fully automated manufacturing process, a typical price for these products is 3 or 4 cigars for 99 cents.



6. *The Cigar Association of America agrees.*

As the trade association representing the entire cigar industry, the Cigar Association of America wrote that “**cigars rolled by hand-operated, vintage cigar machines are completely unlike modern, high-speed mass-market machine-made cigars.**”⁸

Part III. Definition of Premium Cigars.

A. *The FDA should adopt the definition of “premium cigar” in H.R. 564/S. 294.*

J.C. Newman strongly believes that FDA should define premium cigars using the definition set forth in H.R. 564 and S. 294, the Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2017:

- (i) means any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and—

⁸ Attachment B (Letter from the Cigar Association of America).



(I) has a 100 percent leaf tobacco binder and is hand rolled;

(II) has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or

(III) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and

(ii) does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).

This definition is narrowly tailored to include premium cigars and exclude mass-market cigars, filtered cigars, little cigars, and cigarillos. Paragraph (III) is critical because this language is necessary to include the cigars that we roll in our 108-year-old cigar factory in Tampa, Florida using antique, hand-operated cigar machines from the 1930s. Without this narrowly tailored language, our traditional, American-made premium cigars would be excluded.

B. This definition is widely supported by political leaders, including hundreds of Members of Congress, and it was co-sponsored by Vice President Pence and OMB Director Mulvaney.

This clear and consistent definition has been in Congress since 2011. During that time, hundreds of Members of Congress have co-sponsored this legislation and endorsed this definition, notably including Vice President Mike Pence and Office of Management Budget Director Mick Mulvaney when they served in the U.S. House of Representatives.

Earlier this month, a bipartisan group of 17 United States Senators wrote FDA asking it to exempt premium cigars from regulation using this exact definition.⁹ In their letter, the Senators explained that they were “concerned that additional regulation of premium cigars could force small businesses across the country to close and harm historic, American premium cigar manufacturers that use antique machinery.” After urging “the FDA to exempt premium cigars, as defined above, from these regulations,” **the Senators explained that “[a]ny other definition of premium cigars threatens the loss of American jobs.”**

A group of 13 Members of the U.S. House of Representatives, all of whom voted for the Family Smoking Prevention and Tobacco Control Act in 2009, submitted comments to this ANPRM urging FDA to adopt this legislative definition for premium cigar because “it excludes tobacco products that are marketed towards children and that are smoked on a frequent basis. . . is supported by 145 members of Congress, is grounded in a rational basis and is accepted

⁹ Attachment D (Letter from Senators Nelson, Rubio, Boozman, Casey, Cotton, Donnelly, Ernst, Gardner, Grassley, Heller, Hirono, Inhofe, Kennedy, Manchin, Menendez, Tester, and Toomey).



widely.”¹⁰ They further explained that it was not Congress’s intent to regulation premium cigars. “[W]e do not believe applying the agencies current regulatory regime to premium cigars as described above is consistent with the intent of the Tobacco Control Act,” they wrote. “It is clear to us that premium cigars are not used by or marketed to children and thus not subject to regulation under the Tobacco Control Act.”¹¹

Florida Governor Rick Scott and Lt. Governor Carlos Lopez-Cantera have echoed this message:¹²

FDA regulations threaten to create an undue burden on J.C. Newman and other premium cigar companies. . . . As America's oldest family owned premium cigar maker, J.C. Newman is also one of America's historic treasures.

Congresswoman Kathy Castor highlighted J.C. Newman’s cultural significance in Tampa:¹³

Premium cigars are distinct and have established artisan traditions and a cultural niche. Traditional handcrafted cigars are different from most other tobacco products because they are not mass-produced or sold in stores frequented by minors. **For example, in Tampa, premium cigars are created through a process that blends “hand-crafting” and historically-significant early 20th century machines.** These refined products are enjoyed by adults in moderation, often at celebratory occasions.

As U.S. Senator Marco Rubio wrote in an editorial published in the *Tampa Bay Times*:

For years, Newman has been a Tampa institution, a cultural symbol and an opportunity creator for thousands of families. **Newman’s time hasn’t passed, but it is time to put a halt to unnecessary federal regulations that threaten its future.**¹⁴

“[O]n behalf of the City of Tampa, and in support of our remaining cigar makers still operating in Tampa's National Historic Landmark District,” Tampa Mayor Bob Buckhorn submitted comments encouraging FDA to exempt premium cigars, including those rolled in our historic Tampa factory from regulation.¹⁵ “[P]remium hand-made cigars are enjoyed by

¹⁰ Attachment E (Letter from Representatives, Castor, Ross, Bilirakis, Hastings, Upton, Courtney, Clay, Ros-Lehtinen, Johnson, Shimkus, Brady, Titus, and Pascrell).

¹¹ *Id.* at 2.

¹² Comments from J.C. Newman Cigar Co., Attachment 2 (Aug. 8, 2014) (Letter from Florida Governor Rick Scott and Lt. Governor Carlos Lopez-Cantera), <https://www.regulations.gov/document?D=FDA-2014-N-0189-81597>.

¹³ Comments from J.C. Newman Cigar Co., Attachment 3 (Aug. 8, 2014) (Letter from Kathy Castor), <https://www.regulations.gov/document?D=FDA-2014-N-0189-81597>.

¹⁴ Rubio, M. “Column: Save a Tampa Cigar Institution,” TAMPA BAY TIMES (Jul. 23, 2014), <http://www.tampabay.com/opinion/columns/column-save-a-tampa-cigar-institution/2189706>.

¹⁵ Attachment F (Letter from Tampa Mayor Bob Buckhorn).



discerning adults, are traditionally beyond the price-point for youth, are used in a celebratory and infrequent manner and are produced in a manner that lends itself to a more artisan specialty product, than one that appeals to the general population,” he said.¹⁶ These sentiments are also supported by the Hillsborough County Commission and the Greater Tampa Chamber of Commerce.¹⁷

C. Alternatively, J.C. Newman’s historic Tampa factory can be added to Option 2.

In the proposed Deeming Regulation in 2014, FDA proposed what is now known as the “Option 2” definition for “premium cigar.”¹⁸ If FDA prefers this definition instead of the legislative definition, our antique, hand-operated machine cigars can easily be added to the “Option 2” framework without creating any loopholes. Attachment A is a chart showing how the agency can easily do this.

D. From an administerability perspective, J.C. Newman’s cigars should be included.

In the comments it submitted to the ANPRM, the New York City Department of Health and Mental Hygiene (NYCDOH) focused on the definition of “premium cigar.”¹⁹ Specifically, NYCDOH explained that it is critically important for premium cigars to be defined in a way that makes it easy for field inspectors to determine which products qualify and which do not:

Whatever characteristic is considered, it is important to recognize that at some point, inspectors in the field may be responsible for distinguishing between cigars regulated by the FDA and premium cigars that are not. **Thus, for an exemption to work, without undermining FDA regulation of non-premium cigars, the distinction should be obvious.**²⁰

As shown above, the cigars that we roll using our antique, hand-operated cigar machines from the 1930s at our historic Tampa, Florida cigar factory have the same look, feel, smell and taste as handmade cigars. They have the same packaging and appearance as handmade cigars and are sold on the same shelves in the same specialty cigar retailers as handmade cigars. As such, consumers cannot readily distinguish between the two.

Excluding our antique, hand-operated machine cigars rolled in Tampa from the definition of “premium cigar” would create the exact situation that NYCDOH warns against – having two products that appear the same and are sold together but are classified differently. To make the

¹⁶ *Id.*

¹⁷ Attachment G (Letter from Hillsborough County Commission) and Attachment H (Letter from the Greater Tampa Chamber of Commerce).

¹⁸ 79 Fed. Reg. 23,171 (Apr. 25, 2014).

¹⁹ Comments from the New York City Department of Health and Mental Hygiene (Jul. 12, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-6107-6476>.

²⁰ *Id.* at 1-2 (emphasis added). Specifically, NYCDOH urges against including retail price or flavors in the “premium cigar” definition because of the difficulty that inspectors would have in determining whether a product on the marketplace meets flavor or price requirements.



distinction between premium and non-premium cigars “obvious” as NYCDOH urges, our antique, hand-operated machine cigars must be included in the definition of “premium cigar.”

E. All three cigar industry trade association support exempting J.C. Newman’s cigars.

All three of the cigar industry’s trade associations – the Cigar Association of America (“CAA”), Cigar Rights of America (“CRA”), and the International Premium Cigar and Pipe Retailers Association (“IPCPR”) – support exempting cigars rolled by our antique, hand-operated cigar machines in addition to handmade cigars.

After discussing the history of premium cigar making in America and our 123-year-old family business, CAA explained:

[C]igars rolled by hand-operated, vintage cigar machines are completely unlike modern, high-speed mass-market machine-made cigars, because:

- modern, high-speed mass-market cigar machines are fully automated and make hundreds of thousands of cigars per hour;
- mass-market cigars do not have natural tobacco leaf wrappers; they look, feel, smell, and taste very different;
- mass-market cigars are sold in gas stations and convenience stores;
- mass-market cigars are packaged and marketed differently;
- and mass-market cigars are much cheaper.

Because of these substantial differences, hand-operated, vintage machine-made cigars can be narrowly defined so as to not create a loophole for other, different products. . . . **CAA believes that both handmade, premium cigars and hand-operated vintage machine-made cigars should not be regulated by FDA, and supports legislation using the definition in the bill to define the latter group.**²¹

Similarly, the International Premium Cigar and Pipe Retailers Association (“IPCPR”), which represents 1,000 cigar retailers, submitted comments in 2014 stating:

IPCPR believes that hand-operated, vintage machine-made cigars should be treated the same as premium cigars because they have the same look, feel, smell, and taste as value-priced handmade cigars. They have the same style of packaging, and have similar retail prices. They are often sold by IPCPR members, on the same shelves as other value-priced premium cigars. Like premium cigars, they present minimal public health and youth

²¹ Attachment A (Letter from Cigar Association of America).



access issues, and consumers perceive these cigars to be just like value-priced premium cigars.²²

These comments were echoed by Cigar Rights of America (“CRA”), an association representing premium cigar consumers, retailers, and manufacturers, which submitted comments in 2014 stating:

The FDA should treat cigars that are rolled by hand-operated, vintage cigar machines just like value-priced handmade cigars because they:

- Look, feel, smell, and taste similarly
- Use the exact same components, except for binder tobacco
- Have the same style of packaging and appearance
- Are sold on the same shelves in specialty cigar retailers
- Have similar retail prices
- Use a slow, labor-intensive manufacturing process
- Are marketed only to adults
- And are purchased by the same adult consumers and smoked in the same way

Most importantly, **when comparing one of J.C. Newman’s hand-operated, vintage machine-made cigars to a value-priced handmade cigar, one cannot readily tell them apart. Because of this, consumers perceive them to be the just like value-priced handmade cigars and treating them differently would create a significant administrative problem for the FDA.** Moreover, from a public health perspective, hand-operated, premium cigars are functionally equivalent to handmade, premium cigars. Neither appeal to youth.²³

IPCPR and CRA restarted their support for our historic, Tampa cigar factory and the cigars that we roll using our antique, hand-operated cigar machines in joint comments filed in response to this ANPRM.²⁴

F. More than 25,000 Americans have submitted comments supporting J.C. Newman

During the Deeming Regulation’s comment period in 2014, 6,700 Americans submitted comments in support of saving J.C. Newman’s historic Tampa cigar factory.²⁵ During the

²² Comments from the International Premium Cigar and Pipe Retailers Association (Aug. 7, 2014).(emphasis added), <https://www.regulations.gov/document?D=FDA-2014-N-0189-76463>.

²³ Comments from Cigar Rights of America (Aug. 8, 2014) (emphasis added), <https://www.regulations.gov/document?D=FDA-2014-N-0189-79895>.

²⁴ Attachment B (Letter from the International Premium Cigar and Pipe Retailers Association and Cigar Rights of America).

²⁵ Memorandum from FDA CTP regarding Summary of Write In Campaigns to Docket FDA 2014 N 0189 (Aug. 3, 2018), <https://www.regulations.gov/document?D=FDA-2014-N-0189-82900>.



ANPRM comment period this year, more than 25,000 adult Americans²⁶ submitted comments electronically or through the mail stating:

I am an American adult who enjoys premium cigars. I strongly urge you to both exempt premium cigars from FDA regulation and save America's last premium cigar factory by including the cigars that J.C. Newman Cigar Company rolls in its historic Tampa, Florida cigar factory in the definition of "premium cigar."

More comments were submitted to both the proposed Deeming Regulation and to this ANPRM in support of our family business, our historic cigar factory in Tampa, and the cigars that we roll using its antique, hand-operated machines than any other company or segment of the premium cigar industry.

Part IV. Use Patterns of Premium Cigars.

The patterns of use for premium cigars are completely unlike those for cigarettes and all other tobacco products. Premium cigars are not used by children but are instead enjoyed by adults in moderation.

A. Children do not smoke premium cigars

Last year, an article written by FDA staff, funded by FDA, and published in the *New England Journal of Medicine* analyzed **the PATH study data and found no statistically significant use of "traditional cigars"**²⁷ **by persons younger than 18 on a "daily" or "frequent" basis.**²⁸ Moreover, a second article written by FDA staff, funded by FDA, and published in Oxford University Press's *Nicotine and Tobacco Research* found that the median age of "first regular use" for "premium cigars" is 24.5 years with a 95% confidence interval of 18.8 years to 32.6 years.²⁹ Accordingly, FDA's own research has found that children are not smoking premium cigars – including J.C. Newman's antique hand-operated machine cigars.

B. Premium cigars are used infrequently, which is inconsistent with addictive behaviors.

Another FDA-funded study published in the U.S. Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report* analyzed the 2012–2013 National Adult Tobacco Survey and found that **96.7% of premium cigar consumers smoke fewer than one premium cigar per day.**³⁰ A third FDA-funded study published in Oxford University Press's

²⁶ This number is likely to significantly increase once FDA finishes publishing all comments.

²⁷ The category of "traditional cigars" in the PATH study was defined in a way that included *both* handmade cigars and the antique, hand-operated machine-made cigars that J.C. Newman rolls in its historic Tampa cigar factory.

²⁸ Kasza, K. et al., "Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014," 376 *NEW ENGLAND JOURNAL OF MEDICINE* 342–353 (Jan. 26, 2017).

²⁹ Corey, C., *NICOTINE & TOBACCO RESEARCH*, at 5.

³⁰ 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).



Nicotine & Tobacco Research analyzed the first wave of the PATH study and concluded that the median premium cigar consumer smokes 1.7 cigars per month.³¹ **The definition of “premium cigar” used in all of these studies includes J.C. Newman’s antique, hand-operated machine cigars.** Because the typical consumer is using a premium cigar just once or twice per month,³² premium cigars are simply not being used frequently enough to suggest that they are being used as a nicotine delivery system or as the result of addictive behavior.

C. *The demographics of premium cigar consumers are distinct.*

FDA staff’s analysis of the first wave of PATH data went further and recognized that the demographics of those who consume premium cigars – including J.C. Newman’s antique, hand-operated machine cigars – are distinct from users of other tobacco products:

Consumer Demographics from PATH Study, Wave I (2013-2014)					
	Premium Cigars	Nonpremium Cigars	Cigarillos	Filtered Cigars	Cigarettes
At least some college	73.8%	45.2%	46.0%	40.8%	45.0%
Household income > 200% FPL	62.7%	29.0%	22.6%	18.4%	32.3%
Smoke daily	6.7%	25.3%	22.0%	37.3%	79.5%
Days smoked in past 30	1.7	9.2	7.5	14.0	29.4
Number smoked per day	0.1	0.4	0.3	1.6	10.1
Age at first regular use	24.5	19.5	18.0	26.8	16.6

Source: Corey, C. et al., “US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the Population Assessment of Tobacco and Health (PATH) Study, 2013–2014,” *Nicotine & Tobacco Research*, at Table 1 (Sep. 15, 2017).

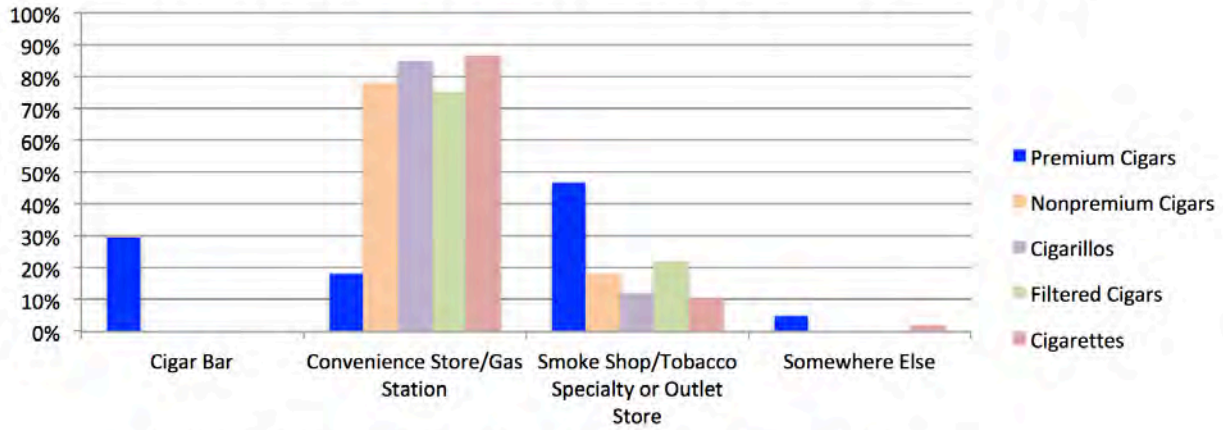
D. *Similarly, the smoking patterns of premium cigar consumers are also distinct.*

Not only are the demographics of premium cigar smokers distinct, but their smoking patterns – how they buy and smoke premium cigars – are distinct from other tobacco products as well:

³¹ Corey, C., NICOTINE & TOBACCO RESEARCH, at 7. This study also concluded that 93.3% of premium cigar consumers smoked fewer than one cigar per day, slightly lower than the 96.7% reported in 2014.

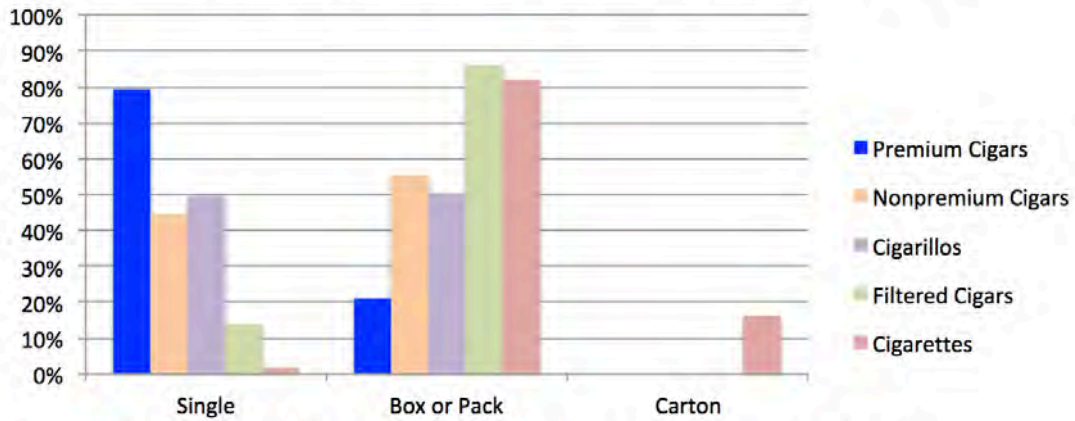
³² *Id.*

Where Purchased from PATH Study, Wave I (2013-2014)



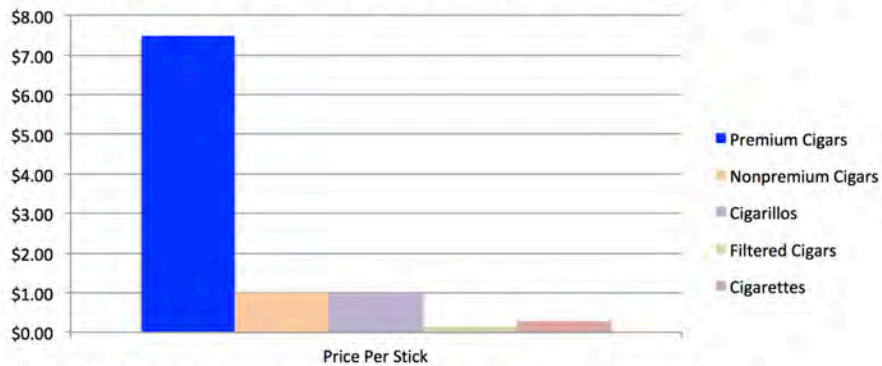
Source: Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the PATH Study, 2013–2014," *Nicotine & Tobacco Research*, at Table 1 (Sep. 15, 2017).

Quantities Purchased from PATH Study, Wave 1 (2013-2014)



Source: Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the PATH Study, 2013–2014," *Nicotine & Tobacco Research*, at Table 3 (Sep. 15, 2017).

Typical Price from PATH Study, Wave 1 (2013-2014)



Source: Corey, C. et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the PATH Study, 2013–2014," *Nicotine & Tobacco Research*, at Table 3 (Sep. 15, 2017).



- E. *FDA staff have recognized that premium cigars are distinct from other tobacco products.*

FDA staff have recognized that premium cigars are distinct. In the article published last year in *Nicotine & Tobacco Research*, after presenting the demographic and smoking pattern data from the first wave of the PATH study, the authors concluded that the data “illustrate clear distinctions between premium and non-premium [cigar] smoker characteristics, use patterns and purchasing behaviors.”³³ **Again, the PATH study included J.C. Newman’s antique, hand-operated machine cigars in the category of “premium cigar.”**

Part V. Public Health Considerations.

- A. *FDA should apply a population-based risk evidentiary standard.*

In the ANPRM, FDA requested comments and scientific data related to the “positive health impacts from premium cigars.”³⁴ This language suggests that FDA will be applying the appropriate population-based-risk evidentiary standard. In the proposed Deeming Regulation, the FDA took a similar approach when analyzing the risks of premium cigars and proposing an exemption for premium cigars. Unfortunately, the final Deeming Regulation changed the evidentiary standard from a population-risk standard to an any-individual-hazard standard, thus shifting the burden of proof from the agency to the premium cigar industry. This effectively put the burden of proof on commenters to establish that premium cigars should not be regulated. Instead of providing a sufficient scientific basis for regulating premium cigars and demonstrating that the likely benefits of the regulation justify the costs, FDA took a precautionary approach and effectively declared that *any* hazard or any risk, no matter how slight, justifies full regulation for premium cigars, regardless of the impact on the industry.

We strongly encourage FDA to adopt a population-risk standard and recognize that waves of new research have established that premium cigars are distinct from all other tobacco products. We urge FDA to conduct the required cost/benefit analysis for premium cigars because doing so would certainly show that premium cigars should be exempt from regulation.

- B. *Smoking premium cigars does not increase the risk of mortality*

As explained above, the patterns of use for premium cigars are very different than those for all other tobacco products. Nearly all premium cigar consumers smoke fewer than one cigar per day with the median consumer using a premium cigar 1.7 days per month.³⁵ This is important because government-funded studies of data spanning decades have concluded that smoking cigars infrequently does not significantly increase the rate of mortality.

³³ *Id.* at 7.

³⁴ 83 Fed. Reg. 12,902 (Mar. 26, 2018).

³⁵ See Corey, C., NICOTINE & TOBACCO RESEARCH, at 7.



Earlier this year, FDA staff and other researchers published an article in *JAMA Internal Medicine* that analyzed 25 years of data from the National Longitudinal Mortality Study. They found that there is no statistically significant increase in mortality for adults who smoke fewer than one cigar per day – just as 97% of premium cigar smokers do.³⁶ They analyzed not only overall mortality but also deaths related cancer, cardiology, respiratory, and diabetes, among others. In each instance, the authors found no statistically significant increase in mortality for non-daily cigar smokers. These findings can be seen in the following excerpt from the article’s Table 3:

Excerpt from Table 3 of "Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population."

All-Cause and Cause-Specific Mortality HRs by Current Tobacco Use Status, Daily, and Nondaily Use, 1985-2011

Outcome	Number of Deaths	Exclusive Cigar, Nondaily Use	
		Multivariable Hazard Ratio	95% Confidence Interval
All cause	36	1.12	(0.82-1.53)
All tobacco-related cancer	N/A	1.08	(0.45-2.61)
Lung Cancer	N/A	0.74	(0.08-7.26)
Oral Cancer	0	N/A	N/A
Circulatory	N/A	1.30	(0.78-2.17)
Cardiovascular	N/A	1.20	(0.67-2.15)
Cerebrovascular	0	N/A	N/A
Respiratory	0	N/A	N/A
COPD	0	N/A	N/A
Diabetes	N/A	1.55	(0.38-6.36)

Here, the results are not statistically significant because the 95% confidence interval (highlighted in red) for each hazard ratio (the likelihood of death) extends below 1.0 (the baseline). The U.S. Court of Appeals for the Fifth Circuit explained this concept as follows: “If the confidence interval is so great that it includes the number 1.0, then the study will be said to show no statistically significant association between the factor and the disease.”³⁷

³⁶ Christensen, C. et al., “Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population,” *JAMA INTERNAL MEDICINE* (Feb. 19, 2018), at E6 (Table 3).

³⁷ *Brock v. Merrell Dow Pharm., Inc.*, 874 F.2d 307, 312 (5th Cir. 1989) (“Just because an epidemiological study concludes that a relative risk is greater than 1.0 does not establish that the factor caused the disease. . . . For example, if a study concluded that the relative risk for Bendectin was 1.30, which is consistent with a 30% elevated risk of harm, but the confidence interval was from 0.95 to 1.82, then no statistically significant conclusions could be drawn from this study because the relative risk, when adjusted by the confidence interval, includes 1.0. Again, it is important to remember that the confidence interval attempts to express mathematically the magnitude of possible error, due to the above mentioned sources as well as others, and therefore a study with a relative risk of greater than 1.0 must always be considered in light of its confidence interval before one can draw conclusions from it.”).



This new research confirms the analysis published in 1998 by the National Cancer Institute (“NCI”) in Monograph No. 9. That report was drafted by a group of “over 50 scientists both within and outside the Federal Government [including t]hirty experts [who] participated in the multi-stage peer review process” in order to present “a complete review of what is known about cigar smoking.”³⁸ NCI stated, “The conclusions presented in the monograph represent the best scientific judgment, not only of the NCI, but also of the larger scientific community.”³⁹ Just like the recent study published in *JAMA Internal Medicine*, Monograph No. 9 found no statistically significant increase in death from any of the causes listed when smoking two or fewer cigars per day:

Excerpt from Table 1 of Monograph No. 9
Mortality ratios, and 95% confidence intervals, for select causes of death in male cigar only smokers. Cancer Prevention Study I, 12 year follow-up

Cause of death	Hazard Ratio		95% Confidence Interval
	Nonsmoker	1-2 Cigars Per Day	
All causes of death	1.0	1.02	(0.97-1.07)
Cancer of buccal cavity & pharynx combined	1.0	2.12	(0.43-6.18)
Cancer of esophagus	1.0	2.28	(0.74-5.33)
Cancer of larynx	1.0	6.46	(0.72-23.27)
Cancer of lung	1.0	0.99	(0.54-1.66)
Cancer of pancreas	1.0	1.18	(0.69-1.89)
COPD	1.0	1.39	(0.74-2.38)
Coronary heart disease	1.0	0.98	(0.91-1.07)

Together, after analyzing decades of data the “best scientific judgment, not only of the NCI, but also of the larger scientific community” has found that there is no statically significant increase in mortality for when smoking fewer than one cigar per day – as nearly all premium cigar smokers in America do.

C. *Applying studies on non-premium cigars and cigarettes to premium cigars is inappropriate because the patterns of use are distinct.*

In the Deeming Regulation, FDA considered exempting premium cigars from regulation but ultimately decided to regulate all tobacco products. In doing so, the agency relied on a range of studies that did not distinguish between the nature and use of premium cigars and other products. In fact, the authors of one study FDA cited specifically noted this problem:

Given the changes in cigar use patterns in the US and elsewhere since the 1960s, this review highlights the critical need for updated estimates of mortality risks due to cigar smoking. . . . Data

³⁸ “Cigars Health Effects and Trends: Smoking and Tobacco Control Monograph No. 9,” NATIONAL CANCER INSTITUTE (1998) at *i*.

³⁹ *Id.*



collection and analysis that include detailed information on the types of cigars typically used, the average number of cigars smoked per day, the depth of inhalation of cigar smoke, and the number of years smoking cigars would give a better sense of any dose–response relationship.⁴⁰

As the authors of that study noted, because the patterns of use for premium cigars are distinct from other tobacco products, studies on cigarettes and all cigar products grouped together are not applicable to premium cigars. Since that study was published in 2015, new research on premium cigars alone has found that they are not used by children, are smoked infrequently by adults, and do not significantly increase the risk of mortality. We respectfully request FDA to please not rely on outdated studies that do not distinguish premium cigars from other tobacco products.

Part VI. The massive cost of regulating premium cigars greatly outweighs the benefits.

If fully implemented,⁴¹ the Deeming Regulation will force J.C. Newman to close its famous and historic cigar factory in Tampa, Florida that currently employ 135 Americans. This is not an idle threat, nor is this very strong statement made lightly. The costs of complying with the Deeming Regulation are so extreme that there is simply no way that J.C. Newman can bear them.

In comments that it filed with FDA earlier this year,⁴² the Cigar Association of America (“CAA”) provided a detailed analysis of the various costs of each component of the Deeming Regulation. CAA projected the following costs for the most expensive regulatory requirements:

- To prepare substantial equivalency reports is a minimum of \$250,000 per SKU;
- To test for HPHCs is \$5,000 to \$20,000 per SKU;
- To redesign packaging for new health warnings is hundreds of thousands of dollars;
- To pay FDA user fees is \$900,000 per year.

J.C. Newman rolls 128 SKUs of premium cigars in Tampa, many of which will likely require substantial equivalency reports. **The total cost for J.C. Newman’s historic Tampa cigar factory to comply with the Deeming Regulation is projected to exceed \$30 million – more than three times the annual gross sales from its Tampa cigar factory!** These costs are real and staggering, and J.C. Newman simply cannot absorb them.

A series of Executive Orders require agencies to analyze the costs and benefits of regulation and consider a wide range of alternatives. Specifically, Executive Order 12886 requires an agency to “design its regulations in the most cost-effective manner to achieve the

⁴⁰ Chang, C.M. et al., “Systematic review of cigar smoking and all cause and smoking related mortality,” BMC PUBLIC HEALTH at 18 (Apr. 24, 2014). In the final Deeming Regulation, FDA cited this study in explaining its decision to reject the “Option 2” exemption for premium cigars. 89 Fed. Reg. 29,021 (May 10, 2016).

⁴¹ Although the Deeming Regulation took effect on August 8, 2016, its costly and onerous provisions have not yet been implemented.

⁴² See Comments submitted by the Cigar Association of America, Docket No. FDA-2017-N-5095 (Feb. 5, 2018), <https://www.regulations.gov/document?D=FDA-2017-N-5095-0032>.



regulatory objective”⁴³ and “propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”⁴⁴ Additionally, Executive Order 13563 states that “each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public.”⁴⁵ Executive Orders 13771 and 13777 further direct agencies to reduce or eliminate unnecessary regulatory burdens.

As explained above, because premium cigars are not used by children and are instead smoked by adults infrequently, and because smoking premium cigars does not significantly increase the risk of mortality, the likely benefits of regulating premium cigars are very slight compared with the staggering costs of regulation. Accordingly, consistent with the directives of Executive Orders 12,886; 13,563; 13,771; and 13,777, the FDA should consider all of the additional information presented to it in this ANPRM and exempt premium cigars from regulation – including the cigars rolled on our antique, hand-operated machines in Tampa, Florida.

Part VII. We support the comments submitted by the Cigar Association of America, Cigar Rights of America, and the International Premium Cigar and Pipe Retailers Association.

Our three trade associations, the Cigar Association of America, Cigar Rights of America, and the International Premium Cigar and Pipe Retailers Association, have submitted comments addressing these issues in more depth. We join and support those comments, except in regards to the definition of “premium cigar.” As explained above, we urge the FDA to adopt the legislative definition because it is narrowly tailored to include handmade cigars that those cigars rolled in our Tampa factory using antique, hand-operated cigar machines.

Part VIII. Conclusion.

We hope that these comments are helpful to FDA as it considers the regulation of premium cigars. We respectfully request that the agency adopt the definition in H.R. 564 and S. 294 for “premium cigars” and exempt all premium cigars – including our antique, hand-operated machine cigars – from regulation.

On behalf of our 123-year-old, four-generation family business and the 135 employees in our historic Tampa cigar factory, thank you very much for the opportunity to submit these comments and for your consideration of them. We sincerely appreciate it and would be very happy to answer any questions or provide any additional information at any time.

⁴³ Exec. Order 12,886, at § 1(b)(5) (Sep. 30, 1993).

⁴⁴ *Id.* at § 1(b)(6).

⁴⁵ Exec. Order 13,563, at § 4 (Jan. 18, 2011).



Respectfully submitted,

Eric Newman
President
Grandson of the Founder

Bobby Newman
Executive Vice President
Grandson of the Founder

Drew Newman
General Counsel
Great-Grandson of the Founder



J.C. Newman Cigar Company in 1905:



And in 2018:



Attachment A

How to Modify Option 2 to Include J.C. Newman's Historic American Factory

How to Modify Option 2 to Include J.C. Newman's Historic American Factory

<u>Original Option 2</u>	<u>Modified Option 2</u>	<u>Explanation</u>
(1) Is wrapped in whole tobacco leaf;	(1) Is wrapped in whole tobacco leaf;	Same.
(2) Contains a 100 percent leaf tobacco binder;	(2)(a) Contains a 100 percent leaf tobacco binder; contains primarily long filler tobacco; and is made by combining manually the wrapper, filler, and binder; OR	Same as the original (2), (3), and (4).
(3) Contains primarily long filler tobacco;	(b) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar;	Add language from H.R. 564 / S. 294 that is narrowly tailored to include the hand-operated vintage cigar machines in J.C. Newman's historic American factory.
(4) Is made by combining manually the wrapper, filler, and binder;	(3) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;	Same.
(5) Has no filter, tip, or non-tobacco mouthpiece and is capped by hand;		Because of a wide range of state tobacco taxes across the country, a retail price element is unworkable.
(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);	(4) Does not have a characterizing flavor other than tobacco; and	Same.
(7) Does not have a characterizing flavor other than tobacco; and	(5) Weighs more than 6 pounds per 1000 units.	Same.
(8) Weighs more than 6 pounds per 1000 units.		Same.

Attachment B

Letter from the Cigar Association of America

CIGAR ASSOCIATION OF AMERICA, INC.

1100 G Street NW
(Suite 1050)
Washington, DC 20005

(202) 223-8204
(202) 833-0379 fax

www.cigarassociation.org

July 25, 2018

Submitted via www.regulations.gov

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

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

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.

The purpose of these supplemental comments is to express CAA’s strong support for treating hand-operated, vintage machine-made cigars that are made by only two factories in America -- including those rolled by J.C. Newman Cigar Co. (“J.C.

Newman”) in Tampa, Florida -- the same as handmade, premium cigars and exempting both from FDA regulation.

In its primary comments, CAA states that the FDA should not regulate premium cigars because they do not have the youth usage, dual use, or public health effects of other tobacco products. In addition to handmade cigars, cigar retailers also sell millions of cigars rolled in America using hand-operated, vintage cigar machines. Because these cigars are wrapped with 100% natural cigar wrapper leaves, these cigars look, feel, smell, and taste just like value-priced handmade cigars. Their components are almost identical, and they have packaging and marketing similar to value-priced handmade cigars. They are rolled using a hand-operated manufacturing process, and are sold only to adults. Cigar retailers sell them together on the same shelves as value-priced handmade cigars. For these reasons, consumers perceive these hand-operated, vintage machine-made cigars to be just like value-priced handmade cigars.

About Cigar-Making in America

Cigars have been rolled in America since the earliest days of the Virginia colonies. In the late 1800s, there were over 40,000 federally registered cigar factories in America. Today, only two traditional, vintage machine-made cigar factories are left:

- J.C. Newman Cigar Co. in Tampa, Florida
- FX Smith’s Sons in McSherrystown, Pennsylvania

Both of these companies are family-owned and operated, and are around 100 years old. J.C. Newman was founded by Julius Caesar Newman in 1895. One hundred and twenty-three years and four generations later, J.C. Newman is the oldest family-owned cigar company in America. J.C. Newman employs 135 people in the last working factory in Tampa’s Ybor City cigar district. Inside

their 108-year-old historic cigar factory, J.C. Newman rolls cigars using hand-operated, vintage cigar machines built in the 1930s.¹

The Legacy of Julius Caesar Newman in Tampa, Florida

Although FDA is analyzing every comment from the cigar industry's association, companies and consumers; we pause from this very clinical process to take a moment to add some humanity. Understanding the contribution the Newman family has made to the Tampa community and to many school aged children in the Dominican Republic as a result of their family-owned and operated cigar business should not go unnoticed as it has made a dramatic difference in the lives of so many. The sons of Julius Caesar Newman, Bobby and Eric, continue to lead and manage the company. Not only are they "in the cigar business" but they have made a difference in our community. Bobby started a program for Southeastern Guide Dogs called the Paws for Patriots which provides guide dogs to soldiers returning from the Afghan-Iraq Global War on Terror and Veteran Service Dogs to these men and women coming home with severe Post Traumatic Stress Disorder ("PTSD"). Bobby heard from one of his customer's about Corporal Michael Jernigan, the first American serviceman to lose both eyes in the Global War on Terror. He became the first recipient of this program.

The Newman and Fuente cigar families possess a large sense of community and a commitment to give back. So in 2001, the two families formed the non-profit Cigar Family Charitable Foundation which has built two schools, a medical clinic, sports facilities and organic farming area in the Dominican Republic. Together, with the help of generous premium cigar consumers and a

¹ See Alvarez, L., "After 128 Years of Rolling Them, Tampa Is Close to No Cigars," *New York Times*, <http://www.nytimes.com/2014/07/22/us/after-150-years-of-rolling-them-tampa-is-close-to-no-cigars.html>.

network of premium cigar retailers around the world, the lives of children in the Dominican Republic are improving in part due to the generosity of the Newman family.

Exempting Hand-Operated, Vintage Machine-Made Cigars

FDA should treat cigars that are rolled by hand-operated, vintage cigar machines just like value-priced handmade cigars for numerous reasons. These cigars:

- look, feel, smell, and taste similarly;
- use the exact same components, except for binder tobacco;
- have the same style of packaging and appearance;
- are sold on the same shelves in specialty cigar retailers;
- have similar retail prices;
- use a slow, labor-intensive manufacturing process;²
- are marketed only to adults;
- and are purchased by the same adult consumers and smoked in the same way.

Because of the above, consumers perceive them to be the just like value-priced handmade cigars, and treating them differently would create significant enforcement issues for FDA. Moreover, from a public health perspective, hand-operated, premium cigars are functionally equivalent to handmade, premium cigars. For example, neither appeals to, nor is used by, youth.

² J.C. Newman's hand-operated, vintage cigar machines are slow. They roll a maximum of 840 cigars per hour, compared to mass-market cigar machines that make 225,000 cigars per hour and cigarette and cigarillo machines that make 1,000,000 units per hour.

In contrast, cigars rolled by hand-operated, vintage cigar machines are completely unlike modern, high-speed mass-market machine-made cigars, because:

- modern, high-speed mass-market cigar machines are fully automated and make hundreds of thousands of cigars per hour;
- mass-market cigars do not have natural tobacco leaf wrappers; they look, feel, smell, and taste very different;
- mass-market cigars are sold in gas stations and convenience stores;
- mass-market cigars are packaged and marketed differently;
- and mass-market cigars are much cheaper.

Because of these substantial differences, hand-operated, vintage machine-made cigars can be narrowly defined so as to not create a loophole for other, different products. The Traditional Cigar Manufacturing and Small Business Jobs Preservation Act would exempt both handmade, premium cigars and hand-operated, vintage machine-made cigars from FDA regulation. The bill defines the latter category as follows:

[A]ny roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and . . . has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and does not include a cigarette (as such term is defined by section 900(3)) or a little cigar (as such term is defined by section 900(11)).

To further tighten this definition, FDA could limit it to vintage machines that make fewer than 1,000 cigars per hour since modern, mass-market cigar machines make approximately 225,000 cigars per hour. CAA believes that both handmade, premium cigars and hand-operated vintage machine-made cigars should not be regulated by FDA, and supports legislation using the definition in the bill to define the latter group.

As explained in CAA's primary comments to the ANPRM on premium cigars, the provisions of the May 2016 Final Rule, most notably the extensive HPHC testing, "pre-market review," and health warning label requirements, would make it impossible to introduce new products and would substantially increase costs, ultimately causing the closure of America's last remaining traditional, vintage machine-made cigar factories.

Conclusion

In sum, and for the reasons discussed above, FDA should treat cigars rolled by hand-operated vintage cigar machines just like handmade, premium cigars and exempt both from FDA regulation. Thank you for the additional opportunity to comment in support of America's last remaining hand-operated, vintage machine-made cigar factories.

Respectfully Submitted,

A handwritten signature in black ink that reads "Craig P. Williamson". The signature is written in a cursive style with a large, looping initial "C".

Craig Williamson
President
Cigar Association of America, Inc.

Attachment C

Letter from the International Premium Cigar and Pipe
Retailers Association and Cigar Rights of America



July 25, 2018

VIA ELECTRONIC SUBMISSION

The Honorable Scott Gottlieb
c/o Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Dear Commissioner Gottlieb:

The International Premium Cigar and Pipe Retailers Association (“IPCPR”) is a not-for-profit trade group representing premium cigar and tobacco retail shops located throughout the United States and abroad. Established in 1933, IPCPR’s members are small businesses, typically family-owned and operated, that operate more than 3,000 retail stores. Cigar Rights of America (“CRA”) is a national advocacy organization dedicated to protecting the interests of consumers, retail tobacconists, suppliers, distributors, importers and manufacturers of premium cigars.

In 2014, both IPCPR and CRA submitted comments to the proposed Deeming Regulation urging the U.S. Food and Drug Administration (“FDA”) in support of the last cigar factory in the nation, given its historic and community economic significance.

In a lengthy comment submitted contemporaneously with this letter, we urge the agency to adopt a definition very similar to the one the FDA

proposed, requiring several aspects of hand construction. We believe handcrafting of cigars lies at the core of the premium category.

At the same time, we recognize the historical significance of the J.C. Newman factory, more than a century old, in Ybor City, Florida. That community is on its historic foundation with the cigar industry. The Newman plant is the last remaining symbol of that rich history. The undersigned organizations therefore do not oppose a very limited exception to the handcrafting requirement so long as it is strictly limited to the historic J.C. Newman facility.

Cigars have been rolled in America since the earliest days of the Virginia colonies. In the late 1800s, there were over 40,000 federally registered cigar factories in America. One prominent example of this legacy is J.C. Newman, which was founded by Julius Caesar Newman in 1895. Four generations and 123 years later, J.C. Newman is the oldest family-owned cigar company in America. J.C. Newman employs 135 Americans in the last working factory in Tampa's Ybor City National Historic Landmark District. It is against this backdrop that we support a limited provision for J.C. Newman's historic factory.

Sincerely,



Scott Pearce
Executive Director
International Premium Cigar and
Pipe Retailers Association



J. Glynn Loope
Executive Director
Cigar Rights of America

Attachment D

Letter from Senators Nelson, Rubio, Boozman, Casey, Cotton, Donnelly,
Ernst, Gardner, Grassley, Heller, Hirono, Inhofe, Kennedy, Manchin,
Menendez, Tester, and Toomey

United States Senate

WASHINGTON, DC 20510

June 28, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

We write with regard to the pending rule related to the Food and Drug Administration's (FDA) regulation of premium cigars under the Food, Drug, and Cosmetic Act. We were pleased to see the FDA's recent announcement to extend the comment period for the proposed rule, as it will give the premium cigar industry and its consumers across the country additional time to provide the FDA with the comprehensive data requested.

We remain troubled with the FDA's regulations under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) of 2009 as applied to premium, hand-rolled cigars. The 2009 law aimed to protect the health of the American public and prevent the use of tobacco products by children – goals that we all support and share. However, we have consistently heard from those impacted that the FDA's regulation of premium cigars fails to recognize that these cigars are a unique product with a unique consumer base. We are concerned that additional regulation of premium cigars could force small businesses across the country to close and harm historic, American premium cigar manufacturers that use antique machinery.

As the proposed rule accurately noted, the Population Assessment of Tobacco and Health (PATH) Study analyzing findings from the 2013 and 2014 found that the American population's overall consumption of premium, or traditional, cigars is significantly less than that of cigarettes. Moreover, less than one percent of surveyed youth between the ages of 12 and 17 reported trying a traditional cigar in the prior 30 days compared to over 13 percent experimenting with cigarettes. When it comes to daily use, the PATH Study found no statistically significant use of traditional cigars amongst youth.

With that in mind, we respectfully request that the FDA exempt premium cigars from the FDA's regulations under the FSPTCA and use the definition of a traditional cigar provided in the *Traditional Cigar Manufacturing and Small Business Jobs Preservation Act of 2017*, bipartisan legislation that we support. Specifically, we ask the FDA to define premium cigars to be:

- (a) any roll of tobacco that is wrapped in 100-percent leaf tobacco, bunched with 100-percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and—
 - (1) has a 100-percent leaf tobacco binder and is hand rolled;

(2) has a 100-percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or

(3) has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100-percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar.

We request that the FDA to exempt premium cigars, as defined above, from these regulations. Any other definition of premium cigars threatens the loss of American jobs. We urge you to provide certainty for manufacturers, retailers and consumers and work with us to maintain this industry's vibrant history in our country.

We thank you for your consideration of this matter and look forward to hearing from you.

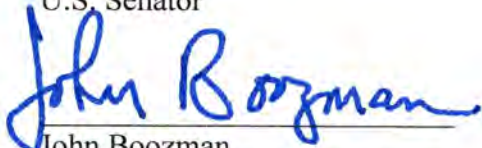
Sincerely,



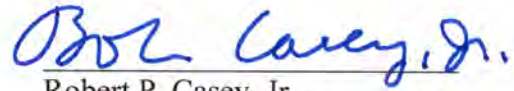
Marco Rubio
U.S. Senator



Bill Nelson
U. S. Senator



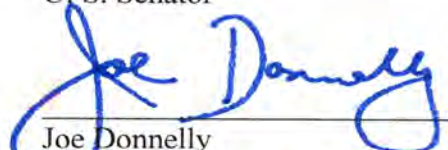
John Boozman
U.S. Senator




Robert P. Casey, Jr.
U. S. Senator



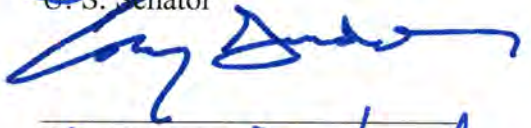
Tom Cotton
U.S. Senator



Joe Donnelly
U. S. Senator



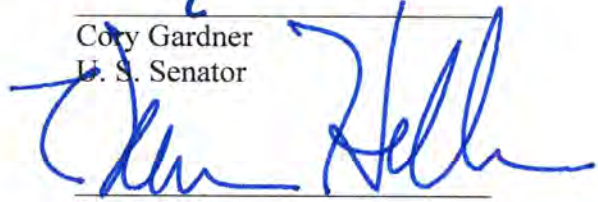
Joni Ernst
U.S. Senator



Cory Gardner
U. S. Senator



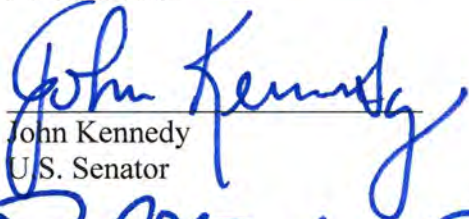
Chuck Grassley
U.S. Senator



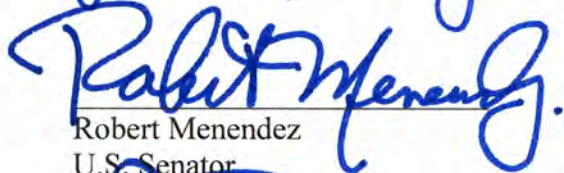
Dean Heller
U. S. Senator



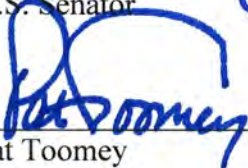
Mazie Hirono
U.S. Senator



John Kennedy
U.S. Senator



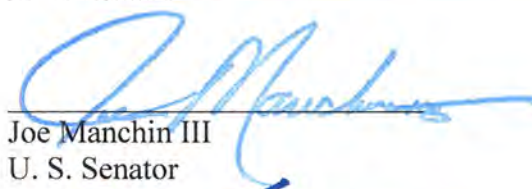
Robert Menendez
U.S. Senator



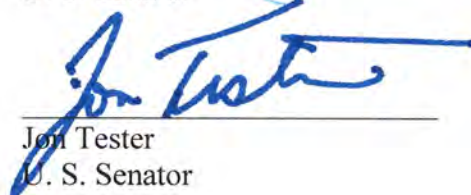
Pat Toomey
U.S. Senator



James M. Inhofe
U. S. Senator



Joe Manchin III
U. S. Senator



Jon Tester
U. S. Senator

Attachment E

Letter from Representatives, Castor, Ross, Bilirakis, Hastings, Upton, Courtney, Clay, Ros-Lehtinen, Johnson, Shimkus, Brady, Titus, and Pascrell

Congress of the United States
Washington, DC 20515

July 23, 2018

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

Dear Commissioner Gottlieb,

As Members of Congress who served in the 111th Congress and voted in support of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), we write with regard to Congressional intent of the law as part of FDA's Advanced Notice of Proposed Rulemaking (ANPRM) concerning premium Cigars (FDA-2017-N-6107-0001). We applaud FDA for undertaking this new review and are hopeful our expression of intent will be helpful in exempting this small niche product – premiums cigars as defined below - from regulation, consistent with the intent of the Tobacco Control Act.

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

- a. Any roll of tobacco that is wrapped in 100 percent leaf tobacco, bunched with 100 percent tobacco filler, contains no filter, tip or non-tobacco mouthpiece, weighs at least 6 pounds per 1,000 count, and--
 1. has a 100 percent leaf tobacco binder and is hand rolled;
 2. has a 100 percent leaf tobacco binder and is made using human hands to lay the leaf tobacco wrapper or binder onto only one machine that bunches, wraps, and caps each individual cigar; or
 3. has a homogenized tobacco leaf binder and is made in the United States using human hands to lay the 100 percent leaf tobacco wrapper onto only one machine that bunches, wraps, and caps each individual cigar; and
- b. does not include a cigarette or a little cigar

Now, specifically as to Congressional intent, throughout the findings section of the law, two themes are clear: preventing underage access to tobacco products and mitigating the health

effects of habitual consumption of addictive tobacco products. We continue to strongly support these goals and recognize the critical progress FDA's actions have made in advancing the public health. However, we do not believe applying the agencies current regulatory regime to premium cigars as described above is consistent with the intent of the Tobacco Control Act

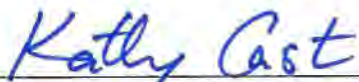
Our districts are all home to premium cigar retail stores and one of our districts is home to the only premium cigar factory left in the United States. By-and-large, premium cigars are sold in small business retail stores, often family-owned, who are proud of their record of enforcing existing laws preventing sales of tobacco products to underage individuals. We have observed this practice and pride in halting underage consumption for decades in our districts. It is clear to us that premium cigars are not used by or marketed to children and thus not subject to regulation under the Tobacco Control Act.

Apart from the specifics of the intent of the Tobacco Control Act, it is important to note that the cigar factory is and the vast majority of retail establishments are owner-operated businesses embedded in their communities. These stores and the factory represent tens of thousands of jobs nationwide and include thousands of "brick and mortar" storefronts.

We are aware that following the enactment of the Act, a Congressional investigation uncovered instances of products being manipulated in order to be sold as "cigars" and thus not subject to regulations. We believe these products to be inconsistent with our intent in supporting the Tobacco Control Act and applaud FDA's efforts to ensure products intended to be regulated are. Further, the definition of premium cigars we support above has been carefully drawn to ensure bad actors in the market do not have loopholes to exploit. Therefore, acceptance of the above definition would underscore that regulating premium cigars would be inconsistent with the aims of the Tobacco Control Act.

Thank you again for this opportunity to participate in the ANPRM. We feel our most significant contribution, consistent with our duties as the co-equal legislative branch is to ensure that the executive branch is clear on our intent in passing a law. As FDA continues to evaluate its definition and treatment of premium cigar products, we submit this letter for your use in tracking regulations tightly to their underlying legislation. Thank you for your consideration of our views.

Sincerely,



Kathy Castor
Member of Congress



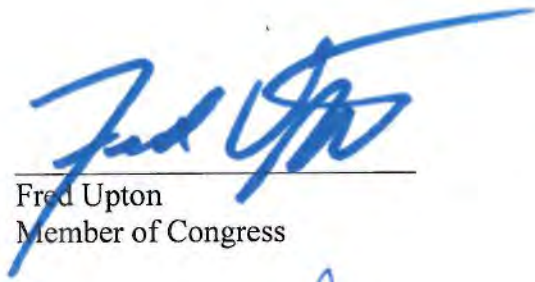
Dennis A. Ross
Member of Congress

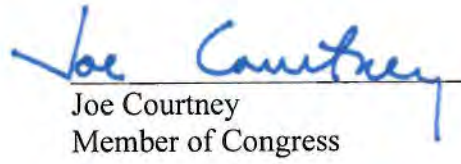


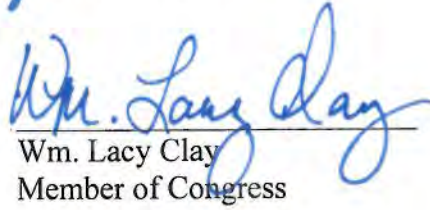
Gus M. Bilirakis
Member of Congress



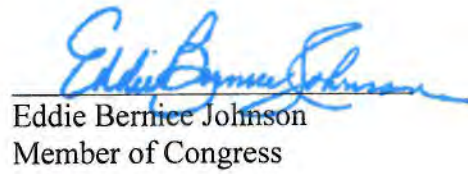
Alcee L. Hastings
Member of Congress

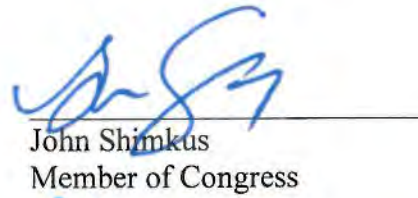

Fred Upton
Member of Congress

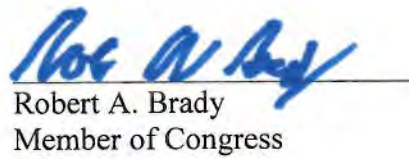

Joe Courtney
Member of Congress

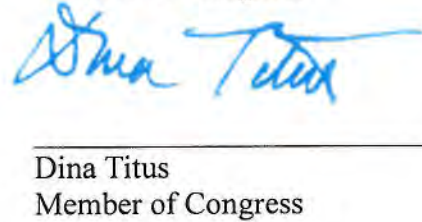

Wm. Lacy Clay
Member of Congress


Ileana Ros-Lehtinen
Member of Congress


Eddie Bernice Johnson
Member of Congress


John Shimkus
Member of Congress


Robert A. Brady
Member of Congress


Dina Titus
Member of Congress


Bill Pascrell, Jr.
Member of Congress

Attachment F

Letter from Tampa Mayor Bob Buckhorn



CITY OF TAMPA

Bob Buckhorn, Mayor

July 20, 2018

The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Springs, MD 20993

Dear Commissioner Gottlieb:

On behalf of the City of Tampa, and in support of our remaining cigar makers still operating in Tampa's National Historic Landmark District, Ybor City, I respectfully request that as you reconsider the recently enacted FDA regulation of tobacco products, you consider exempting "premium cigars". Implementation of these new provisions will have a negative impact on these businesses that play a strong and vibrant role in our economy.

The original intent of the Act was to address youth access to tobacco and chemical addiction, a goal that we can all support and work towards. However, premium hand-made cigars are enjoyed by discerning adults, are traditionally beyond the price-point for youth, are used in a celebratory and infrequent manner and are produced in a manner that lends itself to a more artisan specialty product, than one that appeals to the general population.

In response to your most recent request for comments on the proposed rules regulating premium cigars, I ask that you:

- (1) Include the cigars made by hand-operated vintage cigar machines, such as those in J.C. Newman's Tampa factory, in the definition of "premium cigars", and
- (2) Exclude premium cigars from FDA regulation.

Thank you for your consideration of this important issue that will help keep our historic Tampa cigar makers open and the tradition of cigar making in Ybor City alive.

Sincerely,

Bob Buckhorn

BB:dhs

Attachment G

Letter from the Hillsborough County Commission

Sandra L. Murman, District 1
Chairman

Victor D. Crist, District 2
Vice Chair

Stacy R. White, District 4
Chaplain

Lesley "Les" Miller, Jr., District 3

Ken Hagan, District 5

Pat Kemp, District 6

Al Higginbotham, District 7



Michael S. Merrill
County Administrator

Christine Beck
County Attorney

Peggy Caskey
County Internal Auditor

July 25, 2018

The Honorable Scott Gottlieb, M.D., Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Letter of Support for J.C. Newman Cigar Factory

Dear Commissioner Gottlieb:

I am writing in support of the J.C. Newman Cigar Factory and respectfully request that the FDA:

- (1) Include cigars made by the hand-operated vintage cigar machines used in J.C. Newman's Tampa factory in the definition of "premium cigars" and
- (2) Exclude premium cigars from FDA regulation.

J.C. Newman is a 123-year-old, fourth-generation, family-owned small business in Tampa, Florida. For the last 89 years, the J.C. Newman Cigar Co. has been making cigars using its vintage cigar machines built in the 1930s. We understand that these machines hand-operated, and roll cigars with natural leaf tobacco wrappers and natural tobacco fillers that are indistinguishable from J.C. Newman's original handmade cigars. While J.C. Newman's hand-operated vintage cigar machines can roll 14 cigars per minute, the modern machines used to make mass-market cigars are fully automated and produce thousands of cigars per minute. The packaging and marketing of these cigars are completely different.

J.C. Newman's vintage machine-made cigars are crafted, packaged, sold in the same specialty stores, positioned on the same shelves, and marketed to only adults as handmade cigars – We understand this makes them so much like handmade cigars that consumers cannot readily distinguish between them and handmade cigars.

We have learned that the FDA proposed rule would require J.C. Newman:

- (1) To obtain prior approval from the FDA before creating or repackaging any new cigars. The FDA estimates that this "premarket review" would require 5,000 hours, making it impossible for a small business like J.C. Newman to create new products.
- (2) To obtain rigorous scientific analysis of every type of cigar sold. Because of the boutique nature of the premium cigar industry, J.C. Newman sells hundreds of cigars under dozens of brand names. Requiring extensive laboratory analysis of each of them would be cost-prohibitive.
- (3) To change its manufacturing practices. J.C. Newman has been rolling cigars the same way for over 75 years. If regulated, the FDA would have the authority to order J.C. Newman to adopt the "good manufacturing practices" and other "tobacco products standards," even if its 1930's-era vintage cigar machines cannot meet them.

The Honorable Scott Gottlieb, M.D.
July 25, 2018
Page 2

(4) To pay hundreds of thousands of dollars per year in user fees and comply with other many other restrictions.

In 1886, Vincente Martinez Ybor brought the cigar industry to Tampa from Key West. In its heyday in Tampa had 150 factories – and now there is one. As the last remaining cigar factory in the “Cigar City” of Tampa, Florida, J.C. Newman might be forced to close if these proposed regulations were enacted. This would be a significant economic and cultural loss for Hillsborough County, the city of Tampa, and the state of Florida.

To prevent this from happening, we respectfully request that the vintage cigars made by the hand-operated Depression-Era cigar machines in the J.C. Newman factory be included in FDA’s definition of premium cigars, and exempted from FDA regulation.

I would appreciate your positive consideration of this very significant issue.

Sincerely,

A handwritten signature in cursive script that reads "Sandra L. Murman". The signature is written in black ink and is positioned above the typed name.

Commissioner Sandra L. Murman,
Chairman, Hillsborough County Commission, District 1

Attachment H

Letter from the Greater Tampa Chamber of Commerce



July 24, 2018

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Dr. Gottlieb:

As active business partners in the Tampa Bay area, the Greater Tampa Chamber of Commerce urges the Food and Drug (FDA) to cease efforts in regulating premium cigars under the Tobacco Control Act. Representing over 1,400 businesses in the community, the Greater Tampa Chamber of Commerce believes that tourism and attractions such as J.C. Newman Cigar Company enhance the community and play a role as a regional economic driver and asset to the region.

The FDA has imposed on premium cigars the strict, onerous and costly regulatory regime designed for the cigarette industry, causing a moratorium on selling new premium cigars in America. Ybor City is a National Historic Landmark District created by the cigar industry, and a century ago there were 150 large cigar factories in the city. J.C. Newman Cigar Company, our local cigar shop, a 123-year-old, four-generation, family-owned establishment, is the only cigar factory still operating in Ybor City Tampa.

Complying with the requirements imposed by the FDA for premarket review, product standards, product testing, etc. will cost J.C. Newman upwards of \$30 million. They are currently paying \$3,000 per day in user fees to the FDA due to the regulations. Pushing out these small family owned businesses will have a monopolistic effect by favoring Big Tobacco.

The Greater Tampa Chamber of Commerce asks that the Food and Drug Administration:

1. Exempt premium cigars from FDA regulation, and
2. Include the cigars rolled at J.C. Newman's Tampa factory in the definition of premium cigar.

Tampa earned the nickname "Cigar City" at a time when cigars were our major industry. In modern times, Tampa premium cigars are a link to our history, a tourist's souvenir, or a sign of celebration. The Greater Tampa Chamber of Commerce asks that the Food and Drug Administration cease efforts to regulate the premium cigar industry.

Sincerely,

A handwritten signature in black ink that reads "Bob Rohrlack".

Bob Rohrlack
President & CEO, Greater Tampa Chamber of Commerce